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OVERSIGHT CHALLENGES IN THE MEDICARE PRESCRIPTION DRUG PROGRAM

HEARING

BEFORE THE

FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, FEDERAL SERVICES, AND INTERNATIONAL SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON
HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

OF THE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

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OVERSIGHT CHALLENGES IN THE MEDICARE PRESCRIPTION DRUG PROGRAM

WEDNESDAY, MARCH 3, 2010

U.S. SENATE,
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, FEDERAL SERVICES,
AND INTERNATIONAL SECURITY
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:34 p.m., in room SD–342, Dirksen Senate Office Building, Hon. Thomas R. Carper, Chairman of the Subcommittee, presiding.

Present: Senators Carper, McCaskill, and McCain.

Also Present: Senator Klobuchar.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. Let me call this hearing to order, if I could. Welcome, one and all, especially to our witnesses who have joined us, those who went to high school in Delaware and those who did not. [Laughter.]

To those whose last name rhymes with the word that legislators fear, that is, "veto," whether in the Congress or State legislatures, and to those that are in our audience, welcome. We are glad that you are here.

Today we are going to hear from several witnesses about the Medicare prescription drug program, something I actually voted to create, and we want to hear about not just the good that it is doing. I understand that it is a program that roughly 85 percent of the folks who use it think is a good program, and it is a program that is coming in at or under budget, I think, for the last 4 years. And that is all well and good. It is not a perfect program. It has a certain vulnerability to waste, fraud, and abuse, as do other programs of this nature.

The witnesses today will tell an important story. I was surprised when I first heard about the Government Accountability Office (GAO) and Inspector General reports showing that the critical and basic anti-fraud safeguards for the Medicare prescription drug program were not in place, at least not yet, putting the program at a higher risk to waste and fraud.

Let me just say one of the interesting things about being on this Committee, the Homeland Security and Governmental Affairs Committee, is the opportunity to delve into literally every corner of the Federal Government. We look at programs where we are

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doing an especially good job for our taxpayers, the people who we work for, put a spotlight on those, and look for programs where we can do a better job, and sometimes look at programs we ought to end because they are not serving the purpose for which we are actually paying for them to serve.

This is a program that we are going to talk about today, the Medicare prescription drug program, that actually helps keep a lot of people out of hospitals, saves lives, and it is a very good thing for our citizens. It is also a program that, as I said earlier, is susceptible to waste. And while we do not want to diminish the very positive aspects of the program, we want to focus on what we can do better. And as my staff here has heard me say time and again, everything I do I know I can do better. And one of my favorite sayings is if it is not perfect, make it better. And as good as this program is, it is not perfect, and we can make it better, and we want to do that. And it is especially important that we have that kind of focus in a day and age when as a Nation, just in the last 8 years, we have basically doubled our Nation's debt. Think about that. In 8 years, we have increased our debt by as much as we did in the first roughly 208 years of our Nation's history. That is pretty amazing, isn't it? And we are on track to do that again in less than 8 years, so it is important for us to do a variety of things. The President has called for a freeze on discretionary spending starting this October 1. He has called for creating—he has already appointed folks to serve on a bipartisan, I will call it, blue-ribbon commission to focus on entitlement programs, entitlement spending, and revenues. And it is important that we look at other spending to see how we can provide benefits and do so maybe for not much more money, or maybe for even less money.

The safeguards that we have in place are important. And the safeguards that we need to have in place are not only important to protect taxpayer money, but they are important for us to avoid diversion of prescription drugs for criminal activity and to support drug addiction. Medicare, as you know, is a critical component of the health care of our Nation. I am told that almost 45 million seniors participate in Medicare. Think about that, 45 million folks in this country participate in Medicare.

The prescription drug program, which is known affectionately as Medicare Part D, began in January 2006. We are now into our fifth year. The overall reviews of the program have been positive. Again, roughly 85 percent of the people who are in the program like the program, about 27 million seniors participating, and the program has come in basically at or under budget for 4 years in a row.

As I said before, no program is perfect. During its first few years, the prescription drug program went through some serious growing pains. There are still many seniors that experience problems. However, Medicare Part D is here to stay. Congress must ensure that the $49 billion, almost $50 billion a year that we are spending works effectively and cost-effectively.

As we are all aware, Congress and the American people are in the midst of an important conversation about our Nation's health care system. There has been some disagreement about exactly what needs to be done. Wasn't that a nice way to understate it? There has been some disagreement about exactly what needs to be

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done. But almost everyone agrees that the cost of our system must get under control.

I met with a bunch of students, high school students from across the world. They were in Dover, Delaware, the other day, and I had a chance to spend some time with them. Several of them were from Japan. They were asking me questions, and one of the questions they asked is: How did your health care system get so screwed up? And by that, they meant: Why is it that you spend roughly twice as much as the rest of the world, get worse results, and have all these people that are not covered? I thought it was a pretty good question. That is really the case in Japan. They spend half of what we do for health care coverage, they get better results, I think, objectively measured, and they cover everybody, and we do not. I like to think they cannot be that smart and we cannot be that dumb. We have to figure out how to do this and how to compete better against them globally and in Europe and here at home.

Well, there has been a lot of talk around here about trying to "bend the cost curve" of health care. I have used that term once or twice myself. There are a number of reasons for the rise in health care costs over the past few decades, and it is clear that prescription drugs are one of the drivers of that increase.

The benefits of modern pharmaceuticals are evident, but so are the costs. In 1985, I am told, the average American spent about $90 a year for prescription medicines. Today we spend over $700 a year. That is an increase of about 740 percent.

Having said that, there are a lot of medicines that we can take today that save lives, keep people out of hospitals, keep people from having to be in clinics on a regular basis. So for those who would say is the cost really worth it, well, I think we could arguably say it probably in many cases is.

But, of course, eliminating fraud is an important and straightforward way of lowering costs for prescription drugs. Unfortunately, health care is too often the focus of criminals who wish to take advantage of our system. And whether the care is provided through government programs or through the private sector, attempts to defraud the system are, unfortunately, on the rise.

U.S. Attorney General Eric Holder estimates that Medicare fraud totals around $60 billion a year, an estimate echoed by others in law enforcement. In Medicare, $60 billion a year. That is not all in the prescription drug program, but some of it is.

A second estimate of waste and fraud in the Federal program is the level of improper payments. Each year, the Federal Government lists the estimates of overpayments, underpayments, undocumented expenditures, and other kinds of mistakes and fraud experienced by each agency. The total for the last fiscal year, fiscal year 2009, was almost $100 billion in improper payments—$100 billion—and Medicare has the largest reported share of that total at about $36 billion. So roughly a third of the improper payments emanate from Medicare.

Unfortunately, the Department of Health and Human Services (HHS) has not been able to determine the level for the prescription drug program, so the amount wasted in Part D is still largely unknown, and that is something we are anxious to get under control.

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Why the rise in Medicare fraud? Well, when Willie Sutton, an infamous 20th Century bank robber, was asked why he robbed banks, he always replied, "Well, because that is where the money is." And there is a lot of money in Medicare, and that attracts, unfortunately, a fair amount of criminal activity.

However, there is another reason, and it is the drugs themselves and the growing problem of addiction to over-the-counter medications. The problem of Medicare prescription drug fraud is more than just a loss of taxpayer money. It is also about harm to our citizens when fraud results in drugs diverted to illegal use. I think we have a chart here that demonstrates the impact.[1]

Senator McCaskill, welcome. It is good to see you.

Senator MCCASKILL. Thank you.

Senator CARPER. You are just in time to see this chart. Our first chart of the day.

We are looking here at growth from 1994 to 2004, and the prescription drug abuse up by about 80 percent, and at a time when the use of drugs looks like it is up by about 68 percent. Our population is not growing by 80 percent or 68 percent. It is growing by about 12 percent. So that is a good picture for us to keep in mind.

The only thing that has outpaced this figure is the rate of abuse among those drugs, and they have grown about 80 percent.

In fact, more Americans abuse prescription drugs than the number who abuse cocaine, heroin, hallucinogens, Ecstasy, and inhalants combined. In fact, one out of five teenagers in America has abused or is abusing a prescription drug.

Aside from our financial responsibility, though, we have a social responsibility to ensure that our public health care system is not used to further intensify and subsidize a public health crisis.

In a previous report focused on a similar problem with Medicaid, the GAO reported to this Subcommittee some major sources of fraud and abuse involving controlled substances. I understand that some of these same fraud techniques are used with Medicare.

The first fraud technique included beneficiaries engaged in a practice commonly known as "doctor shopping," in which recipients go to six or more doctors for the same type of drug. In these cases, beneficiaries are either feeding their addiction or selling the extra pills on the street. Drug dealers make the profit while the Federal Government—unfortunately, the taxpayers, foot the bill.

Fraud and abuse of prescription drugs also appears to be going on beyond the grave when prescriptions are "received" by dead beneficiaries or "written" by dead doctors.

The Department of Health and Human Services—specifically, the Centers for Medicare & Medicaid Services (CMS)—has established a set of oversight schemes to protect the Medicare prescription drug program and its beneficiaries from fraud and abuse. Sometimes called program integrity, protecting the program from fraud is a team effort involving Federal workers in Medicare, involving law enforcement at both the State, the Federal, and local levels, Medicare prescription drug plans, pharmacies and doctors, and the beneficiaries themselves.

[1] The chart referred to by Senator Carper appears in the Appendix on page 85.

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As a recovering governor, I understand the unique challenges that come along with running a major program like Medicare. But as many of us have heard, including in this room even today, if it is not perfect, let us make it better. We all share the responsibility to do just that with the Medicare prescription drug program.

Our witnesses are going to report to us today not only on the current challenges of waste, fraud, and abuse in the Medicare prescription drug program, but are going to help us to identify some solutions. And before they do that, let me yield to Senator McCaskill for whatever she would like to say, and say thank you very much for your commitment to ferreting out waste, fraud, and abuse wherever it occurs, including in the Medicare prescription drug program. Thank you.

OPENING STATEMENT OF SENATOR MCCASKILL

Senator MCCASKILL. Well, thank you, Mr. Chairman, for holding this hearing. I was particularly interested in your comments about prescription drugs and the abuse of prescription drugs. It has become a common fact that in many communities in this country, heroin is now cheaper than Oxycontin on the streets, which gives you some idea of what is going on with Oxycontin. It is a serious and significant opiate that is highly addictive, that has been widely prescribed—in lay opinion, inappropriately prescribed. And right now for kids that are on heroin, it is cheaper for them to get the heroin than Oxycontin, which, by the way, Oxycontin feels very similar to heroin.

So it is a serious issue, and the oversight of prescription drugs is incredibly important. I look forward to drilling down about our oversight of this program. Medicare Part D is a wildly expensive program for this country. By 2018, we are going to be spending $3,000 per recipient. Ninety percent of all the money that is spent on this program comes right out of the Federal Treasury. And, of course, there has never been an attempt to pay for that with any kind of offsets or pay-fors. It was all put on the credit card when it was passed, which I find highly ironic some of the righteous indignation from my friends on the other side of the aisle about "how dare the Federal Government enter into a new entitlement program run by the government without paying for it?" Or that it is expensive, when that is exactly what Medicare D was.

So I think it is time we take a very hard look at this program as to whether or not the taxpayers are getting a bang for their buck, whether they are requiring the kind of competition that brings value to the taxpayers for this, and whether we are doing an aggressive enough job of finding the cheaters—because we all know they are out there—or are we investing enough to find the cheaters and the abusers that are taking advantage of this very generous government program.

Thank you, Mr. Chairman.

Senator CARPER. Thank you, Senator McCaskill.

Senator Klobuchar, welcome. Thank you for joining us. A special guest appearance.

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OPENING STATEMENT OF SENATOR KLOBUCHAR, A U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator KLOBUCHAR. Well, thank you, Mr. Chairman, and thank you for allowing me as a special guest to join this Subcommittee for one hour, like Cinderella, but I am very pleased to be here. I am actually a member of the Judiciary Committee and have taken a particular interest in Medicare and Medicaid fraud just because when dollars are so tight and people can hardly afford to pay their premiums, it is just outrageous that we are losing about $60 billion going out of the system to places that it should never go.

Senator CARPER. Was this an issue that you had some interest in in your previous work back in Minnesota?

Senator KLOBUCHAR. I did. As a prosecutor, we really beefed up our white-collar fraud area, and we did a lot in this kind of Medicaid/Medicare fraud, and it was always the most vulnerable people that were getting ripped off and the monies going to, storefronts with names that do not even provide any services.

The other thing I learned since coming to the Senate and being on the Judiciary Committee is that a lot of this fraud sometimes takes place in certain hot spots, they call them in the Department of Justice, certain areas that have the least efficient health care systems where not only is the government not checking on them, but private companies do not work together well enough, and so there is just no check on this kind of fraud. They basically are robbing the American taxpayers of money.

I have introduced a bill called the IMPROVE Act, which would deter fraud by requiring direct deposit of all payments made to providers under Medicare and Medicaid. Medicare regulations already require direct depositing or electronic fund transfer, but these regulations have not been uniformly enforced and lack verification and identification requirements that check-cashing stores make it easy for scammers to commit fraud and disappear without a trace. And so this bill would start it off with Medicaid and then codify the existing Medicare regulations. It has been endorsed by AARP, the National Association of District Attorneys, and the Credit Union National Association.

To really make this health care system work, we are going to have to root out the fraud, to deter the fraud from happening in the first place. So thank you very much for holding this hearing and allowing me to sit in.

Senator CARPER. We are delighted that you are here. Thanks for your previous work in these venues and for bringing that experience to bear here with us today.

All right. I am going to briefly introduce our witnesses. We will be joined by some other Members of our Subcommittee. I am told we are going to have a series of votes that starts any minute now, and we will have two votes, and what we will do is probably go for about 10 minutes or so after the votes begin, and we will recess very briefly. We do two votes back to back and come right back.

Our first witness today is Kathleen King, Director of the Health Care team at GAO, where she is responsible for leading various studies of the health care system, specializing in Medicare management and prescription drug coverage. Ms. King has over 25 years of experience in health policy and administration. We thank her for

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being here today, and I learned just during our introductions earlier that she grew up in Wilmington, Delaware, and is a graduate of Ursuline Academy, one of the finest schools around. So we are glad that you are here.

Our next witness is Robert Vito, Regional Inspector General for Evaluation and Inspections at the Department of Health and Human Services. Mr. Vito works in the Inspector General's Philadelphia office which under his leadership has been credited with identifying billions in savings for the Medicare program. Thank you for that.

Our final witness here on this panel is Jonathan Blum, Director of the Center for Medicare Management and the Acting Director of the Center for Drug and Health Plan Choice. These two centers have budgets in the hundreds of billions of dollars and are responsible for the regulation and payment of Medicare fee-for-service providers and the Medicare prescription drug program. We thank Mr. Blum for being with us today and look forward to his testimony.

All right. Ms. King, why don't you go right ahead? Try to stick to close to 5 minutes, if you will. If you go well beyond that, we may have to leave and vote.

Ms. KING. I see the light.

Senator CARPER. But we want to get to each of your testimony, and thanks.

TESTIMONY OF KATHLEEN M. KING,[1] DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. KING. Mr. Chairman, Members of the Subcommittee, thank you so much for having me appear today to talk about GAO's work on Medicare Part D, especially work on fraud, waste, and abuse in Medicare Part D.

As you know, Medicare Part D is a voluntary outpatient prescription drug program that is administered by CMS with contracts to private health insurers and pharmacy benefit managers. In 2009, there were over 27 million enrollees and $51 billion in expenditures. GAO has considered Medicare to be high risk since 1990 due to its greater vulnerability to fraud and abuse.

The Medicare Modernization Act (MMA), which created Part D, required all sponsors—those who provide Part D benefits—to have programs in place to safeguard Part D from fraud, waste, and abuse. And CMS issued regulations requiring sponsors to have compliance plans detailing their plans to prevent and detect fraud, waste, and abuse. Those plans have seven required elements that reflect industry best practices. I am not going to name all of those elements here today. They are in my written statement. But they include things like having written policies, effective lines of communication, and a compliance officer that reports to senior management.

After the implementation of Medicare Part D, we were asked to look at the compliance plans offered by the sponsors and CMS's oversight of those plans, and we issued a report in July 2008 that

[1] The prepared statement of Ms. King appears in the Appendix on page 44.

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is the basis for my statement today, although we did speak to CMS recently to update it.

As part of our work, we looked at five sponsors that provided Part D benefits to more than one-third of beneficiaries, and our team went on site, spoke to individuals, reviewed documents, kicked the tires, if you will. And what we found in that study is that none of the five sponsors had implemented all of the seven elements of the required plans. Five sponsors had completely implemented three of the elements, and from there it varied downward.

We also found at that time that CMS's oversight of the process was limited. For example, in 2008, we found that oversight was limited to review of the initial plans that sponsors submitted as part of their application, and in 2006, CMS issued what is called Chapter 9, which is their guidance to plans on how to implement their compliance plans, and plans were not required to update their compliance plans after that date, nor were they required to update them for the 2007 and 2008 years.

Turning to audits, we found that CMS did not do the audits that it specified in its 2005 oversight strategy. There were a number of audits supposed to be done, 10 by Medicare drug integrity contracts (MEDICs)—and I think you are going to hear from MEDICs later—in 2005 and 2006, and 35 in 2006 and 2007. At that point, in 2006, CMS said that resource constraints, due in part to an increase in the number of plans participating in Part D, did not enable them to do all the audits that they had planned and to switch some audits from on-site audits to desk audits, which involve reviewing documents and papers sent by the Part D plans.

To update our report for this presentation today, we spoke to CMS again, and they told us that recently, between 2008 and 2009, the MEDICs had conducted 16 audits, desk audits, of the Part D compliance plans, and after that decided to change their audit strategy to on-site audits. And as part of that, they have conducted two on-site audits as part of a pilot program and they found some deficiencies. CMS plans to do more on-site audits. As of today, they have not decided exactly how many they should do.

CMS also issued a proposed regulation in 2009 to update its instructions to plans on how to develop effective compliance plans because they found that not all the sponsors understood them, and they told us recently that they expect this regulation to be made final very shortly.

That concludes my prepared statement. I am happy to answer any questions.

Senator CARPER. Great. Thanks so much. Mr. Vito, please. And, again, all of your statements, full statements, will be made part of the record. Just feel free to summarize as you wish. Thank you.

TESTIMONY OF ROBERT VITO,[1] REGIONAL INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. VITO. Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Robert Vito, Regional Inspector General for

[1] The prepared statement of Mr. Vito appears in the Appendix on page 52.

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Evaluation and Inspections at the Department of Health and Human Services' Office of Inspector General (OIG). I would like to thank you, Mr. Chairman, for holding this hearing on the important topic of Part D oversight.

Fraud, waste, and abuse have long been recognized as significant problems in the Medicare program, resulting in perhaps billions of dollars in losses to taxpayers each year. Fraud, waste, and abuse also negatively impact Medicare beneficiaries by causing them to pay more for their health care through higher premiums and rising copayments.

The complexity of the Part D program as well as its short implementation timeline makes it vulnerable to fraud, waste, and abuse. However, the creation of the Part D benefit also provides an opportunity to use the knowledge we gained in all the years of fighting fraud in the Medicare and Medicaid programs. To that end, we should use this opportunity to design a system that works to prevent fraud and improper payments before they occur rather than trying to recover the funds after the money has been spent. CMS plan sponsors and Medicare drug integrity contractors, known as MEDICs, all play key roles in this effort.

Since the inception of the Part D benefit, OIG has developed a body of work that assesses the program integrity and payment accuracies that each of these groups has in place. In short, we found that while some safeguards have been in place since the benefit's inception, others have been employed in a limited capacity, and some remain unimplemented.

To put it simply, there is more work to be done by CMS, the plan sponsors, and the MEDICs. As the administrator of the benefit, CMS plays a primary role in preventing and detecting fraud, waste, and abuse. Although CMS has developed a safeguard strategy, the strategy did not address the coordination that is needed between the different groups within CMS and lacks the details that would turn it from a broad strategic concept into a useful management tool. Furthermore, although CMS required Part D plan sponsors to have compliance plans and had provided guidance on their development, it has yet to finalize any audits to ensure the plans are comprehensive and effective—this despite the fact that OIG found that sponsors' compliance plans did not fully address all the CMS requirements.

Specifically, OIG found that compliance plans from certain sponsors contained only broad outlines of a fraud and abuse strategy or were missing one or more of CMS's required elements, including the development of internal auditing and monitoring procedures.

Further, although CMS required sponsors to initiate corrective action where evidence of fraud exists, we found that many plan sponsors that identified potential fraud did not do so. Even more disturbing is the fact that 28 percent of the sponsors did not identify a single incident of fraud or abuse. If there really was no fraud, that would be remarkable. But given our experience, it seems highly unlikely.

In addition to relying on the plans to target fraud and inappropriate payments, CMS has publicly stated that by using state-of-the-art systems and expertise, the agency and the MEDICs would prevent problems before they occur, which is the optimal goal. Yet

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we found that rather than using the advanced data techniques, CMS and MEDICs relied largely on complaints. While complaints have their place in fraud detection efforts, they are, by their definition, reactive rather than proactive. Unfortunately, the MEDICs were unable to engage in more proactive measures in large part because they did not gain access to the Part D pharmacy data until the second year of the program and did not get the data on the physician services until the third year.

Furthermore, when the MEDICs investigated potential fraud and abuse incidents, they did not have the authority to directly obtain information such as prescriptions and related medical information from pharmacies, pharmacy benefit managers, and prescribing physicians. Finally, while the MEDICs were prepared to audit sponsors in an effort to evaluate their compliance plans, the MEDICs were not given the approval to do so.

Again, it is up to CMS to address the issues we found with the sponsors and the MEDICs. To accomplish this task, we recommend that CMS develop a comprehensive program integrity plan that includes specific action items, target dates, and staff assignments. CMS also needs to conduct audits of sponsors in a timely manner and establish mechanisms to hold sponsors accountable for problems identified. CMS should also address the issues that prevent the MEDICs from directly obtaining information they need from pharmacies, pharmacy benefit managers, and physicians.

Finally, and perhaps most importantly, we recommend that all key players perform more innovative data analysis of claims and payment information and embrace proactive methods of fraud detection.

In closing, I can assure you that the Part D issues will continue to be a major focus of the OIG work. We are currently performing additional reviews, some of which will likely identify improper Part D payments that might have been prevented if there were strong detection and prevention programs. Clearly, there is more to be done by CMS and its partners to ensure the integrity of the Part D program, and we stand ready to assist them in their efforts.

I would be happy to answer any questions you may have.

Senator CARPER. Well, you are going to have to wait just a few minutes because we are going to recess and come back in about 20 minutes and ask Mr. Blum to make his statement, so you are on deck. And we thank you for your patience. We will be back in about 20 minutes. Thank you.

The Subcommittee stands in recess.

[Recess.]

Senator CARPER. All right. That is enough fun. [Laughter.]

We have concluded at least these first two votes, and we may have some more later on. But, Mr. Blum, thanks for your patience. We welcome your testimony. Thanks for joining us today. You are recognized.

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TESTIMONY OF JONATHAN BLUM,[1] DIRECTOR, CENTER FOR DRUG AND HEALTH PLAN CHOICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. BLUM. Great. Thank you very much, Chairman Carper, and thank you for the opportunity to come here today to talk about CMS's efforts, CMS's strategies to improve the performance, to improve the quality, to elevate the overall accountability of the Part D program.

The administration, CMS, is very much committed to ensure that we have the best program possible, the strongest program possible. We understand that we have a tremendous responsibility and a tremendous obligation to ensure that we provide benefits consistent with the law, protect taxpayers' dollars, and ensure beneficiaries have the high-quality program that they expect.

I want to highlight just a few points from my testimony, but I would be happy to answer any questions that you may have.

The first point that I want to highlight is that the Part D program is tremendously complex. We have 4,000 different contracts that provide Part D benefits. These are plans that are stand-alone drug plans, comprehensive HMOs, but the Part D benefit is delivered by 4,000 different private entities. That requires CMS to develop many different strategies, many different ways to oversee the program and to ensure that all 4,000 contracts have the same consistent values, the same consistent goals that CMS has.

The second point that I want to emphasize is that CMS uses—in order to manage this very large program delivered by 4,000 different contracts, we use a range of different data to ensure that we are monitoring the program, we are understanding issues, we are acting on issues, we are being as proactive as possible. CMS collects quality metrics. CMS collects and analyzes prescription drug claims. We monitor beneficiary complaints, physician complaints, and CMS responds very quickly, very proactively, to any issues these different data sources tell us.

CMS also has a very aggressive, a very robust audit strategy. In 2009, CMS conducted 348 different targeted and routine audits. We ensure that bids submitted to CMS are accurate. We ensure that plans follow our rules. We ensure that plans understand our rules. We ensure that our payments are accurate. We ensure that beneficiaries receive the services they are entitled to. But, again, given the breadth, given the scope, given the complexity, CMS has to dedicate our resources as prudently as possible. We have to target our resources as prudently as possible. But we are committed to overseeing through audits, both desk audits and on-site audits, a strategy to make sure we have the best possible program.

CMS has shifted to a more performance-based auditing system, meaning that we target our audit resources to those Part D plans that present the highest probability for vulnerability. We do not just do random audits, but we target those audits to those plans that present the biggest vulnerability to the program.

CMS has undertaken several new initiatives to further strengthen our ability to oversee the program. As Ms. King mentioned, CMS in the fall proposed 70 new regulations to improve oversight

[1] The prepared statement of Mr. Blum appears in the Appendix on page 63.

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of the Part D program. We expect to finalize those regulations. Our goal is to make the Part D benefit simpler for beneficiaries to understand, to ensure that CMS has more tools, to hold plans more accountable to the Part D program, and also to make sure we have the strongest possible compliance strategies, both operated by our Part D contractors but also by CMS. Again, CMS intends to finalize these rules this month to be effective for the 2011 contract year.

We have heard loud and clear the concerns regarding our contractors, the so-called MEDICs. CMS has changed the way that we contract with the MEDICs. We have a new strategy; we have a new focus. And I am confident that we will see even better results from these MEDIC contractors.

Last, we are working very hard to complete a composite error rate for the Part D program. We understand this is a high priority for you, this is a high priority for the Congress. We understand this is a high priority for the President. We have completed three components to this five-part composite error rate, and we expect to produce all five components to produce a composite Part D error rate by the end of next year.

Last, the President has made fraud and abuse program integrity one of his highest priorities for the Medicare program. He has proposed historic new resources to root out, to fight Medicare fraud and abuse for the traditional fee-for-service program, but also the Part C and Part D programs. It is true that in the past CMS lacked the resources to do sufficient oversight, to do sufficient auditing. But I am confident that with the resources we have that the Congress has given CMS, we have sufficient resources to address concerns of the past.

CMS has more work to do. We have made tremendous progress, but we have more work to do. We have several concerns that we are working very hard to address. We have concerns about marketing practices by our Part D plans, and we are working very hard to ensure that when Part D plans market their plans to beneficiaries, those communications are accurate, are responsible, and are appropriate.

We have concerns about plans providing appropriate clinical access to drugs. We also have concerns about plans that have very aggressive growth strategies. Those plans that grow the fastest seem to us to present the highest vulnerability to the Part D program, so CMS will be targeting more of its resources towards those plans that seem to be growing the fastest.

With that, I will stop, and I would be happy to answer any questions you may have.

Senator CARPER. All right. Thank you, Mr. Blum.

Let me just, if I can, throw out a question to you, but I would invite our other witnesses to respond, too. When I was an undergrad and later as a graduate student, I studied some economics, and I have always been intrigued. My professors at Ohio State would say, "Well, he did not study enough." I finally got the hang of it. But one thing that has always intrigued me is how do we harness market forces in order to help shape good public policy behavior. I will give you a couple of examples.

We have a hard time with Federal agencies actually selling the surplus property that is within their purview. They just hold on to

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it. We pay the utility bills. We pay security costs and so forth. And we find out that for the most part agencies, if they go to the trouble and expense of fixing up a property so they can sell the property, they do not get anything out of it. The money goes back to the Treasury. None of it stays within that agency. It cannot be used to help pay for the fix-up costs. Veterans Affairs is different. We let the VA keep maybe about 20 percent of the sale proceeds to use it for their program, to pay for the fix-up costs to sell that property.

Another example where we actually try to harness market forces is the health care bill that has passed the Senate, that is pending action in the House right now, but trying to incentivize people, employees of companies too, if they are overweight, lose weight; if they smoke, stop smoking; if they have high blood pressure, high cholesterol, bringing it down and keeping it down. And how do we do that? One of the ideas is to allow the employees who stop smoking, lose weight, control their cholesterol, control their blood pressure to actually receive premium discounts for up to 30 percent if they do the right thing for themselves and for the group under which they are insured.

Another example we have under Federal law—let us say you are a whistleblower. You work for Mr. Vito, and the work that Mr. Vito's company does for the Federal Government, they are crooks. That is a big leap of faith, I know. But they improperly bill us. They take money that they do not deserve—and you are an employee. You know about it. You report it. You blow the whistle. And it used to be Mr. Vito would turn around and fire you. You are history, you are out of here. That was pretty much it. And then we got involved and said, no, if we want to incentivize people to be whistleblowers, why don't we at least try to protect them so that they can get their job back and recover lost wages? So we did that.

Then we decided to take it a step further and say if you are a whistleblower, not only will your job rights be protected, not only will you get your wages back, but if there is a recovery for the Federal Government, you can participate and receive anywhere from, I think, 15 to 30 percent of the recovery for the Federal Treasury.

And I am told that the IRS may have a similar kind of arrangement where folks reporting tax fraud, tax evasion, if there is money recovered, some participation, some reward, if you will, can be provided to those who do the reporting.

We can have all this stuff we are talking about here in terms of Federal agency oversight and so forth and trying to make sure people are doing their job and all. Part of me says one of the ways to make sure that is happening is to actually incentivize folks, if they are aware of fraud, to report it, and with the knowledge that if they do, not only will they feel good as citizens that they have done the right thing, but they will also actually improve and enhance their own financial or economic situation by participating in the recovery.

Is this something that might work here? And if so, in fact, all of you, just be thinking how that kind of approach might be implemented with respect to identifying fraud in Medicare Part D and help reduce the huge deficits that we face; strengthen the Medicare trust fund; and try to do this in a way where we harness market forces in an effective way to do the policing for us. Go ahead,

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please. Mr. Blum, you take the first shot at that, and then I will ask Mr. Vito and Ms. King.

Mr. BLUM. Well, thank you for the question, Senator.

Senator CARPER. It was a long question, wasn't it? [Laughter.]

But a good one.

Mr. BLUM. Very good question. I think the greatest challenge that CMS has with the Part D benefit is to ensure that all the contractors that have contracts with the program share consistent goals and share consistent values with CMS, and those values are to ensure the beneficiaries receive the benefits in the best possible way, but that also taxpayer dollars are used as prudently as possible.

CMS has more work to do. We have to create a stronger culture of accountability. We have to ensure that our Part D contractors understand that they should have the same responsibilities as CMS does. And we are open to every idea to promote that accountability with our Part D contracts.

I understand that you have legislation to require Part D plans to report fraud. That is a very interesting idea. To our minds, that requires Congress to give CMS that authority. But I think any tool that CMS can add through regulation or that Congress can provide to ensure that our contractors, who are the front lines for the Part D benefit, share the same values that you have and also share the same values that CMS has.

Senator CARPER. OK. I am going to come back to you for a follow-up, but I want to hear a more specific response on the idea of sharing in the recovery. Just think about it.

Go ahead.

Mr. VITO. I believe that is happening in the Medicare program already, also in the Medicaid program. Some of our largest settlements have come from qui tams in which——

Senator CARPER. I am sorry. I do not like acronyms. What are qui tams?

Mr. VITO. That is when a whistleblower, someone who works in a company, realizes that the company has done something wrong, and then they come and—either they come to the government or they submit it and say that there is a problem here, we would like you, the government, to be aware of it, and see if you would like to join with us in going after this case. And some of the largest settlements that we have ever achieved have come from those actions.

So what you are suggesting is something that is working and can work very well.

Senator CARPER. All right. Thank you. Ms. King.

Ms. KING. Senator, I think one of the most effective strategies on fraud and abuse is to prevent it from occurring in the first place, and so I think that we would really encourage the front-end things, like having effective compliance plans in place and having CMS oversee them carefully as a sentinel effect, because it is much more effective to prevent fraud from occurring than paying and chasing.

Senator CARPER. OK. Well, I would suggest maybe we need all the above.

We have been joined by Senator McCain. What I am pursuing here, Senator McCain, is trying to figure out how do we incentivize folks to actually go out and help us identify the fraud that is occur-

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ring, and I pointed to what we do with whistleblowers when whistleblowers actually lead to a financial recovery for the government, they get to participate in the recovery anywhere from 15 to 30 percent. I think IRS has a similar kind of approach where we recover monies that have been, frankly, recovered because of tax evasion. And we have some other programs where we incentivize, I think, for the sale of government property, the VA actually gets to keep part of the proceeds of the abandoned properties or the excess properties that they do not need. Just looking for ways to use financial forces, economic forces to do a better job, and we are not doing a great job in this area, as you probably know. Let me yield to you. If you have a statement, go ahead. If you just want to jump into questions, feel free.

OPENING STATEMENT OF SENATOR MCCAIN

Senator MCCAIN. Thank you, Mr. Chairman. I apologize to the witnesses. As you know, we had a vote. We were interrupted by a vote, and I thank all of you for taking the time here and helping us with this very important issue. I would ask that my statement be made part of the record.[1]

Senator CARPER. Without objection.

Senator MCCAIN. Mr. Blum, as I understand it, the Medicare Prescription Drug Improvement and Modernization Act requires that all Part D sponsors have a program to detect and prevent fraud, waste, and abuse. CMS regulations establish the requirements for comprehensive compliance plans for Part D plan sponsors. CMS contracted, as you know, with medical drug integrity contractors, from now on MEDICs, to audit the compliance grants. Sixteen desk review compliance plan audits were conducted in late 2008 and 2009. CMS determined their value in monitoring and oversight efforts was limited. CMS is now engaging the MEDICs to conduct comprehensive on-site compliance plan audits and expects to have 20 or 30 of them completed this year.

We are in agreement so far, Mr. Blum?

Mr. BLUM. Yes, Senator.

Senator MCCAIN. OK. According to the HHS Inspector General, however, although MEDICs were given task orders to conduct compliance plan audits, they were not given the authorization to proceed. Why weren't they given the authorization? And does this mean that CMS paid for audits that were never done?

Mr. BLUM. Thank you for the question, Senator. It is my understanding that in the past CMS, through its contractors, its MEDICs, undertook these audits through desk audits, meaning that the audits focused on reviewing plans, papers, documents, do they have compliance plans in place.

CMS found those audits to have very limited value. To our minds, it is one thing to check documentation, but it is another thing to go on-site to a Part D plan to ensure they have the programs in place, they have the education processes in place. And so the agency completed 16 audits in the past, but decided not to issue final reports.

[1] The prepared statement of Senator McCain appears in the Appendix on page 42.

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We have changed that process, and we have changed the process to be more on-site audits to ensure that our Part D contractors share the same values that CMS does.

Senator MCCAIN. Now, when is this going to start?

Mr. BLUM. The process has started. Now we are finalizing our plans going forward, and I expect us to fulfill our obligation and also to make sure that our contractors, the MEDICs, also share in that as well.

Second, CMS is in the process of finalizing new regulations to give us more oversight on these compliance plans, to further define what plans have to follow, and part of our strategy, too, is to have a tighter regulatory process to have stronger processes in place.

Senator MCCAIN. Part D is currently in its fifth year of operations.

Mr. BLUM. Well, I cannot speak to the past, but I can speak to the present, and it is our—we are very much committed to fulfill the——

Senator MCCAIN. Who does speak for the past? If you do not, who does?

Mr. BLUM. Well, again——

Senator MCCAIN. Your predecessor? Is that what you are saying?

Mr. BLUM. Correct.

Senator MCCAIN. Ms. King, do you have a comment on this?

Ms. KING. Senator, I think that we recommended in 2008 that CMS conduct these audits, and they have started them, we believe that audits and on-site audits, as we conducted when we did our work, are really helpful and have a strong sentinel effect.

Senator MCCAIN. Do you have confidence that now in the fifth year of operations we will get it right?

Ms. KING. Well, Senator, we are an evidence-based operation. [Laughter.]

We do not speculate about the future, but we do look at the evidence before us.

Senator MCCAIN. And the evidence before you indicates?

Ms. KING. We have spoken to CMS about their plans to do on-site audits, and they are in the process of making final a regulation that will clarify what constitutes an effective plan. So I have no reason to think that they are not going to do what they say they are going to do, but we cannot make a judgment about its completion or effectiveness until after it has happened.

Senator MCCAIN. Well, could I suggest, Mr. Chairman, that maybe 6 months from now we could get a report from the Government Accountability Office. And maybe you can tell us what the evidence is then?

Ms. KING. Yes, sir.

Senator MCCAIN. Mr. Vito, do you have a comment on this?

Mr. VITO. Yes, sir. I want to tell you that we have been doing this work. We believe that prevention is the best way to make the program run, so——

Senator MCCAIN. Prevention of what?

Mr. VITO. Fraud, waste, and abuse. And the way you prevent it is you set up systems that prevent the payments that are problematic from going out before they occur.

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Senator MCCAIN. OK. I say with great respect I understand that prevention is vital, but finding out whether the prevention has been carried out is——

Mr. VITO. Yes, we agree with you. We started doing the audits in 2006 to see if the compliance plans—if the plans had compliance plans.

Senator MCCAIN. And what did you find out?

Mr. VITO. We found that they had them, but they did not have all the elements, and we were not certain that they were there protecting the program. We recommended at that time that CMS do audits in 2006. We continued to follow up through 2009 to see if they have done that.

Senator MCCAIN. What did you see?

Mr. VITO. We saw that they had not been successful in meeting what we have asked them to do. That is why we continue to follow up to make sure that happens. We are interested, just like you.

Senator MCCAIN. Mr. Chairman, the reason why I am focusing a lot of attention on this is because, as you know, at Blair House this issue was discussed and agreed upon by the President and all Members who were there. And I guess my only point is that in the fifth year of operation, I think we have the right to expect a little bit of something more than what we are finding out here today. And I am not, Mr. Blum, blaming you personally or anyone else, but it seems to me in the fifth year of operations, given the acceptance on all sides that there is significant fraud, abuse, and waste that can be eliminated, the President's plan is talking about eliminating $500 billion in fraud, abuse, and waste, that I right now do not have a lot of confidence that we have the procedures in place to really significantly impact it. I hope that I am incorrect in that impression, at least up to date, but I am encouraged by the comments of the witnesses.

There are a lot of other areas to discuss, but I see Senator McCaskill is here also, so I thank you for the time, and I thank the witnesses.

Senator CARPER. I think your idea of asking GAO to come back to us in about 6 months is a good one. And I think the idea of us having a hearing, maybe with these same witnesses, maybe with others, to see what kind of progress is being made—because in the last 4 or 5 years, what we have made is not enough. And I think I hear our witnesses—what I try to focus on is how do we incentivize—when fraud has occurred, how do we incentivize folks financially to help identify that fraud, to report it, and make sure we recover money.

What I think I hear our witnesses saying is that is maybe all well and good, but we also need to focus at the front end on the prevention side. So we start on the prevention, and you do the cost recovery at the end, but everything in between—and we need everything in between, given the amount of money that we are talking about.

Senator McCaskill.

Senator MCCASKILL. Thank you, Mr. Chairman.

I was reading my materials for this hearing, and, I had one of those moments where I read a sentence, and I went, "Huh?" And then I read it again, and I went, "Huh? Are you kidding?" Twenty-

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four of the 86 Medicare D sponsors, in 2008, did not report one incident of fraud. OK. And I believe in Santa Claus and the Tooth Fairy. If you have that many of these sponsors that are saying there are no incidents of fraud, then the auditor in me goes, "OK, there is high risk, we are on that." And I know, Mr. Vito, that the IG's report is what talked about this. And one of the things in the IG's report that I noticed was that we do not even require them, we suggest that they report fraud. Are you kidding me? We are giving them 90 percent of the money for this program right out of the general Treasury, and we are not even requiring that these people report fraud?

Mr. Blum, is that a regulation that has been proposed? Is there something we need to do to say that they are required to report every incident of fraud that they believe is occurring?

Senator CARPER. Mr. Blum, before you respond, we have offered legislation. Our hope is it is going to be in the—if we end up taking a sidecar approach in terms of adding to the Senate-passed health care bill, one of the elements of that would be to require that the fraud be reported. I do not think we have the ability in that legislation to also provide the incentives, the kind of financial incentives we do for whistleblowers at the IRS. I am very much interested in doing that. I am sorry to interrupt.

Senator MCCASKILL. Well, I am just curious if you have the ability to require people that we give that much Federal money to, to report fraud without a law. It seems to me that we ought to be able to do that by regulation without a law. If we cannot require them to report fraud, we might as well give them a gun and tell them to hold up the bank.

Mr. BLUM. Senator, our current regulations have voluntary reporting requirements. But it seems to me very awkward to have something through regulation that is voluntary. To me, a regulation should be required.

We have concluded, CMS has concluded that CMS could change its regulations to have mandatory reporting requirements, but CMS would not have the authority to enforce it. So to our conclusion, Congress would have to give us the authority to enforce that would make this change meaningful. CMS could change the regulation, but we could not enforce it, which says to us Congress would have to give us that authority.

Senator MCCASKILL. That is depressing to me that we would have to—that is something that would take a law to require people that we are giving money to, to tell us if they think that there is fraud going on. I do not want to argue the point with you, but if we are going to try to get it fixed, that is terrific.

We have talked a lot about fraud and abuse. I would like to for a minute get the reaction of GAO and the IG on the issue of waste. We have a mind-numbing number of choices out there for seniors, and if someone has to take Lipitor, maybe plan 42 is the best for them. If they have to take Aggrenox, maybe plan 21 is the best for them. And there can be a real difference in cost savings depending on which plan has negotiated the best price for which drug is covered in each of these mind-numbing number of choices.

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Do we have any data systems in place—and if we do not, shouldn't we—that track whether or not the seniors have made the best choice based on what their prescription needs are?

Now, let me preface this question, and I will look forward to your answers. It is not that I am interested in what seniors are taking. But if they have not made the best choice, guess who is paying for it? We are paying for it. So if they are in completely the wrong plan and they could save 50 percent by switching a plan, up to 45 percent of that money they could save is coming directly out of the U.S. Treasury. So what attempts have there been made to identify by data points that kind of massive amount of waste that has to be in this system that is enriching the profits of these pharmaceutical companies?

Ms. KING. Senator, if I may, and I can give you a long answer that I hope answers your question, but I am not aware of any data systems that actually capture whether seniors are making the best choices. CMS does have something called a Plan Finder which enables people to go on a website and figure out which drug plan best meet their needs. And we do not know how many do that. But there is also a provision in law that has to do with people who are dually eligible for Medicare and Medicaid. And in some cases—and they are in subsidized plans, so they are not paying a premium.

Year to year, a number of those people——

Senator MCCASKILL. So we are paying 100 percent of those costs.

Ms. KING. We are. Basically, yes. Year to year, if those plans go above the average, then the people in those plans are randomly assigned to other plans. And there is something—it is called intelligent assignment—where you can figure out what would be the best plan for them, but the law actually requires random assignment.

Senator MCCASKILL. So the law is saying it is OK if we placed Mrs. Jones in the plan that is going to make her plan twice as expensive because you are required to do it randomly?

Ms. KING. The plan is not twice as expensive, because they are reassigned to plans that are all below a certain level. But that person might be reassigned to a plan that does not best meet their drug needs.

Senator MCCASKILL. Well, what I am saying is that they could be reassigned to a plan that is going to cost the U.S. Government more than it should because that particular plan has not negotiated a good deal with a given drug company that particular recipient might need more of.

Ms. KING. Yes. And I think there are provisions in some of the health reform bills that would address this issue.

Senator MCCASKILL. Thank you, Mr. Chairman.

Senator CARPER. You bet. Thank you so much.

Senator Klobuchar, again, we are delighted you are here. Welcome.

Senator KLOBUCHAR. Well, thank you very much. Thank you for allowing me to be here, and as I mentioned, I have focused on this issue a lot on the Judiciary Committee, and I just continue to be astounded that we lose so much money when budgets are tight and people can hardly afford their premiums and we are losing $60 billion every year on Medicare or Medicaid fraud.

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And I was thinking, as Senator McCaskill was talking about someone robbing a bank with a gun, one of my favorite bank stories out of Minnesota was when a guy did come in and rob a bank with a gun, and then he passed the note to the teller, and the note he wrote on, on the back was his own check with his address and name on it. And that is what I was thinking is basically happening here. A lot of these people, when you look at the 90 percent of fraud cases that Senator McCaskill was referring to, Mr. Vito, in your agency's October 2008 report, they are associated with just seven companies. I mean, some of this is like not just low-hanging fruit; it is falling and rolling around on the ground.

So based on these findings, it would appear that the resources at CMS might be best utilized by focusing on, to use the fruit analogy, a few bad apples. So does CMS have the ability to focus its fraud prevention efforts on companies who appear to have an increased incidence of fraud?

Mr. VITO. Well, thank you for the question. I believe a lot of things play into this question. First of all, CMS does not get those statistics so they would never know. We got them because we wanted to find out.

What we were trying to learn about, we knew that the compliance plans, nobody was doing the reviews of those, so that we knew that CMS had no idea how effective compliance plans they were in detecting fraud, waste, and abuse. And we tried to get that to be done, but that was not done. So another way of us attacking it was to go and get the information from the plan sponsors to find out how much they have detected.

There are a lot of things that go into that, but when you look and then you do not know how well the plan's compliance plans are working and then you see those statistics, then it makes you really wonder what needs to be done here and how—do you focus on the ones that are reporting the large numbers, or do you focus on the ones that are not reporting any numbers?

But you see what I am trying to say? When you get both of those pieces together, then you are able to target exactly what you are saying, because when you see a compliance plan that is not identifying fraud, waste, and abuse, that does not have internal monitoring, and then you see the plan has no reported incidents or investigations, then you know that is a place to look.

Senator KLOBUCHAR. And are we targeting them now? Because, I mean, I know we are trying with this health care bill to put a bunch of tools in place, and we want to get it electronically. But what are we doing right now? Because I guess, Ms. King, are you aware of any enforcement action being taken against these sponsors that are found to not be compliant? Is that going on right now?

Ms. KING. That was not in the scope of our work, and I cannot answer that directly. Mr. Blum may be able to answer that.

Mr. BLUM. CMS has a range of tools that it uses to enforce our requirements. We have corrective action plans. We have enrollment suspensions. We have termination, kind of worst-case scenario. I am not personally satisfied with the information that was reported. CMS needs to do better. We need to identify plans that present the highest risk to the program. We are targeting our audit resources towards those plans that have the highest risk, and I think one fac-

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tor that CMS should consider is plans not reporting fraud may give us an indication as to that is where audit resources need to be applied.

We are moving to a strategy to apply resources, to apply audit resources towards those plans that present the greatest vulnerability. We collect a range of different data to help us identify those vulnerabilities. But I think this is an area CMS should explore to do more with.

Senator KLOBUCHAR. Well, I would hope so when we are talking about so much money. I think people would be outraged. When Bill Corr at your agency came and testified in front of the Judiciarym Committee, he described hot spots for fraud, specifically focusing on the durable medical equipment program. Have you looked at that for what these hot spots are for certain types, not just plans but types of provision of services?

Mr. BLUM. CMS agreed that we have geographic areas of the country that seems to be higher-fraud areas. We have certain services that tend to be higher-fraud services. We are dedicating more of our resources towards those hot spots. Deputy Secretary Corr talked about Operation HEAT, a whole new partnership, how we are working with the IG's office, with the Department of Justice, to target those parts of the country that present the greatest vulnerability to the Medicare program, writ large.

Senator KLOBUCHAR. Because it does seem to me, if you could get some wins and get some major people prosecuted and get some major money in, it sends a message to the whole system. And right now we do not have that. People just think they can rip people off. And we need those kinds of wins, and we need those kinds of examples. And I know people are—it feels like people are just trying to diagnose the symptoms and not treating them yet.

Mr. BLUM. We agree. The Administration, I believe, has taken unprecedented action in the past year to dedicate more resources, to require more resources from the Congress, and to take a historic new investment in Operation HEAT. It has proven successful. We have more convictions. CMS, I think, in the past did not share information with law enforcement partners. We have broken down those communication barriers, and the Secretary and the Deputy Secretary have been very clear that CMS needs to work in partnership with the IG's office, with the Department of Justice, to address the concerns that you are raising.

Senator KLOBUCHAR. Last year, an investigation found that Medicare claims contained the identification numbers of an estimated 16,500 to 18,200 deceased physicians involving approximately 385,000 to 572,000 claims for medical equipment. In every case study cited, these deceased physicians were obviously unwitting instruments, since they were not alive, in transactions that meant easy money for unscrupulous crooks.

What are you doing to combat criminals using the identity of deceased providers? Have you seen this type of fraud with Medicare Part D?

Mr. BLUM. I am not aware of this kind of fraud with deceased providers in Part D. But we do acknowledge that it is an issue for our traditional fee-for-service program.

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Again, I think part of our strategy is to use data and to use data analysis in much different ways, not focusing on the back end but focusing on the front end. CMS needs to do more with pre-payment review, with claims processing, data sharing.

Senator KLOBUCHAR. And making sure that everything is electronically deposited and that it is going to the right place?

Mr. BLUM. Absolutely. And CMS in the past has had various barriers to data sharing, data analysis. We are working as hard as we can to break those down and to be as transparent as we can with our data resources.

Senator KLOBUCHAR. Thank you.

Senator CARPER. Again, thanks for joining us and for your questions.

I want to stick to this issue or return to the notion again that if we want to recover these monies, in some cases prevent the fraud from occurring but recover monies that have been defrauded or taken from the Medicare trust fund or monies really from the taxpayers' pockets, we need to incentivize somebody to help recover the money.

One of the things we do in the Medicare program, in maybe the last 3 years or so, I think we have been using recovery audit contractors. We have deputized them and put them to work initially in three States—I think California, New York, and Florida—to go out and try to track down fraud and recover money where we can.

I am told the first year that we did that, we recovered almost nothing. The second year they recovered a little bit. Last year they recovered about, I think, a total of almost $700 million for the three years. And I believe the idea is to extent that to all 50 States, and, Mr. Blum, can you tell us what kind of timetable we are looking at for the extension of that kind of effort in all 50 States?

I would also add that I think the recovery audit contractors get to keep anywhere from around 10 percent of the monies that they recover, anywhere from 9 to 12.5 percent. Can you confirm that for us?

Mr. BLUM. We agree that the RAC program has been very successful——

Senator CARPER. And the RAC program refers to?

Mr. BLUM. Recovery audit contractors.

Senator CARPER. Thank you.

Mr. BLUM. They are contractors; they are allowed to keep a share of recoveries. They are right now primarily focused on fee-for-service claims, Part A and Part B claims, in the traditional fee-for-service program. It is my understanding that we are implementing this program on a nationwide basis. CMS agrees that the 3-year pilot has been successful, and that it is appropriate to bring the program nationwide.

To date, we have not applied the RAC contractors to the Part D program. I think that is a very interesting idea and something that Congress should consider, CMS should consider. But to date, the RAC contractors have been focused on the traditional fee-for-service program.

Senator CARPER. Do you need congressional authorization, do you need legislation to allow the recovery audit contractors to work in the Medicare Part D vineyards?

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Mr. BLUM. I believe we need authorization to extend the RAC program to the Part D——

Senator CARPER. Can you just come back to us on the record on that, please, if you would?

Mr. BLUM. Yes.

[The information for the record submitted by Mr. Blum follows:]

INFORMATION FOR THE RECORD

When the Recovery Audit Contractor (RAC) program was first created, it focused on FFS Medicare claims. With the enactment of the Patient Protection and Affordable Care Act of 2010, CMS now has the statutory authority to expand the RAC program to Medicare Parts C and D.

Senator CARPER. Let me come back to, I think, Ms. King and also Mr. Blum on the next question. Your testimony described, I think, that only 16 audits had been performed, I think during the last 2 years, out of, I understand—is it 86 sponsors? Are we talking about audits of sponsors? Is that it? I think you also referred to about 4,000 plans. What I would like to understand is the 16 audits involving 86 sponsors, so if we had audited everybody, there would be 85 audits. Just help me explain that.

Ms. KING. I think I might be able to help bring—I am going to give you some numbers that I think are right, but I can confirm them for the record.

Senator CARPER. If it is like 16 out of 4,000, that is not so good. If it is 16 out of 86, that is better. If there are 16 audits that are not worth the paper they are written on, that is not so good either. So I am trying to get to the bottom of this.

Ms. KING. The sponsors are at the corporate level, so the sponsors have contracts, and then they have plans. So there are a relatively small number of sponsors, and I think the 86 is about that number.

Senator CARPER. Does that sound right, Mr. Blum?

Mr. BLUM. That sounds correct.

Senator CARPER. OK. Thanks.

Ms. KING. But when you get down to Mr. Blum, it is like there are sponsors and then there are contracts, and contracts can have multiple plans. And then, that is how you get down to 4,000.

But most of the compliance programs I believe are at the corporate level, so they would be at the sponsor level. So the right comparison I believe would be to the 86.

Senator CARPER. All right. So 16 out of 86, and I think this was after at least one false start when the original plan to start out I guess just never happened. Now we are hearing that CMS will redo the first 16 audits. I think that is what we have heard here today, and it looks to me that the new administration is making a stronger, a more serious effort to audit these anti-fraud compliance plans. But I think we are really still at the starting gate. It really sounds to me like we are back at the starting gate. Is that a correct characterization?

Mr. BLUM. I think it is fair to characterize it that we are creating and implementing a new strategy for our audits of these compliance plans. I think it is fair to say that in the past CMS dedicated limited resources towards these audits. We have changed that. Thanks to the Congress, we have new resources for Part C, Part

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D oversight, and we have dedicated adequate resources for these compliance audits.

It is also true that in the past CMS conducted these audits through desk reviews, and——

Senator CARPER. You say through desk reviews?

Mr. BLUM. Through desk reviews, and we found those desk reviews to be of very limited value. And through our work with the MEDICs and through criticism and very good suggestions by the GAO and the IG, CMS believes these audits should be conducted on site. We need to make sure that plans just do not have the documentation in place but that they have the processes, they have the systems, they have the education programs, their executives understand these rules. And to our minds, we have to do these on site. We have put in place processes and plans to do on-site audits, and that is our current strategy for these compliance plans.

Senator CARPER. One last question, and I will yield to Senator McCain. I understand that Health and Human Services reported about $36 billion in improper payments for 2009. I think we had almost $100 billion in improper payments reported—the good news is we are thinking about improper payments; agencies are starting to identify it, report it. The next step is to go out and recover the money that has been improperly paid if there is a recovery to be had.

But that $36 billion figure of improper payments for Medicare in 2009 did not include improper payments for the prescription drug program of Medicare. When will the Centers for Medicare & Medicaid Services have improper payments for Medicare Part D? And what I have heard before anecdotally is 2012, you are always saying 2012, and that just seems a long way in the future. And I would just say if that is indeed what you are going to tell us, I hope you can work with our Subcommittee, work with the Congress, and others to find a way to speed up that process. But is 2012 what you are looking at?

Mr. BLUM. We are on track to complete the five-part composite error rate for the Part D program by the end of next year, so before 2012, by the end of 2011. We are placing a very high priority on completing the Part D error work. We understand that the Congress and the Administration, in order to correct issues, need to understand what the issues are. We have completed three of the components, and we are working very hard to finish the last two components to have a five-part composite error rate reported by the end of next year.

Senator CARPER. All right. So that means by the end of next calendar year?

Mr. BLUM. Correct.

Senator CARPER. And just tell us in very simple terms, when you complete the five components, what will that actually mean? They are actually reporting systemwide for Medicare Part D all the improper payments? It does not mean that we are going out and getting the money, but it means at least what, it is being all reported?

Mr. BLUM. Well, the way that CMS currently is proceeding is a five-part error rate. The first part that has been completed is an error rate regarding how well CMS's systems pay the claims. We have a very low error rate for that, less than 1 percent.

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The second component is to measure how accurately CMS pays low-income subsidies. Again, that error rate is less than 1 percent—0.25 percent.

The third component is to measure how accurately CMS makes payments for dual-eligible beneficiaries, those that qualify for Medicaid status. That error rate currently hovers about 1 percent.

Relative to fee-for-service error rates, those three components have very low error rates. But that is not the full picture. The full picture also has to be how accurately do Part D plans pay claims and how accurately do Part D plans report rebates they collect from pharmaceutical manufacturers. That is a much more data-intensive process, and to be frank, again, CMS did not dedicate the resources in the past to complete those two components timely. We have dedicated those errors. They are a priority——

Senator CARPER. Dedicated those errors or dedicated the resources? You said "dedicated those errors," but you mean dedicated resources.

Mr. BLUM. Yes, thank you, Senator. We have dedicated those resources to completing those last two components. I do not have an estimate—I cannot tell you what range they will be in. But we are very much committed to providing the Congress that five-part composite error rate.

Senator CARPER. Good. Thanks very much. Senator McCain.

Senator MCCAIN. Well, very briefly, if I could try to put this in perspective, Mr. Blum, my information is that in 2009 CMS estimated $24.1 billion in improper payments for Medicare fee-for-service and $12 billion for Medicare Advantage. That is a little over $36 billion. And what is the total payments that were made in Medicare fee-for-service and Medicare Advantage?

In other words, what I am trying to get, what is the percentage here of improper payments?

Mr. BLUM. I will get you accurate figures for the record.

[The information for the record submitted by Mr. Blum follows:]

INFORMATION FOR THE RECORD

Here are the accurate figures for the record. For 2009, CMS improved how it reviews Medicare claims for inpatient hospital services and eliminated the use of past billing records as part of a complex medical review. As a result of this heightened scrutiny, increased oversight, and more complete accounting of Medicare FFS claims, CMS is reporting a 2009 FFS error rate of 7.8 percent, or $24.1 billion of $308.4 billion total dollars paid, compared to 3.6 percent in 2008.

Meanwhile, the baseline composite Medicare Advantage, or Part C, error rate, based on payment year 2007, is 15.4 percent, or $12.0 billion of $77.8 billion total dollars paid. The Medicare Part D composite error rate is under development with three components being reported this year: A payment system error of 0.59 percent, the low-income subsidy payment error of 0.25 percent, and payment error related to Medicaid status for dual eligible Part D enrollees of 1.06 percent. Part D spent a total of approximately $49.5 billion in FY 2007.

Mr. BLUM. Currently I believe Medicare spends about $450 billion on the traditional fee-for-service program, the Part A and the Part B program. Medicare Advantage, CMS pays about $130 billion to private Part C plans. And on the Part D side, we spend about $50 billion for Part D contractors.

The fee-for-service error rate that was reported this past fall was 7.8 percent. The Part C error rate is higher, 15.6 percent.

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Senator MCCAIN. Why would there be that disparity between 7.8 and 15.6 percent?

Mr. BLUM. We used different measures because the fee-for-service program and the Part C program are so different: For fee-for-service we pay on a claims basis, per claim basis. For Part C plans, we pay on a capitated basis. So we use different processes, different measures to calculate the error rate.

For the fee-for-service program, in essence, contractors audit the claims to make sure there is documentation to support those claims. The error rate is not a fraud rate, but it is a rate of how accurately, according to CMS's fee-for-service rules, the claims were paid.

On the Part C side, that is a capitated payment per member per month, but Part C plans report health status data to CMS because their payments vary by the health status of their enrollees. And what CMS has found is that the health status reported by plans does not match the documentation they provide to support those health status claims.

Senator MCCAIN. And my understanding is that 87 percent of potential fraud and abuse were identified through external sources. Is that a little disturbing, that 87 percent should be identified by people who were doing their duty?

Mr. BLUM. CMS has used contractors in the past for the majority of the reviews, sort of the back-end reviews, to measure and to identify fraud. We, as an agency, believe that our role is to prevent fraud before it happens. We have dedicated——

Senator MCCAIN. I want to emphasize again, Mr. Blum, there is no one who would disagree with trying to eliminate fraud before it happens. But it is obviously happening, and it is obviously not being detected when only 13 percent of the detections are done by the agency itself and 87 percent are done by other citizens. Mr. Blum, there is no one that disagrees that we should try to prevent it, but we know it occurs. So don't you think you should be focusing more attention on that side of the equation rather than relying on patriotic citizens to identify this fraud and abuse?

Mr. BLUM. I agree with you, Senator, that the agency has a responsibility and a role to make sure that every claim, to the extent possible, is paid accurately. Congress has given CMS new resources. The President has requested new resources, and we have changed the way that CMS interacts with law enforcement agencies to ensure that they also have access to the same information we have. And I agree with you, the agency can do more, has done more, and will continue to do more.

Senator MCCAIN. Well, just finally, Ms. King, are you satisfied that we are taking the necessary steps to at least address this problem seriously?

Ms. KING. We will be interested to see with respect to Part D what CMS's revised audit strategy looks like, because they are still revising it. We believe a strong and effective audit strategy is essential. So we are in the trust but verify position.

Senator MCCAIN. Thank you very much.

Thank you, Mr. Chairman. I thank the witnesses, and I know that this is very difficult when we are talking about these sums of

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money there. But because we are talking about these sums of money there is a reason for us to continue to pursue this effort.

Thank you, Mr. Chairman.

Senator CARPER. You bet.

We know we have these huge budget deficits. We know the Medicare trust fund is running out of money, and we are trying to pass legislation that would sort of extend the life of the Medicare trust fund from maybe 7 or 8 years to at least double that. Hopefully, we will be able to get that done this year.

All that notwithstanding, there is work to be done on the prevention side. That is clear. We have an obligation to help you, provide and make sure you have the resources and also the encouragement to do the good work that is needed there.

There is, I think, good work that can be done by the recovery audit contractors, just like they are working in other parts of Medicare. I think those resources can be brought to bear here, and it is almost an incentive system. They get 9 to 12 percent of the monies they recover. That is a pretty good incentive. And I want us to look long and hard at what we are doing with whistleblowers to compensate them for blowing whistles and being willing to take a risk to make sure we cannot—hopefully, we are going to pass legislation this year, maybe even this month, that says rather than we encourage folks to report fraud in the case of Medicare Part D or Medicare, we are going to require them to, and then come back later on this year with some way to incentivize them to do that, not just because it is something they ought to do.

One last question I have for Mr. Vito. Your testimony described the importance of proactive data analysis, what some call data mining, and Medicare drug integrity contractors are tasked with proactively analyzing the purchases, cost, and distribution of medications to root out waste, fraud, and abuse. MEDICs did very little, I am told, according to your audits and testimony. Could you comment more on the situation and why this work is critical? And I think we are going to soon hear from the MEDICs, and they are going to testify that they have increased their proactive data analysis. Does this indicate an improvement? Should more be accomplished? Can more be accomplished? Thank you.

Mr. VITO. Well, largely their efforts of identifying fraud were based on the complaints, which, in fact, is something that happened already. Their strategy at CMS and the MEDICs was to use proactive data analysis to identify the problems and prevent them before they occurred. That largely did not happen because the MEDICs who were tasked to do that did not have the data to do that analysis.

Senator CARPER. And can you tell us why they did not have the data?

Mr. VITO. I cannot tell you specifically why they did not. That would be a question for CMS. But when we went to them and asked them to tell us what you are——

Senator CARPER. When you say "them," them being CMS or the MEDICs?

Mr. VITO. I am sorry. When we went to the MEDICs as part of our MEDIC review, we said, let us see the proactive data analysis, let us see what you are doing to prevent and detect fraud, waste,

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and abuse, because, for example, you put up information today about people who are abusing drugs. If you had proactive data analysis, you might be able to find that. You might be able to see that happening. And when you see that happening, then you could prevent it at that time rather than waiting until after the fact when something bad might happen besides just paying the money. So there are significant benefits.

CMS recognized how important it is to do that proactive data analysis, and they wanted to get it done, but they just had problems implementing it and making it happen. Now we are told that the MEDICs have the data, and they are actually utilizing that data to do proactive data analysis.

We are also in the trust but verification work as well, so our goal will always be to find out if exactly that is happening. What you need now is you have the data; now they have to start utilizing the data to the best way that they would be able to get the best benefit out of it. And CMS has to be monitoring them to make sure and helping them to make sure that they are able to get that done. And we will as well.

Senator CARPER. This is the last question before we excuse this panel. Every now and then I ask witnesses—as we try to drill down and find out where we can save some money, I ask the witnesses to just say what can the Legislative Branch of our government be doing better. I talked about the agencies. Everything we do we can do better. I know that is true for me, and I suspect it is for all of us. What more, or what less, should the Legislative Branch be doing here, this Subcommittee in particular, to make sure that, one, we are preventing fraud from occurring, and in the second place, to the extent that it is occurring, that we identify it; three, make sure that we stop it; and, four, that we go out there and recover as much of this money as we can for the trust funds and for the taxpayers? What more should we be doing, Ms. King?

Ms. KING. Senator, I think oversight hearings such as this draw attention to these issues and point out where improvements can be made. We are always available to do further investigation into issues like this, so we would be happy to assist you in that.

Senator CARPER. Good. Thanks. Senator McCain alluded to that, and we would like to follow that up with you. Mr. Vito.

Mr. VITO. As it relates specifically to this hearing and this work, one of the areas that we saw is that the MEDICs did not have the opportunity to directly go to the pharmacies, the plan benefit managers (PBMs), and did not have the opportunity to go to the physicians directly. If you would provide some legislation in that area, that would help them accomplish that and help them.

Senator CARPER. All right. Thanks. Thanks for that.

Mr. Blum, would you comment on the point that Mr. Vito just made and then add to that whatever you would like?

Mr. BLUM. I agree that Congress can help CMS share information, give access to information, both with CMS staff and also with the various partners that we use to help us oversee the program.

But I think there are some very important provisions pending now in health reform that will give CMS more tools to oversee and to strengthen the Part D program. One provision that is pending both in the Senate-passed and the House-passed bills would give

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CMS more authority to reject plan bids. Today we have very limited authority. Plans have to meet certain screens, have to meet certain checks. But at the end of the day, CMS has few opportunities to reject Part D plan bids altogether. Having that tool will give CMS more ability to promote the best possible Part D contractors. I think that is one area that Congress can help CMS.

Senator CARPER. Good. All right. We appreciate your being here. We appreciate your preparation for the testimony, and we realize we are making some progress. But we are not making enough, as you know, and I feel and I think my colleagues feel there is a certain passion to want to step this up, take this up to the next level, from our end and from your end as well. And this is one that we are going to continue to follow up on, see how we are doing, and to see if we are making progress, and to find out what more you all need to be doing, and particularly CMS, to find out what we need to be doing, too, to support those efforts and encourage those efforts.

Thank you very much for joining us today.

Ms. KING. Thank you.

Senator CARPER. With that, we will invite our second panel to the table. Thank you.

[Pause.]

Senator CARPER. All right. I will ask the Subcommittee to come back to order, and the audience. Welcome to our second panel, Mr. Apple and Dr. Jensen.

Our first witness is Howard Apple, President of SafeGuard Services. SafeGuard Services, I am told, is one of the contractors who provide compliance fraud, waste, and abuse services for the Center for Medicare & Medicaid Services.

Our second witness today is Dr. Christian Jensen, who is the chief executive officer of Quality Health Strategies. And Quality Health Strategies, I understand, is another of our contractors that provide fraud analysis and oversight for the Medicare Part D program.

Welcome. You are both recognized, and I would ask you to try to give us your statement in about 5 minutes apiece, roughly. If you go a few minutes over that, that will be fine. But if you go much over that, I will have to rein you in. I have a meeting at about 5 o'clock that starts with the Finance Committee, so we will get right into it. But let us have your testimony, and then we will ask some questions. Thanks so much for joining us. Mr. Apple, you are recognized.

TESTIMONY OF HOWARD B. APPLE,[1] PRESIDENT, SAFEGUARD SERVICES, LLC, ACCOMPANIED BY DOUG QUAVE, PROGRAM DIRECTOR, COMPLIANCE AND ENFORCEMENT MEDIC

Mr. APPLE. Thank you, Senator, and I will have a written statement for the record. This will be an abbreviated statement.

Senator CARPER. That would be great. Thanks.

Mr. APPLE. Mr. Chairman and distinguished Members of the Subcommittee, thank you for the opportunity to discuss SafeGuard Services' role in helping CMS combat fraud and abuse in the Medi-

[1] The prepared statement of Mr. Apple appears in the Appendix on page 77.

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care prescription program. My name is Howard Apple, and I am the President of SafeGuard Services.

For background, the enactment of the Medicare Modernization Act of December 8, 2003, represented the largest change to Medicare since its inception by creating a new prescription drug benefit for Medicare beneficiaries, which is Part D. Beginning in September 2006, CMS geographically divided the United States and awarded contracts to three Medicare Part D integrity contractors, the MEDICs. They were MEDIC North, South, and West. Each MEDIC was responsible for performing program safeguard functions to detect, deter, and prevent fraud, waste, and abuse and to mitigate vulnerabilities associated with the Part D benefit services provided within their geographic jurisdiction. SGS was awarded the contract for MEDIC North, which consisted of 24 of the States in the Northern United States, the District of Columbia, and the U.S. Virgin Islands.

In September 2008, CMS reduced the number of MEDIC contractors to two organizations, resulting in the reassignment of MEDIC West States to the MEDIC North and South. MEDIC North's jurisdiction expanded to include 35 States, four U.S. Territories, and the District of Columbia. Additionally, the MEDICs were tasked with supporting the Center for Drug and Health Plan Choice's Efforts to address new or emergent areas of compliance and enforcement related to Medicare Advantage, Part C, Part D, and the program of all-inclusive care for the elderly for these States and Territories.

Under the MEDIC North contract with CMS, SGS's responsibilities included the investigation of allegations or suspicions of fraud, waste, and abuse in the Part D program within our jurisdiction. Complaints were received from a variety of sources. The majority of complaints were received via the CMS's toll-free Part D hotline and through CMS's Complaint Tracking Module. Typically, complaints involved telemarketing scams, inappropriate enrollment or disenrollment within a plan, Explanation of Benefits errors, improper marketing practices, and drug diversion. Additional responsibilities included using innovative data analysis techniques to identify potential fraud, waste, and abuse, fulfilling requests for information from law enforcement agencies, and conducting compliance plan audits of Part D sponsors.

In October 2009, SGS's contract again was modified when CMS decided to realign the responsibilities of the MEDICs functionally rather than geographically. MEDIC North became the compliance and enforcement MEDIC with the mission of providing nationwide support of CPC's compliance and enforcement strategy and to bridge the gap between compliance and enforcement activities managed by the Program Compliance & Oversight Group in CPC, and the nationwide fraud, waste, and abuse activities tasked to Health Integrity and managed by the Program Integrity Group. Our responsibilities now include providing audit technical assistance; conducting plan sponsor readiness and ongoing compliance assessment; investigating complaints against agents and brokers involving violations of the Medicare regulations; and monitoring and evaluating sponsors' compliance plans and the effectiveness of those plans.

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I just want to read a few accomplishments that we have had to date.

From December 2006 through November 14, 2009, we received over 10,000 calls via the toll-free hotline. We handled over 3,200 complaints from beneficiaries. We initiated over 1,100 investigations. We referred over 120 instances of fraud and abuse to the OIG and other law enforcement agencies. We also fulfilled 300 requests for information, such as Part D data, from law enforcement agencies and referred over 170 agent or broker misconduct cases to State insurance commissions.

These accomplishments resulted from developing a collaborative and constructive relationship with CMS at all organizational levels which we continue to foster through weekly meetings, ad hoc meetings, and conference calls.

Thank you, Mr. Chairman, for the honor of speaking with you today, and I would be happy to answer any questions that you or Members of the Subcommittee may have.

Senator CARPER. Thanks for your testimony.

Dr. Jensen, I am going to ask you to hold up for just one moment. I am getting a phone call that I need to take. We will recess for 2 minutes, and I will be right back. Do not go away.

[Recess.]

Senator CARPER. All right. Dr. Jensen, please proceed. Thank you.

TESTIMONY OF CHRISTIAN JENSEN, M.D., MPH,[1] PRESIDENT AND CHIEF EXECUTIVE OFFICER, QUALITY HEALTH STRATEGIES, AND MEMBER, BOARD OF DIRECTORS, HEALTH INTEGRITY, LLC

Dr. JENSEN. Thank you very much, Senator Carper. I am Dr. Christian Jensen, and I am the CEO of Quality Health Strategies (QHS), which is a nonprofit corporation. Health Integrity is one of QHS's subsidiaries and has a Medicare drug integrity contract. Our written testimony that we have submitted contains many more details on our experience with Medicare program integrity contracts, but I wanted to note that we are also the holder of the Zone Program Integrity Contract for Region 4, which includes the Southwest, and for Task Orders 1 and 5 of the Audit Medicaid Integrity Contract.

The history of these contracts has been well covered by Mr. Apple, and as the program has evolved, CMS has taken some important steps to try to improve the integrity of Medicare and Medicaid.

There are some unique differences between Medicare fee-for-service and Medicare managed care programs and Medicare Part D, and the complexity of Medicare Part D was alluded to by Mr. Blum. The data systems and the data itself are much less mature with Medicare Part D, and the risk model is much more complex. It includes cost sharing, risk sharing, and coverage gaps and so forth. And there has been, as has already been alluded to, a lack of direct access of the MEDICs to downstream providers. For exam-

[1] The prepared statement of Dr. Jensen appears in the Appendix on page 82.

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ple, we were not able to get physician and pharmacy records for most of the time of our existence.

I would like to share with you that the OIG report represented a picture of the MEDICs as of the end of calendar year 2008. However, during 2009, many of the challenges and the difficulties that we had encountered in bringing this program to successful maturation were overcome. I cite a few.

Medicare Part B data access was obtained in late 2008. During 2009, and that is what the following numbers allude to—about 2,500 call center complaints were received and processed: 138 requests were processed for law enforcement; 121 fraud referrals were made to law enforcement; 157 referrals were made to State insurance commissioners; 47 proactive analyses were completed; 662 investigations from all sources are now open, and 267 investigations resulted from proactive analyses, with 28 percent of all our investigations during 2009 resulting from proactive analyses. Twelve referrals have resulted from our proactive analyses, and we have 203 investigations from proactive analysis which are still underway.

Also during 2009, Health Integrity focused great efforts on trying to ensure that the law enforcement community and the plans were fully educated concerning the differences and the subtleties and the financial impact of Part D fraud. And as a result, we have seen three Part D indictments in 2009 and 2010.

We have had a great deal of success in collaborating with plan sponsors. We have established Part C and Part D plan working groups. They meet quarterly and include law enforcement, the ZPICs, and the plan sponsors. And, as a result, the referrals that we receive from plan sponsors went up from 90 in 2007 to 396 in 2009, and we have already had 244 in the first 2 months of 2010.

Health Integrity has only been the national benefit integrity MEDIC since October 2009, 5 months, but already this national experience has strengthened our ability to identify new and emerging regional fraud schemes, to identify existing national scope issues, and to focus on fraud and its prevention through vulnerability reporting, fraud alerts, and other measures. And I would like to thank Senator Carper and the Subcommittee for this opportunity to offer my comments, and I am pleased to answer any questions.

Senator CARPER. Thanks, Dr. Jensen.

In your statement you mentioned—I will paraphrase, but I think you said we have had a great deal of success in—I think "coordinating" was the word that you used—in coordinating with plan sponsors. How do you measure success in the work that you do? In your statement, you talked about referrals and investigations begun.

Sometimes in our schools we measure success not by whether the kids make progress, academic progress from the beginning of the school year to the end of the school year. We judge success on whether they show up or whether there is lack of disciplinary problems. But how do you measure success?

Dr. JENSEN. Well, one measure of success, although it is perhaps a progress or a process measure rather than an outcome measure—because we are not at the outcome stage yet with many of these investigations—is by the number of referrals and their dramatic in-

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crease from the plans. Somebody is getting the message there at the plans that the MEDICs are here and that they can handle these complaints or referrals that they receive about fraud, and that there is a responsibility on the part of the plans to make those referrals.

Senator CARPER. Thank you.

Mr. Apple, how do you measure success?

Mr. APPLE. Well, there are two ways of measuring success. You could look at quantity and say we referred this many cases to law enforcement. But what I look at more and what my team looks at more for metrics is the quality of our work.

So, for example, if in 1 year we referred 10 cases to law enforcement and five of them ended up not being accepted because they did not believe the quality of the work was that good, there is a benchmark. If the next year we find 100 percent of our cases were accepted because of quality, that is one benchmark, to me, of success. And at SGS, we truly—the mantra is not quantity. You want, of course, quantity. But the mantra really is quality of work. When we refer cases to law enforcement, when we do responses to law enforcement for requests for information, if we get a letter back from law enforcement saying that was very helpful, that saved us tons of hours of work to get this case through, that to me is a measure of success.

Senator CARPER. Is there some way that we are measuring success in the work that you all do, we actually quantify dollars that we have prevented from being defrauded from the program or dollars that we have recovered that were fraudulently diverted? Is that part of the measurement of success?

Dr. JENSEN. There is, of course, the return on investment measure: Comparing what CMS puts into funding its contractors, to what are they getting back and what the taxpayers are getting back. And that is a difficult thing to measure sometimes when you have a lot of variables.

Senator CARPER. Let me just interrupt you if I can. I mentioned earlier the program that we are running, initially in three States, with the recovery audit contractors where we recovered through last year about $700 million. That is pretty easy to say this program is working. They get 9 to 12 percent as a percentage to compensate them for their efforts. But, we could say, well, we are getting $600 million, $700 million, that is a pretty good way to measure success.

But what I am looking for is a way to quantify your efforts and the efforts that you have described here in ways that are relevant to us as the $600 million or $700 million figure is relevant. I am sorry. Go ahead.

Mr. APPLE. Well, I was going to say SGS does more than just the MEDIC work. We are also a ZPIC. We also are a program safeguard contractor in several States. And let me just digress a little bit from the MEDIC, if I may.

In the other programs, as a ZPIC and a program safeguard contractor, we really are prohibited by CMS from measuring success by return on investments, and the reason being is we do not want to be perceived as bounty hunters. So, in other words, you do not

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want to just say we referred 50 cases to law enforcement and not really look at the quality of our work.

But in the ZPICs and in the program safeguard contract, we know how much we recover. There is a mechanism for us to know how much was recovered, and that is one way of knowing that the return is far greater than the expense of running our programs.

I have behind me Doug Quave, who is my program director, and, he has told me we have no way of really getting the records to know how much was recovered on the MEDIC Part D.

Senator CARPER. Feel free to come to the table and identify yourself for the record, please.

Mr. QUAVE. Thank you. For the record, my name is Doug Quave. I am the program director for what is now the Compliance and Enforcement MEDIC. We used to be MEDIC North, as Mr. Apple referred to.

The problem is because of the intricacies in the ways that the Part D and Part C programs are paid in a capitated rate, it is difficult to quantify the loss to the government. It is not like Parts A and B, where somebody submits a claim and gets paid so much for a claim. Instead, they get paid a monthly rate per member to administer the plan. And then they bid, the sponsors bid a certain amount and say this is how much we think we can quantify—we can provide this plan for the beneficiaries.

So it is very difficult to quantify the loss. That is why it is difficult for us to turn around and show the return on investment by a referral. At this point, we have been referring law enforcement to CMS for assistance in trying to quantify that amount on our referrals.

Mr. APPLE. And let me just add on to that what I was saying is under the Part A and Part B program, there are different mechanisms to see the metrics. Number one, you could stop payments from going out the door. You could put pre-payment edits in. You could make recovery of overpayments. So that is a more definitive way of knowing what was recovered and what your return was. You do not have that in the MEDIC program.

Senator CARPER. All right. Somebody else? Dr. Jensen.

Dr. JENSEN. There are anecdotal or isolated reports so, for example, we conducted an investigation into allegations about a pharmacist in a Southern State who was submitting high-volume—false claims for high-cost HIV and anti-psychotic drugs to eight Part D plan sponsors. The investigations revealed that particular pharmacist had submitted $200,000 worth of prescriptions to Medicare Part D which were never provided to the beneficiaries or prescribed by the physicians. That pharmacist was taken out of practice. That perhaps is one example of a saving.

Another also took place in a prominent Southern State where a pharmacy billed Medicare's Part D for medications that were never rendered to beneficiaries nor prescribed by physicians which totaled over $1 million between February 4, 2008, and June 26, 2009. The owner of the pharmacy was indicted in the Southern District of that State on charges that he owns two pharmacies which billed Medicare for approximately $20 million and received $6 million in payments. He was sentenced to 112 months' incarceration.

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But, Senator, there are other values to this program which cannot be measured in dollars. I point out also an investigation of a physician and a nurse practitioner who were overprescribing controlled-substance narcotic analgesic drugs. Known drug traffickers were seen going into the office, and as a result of his prescribing, 10 patients died of overdoses of prescription drugs. That doctor was indicted in October 2008 on 14 counts that alleged her actions led to the death of three patients in 2006. Her trial is set for next month.

And the director of an assisted living facility who stole controlled-substance medications from chronically ill patients for her own personal use was indicted on 11 counts of false statements relating to a health care matter.

Those things are important perhaps, but it is difficult to measure them in money.

Senator CARPER. OK. Thank you.

A question really for both Dr. Jensen and Mr. Apple—maybe a couple of questions. Your comments and your testimony have suggested some improvements on several fronts identified by the GAO and by the Inspector General. MEDICs, I believe, were supposed to ensure that the sponsors' anti-fraud compliance plans were in order and being implemented correctly. Yet the Center for Medicare & Medicaid Services prevented you from actually starting the audits. At least that is what I am told.

Would you say that the progress on auditing the compliance plans started once you were given the authority to audit the anti-fraud plans of the sponsors?

Second, why were you not given the authority before 2008?

And, finally, are there current tasks or auditing that you are awaiting permission to begin?

Mr. APPLE. Well, I could start with that. Quite frankly, we do not know why we were not given the authority. We were just told we were not able to conduct audits until—I believe it was October 1, 2008, and, again, this is the customer telling us this, and we follow what the task order required of us.

We believe that as we do more audits and as we——

Senator CARPER. Let me just interrupt you. Are there current tasks or audits that you are awaiting permission to begin, either of you?

Mr. APPLE. As I speak here today, we are conducting an on-site audit, under the new program an expanded audit, and we are told that many more are being planned.

Senator CARPER. OK. Are there audits that you are awaiting permission to begin?

Mr. APPLE. No, because we do not request permission from CMS. They tell us which audits they want conducted. This is directed by CMS.

Senator CARPER. Dr. Jensen.

Dr. JENSEN. We did, while we had the authority to do it, 10 audits, which were desk audits, and I will say that we, too, were prepared to do many more audits. The MEDICs were ready to carry out that responsibility, but the orders did not come.

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Of the 10 desk audits we did, we did find some areas of weakness, but the desk audits are subject to the criticisms that have been made already here this afternoon.

Senator CARPER. Let me just interrupt you again, if I may. Describe for us in terms that everybody could understand what a desk audit is. Describe for us in terms that everybody can understand the kind of audits that you ought to be conducting, if allowed.

Mr. APPLE. Well, the desk audit itself was essentially you asked for information from the sponsor for——

Senator CARPER. "You" being?

Mr. APPLE. SGS would ask——

Senator CARPER. SGS stands for?

Mr. APPLE. SafeGuard Services. That is my company, SafeGuard Services. And a request would be made of the sponsors, the plans, to provide us the data to prove that they were meeting the seven elements required to be a sponsor.

The difference between that and what SGS is doing now is now we are going on site and we are looking at the effectiveness of their programs, of their compliance programs. And this would be the best example, Senator. On a desktop audit, SGS might receive information that had proof that training sessions were provided on the following dates, A, B, C, D, E. When you go on site, you could get extra records like attendance records. How many people actually attended? Let me see the curriculum that you provided the attendees to make sure it is relevant to the work you are doing. So you really can delve into the effectiveness, not just the fact that they checked the box and had compliance.

Senator CARPER. Dr. Jensen, same question. Just compare for us a desk audit to the kind of audit that you think you ought to be doing.

Dr. JENSEN. In my view, an on-site audit has many advantages over the desk audit, the opportunity to verify on site directly and experientially what has been stated in a document.

Senator CARPER. OK. And do you feel like you now have the ability to go on site and conduct the kind of on-site audit that is more appropriate?

Mr. APPLE. Mr. Chairman, the audits we are doing now are much more effective, and my team believes that these audits will be very effective.

Senator CARPER. Dr. Jensen.

Dr. JENSEN. The division of labor between the two MEDICs leaves that responsibility now with Mr. Apple's organization.

Senator CARPER. OK. Now, one of the questions I asked at the end of the first panel, I asked them to tell us what we needed to be doing in terms of legislation that would enable them to do a better job, especially CMS, and they gave us a couple of ideas, and we explored some other ideas during the course of their testimony. But in terms of what you need to have in order to be able to be unleashed to be fully effective, what do you need in terms of change in attitude, change in direction, change in regulation, change in legislation? What do you need to unleash a tsunami-like effect in assaulting fraud that has occurred in this program?

Mr. APPLE. Well, Mr. Chairman, I come from a background of law enforcement. I have a long history of law enforcement. And you

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made a reference to Willie Sutton robbing a bank because that is where the money is.

Medicare fraud is a little bit different, and that fraud many times is paper driven. And I will tell you that anytime you have Medicare fraud, if you have sufficient data, you will find that fraud proactively or reactively. And with that as a basis, my comments would be the more data that can be available to the MEDICs, the better off the MEDICs will be.

Additionally, if the MEDICs were allowed to obtain medical records directly rather than going through the sponsors, I believe that would be beneficial.

And, third, something that was not addressed is while the MEDICs are able to look at the A and B data, the fact is that the PSEs and ZPICs that do the A and B are not allowed to look at the D data. And I believe the more people, the more investigators that can wrap their hands around data and crime problems, you will get a better picture and more productive results.

Senator CARPER. Good. We are going to write you and ask you to reiterate that and maybe amplify on the points you just made in writing, if you would.

Mr. APPLE. Mr. Chairman, I would be delighted.

Senator CARPER. Dr. Jensen, would you react to what——

Dr. JENSEN. I echo what Mr. Apple said, particularly with respect to data. One of the reasons we are here and some of the criticisms which have been made of the program are because of the lack of data in a timely way. The larger the database, the greater the potential for identifying fraud, and that is what I am enthusiastic about. Anything that the Legislative Branch can do to facilitate that would be greatly appreciated.

Senator CARPER. OK. Is there anything that either of you want to add or take away from what has been said? Also, not just for this conversation we have had with you on this panel, but looking back to our conversation with our first three guests, just reflect on that. Anything that you would like to underline, underscore, bring to our attention as especially noteworthy?

Mr. APPLE. I think hearings like this are so essential. It makes us all better, and I appreciate the ability to be able to participate in this hearing. Thank you, Mr. Chairman.

Senator CARPER. Sure. Any points?

Mr. APPLE. No. I think every one of their points were on line. I do not think I could add to anything that they said already without just being redundant.

Senator CARPER. That is all right. In a setting like this, redundancy is actually good. [Laughter.]

Mr. APPLE. OK.

Senator CARPER. We are talking about billions of dollars we are trying to capture.

Mr. APPLE. One thing that Mr. Vito mentioned—again, what I said—is to give more data to the plans and also to require the sponsors to report fraud, waste, and abuse and not make it voluntary.

Senator CARPER. OK.

Dr. JENSEN. And in retrospect, considering the testimony from the previous panel, it is important to remember that was a snap-

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shot in time. That was at the end of 2008. And here we are a good year past that, and, Senator Carper, there has been a lot of progress and a lot of upward movement and a lot of successes since then.

Senator CARPER. Would you say we still have some distance to go?

Dr. JENSEN. Absolutely. In your own words, anything can be improved on.

Mr. APPLE. I agree. It is not enough to be good. You have to be great and continue to get better.

Senator CARPER. OK. All right. Well, we appreciate your being here today. Thanks for your preparation and thanks for your responses to our questions.

Thank you for coming out of the audience to pinch hit here at the witness table, Mr. Quave.

Mr. QUAVE. Thank you, Mr. Chairman.

Senator CARPER. Some of our colleagues who were unable to join us today will be submitting questions in writing. I will probably be submitting a couple questions in writing as well. Members have 2 weeks to submit their questions following the conclusion of today's hearing. I would ask when you receive those questions, if you would respond to us promptly.

Again, thank you and we look forward to improve further on the work that is being done. Thanks very much.

With that, this hearing is adjourned.

[Whereupon, at 5:09 p.m., the Subcommittee was adjourned.]

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APPENDIX

FOR IMMEDIATE RELEASE

TOM CARPER

UNITED STATES SENATOR · DELAWARE

FOR RELEASE: March 3, 2010
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SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, FEDERAL SERVICES, AND INTERNATIONAL SECURITY

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

HEARING: "Oversight Challenges In the Medicare Prescription Drug Program"

Opening Statement of Senator Thomas R. Carper, Chairman

Today we will hear from several witnesses about the Medicare prescription drug program, and its vulnerability to waste, fraud and abuse.

The witnesses will tell an important story. I was surprised when I first heard about the GAO and inspector general reports showing that critical and basic anti-fraud safeguards for the Medicare prescription drug program were not in place, putting the program at a higher risk to waste and fraud.

These safeguards are important not only to protect taxpayer money, but to avoid diversion of prescription drugs for criminal activity and to support drug addiction.
Medicare is a critical component of health care in our nation, with over 44 million seniors participating. The prescription drug program, also known as Medicare Part D, began in January, 2006. We are now into the fifth year, and the overall reviews of the program have been positive, with about 27 million seniors participating.

Of course, no program is perfect, and during its first few years the prescription drug program went through some serious growing pains. And there are still many seniors experiencing problems. However, Medicare Part D is here to stay. Congress must ensure sure that the $49 billion a year program works effectively and efficiently.

As we are all well aware, Congress and the American people are in the midst of an important conversation about our nation's health care system. There's been some disagreement about exactly what needs to done, but almost everyone agrees that the cost of the system must get under control.

There's been a lot of talk around here about trying to "bend the cost curve" of healthcare. While there are a number of reasons for the rise in health care costs over the past few decades, it is clear that prescription drugs are one of the main drivers of this increase. The benefits of modern pharmaceuticals are evident, then - but so are the costs. In 1985, the average American spent about $90 a year for prescription medicines. Today, they spend over $700 - an increase of nearly 740%.

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Of course, eliminating fraud is an important and straightforward way of lowering costs for prescription drugs.

Unfortunately, health care is too often the focus of criminals who wish to take advantage of the system. Whether the care is provided through government programs or the private sector, attempts to defraud the system are on the rise. U.S. Attorney General Holder estimates Medicare fraud totals $60 billion a year, an estimate echoed by others in law enforcement.

A second estimate of waste and fraud in a federal program is the level of improper payments. Each year, the federal government lists the estimates of overpayments, underpayments, undocumented expenditures and other kinds of mistakes and fraud experienced by each agency.
The total for fiscal year 2009 was almost a hundred billion dollars. Medicare has the largest reported share of that total at $36 billion. Unfortunately, Health and Human Services has not been able to determine the level for the prescription drug program, so the amount wasted in Medicare Part D is still largely unknown.

Why the rise in Medicare fraud? Well, as when Willie Sutton, an infamous twentieth-century bank robber, was asked why he robbed banks, he replied, "Because that's where the money is." There is a lot of money in Medicare, and that attracts a lot of criminal activity.

However, there is another reason- the drugs themselves and the growing problem of addiction to over the counter medications.

The problem of Medicare prescription drug fraud is more than just a loss of taxpayer money. It is also about harm to our citizens when fraud results in drugs diverted to illegal use.
The chart behind me shows the impact.

Between 1994 and 2004, the population of the United States grew 12%, while at the same time the number of prescription drugs dispensed grew nearly 68%. The only thing that has outpaced this figure is the rate of abuse of those drugs, growing nearly 80%. In fact, more Americans abuse prescription drugs than the number who abuse cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined. In fact, one out of five teenagers in America has abused, or is abusing, prescription drugs.

Aside from our financial responsibility, we have a social responsibility to ensure that our public health care system isn't used to further intensify and subsidize a public health crisis. In a previous report focused on a similar problem with Medicaid, the GAO reported to the Subcommittee some major sources of fraud and abuse involving controlled substances.
I understand these are the same techniques used with Medicare.

The first fraud technique included beneficiaries engaged in a practice commonly known as "doctor shopping" in which recipients go to six or more doctors for the same type of drug. In these cases, beneficiaries are either feeding their addiction or selling the extra pills on the street. Drug dealers make the profit, while the federal government foots the bill.

Fraud and abuse of prescription drugs also appears to be going on beyond the grave when prescriptions are "received" by dead beneficiaries or "written" by dead doctors.

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The Department of Health and Human Services, specifically the Centers for Medicare and Medicaid Services, has established a set of oversight schemes to protect the Medicare Prescription Drug Program and its beneficiaries from fraud and waste. Sometimes called program integrity, protecting the program from fraud is a team effort involving the federal workers in Medicare, law enforcement at the federal, state and local levels, the Medicare prescription drug plans, pharmacies and doctors, and the beneficiaries themselves.

As a recovering Governor, I understand the unique challenges that come along with running a major program like Medicare. But as many of you have heard me say before, "If it's not perfect, make it better," and we all share a responsibility to do just that with the Medicare prescription drug program. Our witness will report today on not only the current challenges of waste and fraud in the Medicare prescription drug problem, but identified solutions.

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STATEMENT OF SENATOR JOHN MCCAIN, RANKING MEMBER

SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, FEDERAL SERVICES AND INTERNATIONAL SECURITY

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

"Oversight Challenges in the Medicare Prescription Drug Program"

March 3, 2010

Thank you, Chairman Carper, for holding this hearing. I join you in welcoming our witnesses today to examine the challenges faced in the oversight of the Medicare Part D prescription drug benefit.

The Medicare program overall faces enormous fiscal challenges. Medicare Trustees are currently projecting the program will be insolvent in 2017. This insolvency will occur nine years sooner than what the trustees projected back in 2003, when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act establishing Medicare Part D.

As part of our oversight responsibilities, we must examine the root causes of the deteriorating fiscal condition of a program that is so heavily relied upon by seniors and will consume a half trillion dollars of federal government outlays this year. We know demographics play a large role in the projections of solvency, but we also know that the integrity of the program is weak. Fraud is rampant in Medicare: scam artists in the home health program are thriving, Medicare is billed for medical equipment prescribed using DEA numbers of dead doctors, and beneficiaries are doctor shopping to obtain excessive amounts of controlled substances for abuse or resale on the black market.

I am pleased that we are focusing on issues in Part D today. Adding a prescription drug benefit to Medicare in 2003 has been popular, but the program has had its faults. I voted against the creation of the program because it was not paid for

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through offsets. Nevertheless, I understand that seniors are pleased to have a drug benefit, however imperfect. To ensure the program is sustainable, we must remain vigilant and continue robust oversight of it.

Without true reform of the Medicare program, we cannot prevent its inevitable collapse. But we can slow the hemorrhaging through effective implementation and execution of controls to detect and prevent fraud and abuse. Fortunately, Congress recognized that existing parts of Medicare were wrought with fraud, waste, and abuse, and instituted safeguards within the Medicare Part D prescription drug benefit.

Although the Centers for Medicare & Medicaid Services, commonly referred to as CMS, contracted with Medicare Drug Integrity Contractors, also known as MEDICs, to perform much of the Part D oversight, it failed to provide the MEDICs with quality claims information to perform proactive data analysis for several years. This, in turn, hindered the detection of potential fraud and abuse.

Additionally, CMS did not grant MEDICs, which are also responsible for auditing sponsors' compliance plans, the authorization to proceed with the audits until just recently. Why were there years of delay? Was it a case of inadequate resources or just gross mismanagement?

As our witness from the Inspector General's Office at the Department of Health and Human Services will testify, Part D sponsors' fraud reporting has been sparse. Such reporting is crucial as Part D sponsors are the first line of defense against fraud and abuse. MEDICs and CMS are not able to investigate potential fraud and abuse incidents if none are reported.

In closing, I want to thank the witnesses for their participation, and I look forward to hearing their testimony on how we can strengthen oversight on the Medicare Part D prescription drug benefit.

Thank you again, Mr. Chairman.

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United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Homeland Security and Governmental Affairs Committee, U.S. Senate

For Release on Delivery
Expected at 2:30 p.m. EST
Wednesday, March 3, 2010

MEDICARE PART D

CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion

Statement of Kathleen M. King
Director, Health Care

GAO-10-481T

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Highlights

Highlights of GAO-10-481T, a testimony before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security, Homeland Security and Governmental Affairs Committee, U.S. Senate

Why GAO Did This Study

Medicare Part D, the voluntary, outpatient prescription drug benefit for eligible individuals 65 years and older and certain individuals with disabilities, is at risk for fraud, waste, and abuse. Part D is administered by the Centers for Medicare & Medicaid Services (CMS). All Part D sponsors—private companies that operate Part D benefit plans—are required to have programs to safeguard the Part D program from fraud, waste, and abuse. GAO refers to these programs as fraud and abuse programs.

This statement discusses CMS's oversight of Part D sponsors' fraud and abuse programs, including its past efforts and planned oversight activities. It is primarily based on the GAO report, *Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited* (GAO-08-760). The five Part D sponsors GAO reviewed for that report had not completely implemented all of CMS's elements for Part D fraud and abuse programs at that time. CMS agreed with GAO's recommendation in the report that it conduct timely audits of Part D sponsors' fraud and abuse programs.

For the 2008 report, GAO reviewed laws, regulation, and CMS documents, including fraud and abuse program guidance. GAO also interviewed CMS officials. For this statement, GAO updated selected information on CMS's oversight by interviewing CMS officials and reviewing agency documents.

View GAO-10-481T or key components. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

March 3, 2010

MEDICARE PART D

CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion

What GAO Found

In July 2008, GAO reported that CMS's review of fraud and abuse program plans was limited to the review and approval of Part D sponsors' fraud and abuse program plans submitted as part of the initial contract-application process. For example, CMS indicated that the agency did not require Part D sponsors to submit new or updated fraud and abuse program plans during the contract renewal process for program years 2007 or 2008. Further, in the July 2008 report, GAO noted that CMS had not conducted audits as it had detailed in its 2005 Part D Oversight Strategy to ensure that sponsors had implemented fraud and abuse program plans. In February 2010, CMS officials told us the agency had completed desk audits (reviews of requested documents) in 2008 and 2009 and was beginning to implement an expanded oversight strategy. CMS officials reported that between October 2008 and April 2009 the agency's contractors had completed 16 desk audits of selected Part D sponsors' fraud and abuse programs. These officials reported that the agency has revised its audit protocol and piloted on-site audits (which include interviews and other face-to-face evaluations) to assess the effectiveness of these programs more thoroughly. In addition, CMS issued a proposed rule in 2009 to increase its oversight efforts and ensure that sponsors have effective compliance programs in place. CMS noted in issuing the proposed rule that GAO requested that CMS take actions to evaluate and oversee fraud and abuse programs. CMS expects the rule to be finalized in March 2010.

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Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss CMS's oversight of programs that address the risks for fraud, waste, and abuse in Medicare Part D. The Medicare Part D program, administered by the Centers for Medicare & Medicaid Services (CMS), provides a voluntary, outpatient prescription drug benefit for eligible individuals 65 years and older and eligible individuals with disabilities. CMS contracts with private companies—such as health insurance companies and companies that manage pharmacy benefits—to provide Part D prescription drug benefit plans for Medicare beneficiaries. These companies are referred to as Part D sponsors. About 27 million individuals were enrolled as of December 2009, and estimated Medicare Part D spending was $51 billion in fiscal year 2009. Because of its vulnerability to fraud, waste, and abuse, GAO has designated Medicare as a high-risk program since 1990.[1] We and others have previously reported that the size, nature, and complexity of the Part D program make it a particular risk for fraud, waste, and abuse.[2]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[3] which established the Part D program, requires all Part D sponsors to have programs to safeguard Part D from fraud, waste, and abuse.[4] CMS regulations require Part D sponsors to have compliance plans detailing their fraud and abuse programs.[5] In April 2006, CMS issued

[1]GAO's audits and evaluations identify federal programs and operations that we determine are high risk due to their greater vulnerabilities to fraud, waste, abuse, and mismanagement. See GAO, *High-Risk Series: An Update*, GAO-05-207 (Washington, D.C.: January 2005).

[2]GAO, *Prescription Drugs: Oversight of Drug Pricing in Federal Programs*, GAO-07-481T (Washington, D.C.: Feb. 9, 2007). U.S. House of Representatives Ways and Means Subcommittees on Health and Oversight, 110th Cong., March 8, 2007 (testimony of Daniel R. Levinson, HHS Inspector General) and U.S. House of Representatives Oversight and Government Reform Committee, 110th Cong., February 9, 2007 (testimony of Lewis Morris, Chief Counsel to the HHS Inspector General).

[3]Pub. L. No. 108-173 § 101, 117 Stat. 2066, 2086 (adding Social Security Act § 1860D-4(c)(1)(D)) (codified at 42 U.S.C. § 1395w-104(c)(1)(D)).

[4]Hereafter, we refer to programs to control fraud, waste, and abuse as fraud and abuse programs.

[5]42 C.F.R. § 423.504(b)(4)(vi).

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guidance in chapter 9 of its Medicare Prescription Drug Benefit Manual on the seven required elements of these plans.[6] (See table 1.)

Table 1: Description of Required Medicare Part D Compliance Plan Elements for Fraud and Abuse Programs

Compliance plan elements	Description
Written Policies, Procedures, and Standards of Conduct	Include written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable federal and state standards.
Compliance Officer and Compliance Committee	Designate a compliance officer and a compliance committee that are accountable to senior management.
Effective Training and Education	Include effective training and education pertaining to fraud, waste, and abuse for the organization's employees, contractors and directors.
Effective Lines of Communication	Include effective lines of communication between the compliance officer and the organization's employees, contractors, directors, and the members of the compliance committee.
Enforcement of Standards through Disciplinary Guidelines	Have well-publicized disciplinary guidelines through which sponsors must enforce standards.
Internal Monitoring and Auditing	Include effective internal monitoring and auditing procedures.
Prompt Responses to Detected Offenses	Include procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives, including responses to potential offenses.

Source: GAO summary of regulations.

In this testimony, we focus on the extent of CMS's oversight of Part D sponsors' fraud and abuse programs, including its past efforts and planned oversight activities. My statement is based primarily on our July 2008 report, which focused on Part D sponsors' implementation of fraud and abuse programs and CMS's oversight of those Part D sponsors' programs.[7]

[6]The Medicare Prescription Drug Benefit Manual consists of multiple chapters related to various Part D program areas and outlines Part D program requirements and CMS guidance. The chapter in the manual entitled "chapter 9—Part D Program to Control Fraud, Waste, and Abuse" addresses fraud, waste, and abuse in Part D.

[7]GAO, *Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited*, GAO-08-760 (Washington, D.C.: July 21, 2008).

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Our July 2008 report is part of a larger GAO body of ongoing work on Part D oversight and fraud, waste, and abuse prevention (see "Related GAO Products," attached). This statement also includes selected updated information on CMS's oversight obtained from CMS since our July 2008 report.

In our July 2008 report, we found that the five Part D sponsors we reviewed, which covered more than one-third of total Part D enrollees, had not completely implemented all seven of CMS's required compliance plan elements for a Part D fraud and abuse program. All Part D sponsors had completely implemented the requirements for three of the seven required compliance plan elements. However, Part D sponsors varied in their implementation of the remaining required elements.[8] For example, only two of the five sponsors met the requirements for effective training and education related to fraud and abuse prevention.

To conduct our evaluation of CMS's oversight for the July 2008 report, we reviewed relevant laws, regulations, and CMS guidance to determine the elements of a comprehensive compliance plan including fraud and abuse programs. We also interviewed officials from CMS and the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG). In addition, we reviewed documentation from CMS, including CMS's Part D oversight strategy, program audit strategies, contracts related to Part D program integrity efforts, and technical assistance provided by CMS specific to the fraud and abuse program. A detailed explanation of our methodology is included in our July 2008 report. For this statement, we also interviewed officials from CMS and reviewed agency documents to obtain selected updated information on CMS oversight. We discussed the information in this statement with a CMS official responsible for Part D oversight.

We conducted the performance audit for the July 2008 report from October 2006 through June 2008 and we updated information regarding CMS's oversight of Part D sponsors' fraud and abuse programs in February 2010, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe

[8]We conducted on-site reviews at five of the largest Part D sponsors to examine the extent to which these Part D sponsors implemented fraud and abuse programs.

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that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

While CMS's Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, the Agency Plans to Expand Its Oversight

While CMS oversight of Part D fraud and abuse programs has been limited, the agency plans to expand this oversight, including adding on-site audits (which include interviews and other face-to-face evaluations) in place of the desk audits (reviews of requested documents only) it has completed. In July 2008, we reported that CMS's review of fraud and abuse program plans was limited to the review and approval of Part D sponsors' compliance plans detailing their fraud and abuse program plans submitted as part of the initial contract-application process. For example, CMS officials reported that Part D sponsors with approved fraud and abuse program plans prior to the issuance of chapter 9 of CMS's Medicare Prescription Drug Benefit Manual in April 2006 were not required to resubmit program plans. In addition, CMS told us the agency did not require Part D sponsors to submit new or updated fraud and abuse program plans during the contract-renewal process for program years 2007 or 2008, which limited CMS's ability to ensure that existing Part D sponsors continued to maintain compliance with this requirement.

In 2008, we also reported that CMS had not conducted audits of sponsors' fraud and abuse program plans as it had detailed in its 2005 Part D Oversight Strategy. In its 2005 comprehensive Oversight Strategy for the program, CMS noted that it would mainly rely on self-reported, unaudited data provided by Part D sponsors, but acknowledged that program audits would be necessary to ensure compliance and to document that CMS had fulfilled its program oversight responsibilities. CMS further stated that it would reserve enforcement activities to large, repeated, or extreme Part D program violations.[9]

Offices within CMS with oversight authority cited resource problems in 2006, Part D's first year of operation, that either prevented audits from occurring or changed the audit strategy to use desk audits rather than on-site audits. In 2007, CMS assessed Part D sponsors' compliance with selected program areas, but did not assess sponsors' implementation of fraud and abuse programs. Moreover, the agency said it did not plan to audit sponsors' implementation of fraud and abuse programs in 2008. In addition, CMS originally estimated that 10 of these audits would be

[9]CMS, Part D Oversight Strategy for Contractors/Industry (Oct. 24, 2005).

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completed by the Medicare Drug Integrity Contractors (MEDICs) during the 2005-2006 contract year of the program and that 35 of these audits would be conducted during the 2006-2007 contract year. However, these audits did not occur.[10]

In February 2010, CMS officials told us the agency had completed desk audits in 2008 and 2009 and is beginning to implement an expanded oversight strategy. CMS officials reported that between October 2008 and April 2009 its MEDICs completed 16 desk audits of selected Part D sponsors' fraud and abuse programs. Since then, these officials reported that CMS has revised its audit protocol and piloted on-site audits, rather than desk audits, to assess the effectiveness of these programs more thoroughly. The agency has conducted two on-site audits in the pilot so far and plans to conduct additional on-site audits of selected Part D sponsors' fraud and abuse programs by April 2010. Similar to our July 2008 findings, in conducting their desk and pilot on-site audits, CMS officials told us they found that sponsors had deficiencies in implementation of two of the required compliance elements—internal auditing and monitoring and training and education. However, the effectiveness of CMS's planned audits cannot be assessed until they are completed.

In addition, CMS issued a proposed rule in 2009 to increase its oversight efforts and ensure that sponsors have effective compliance programs in place.[11] In issuing the proposed rule, CMS noted that we requested the agency take actions to evaluate and oversee fraud and abuse programs to ensure sponsors have effective programs in place.[12] The proposed rule would clarify existing policies regarding the elements of sponsors' compliance plans and CMS expects it to be finalized in March 2010. CMS officials told us that once the proposed rule is finalized, the agency will incorporate it into its expanded on-site audit protocol and update its

[10]CMS contracted with the MEDICs to support its audit, oversight, and antifraud and abuse efforts in Part D. In addition to audits, the MEDICs have been engaged to detect fraud, waste, and abuse in Part D and investigate reports from beneficiaries, sponsors, and other sources; conduct enrollment, eligibility, and marketing surveillance; and identify high-risk sponsors requiring further investigations. These tasks were outside the scope of the July 2008 report and are outside the scope of our current testimony.

[11]*Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, 74 Fed. Reg. 54,634 (proposed Oct. 22, 2009).

[12]In the July 2008 report, we recommended that CMS conduct timely audits of Part D sponsors' fraud and abuse programs. CMS agreed with our recommendation.

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guidance in chapter 9 of the Medicare Prescription Drug Benefit Manual to reflect the changes.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you or other members of the subcommittee may have.

GAO Contact and Staff Acknowledgments

For further information about this statement, please contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Catina Bradley and Martin T. Gahart, Assistant Directors; Jennie F. Apter, Jennel Harvey, Amy Shefrin, and Jennifer Whitworth were key contributors to this statement.

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Testimony of:
Robert A. Vito
Regional Inspector General for Evaluation and Inspections
Office of Inspector General, U.S. Department of Health & Human Services

Good afternoon, Mr. Chairman and members of the Subcommittee. I am Robert Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia at the U.S. Department of Health & Human Services' (HHS) Office of Inspector General (OIG). The Medicare Part D prescription drug program is large and complex with both Federal agencies and Federal contractors charged with protecting the integrity of the program. With approximately $50 billion at risk in the program each year, it is important that all of us who have programmatic and oversight responsibilities work collaboratively to ensure that program vulnerabilities are identified and resolved.

Since the inception of the Part D program in 2006, OIG has developed a body of work to review program integrity and payment accuracy safeguards that are in place to protect the program from fraud, waste, and abuse. To date, OIG's work has demonstrated that the Part D program oversight by the Centers for Medicare & Medicaid Services (CMS), the Part D plan sponsors, and CMS's benefit integrity contractors has been limited. As a result, the program is vulnerable to fraud, waste, and abuse. There are opportunities to significantly enhance oversight of the Part D program, and on behalf of the Inspector General, I would like to thank you, Mr. Chairman, for holding today's hearing on this important topic.

After briefly describing the oversight role of the OIG and providing some background on the Medicare Part D program, I will summarize the Part D vulnerabilities we have identified and OIG recommendations to improve the integrity of the Part D program.

I. OIG'S MISSION TO PROTECT THE MEDICARE AND MEDICAID PROGRAMS AND BENEFICIARIES

OIG is an independent, nonpartisan agency committed to protecting the integrity of the more than 300 programs administered by HHS. OIG fights health care fraud, waste, and abuse through a nationwide network of investigations, audits, evaluations, and enforcement and compliance activities. OIG is comprised of more than 1,500 professionals who perform comprehensive health care oversight and enforcement activities, including:

- Office of Investigations: conducts criminal, civil, and administrative investigations of health care fraud, which result in convictions, civil and administrative actions, and monetary recoveries;
- Office of Audit Services: conducts and oversees audits of Medicare and Medicaid payments and operations; identifies improper payments and program vulnerabilities; and recommends audit disallowances and program improvements;

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- Office of Evaluation and Inspections: conducts evaluations of the Medicare and Medicaid programs to identify program integrity vulnerabilities and make recommendations to prevent fraud, waste, and abuse and to promote economy, efficiency, and effectiveness; and
- Office of Counsel to the Inspector General: represents OIG in all civil and administrative fraud and abuse cases, and in connection with these cases, negotiates and monitors corporate integrity agreements; provides guidance to the health care industry to promote compliance; and provides legal support to OIG operations.

In FY 2009, OIG investigations resulted in $4 billion in settlements and court-ordered fines, penalties, and restitution, and in 671 criminal actions. OIG audits resulted in almost $500 million in receivables through recommended disallowances. OIG also produced equally important but less quantifiable gains in deterrence and prevention of fraud, waste, and abuse. OIG also has raised awareness of these critical issues among policy makers, government agencies, and the health care community at large. Moving forward, OIG is committed to building on our successes and achieving even greater results in protecting the integrity of government health care programs and the health and welfare of people served by them.

II. THE MEDICARE PART D PROGRAM

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established the Medicare Part D prescription drug benefit. Effective January 1, 2006, Part D provides an optional outpatient prescription drug benefit to all Medicare beneficiaries. CMS administers the Part D program and contracts with private companies, known as plan sponsors, to provide Part D prescription drug coverage. Under Medicare Part D, beneficiaries can enroll in a stand-alone prescription drug plan that covers drugs only, or a Medicare Advantage prescription drug plan that integrates drug coverage with other health care services.

The MMA required an extremely short implementation schedule for the Medicare Part D prescription drug benefit. In the two years between the passage of MMA and the effective date of the program, CMS and its Part D plan sponsors conducted implementation activities, including the development of procedures, data systems, and infrastructure to carry out all the necessary functions. Beginning in November 2005, after expeditious and extensive planning, CMS began enrolling beneficiaries for the 2006 Part D plan year.

As the fifth year of the Part D program begins, there are approximately 27 million beneficiaries enrolled in the program. More than 60 percent of the beneficiaries, approximately 17 million, are in stand-alone plans. Since the inception of the program, Medicare has paid nearly $200 billion, approximately $50 billion each year, for the Part D program.

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III. PART D PROGRAM INTEGRITY

Within the Medicare program, the responsibility for ensuring integrity in the Part D program is shared between Part D plan sponsors, program integrity contractors, and CMS. The plan sponsors serve as the first line of defense against fraud in the Part D program and CMS requires that plan sponsors have compliance plans in place to protect the integrity of the program. CMS requires plan sponsors to include certain elements in their compliance plans. These elements include the designation of a compliance officer, the establishment of effective compliance training for employees and contractors, and the establishment of procedures for effective internal monitoring and auditing. CMS also requires compliance plans to have measures to detect, correct, and prevent fraud, waste, and abuse.

CMS contracts with Medicare Drug Integrity Contractors (MEDICs) to perform integrity functions such as identifying and investigating potential fraud, waste, and abuse in the Part D program. MEDICs, which are the cornerstone of CMS's program integrity efforts, are responsible for safeguard activities, including audits of plan sponsors' compliance plans and identifying fraud through innovative data analysis techniques.

As program administrator, CMS is ultimately responsible for safeguarding the Medicare Part D program. As such, CMS is statutorily required to perform financial audits of the Part D plan sponsors, which provide Part D benefits to Medicare beneficiaries. CMS also can conduct a number of other types of audits of plan sponsors, including bid audits, program audits, benefit integrity audits, and compliance plan audits.

In addition to plan sponsors, MEDICs, and CMS, the Office of Inspector General plays a critical role in combating fraud, waste, and abuse in Medicare Part D. Through its evaluations, audits, investigations, and enforcement actions, OIG has identified significant vulnerabilities in the Part D program and has made numerous recommendations to CMS to correct these vulnerabilities.[1] OIG also has performed targeted followup reviews to determine whether the vulnerabilities were addressed.

IV. STRENGTHENING PART D OVERSIGHT

Overall, OIG's reviews of the Part D program indicate that CMS's program integrity efforts have been limited in scope and may not sufficiently protect the program. Lack of effective oversight exposes the Part D program and Medicare beneficiaries to a wide range of fraud, waste, and abuse, including inappropriate billings, payments for excluded drugs, drug diversion, improper bid submissions, excessive premiums, and illegal marketing schemes. The failure to address these vulnerabilities puts the scarce resources of the Medicare Trust Fund at risk. Below is a brief description of Part D program vulnerabilities identified through OIG's work.

[1] See Attachment A for a list of OIG's completed, ongoing, and planned Part D work on program integrity, payment accuracy, cost controls, beneficiary protections and access, prescription drug pricing, and information technology systems.

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A. Early Challenges to Implementing a Comprehensive Safeguard Strategy

An early review of Part D found that CMS implemented only limited safeguard activities and further development of these activities was needed. In fiscal year 2006, OIG found that while some of CMS's safeguards had been functioning since Part D enrollment began, other critical safeguards were implemented in limited capacity or had not yet been put in place.[2] We also found that CMS relied largely on complaints to identify potential fraud in Part D and not all of these complaints were investigated in a timely way. In addition, we found that no significant data analysis had been conducted specifically to detect or prevent fraud and abuse. One barrier to conducting data analysis was that CMS and its contractors lacked a centralized data repository that would enable proactive data monitoring.

B. MEDICs Have Not Conducted the Full Range of Safeguard Activities Planned

i. MEDICs have relied mainly on external rather than proactive sources to identify fraud

MEDICs play a key role in CMS's strategy to protect the Part D program from fraud, waste, and abuse. This is especially true in the area of using new and innovative techniques to monitor and analyze data to help identify fraud. Using data analysis tools to proactively detect fraud is one of the most important elements of CMS's safeguard strategies.

While proactive data analysis is a key element of MEDICs' responsibilities, OIG found in its October 2009 report that MEDICs identified most incidents of potential fraud through external sources, such as beneficiary complaints, rather than proactive methods.[3] Of the 4,194 potential fraud and abuse incidents MEDICs identified in 2008, 87 percent were identified through external sources and only 13 percent were identified through proactive methods, such as data analysis. In addition, of the 1,320 investigations MEDICs conducted, 96 percent involved incidents identified through external sources.

ii. Limited data access has hindered MEDICs' fraud detection efforts

CMS's strategy called for the use of data analysis to combat fraud and abuse. However, MEDICs reported that barriers hindered their ability to consistently conduct comprehensive data analysis to detect and prevent potential fraud and abuse. These barriers included delays in receiving access to the necessary CMS claims and Part D prescription drug event (PDE) data. MEDICs reported that they needed both PDE data

[2] OIG, *CMS's Implementation of Safeguards During Fiscal Year 2006 to Prevent and Detect Fraud and Abuse in Medicare Prescription Drug Plans*, OEI-06-06-00280, October 2007.
[3] OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, October 2009.

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and Part B data to effectively identify and investigate potential fraud and abuse incidents. However, MEDICs did not receive access to PDE data until August 2007; nearly a year after their contracts began. Once they received access to PDE data, MEDICs found that there were significant limitations in the data and important variables were not available or were stored incorrectly. In addition, two MEDICs were not given access to Part B data (physician services) until the fall of 2008 and the third MEDIC did not receive access to Part B data before its contract ended.

In addition to limited access to data, MEDICs' lack of authority to directly obtain information, such as prescriptions and medical records from pharmacies, pharmacy benefit managers, and physicians hindered their ability to investigate potential fraud and abuse incidents. Also, MEDICs may not have been aware of some potential fraud and abuse incidents because plan sponsors are encouraged to refer potential fraud and abuse incidents to MEDICs but are not required to do so.

iii. MEDICs were not given approval to conduct compliance plan audits

OIG also found that CMS did not give MEDICs approval to conduct audits of plan sponsors' compliance plans in 2008. During OIG's evaluation of the MEDICs, all three MEDICs indicated that they were prepared to conduct compliance plan audits in 2008 but were not given approval by CMS to do so. Between October and December 2008, two years after MEDICs' regional contracts began, the two remaining MEDICs did receive approval from CMS to begin 10 audits of plan sponsors' compliance plans. However, as of December 2009, CMS had not issued final reports on any of these compliance plan audits.

In November 2009, after the issuance of our evaluation report, CMS restructured the MEDIC program. There are now two instead of three MEDICs. One of these two MEDICs, the Compliance and Enforcement MEDIC, focuses solely on compliance activities of plan sponsors, including compliance plan audits and monitoring inappropriate agent/broker activity. The second MEDIC, the Benefit Integrity MEDIC, concentrates on fraud, waste, and abuse efforts including investigating potential fraud and conducting data and investigative analysis. As Part D program integrity efforts continue to evolve at CMS, OIG will continue its review to ensure the effectiveness of these efforts.

C. Sponsors' Compliance Plans Have Been Incomplete

CMS requires that plan sponsors have compliance plans in place to protect the integrity of the program. An effective compliance plan helps plan sponsors protect the integrity of Medicare funds by preventing and detecting fraud, waste, and abuse. CMS requires plan sponsors to include certain elements in their compliance plans. These elements include the designation of a compliance officer, the establishment of effective compliance training for employees and contractors, and the establishment of procedures for effective internal monitoring and auditing.

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OIG has conducted two evaluations, issued in December 2006 and October 2008, on Medicare Part D plan sponsors' compliance plans.[4] Plan sponsors are required to implement compliance plans in order to detect, correct, and prevent fraud, waste, and abuse. CMS's *Prescription Drug Benefit Manual* outlines specific requirements that sponsors' compliance plans must address to ensure that elements established by Federal regulation are met.

OIG's 2006 review found that while all plan sponsors had compliance plans, these plans did not fully address all of CMS's requirements and in some cases, contained only the broad outlines of a fraud and abuse plan and did not include descriptions of specific compliance and anti-fraud processes.

D. CMS Has Not Finalized Audits of Plan Sponsors' Compliance Plans

Because CMS has not finalized any audits of PDP sponsors' compliance plans, we do not know whether this key anti-fraud component is working at the plan level and what improvements plan sponsors can make to improve program safeguards. OIG recently completed an indepth audit of one plan sponsor's internal controls to detect, correct, and prevent fraud, waste, and abuse in the Part D program during 2007 and 2008.[5] This work highlights that audits of individual plan sponsors can provide important insights into how the Part D program is working at the plan level and what improvements plan sponsors can make to improve program safeguards.

In our audit, we found that although most of the plan sponsor's internal controls were adequate, it had several internal control weaknesses that compromised its ability to detect, correct and prevent fraud, waste, and abuse in the Part D program. The plan sponsor generally did not self-report potential fraud to the MEDICs as recommended by CMS guidance. While the plan sponsor had written procedures requiring the self-reporting of potential fraud to the MEDICs, the plan sponsor did not follow its own procedures. We also found that the plan sponsor paid claims for prescriptions written by physicians or other health care professionals who are excluded from Federal health care programs. Furthermore, the plan sponsor did not have a procedure in place to track complaints made against providers as recommended by CMS guidance. Based on these findings, OIG recommended that the plan sponsor strengthen its internal controls and establish and/or adhere to policies and procedures to address issues with payment accuracy and complaint tracking. In response to our work, the plan sponsor outlined a number of corrective actions it had implemented to address the vulnerabilities.

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[4] OIG, *Prescription Drug Plan Sponsors' Compliance Plans*, OEI-03-06-00100, December 2006 and *Oversight of Prescription Drug Plan Sponsors' Compliance Plans*, OEI-03-08-00230, October 2008.
[5] OIG, *Review of SilverScript Insurance Company's Internal Controls to Guard Against Fraud, Waste and Abuse for the Medicare Part D Program*, A-07-09-03124, January 2010.

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E. Plan Sponsors Vary Widely in the Identification of Fraud

Plan sponsors are the initial gatekeeper protecting the Part D program from fraud and abuse. Although CMS requires that sponsors have measures to detect and deter fraud and abuse, the specifics are left to each individual sponsor. However, CMS requires that plan sponsors conduct inquiries and initiate corrective actions if there is evidence of potential fraud and abuse. CMS recommends that after conducting inquiries, if plan sponsors identify potential fraud and abuse, sponsors should refer the incidents to CMS or MEDICs for further investigation.

In October 2008, OIG issued a report reviewing the extent to which plan sponsors identified potential fraud and abuse during the first 6 months of 2007.[6] We found that 24 of 86 sponsors of stand-alone plans did not identify any potential fraud and abuse incidents, either from internal efforts or complaints from external sources. For the 62 plan sponsors that identified fraud incidents, the number of incidents identified ranged from 1 to over 6,000. Ninety percent of all incidents were associated with only seven plan sponsors. We also found that not all plan sponsors that identified potential fraud and abuse incidents conducted inquires, initiated corrective actions, or made referrals for further investigation.

Plan sponsors identified 26 different types of potential fraud and abuse, and of these, the most prevalent type was inappropriate billing. The second most prevalent type was "providing false information," e.g., misrepresentation of a beneficiary's plan enrollment, and the third most prevalent was doctor shopping, i.e., a beneficiary consulting a number of doctors for the purpose of inappropriately obtaining multiple prescriptions for drugs. These types of suspicious behavior and potential abuse are consistent with the types of vulnerabilities that we have identified in other prescription drug benefit programs.

F. Payment Accuracy Vulnerabilities

In addition to addressing the program integrity vulnerabilities identified above, it is critical that CMS strengthen its oversight of Part D payment accuracy. With costs for the Part D program approaching $50 billion a year, it is imperative that Part D payments are made accurately and are based on the best data available. Each year, plan sponsors' bid amounts are the basis for determining the payments Medicare makes directly to plan sponsors. The bid amounts also determine the monthly premiums that beneficiaries will pay.

Medicare makes monthly payments to plan sponsors for providing Part D coverage to beneficiaries. These payments are based on estimates that sponsors provide in their approved bids. These estimates include sponsors' expected profits. After the close of the plan year, CMS must reconcile the monthly payments with sponsors' actual costs. This allows CMS to determine whether sponsors owe money to Medicare or if Medicare owes

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[6] OIG, *Medicare Drug Plan Sponsors' Identification of Potential Fraud and Abuse*, OEI-03-07-00380, October 2008.

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money to sponsors. In addition, CMS must determine whether risk-sharing payments are required. Risk sharing requires the Federal Government to share in sponsors' unexpected profits and losses.

CMS's oversight is essential to reduce inaccuracies and errors in Part D sponsors' bids. Inaccuracies in sponsors' bids have resulted in Medicare paying higher payments and beneficiaries paying higher premiums than they should have. OIG has continually recommended that CMS strengthen its oversight and enforcement approach to hold plan sponsors accountable for their bids.

i. The majority of Part D sponsors' bids in 2006 and 2007 overestimated the cost of providing the benefit

OIG assessed the estimated reconciliation amounts that Part D sponsors would owe to or receive from Medicare for plan years 2006 and 2007.[7] In 2006, Part D sponsors owed Medicare more than $4 billion. Although the overall net amount that sponsors owed in 2007 was substantially lower at only $18 million, we continued to find that most Part D sponsors overestimated the costs of providing the benefit in their bids and made profits large enough to trigger risk sharing. In 2007, 71 percent of sponsors made unexpected profits large enough to trigger risk sharing. In total, they overestimated their bids by more than $1 billion, which triggered risk-sharing payments of $795 million to Medicare.[8]

These overestimates resulted in payments to sponsors by Medicare and by beneficiaries that were higher than they should have been. Although Medicare was able to recoup a portion of the amounts that were overpaid – because of risk-sharing requirements – there is no mechanism for seniors to recoup any of the money that they paid in higher premiums.

Based on these findings, we recommended that CMS ensure that sponsors' bids accurately reflect their costs of providing the benefit, and when sponsors fail to do so, that CMS hold sponsors more accountable for inaccuracies in the bids. We also recommended that CMS determine the appropriateness of any proposed changes to their methods of calculating risk sharing.

[7] OIG, *Medicare Part D Sponsors: Estimated Reconciliation Amounts for 2006*, OEI-02-07-00460, October 2007, and *Medicare Part D Reconciliation Payments for 2006 and 2007*, OEI-02-08-00460, September 2009.

[8] The increased direct subsidy payments resulting from these overestimated bids were generally offset by reinsurance and low-income cost sharing subsidy payments that were too low, resulting in the lower net amount owed to Medicare.

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ii. CMS's Part D audit processes do not sufficiently ensure accountability

The two audit mechanisms CMS has in place to ensure the accuracy of the bid, the bid audit and the financial audit, are largely ineffectual for detecting and correcting inaccuracies in the bid amounts.

The bid audit is focused on the actuarial assumptions that are used to calculate the bid amount. For plan years 2006 and 2007, one-quarter of all bid audits identified at least one material finding that, if corrected, would result in at least a 1-percent change in the bid amount or at least a 10-percent change in any bid element. However, the bid audits are not designed to result in adjustments to bid amounts. According to CMS staff, one reason that adjusting bid amounts as a result of bid audit material findings is problematic is because the audits are completed after contracts have already been signed with plan sponsors. Instead, CMS uses bid audits to influence the submission, review, and audit of future bid amounts.

Financial audits verify the accuracy of the financial data that plan sponsors submit with their bids. CMS is statutorily required to conduct a financial audit of at least one-third of plan sponsors annually. However, only 4 percent of the required financial audits of plan year 2006 had begun as of April 2008. CMS's delays in conducting required financial audits of plans increases the risk that inaccuracies in the financial data underlying bids will go undetected and affect future bids.

V. RECOMMENDATIONS FOR IMPROVING OVERSIGHT

Oversight of the newest benefit in Medicare, the Part D prescription drug program, is imperative. It requires focused attention and a commitment to remedying program vulnerabilities and ensuring bid and payment accuracy. Ensuring that the Medicare Part D program and its beneficiaries are paying appropriately for the benefit is imperative. The program needs systems in place to prevent, detect, and respond to fraud, waste, and abuse.

Below are specific recommendations that OIG believes will improve the oversight and integrity of the Medicare Part D program.

A. CMS Should Implement a Comprehensive Program Integrity Plan That Includes Mechanisms to Ensure Oversight and Accountability

OIG believes that CMS must set out a comprehensive program integrity plan that includes specific action items, target dates, and assigned staff for follow up. Having this comprehensive plan would address the broad coordination needed between different groups within CMS and contain details, deliverables, and timelines that would make it a useful management tool.

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It also is crucial that audits are conducted in a timely manner and that mechanisms are established to hold plan sponsors accountable for the problems identified. While only financial audits are legislatively mandated, CMS established a comprehensive list of audits it expected to perform on plan sponsors. CMS needs to perform more of these audits and needs to perform these audits more timely. That way, vulnerabilities that exist at individual plan sponsors can be remedied quickly and detected problems can also serve as early warning flags for issues that CMS may need to address programwide.

CMS should also evaluate the performance of the plan sponsors by analyzing the number of fraud and abuse incidents identified, the number of inquiries and corrective actions initiated, as well as the number of fraud referrals made to law enforcement.

B. CMS Should Ensure That MEDICs Conduct More Rigorous Oversight, Including Data Analysis, to Detect Potential Fraud, Waste, and Abuse

Complaints from beneficiaries and others are a key part of detecting fraud. However, individual complaints tend to focus on one specific circumstance, which is why the work of the MEDICs is so important. MEDICs' ability to review all of the Part D prescription drug data and data from other Medicare programs allows for comprehensive analyses that can identify global problems, aberrancies, and outliers across the program. MEDICs need to perform more of these analyses as they allow for the identification of systemic vulnerabilities in the program.

MEDICs also should be provided with the legal authority to obtain critical information directly from pharmacies, pharmacy benefit managers, and prescribing physicians. Not being able to directly obtain prescriptions and related medical information can hinder the thoroughness and timeliness of MEDICs' investigations of potential fraud.

C. CMS Should Ensure That Plan Sponsors are Implementing Effective Compliance Plans

Our ultimate goal is to address fraud as early as we can in the process. That is why having comprehensive and successful compliance plans in place at the plan sponsors is so essential. They are able see the prescription drug data in real time. By constantly monitoring that data they can flag potentially fraudulent issues early on.

CMS, MEDICs, and plan sponsors need to perform innovative data analysis of claims and payment information and embrace proactive methods of fraud detection. Data metrics in conjunction with audit results can assist CMS in targeting their resources in the areas that are most vulnerable to fraud, waste, and abuse.

VI. CONCLUSION

Part D provides a valuable prescription drug benefit to Medicare beneficiaries and all of us who have programmatic and oversight responsibilities must be vigilant in safeguarding

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the program. OIG recognizes the immense effort that CMS put forth to develop and administer the Part D benefit under such a tight timeframe. Now that the program is entering its fifth year, it is time to use the lessons and experiences from its initial years to focus on strengthening program integrity of Part D moving forward.

Protecting the Part D program from fraud, waste, and abuse will involve ongoing cooperation among a number of key partners, including CMS, plan sponsors, and MEDICs. OIG has conducted reviews of CMS's audit and oversight functions, on plan sponsors' identification of fraud and abuse, and MEDICs' abilities to detect, investigate, and refer fraud in the Part D program. All of the reviews have identified program vulnerabilities and opportunities to strengthen these key partners' efforts to combat Part D fraud and abuse.

CMS needs to ensure that there is adequate oversight of Medicare Part D payments and beneficiary costs. It also needs to make sure that plan sponsors are held accountable for the accuracy of their bid amounts and CMS needs a mechanism to address bid inaccuracies in the current benefit year and not just future years.

Our work in the Part D program continues. We are currently performing reviews on questionable billing patterns, plan sponsors training programs regarding fraud, the status and results of all audits of plan sponsors, Part D electronic prescribing initiatives, invalid prescriber identifiers on prescription drug data, payments made to excluded providers, reconciliation calculations, and Part D rebates and pharmacy discounts.

Clearly, there are many opportunities for CMS and its partners to strengthen Part D safeguards to ensure the integrity of the Part D program, and we stand ready to assist them in their efforts. I would be happy to answer any questions that the subcommittee may have.

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STATEMENT OF

JONATHAN BLUM

DIRECTOR, CENTER FOR MEDICARE MANAGEMENT
ACTING DIRECTOR, CENTER FOR DRUG AND HEALTH PLAN CHOICE
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

OVERSIGHT CHALLENGES IN THE
MEDICARE PRESCRIPTION DRUG PROGRAM

BEFORE THE

U.S. SENATE COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS,
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, FEDERAL SERVICES
AND INTERNATIONAL SECURITY

MARCH 3, 2010

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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Testimony of
Jonathan Blum

Director, Center for Medicare Management
Acting Director, Center for Drug and Health Plan Choice
Centers for Medicare & Medicaid Services

Before the

U.S. Senate Committee on Homeland Security and Governmental Affairs,
Subcommittee on Federal Financial Management, Government Information,
Federal Services, and International Security

On

"Oversight Challenges in the Medicare Prescription Drug Program"

March 3, 2010

Chairman Carper, Ranking Member McCain, and distinguished Subcommittee members, thank you for inviting me here to discuss the Centers for Medicare & Medicaid Services' (CMS) initiatives to improve the oversight of the Medicare Prescription Drug Program, also known as Part D.

Today, I would like to share with you the Administration and CMS's strategies to oversee and improve the Part D program. Launched in 2006, Part D has provided all Medicare beneficiaries access to prescription drug coverage, and today more than 90 percent of beneficiaries have some form of prescription drug coverage from either Part D or from other sources. We readily acknowledge we have only just begun. CMS has greatly improved and will continue to improve our multi-pronged strategy to oversee the Part D program, including the daily management of our Part D plan sponsors, new regulatory initiatives, and revised audit protocols and compliance review plans to hold Part D plan sponsors accountable to Medicare beneficiaries and tax payers and ultimately strengthen the Part D program and add value to beneficiaries.

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CMS appreciates the thoughtful work of this Subcommittee, the Government Accountability Office, and the Department of Health and Human Services (HHS) Office of the Inspector General and the recommendations made to improve our program.

CMS Part D Oversight Strategy: Day-to-Day Management of the Program

Oversight of this program is complex. The Part D program is made up of a variety of different plans in different categories. There are also extra benefits for low-income beneficiaries, dual eligible Medicaid beneficiaries, and plans included in the Program of All-Inclusive Care for the Elderly (PACE). Today, hundreds of organizations offer Part D benefits to our beneficiaries through 1,576 standalone prescription drug plans and 2,358 Medicare Advantage Prescription Drug plans. Over the past year, CMS has made tremendous improvements in the day-to-day management of our Part D plan sponsors. This is our first-line strategy to improve compliance. To ensure the highest performance possible and to use our resources most efficiently, our efforts are data driven, proactive, and focused on key vulnerabilities.

In administering and monitoring Part D, we use a range of data to develop performance metrics and monitoring measures that inform us how our Part D plan sponsors are performing. These oversight activities are ongoing -- occurring prior to, during, and after the close of each contract year. Prior to the start of the plan year, CMS conducts a comprehensive review of all bids to verify compliance with a broad range of program and financial requirements. Each bid is subject to an actuarial benefit design analysis in order to address and resolve compliance issues.

Throughout the plan year, CMS collects and analyzes performance data submitted by plans, internal systems, and beneficiaries. Incoming data is continuously monitored, and organizations are immediately contacted when the data analysis reveals potential problems. While the

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retrospective audits described below serve as an important oversight tool, our day-to-day monitoring and surveillance activities enable us to quickly identify and proactively resolve deficiencies throughout the program year. Additionally, on an ongoing basis, CMS investigates general grievances, appeals, and beneficiary complaints, monitors plan marketing efforts, monitors claims payment systems, reviews our centralized complaint tracking system, conducts weekly conversations with our appeals resolution contractors, analyzes plan reported data, and reviews the integrity of the prescription drug benefit available for our beneficiaries. Further, we incorporate feedback and lessons learned from this information to implement strategic improvements to the underlying program and our oversight efforts.

CMS conducts targeted audits to supplement the information collected from plans and other surveillance and monitoring activities. Program audits are designed to assess each sponsor's compliance with core program requirements, such as compliance plans, marketing and enrollment activities, and benefit delivery. CMS utilizes a targeted approach in selecting sponsors for audits. We target and apply more intensive staff resources – via account level management, program auditing, and compliance and enforcement actions – toward those organizations that present a statistically higher level of risk or vulnerability for the Agency, whether as a result of their size (large or small), anticipated significant growth in enrollment, or historical actions.

CMS also conducts extensive oversight of plan payment. Following the approval of plan bids, CMS collects prescription drug event (PDE) data, which is pharmacy level claims data on each filled Part D prescription. CMS uses this data along with plan-reported rebate and price concessions information to evaluate each plan's actual incurred drug costs. After the close of each plan year, Part D payments are subject to a reconciliation process. CMS follows statutorily

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defined procedures to adjust bid-based prospective payments for discrepancies between anticipated and actual costs.

Finally, the independent Office of the Actuary at CMS conducts retrospective desk audits of the underlying methodology and assumptions of plan bids in order to improve the accuracy of the bidding process. Additionally, CMS conducts on-site financial audits that review Part D sponsors books. Both of these activities cannot take place until after a plan year is complete.

New Regulatory Oversight Activities

In October 2009, CMS proposed a new regulation (CMS 4085-P), intended to create a stronger oversight framework and improve performance of prescription drug and health plans by strengthening standards to participate in the Medicare program. This regulation builds on many of the administrative actions that we have pursued over the last year to improve our oversight capacity and ensure that sponsors are compliant with all program requirements. The proposed regulation contained approximately 70 proposed regulatory changes. If the rule is finalized, the proposed changes are intended to assist in simplifying and tightening management of the program.

The proposed enhancements are intended to strengthen Medicare Advantage (MA) and Part D performance requirements, extend greater beneficiary protections to people with Medicare, and ensure that companies offering more than one drug or health plan in the same geographic area offer meaningful differences between those plans. Specifically, among other things, CMS is proposing to:

- Strengthen CMS' ability to identify and approve qualified drug and health plans;

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- Improve Medicare beneficiary protections from discriminatory cost-sharing by clarifying health plan requirements relating to out-of-pocket costs and cost-sharing; and

- Eliminate duplication in drug and health plan bids submitted by the same organization by requiring a meaningful difference between an organization's product offerings with regard to premiums, beneficiary out-of-pocket costs, plan types, and formulary offerings. While we support choice for beneficiaries, in terms of their ability to select the health care plan that best meets their unique needs, we want to ensure that distinctions among plans are clear and understandable for our Medicare beneficiaries.

Further, the proposed rule contains numerous provisions aimed at strengthening our oversight authority and improving our ability to act on the oversight and performance information that we collect. Among other things, we proposed to:

- Codify our recently implemented approach of considering sponsor past performance in our review of Part D sponsors and new Part D applications;

- Include a new methodology to assess performance, which would improve our ability to identify compliance issues and take appropriate oversight and enforcement actions; and

- Replace the existing corrective action plan process with an outcome-oriented reasonable period of time process to correct deficiencies as required by statute prior to plan termination.

Additional clarifications CMS is seeking in the proposed rule include a proposal to collect all PDE data elements for non-payment purposes, in order to provide accurate information for analysis of how people with Medicare are using their Part D plan benefits. The proposed rule

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would also clarify that, by 2011, both MA and Part D plans will be expected to pay for the data collection costs associated with the annual Consumer Assessment of Healthcare Providers and Systems (CAHPS) enrollee satisfaction surveys performed by independent contractors. These important provisions will allow CMS to ensure proper day-to-day management of the program for our beneficiaries.

CMS is currently in the process of reviewing the comments on the proposed rule. The Agency is working towards finalizing these policies during 2010 to take effect in calendar year 2011.

Audits and Reviews to Support the Program

CMS' compliance plan activities are an integral part of the Agency's far reaching oversight functions. Strong rules and plan guidance provide the backbone of our oversight of Part D, further strengthened by the work of CMS' Medicare Drug Integrity Contractors (MEDICs) and our routine audits.

In response to concerns about the operation of our MEDICS, in November 2009, CMS restructured the way the Agency utilizes our MEDICs, moving from a regional-based MEDIC program to one that allows the MEDICs to develop efficiencies and expertise in their focus area. Given that many of our Part D sponsors operate across the country, CMS determined that a regional-based approach would duplicate our MEDICs work and impede coordination. Since that time, the Compliance and Enforcement MEDIC focuses on contract compliance activities for the Medicare Part C and Part D programs, including aggressive oversight of marketing activities, compliance plan audits, and serving as a liaison with the state departments of insurance. The Benefit Integrity MEDIC focuses on pursuing fraud, waste, and abuse activities and serves as a resource to law enforcement agencies.

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This restructuring and redesign by workload should allow MEDICs to build on their already considerable successes. They have investigated thousands of complaints and referred nearly 300 cases to law enforcement. This has resulted in aiding prosecutions of rogue insurance agents, owners of fake infusion clinics responsible for billing Part C for millions of dollars in claims, and beneficiaries, healthcare providers, and physicians involved in forging prescriptions and overprescribing, selling, diverting, and trafficking Part D drugs. This past year, the MEDICs also initiated a Part D information sharing workgroup made up of plan sponsors, Pharmacy Benefit Managers (PBMs), and law enforcement representatives. This group has been instrumental in bringing together partners to communicate and share information to reduce pharmacy fraud in Part D.

Similarly, CMS has made significant changes to our compliance plan audits. After MEDICs conducted 16 desk review compliance plan audits, CMS determined that they were of limited value to our monitoring and oversight efforts. As a result, in 2009, CMS took the opportunity to significantly revise its original approach to conducting compliance audits. CMS determined it was necessary to change its approach from a desk review to an on-site review and to develop more comprehensive, meaningful, and robust compliance plan audit protocols focused on evaluating and validating the effectiveness of compliance programs, including the effectiveness of measures to prevent, detect, and correct fraud, waste, and abuse. With the assistance of the MEDICs, CMS piloted these new audit protocols by conducting an on-site compliance plan audit with the largest Medicare Advantage and Part D sponsoring organization in 2009, and with a smaller Medicare Advantage and Part D sponsoring organization in January 2010. CMS made changes to the protocols as a result of lessons learned during these initial audits and also

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incorporated these audits into the October 2009 proposed rule. CMS fully expects the MEDICs to begin these more comprehensive on-site compliance plan audits in the spring of 2010.

As part of CMS' functions in administering the Part D program in line with statutory requirements, we conduct bid reviews, bid audits, and financial audits of plan submissions. These activities are done throughout the plan year, which begins January 1, and preparation begins months before a new contracting cycle. For instance, while the 2010 plan year for beneficiaries began two months ago, CMS is preparing to publish the final 2011 Medicare Advantage and Part D Rate Announcement/Call Letter on Monday, April 5 as required by statute, and staff has already begun working on guidelines for plan year 2012. Meanwhile, payment reconciliation will be conducted for plan year 2009 during this summer and fall. Reconciliation payments are calculated after the close of a plan year to ensure that the prospectively paid direct subsidy, reinsurance subsidy, and low-income cost-sharing subsidy match actual costs incurred by the sponsors. In addition, reconciliation examines whether plans are entitled to risk-sharing money based on unexpected losses or must share a portion of unexpected profit with Medicare.

Further, CMS performs financial audits of one-third of Medicare Advantage-Prescription Drug Plans and standalone prescription drug plans for each plan year. All financial audits performed include a prescription drug program review component. Independent auditing firms under contract with CMS perform these audits, after plan reconciliation is complete. Audit firms issue an opinion on the accuracy of selected financial data and sufficiency of internal controls.

CMS is on track to complete all plan year financial audits. Plan year 2006 includes 169 audits and plan year 2007 consists of 200 audits. Audit firms have completed 213 of the 369 audits for

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these two years. CMS is currently in our procurement phase for plan year 2008, which will include 235 audits. The financial audits include a review of beneficiaries' True Out of Pocket cost calculations, Part D expenses and payments, and Part D direct/indirect remuneration. CMS is evaluating the results to determine meaningful and actionable measures that we should undertake in our effort to improve our programs.

Finally, CMS also conducts a number of other audits for sponsoring organizations, including:

- "LIS readiness" audits to determine a qualifying stand-alone prescription drug plan sponsor's ability to accept one-time annual and recurring monthly low-income premium subsidy (LIS) enrollments assignments from CMS;
- Annual on-site audits of selected sponsoring organizations and selected areas of compliance (e.g. enrollment operations, premium billing, communications to beneficiaries, appeals and grievances, and marketing); and
- Cost report audits for Cost Plan Sponsors.

The Administration is committed to using the lessons learned in our oversight activities and audits to inform the process of future year's bids. New plan expansions were not allowed this past year in certain cases due to past performance issues. This accountability action assures beneficiaries access to high quality plans and requires plan sponsors not meeting CMS standards to focus attention on their current plan areas before being eligible for expansion. We will continue to follow the bid reviews, bid audits, and financial audits that are called for in statute in administering the Part D prescription drug benefit.

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New Initiatives

CMS recently announced a realignment plan that will strengthen our existing efforts to coordinate all Medicare programs and combat fraud and abuse.

The realignment includes the creation of a Center for Program Integrity, integrating similar functions from the Medicare and Medicaid programs to improve intra-agency coordination and deployment of resources to address fraud, waste, and abuse. By housing all Program Integrity efforts in one Center, CMS staff will gain valuable insights and share best practices, which allow the Agency to fulfill the mission of ensuring effective, up-to-date health care coverage and promoting high-value, quality care for our beneficiaries.

In addition, the Administration has made fighting health care fight fraud, waste, and abuse a central part of the FY 2011 Budget Request through an unprecedented increase in CMS program integrity funding and support for aggressive new authorities. The FY 2011 request includes a total of $561 million in discretionary Health Care Fraud and Abuse Control (HCFAC) resources and proposes a new package of legislative and administrative changes that will give CMS new tools that enhance program integrity, Part D oversight, and the important work done by CMS' MEDICs. This funding includes a total of $159 million to strengthen program integrity activities in Medicare Advantage and Medicare Part D. In particular, the Budget requests ongoing investments through MEDICs; Medicare C and D contract oversight; monitoring performance assessment and surveillance; program audits; and compliance and enforcement activities. Not only does this continued investment safeguard the program, it has been proven to save money.

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The HCFAC Account has a return on investment average of 6 to 1 and returned over $13 billion to the Medicare trust funds between 1997 and 2008.[1]

In addition, the President has recently released a health insurance reform proposal that builds on provisions proposed by the House and the Senate health reform bills, as well as Republican bills, to crack down on fraud, waste, and abuse. These efforts include further authorities and initiatives at CMS and other federal agencies to provide proper oversight of Medicare. For example, the President's Proposal speeds access to claims data to identify potentially fraudulent payments more quickly. It also establishes a system for using technology to provide real-time data analysis of claims and payments under public programs to identify and stop fraud, waste, and abuse, among other efforts. It provides additional tools to reduce the number of individuals and agencies participating in Federal health programs that have a history of fraudulent activities. It improves coordination and information sharing in anti-fraud efforts. If adopted, we anticipate these efforts will improve our oversight efforts and stand ready to work with Congress to implement health insurance reform legislation.

Further Concerns

As I have already described, our efforts to deal with oversight challenge include a multi-faceted effort centered around day-to-day management, increased data utilization, proper use of MEDICs, and better targeting our compliance plan and program audits. As we look to future oversight efforts of Part D, CMS remains committed to finding the best methods and tools for oversight and development of our program.

[1] HHS Fiscal Year 2011Budget in Brief, 58.

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However, as an Agency we remain concerned about numerous oversight challenges, including marketing and enrollment abuses, clinical access issues, and plans undergoing rapid expansions. We know that we need to work more closely with our partners to ensure that we share a common vision in serving Medicare beneficiaries, many of whom are vulnerable and sick, and help make choices and access to health care clear and easy. To that end, we are pursuing oversight and compliance efforts, like those in the recent proposed rule ensuring that high quality, strong prescription drug plans are available to our beneficiaries without causing confusion.

In the effort to ensure that CMS' payments to Part D sponsors are accurate, CMS has been developing payment error measures for the Part D program. We have developed and reported the following measures: 1) payment error originating from the Part D payment system, 2) payment error relating to low income payments and 3) payment error relating to incorrect Medicaid status. CMS is currently working on additional complex and elaborate measures that will better take into account claims data from plans and price concessions from manufacturers. In order to report publicly this information, we have needed time to put in place a more thoughtful and robust system to capture and better report Part D error; in the meantime, we are steadily pursuing the full range of our oversight and compliance activities.

Conclusion

CMS is strongly committed to maintaining and improving the health care benefits provided to beneficiaries of the Medicare Part D program and ensuring effective management and oversight of these plans. Since President Obama took office, the Agency has taken significant action to dedicate resources and attention to proper oversight and combating fraud, waste, and abuse. We are proud of the progress we have made. Yet, we know we have more work to do.

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The Agency is committed to examining every part of our day-to-day operations to ensure effective oversight. When potential gaps in oversight or vulnerabilities are identified, we will examine potential regulatory or programmatic changes that will strengthen the program. Further, we will build upon the existing framework of MEDICs, financial audits, and compliance reviews to ensure this information is used in new, targeted, and more effective ways.

I look forward to working with the Congress and this Subcommittee to ensure a strong and effective Part D program and am happy to answer any questions you might have.

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SafeGuard Services LLC

STATEMENT OF HOWARD B. APPLE

SAFEGUARD SERVICES, LLC

ON

OVERSIGHT CHALLENGES IN THE MEDICARE PRESCRIPTION DRUG PROGRAM

BEFORE THE

U.S. SENATE HOMELAND SECURITY AND GOVERNMENT AFFAIRS

SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT

INFORMATION, FEDERAL SERVICES, AND INTERNATIONAL SECURITY

MARCH 3, 2010

Mr. Chairman, Senator McCain, and distinguished members of the Subcommittee, thank you for the opportunity to discuss SafeGuard Services' (SGS) role in helping CMS combat fraud and abuse in the Medicare Prescription Drug Program. My name is Howard Apple. I am the President of SafeGuard Services, LLC.

BACKGOUND

The enactment of the Medicare Modernization Act on December 8, 2003 represented the largest change to Medicare since its inception by creating a new Prescription Drug Benefit for Medicare beneficiaries (Part D).[1] Beginning in September, 2006, CMS geographically divided the United States and awarded contracts to three Medicare Part D Integrity Contractors (MEDICs)--MEDIC North, South and West. Each MEDIC was responsible for performing program safeguard functions to detect, deter and prevent fraud, waste and abuse and to mitigate vulnerabilities associated with Part D benefit services provided within their

[1] Medicare Part D Integrity Contractor Task Order North MEDIC Statement of Work, 06/2006

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geographic jurisdiction. SGS was awarded the contract for the MEDIC North, which consisted of 24 of the states in the northern U.S., the District of Columbia and the U.S. Virgin Islands.

In September 2008, CMS reduced the number of MEDIC contractors to two organizations, resulting in the reassignment of the MEDIC West states to the MEDIC North and South. The MEDIC North's jurisdiction expanded to include 35 states, four U.S. Territories and the District of Columbia. Additionally, the MEDICs were tasked with supporting the Center for Drug and Health Plan Choice's (CPC) efforts to address new or emerging areas of compliance and enforcement related to Medicare Advantage (Part C), Part D, and the Program of All Inclusive Care for the Elderly (PACE) for these states and territories.

Under the MEDIC North contract with CMS, SGS's responsibilities included the investigation of allegations or suspicions of fraud, waste and abuse in the Part D program within our jurisdiction. Complaints were received from a variety of sources. The majority of complaints were received via CMS' toll-free, Part D Hotline and through CMS' Complaint Tracking Module (CTM). Typically, complaints involved telemarketing scams, inappropriate enrollment or disenrollment within a plan, Explanation of Benefits (EOBs) that were in error, improper marketing practices and drug diversion. Additional responsibilities included using innovative data analysis techniques to identify potential fraud and abuse, fulfilling requests for information from law enforcement agencies, and conducting Compliance Plan Audits of Part D sponsors to assess the sponsor's compliance with the Part D regulations found at 42 CFR §423.

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In October 2009, SGS's MEDIC North contract was again modified. CMS decided to realign the responsibilities of the MEDICs functionally, rather than geographically. MEDIC North became the Compliance and Enforcement (C&E) MEDIC with the mission of providing nationwide support of CPC's compliance and enforcement strategy and to bridge the gap between compliance and enforcement activities managed by the Program Compliance & Oversight Group (PCOG) in CPC, and the nationwide fraud, waste and abuse activities tasked to Health Integrity (HI) and managed by the Program Integrity (PI) Group in the Office of Financial Management (OFM of CMS). Our responsibilities now include providing audit technical assistance; conducting plan sponsor readiness and ongoing compliance assessment; investigating complaints against agents and brokers involving alleged violations of the Medicare regulations and guidelines; and monitoring/evaluating sponsors' compliance plans and the effectiveness of those compliance plans.

ACCOMPLISHMENTS

From December 1, 2006 through November 14, 2009, while tasked with the responsibility of investigating Part D fraud, waste and abuse, SGS received over 10,000 calls via the toll-free hotline. We handled over 3,200 complaints from beneficiaries, Part D plans and beneficiary advocacy groups. SGS initiated approximately 1,100 investigations, and referred over 120 instances of fraud and abuse to HHS OIG and other law enforcement agencies. We also fulfilled over 300 requests for information, such as Part D data, from law enforcement agencies and referred over 170 agent or broker misconduct[2] cases to the State Insurance Commissioners (SICs) and Departments of Insurance (DOIs) in 18 states.

[2] Since October 1, 2009, as the C&E MEDIC, we have referred an additional 300 agent/broker referrals to SICs and DOIs.

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During the course of our MEDIC work, CMS and the MEDICs have encountered and experienced several of the challenges and growing pains associated with any new program. . However, over time, as CMS and its partners acquired the necessary tools and built the necessary infrastructures, we began to see our efforts generate results. As the MEDIC Program matured, the MEDICs continue to work with CMS in developing alternative solutions. In 2009, we began to see some of these alternative solutions yield dividends, especially as it related to pharmacy fraud—a prominent problem area in the Part D program.

For instance, we conducted proactive data analysis of the prescription drug event data, Part A and Part B claims data, and analyzed the Complaint Tracking Module to identify red flags with pharmacies participating in the Part D program. Our Data Analysts utilized innovative data analysis software tools to evaluate potential relationships, such as pharmacies and physicians sharing beneficiaries or identifying clusters of beneficiaries obtaining prescriptions from the same group of physicians.

Another challenge involved the MEDIC's lack of the legislative authority to directly obtain medical records, such as prescriptions from pharmacies, pharmacy benefit managers, and physicians, made it difficult to verify the validity of prescription drug events and associated payments. Since the MEDICs only had the authority to request information from the plan sponsors, we reached out to the respective compliance officers and special investigative units of the largest plan sponsors with CMS' approval and proposed conducting joint audits of pharmacies participating in their networks. Several Part D sponsors accepted our offers as their representatives viewed this collaborative opportunity as a mutually beneficial endeavor. They could utilize our investigative skill sets and receive support from our pharmacy

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technicians who possess retail pharmacy experience as well as fraud investigation experience. And, they could expand the scope of audits and increase the number of audits, thereby opening the door for additional payment recoveries. We saw this as an opportunity to strengthen our investigations, detect non-compliances, and develop proactive leads for potential referral to law enforcement. This collaborative activity resulted in MEDIC North's participation in 16 pharmacy audits that detected numerous non-compliance and fraud, waste, and abuse issues. These audits led to the removal of problematic pharmacies from plan sponsor's networks and referrals to law enforcement for potential criminal or civil actions.

CONCLUSION

These accomplishments resulted from developing a collaborative and constructive relationship with CMS at all organizational levels which we continue to foster through weekly status meetings and ad hoc meetings and conference calls to exchange mutual ideas and information to enhance MEDIC and Part C and Part D operations. Despite the challenges we have faced in this relatively new program, SGS is proud of its association with the CMS and its partners and is deeply committed to seeing this program succeed. Thank you, Mr. Chairman for the honor of speaking with you today. I would b happy to answer any questions that you or members of the Subcommittee may have.

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Statement of Christian Jensen, M.D., MPH
President and Chief Executive Officer, Quality Health Strategies
Before the
U.S. Senate Homeland Security and Government Affairs Committee's Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security

March 3, 2010

Chairman Carper, Ranking Member McCain, and Members of the Subcommittee, thank you for the opportunity to testify today on the challenges and opportunities of Medicare Drug Integrity Contractors (MEDICs) in identifying Medicare Part D fraud and abuse.

I serve as the Chief Executive Officer of Quality Health Strategies and as a Member of the Board of Directors of Health Integrity, LLC, one of our subsidiaries. I have 20 years of experience as Medical Director for a number of corporations, including Delmarva Foundation, The DuPont Co., and Computer Sciences Corporation (CSC). In my tenure with CSC, I served as the Medical Director for the Western Integrity Center, a Program Safeguard Contract of the Centers for Medicare & Medicaid Services (CMS). I am a retired Captain in the U.S. Naval Reserve and have served as Commanding Officer of four Naval Medical Reserve units.

Health Integrity was awarded the first Enrollment and Eligibility MEDIC by CMS in September 2005. Our task during this period was to identify potential fraud during the initial enrollment phase and first year of the Part D Program. The following year, two additional MEDIC contractors assumed regional responsibility for Part D complaints and investigations, while Health Integrity assumed Part D benefit integrity responsibility for the Southeastern United States. In September 2008, Health Integrity assumed responsibility for seven additional states and became the South MEDIC covering West Virginia, Virginia, North Carolina, South Carolina, Tennessee, Georgia, Florida, Alabama, Mississippi, Arizona, Louisiana, Oklahoma, Texas, Colorado, New Mexico, and Puerto Rico.

In November 2009, as a result of a positive restructuring of the program by CMS, Health Integrity became the National Benefit Integrity (NBI) MEDIC. Compliance and enforcement issues are now handled by another MEDIC contractor, SafeGuard Services (SGS). As the NBI MEDIC, Health Integrity has responsibility for fraud, waste, and abuse issues in all parts of the United States, and is the contractor responsible for performing benefit integrity tasks for CMS related to the Medicare Part D Prescription Drug Program. In addition to monitoring complaints received through our national call center and initiating fraud investigations for referral to the Office of Inspector General (OIG), Health Integrity performs proactive data analysis to identify new and emerging fraud patterns, applies medical and pharmaceutical experience, performs audits, and provides training.

In September 2008, Health Integrity was awarded the first Zone Program Integrity Contract (ZPIC Zone 4) covering Texas, Colorado, Oklahoma, and New Mexico. We were awarded

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the Umbrella Indefinite Quantity Contract and two Task Orders under the Indefinite Delivery/Indefinite Quantity (IDIQ) Contract. Task Order 1 is to perform Fee for Service (FFS) fraud and abuse detection and investigation for Part A, B, Durable Medical Equipment (DME), Home Health, and Hospice. Task Order 2 is to perform Medi-Medi fraud and abuse detection and investigation. In September 2009, we were also awarded Task Order 3 to perform Home Health fraud detection and investigation in Texas.

In September 2009, CMS also awarded Health Integrity two Audit Medicaid Integrity Contract (Audit MIC) Task Orders: Task Order 5, which performs fraud, waste, and abuse audits for Medicaid providers for 10 Midwestern states: Minnesota, Wisconsin, Michigan, Nebraska, Iowa, Illinois, Indiana, Ohio, Kansas, and Missouri; and the Task Order for the Southeast region of the U.S. (ranging from Pennsylvania to Florida). In combination with our MIC 5 award, Health Integrity has 23 states and the District of Columbia in which we perform four types of fraud, waste, and abuse audits of Medicaid providers: comprehensive onsite audits, focused onsite audits, desk audits, and cost report audits.

CMS has undertaken some bold, but necessary, steps to integrate, streamline, and improve Medicare and Medicaid program integrity. Implementing program integrity strategies for the new Medicare Prescription Drug Program had unique differences not found in the Medicare Fee For Service or Medicare Managed Care Programs. For example, the Prescription Drug Event (PDE) data is less mature, the Risk Share Model more complex, and regulations restrict MEDICs direct access to records of down-stream entities such as pharmacies and providers.

Because of these differences in the Medicare Prescription Drug Program, CMS and the MEDICs needed to perform educational activities for Plan Sponsors and external partners such as law enforcement to assure a better understanding of the Program's unique characteristics. As with any new program, improvement opportunities develop as the program evolves. CMS should be praised for responding to those opportunities as they occurred.

The OIG's October 2009 report focused on what the MEDIC program encountered prior to and during 2008. Many challenges were overcome in 2009, and it is pleasure to report the accomplishments Health Integrity has made during the past year. The chart below highlights these accomplishments and captures Health Integrity's workload activity in 2009.

Health Integrity 2009 Workload Accomplishments	
Call Center Complaints Received and Processed	2,488
Requests Processed for Essential Case Data to Law Enforcement	138
Fraud Case Referrals to Law Enforcement	121
Referrals of Insurance Agent/Brokers to State Insurance Commissioners	157
Investigations as a Result of Proactive Measures	267

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Specific accomplishments from 2009 include:

1. Health Integrity gained experience working with the data to perform more proactive data mining and analyses. Doing so has resulted in a substantial increase in the percentage of total investigations generated by proactive analyses as compared to investigations originating from external sources. During 2009, Health Integrity performed 47 proactive analyses, and these led to 267 investigations. Twenty eight percent of their total investigations resulted from proactive analyses. This is an improvement from the OIG Report where 4 percent was reported for all MEDICs in 2008. A total of 12 referrals resulting from proactive analyses have been made since January, 2009. However, 203 proactive investigations are being actively pursued. External cases received from Plan Sponsors have also dramatically increased from 89 in 2007 to 640 since January of 2009. Additionally, Health Integrity received access to Part B Data in 2009 and this has substantially increased our cross claims proactive data analysis capability and proactive investigation workload.

2. Health Integrity focused its outreach efforts in 2008 and 2009 to ensure federal law enforcement was fully trained in all the program issues that affect Part D investigations and potential prosecutions. For instance, Health Integrity helped lead the efforts to determine the financial impact of fraud on the government for Medicare Part D cases, a critical component for prosecution of health care cases. As a result, we have seen three Part D indictments in 2009 and 2010.

3. Health Integrity has had substantial success in collaborating on fraud, waste, and abuse investigation with Plan Sponsors. We established Part D and Part C Plan Working Groups which meet on a quarterly basis to share information and collaborate with law enforcement, Plan Sponsors, and ZPICs on fraud case development. These working groups have increased plans' awareness of MEDIC operations and improved Plan Sponsor referrals of potential fraud. Health Integrity received 89 referrals in 2007, 277 referrals in 2008, and 396 referrals in 2009. In the first 2 months of 2010 Health Integrity received 244 referrals as the NBI MEDIC.

4. Health Integrity performed 10 Compliance Plan Audits this past year and worked closely with CMS on several Compliance Initiatives. CMS recognizes the value of Compliance Plan activities and has dedicated a substantial amount of resources to the compliance oversight of Part D Plans through creating the Compliance and Enforcement MEDIC to decrease these vulnerabilities.

With such a complex program there will always be challenges but we expect even greater opportunities and outcomes in 2010. Indeed, although Health Integrity has only been the National Benefit Integrity MEDIC since October 2009, already this national perspective has strengthened our ability to:

- Identify new and emerging regional fraud schemes and patterns affecting Part D before they develop into national scope issues.
- Identify existing national scope issues.
- Focus our effectiveness at preventing potential fraud schemes from developing through vulnerability reporting, fraud alerts, and other measures.

I would like to thank the Subcommittee for this opportunity to offer my comments. This concludes my prepared statement, and I would be pleased to answer any questions the Subcommittee may have.

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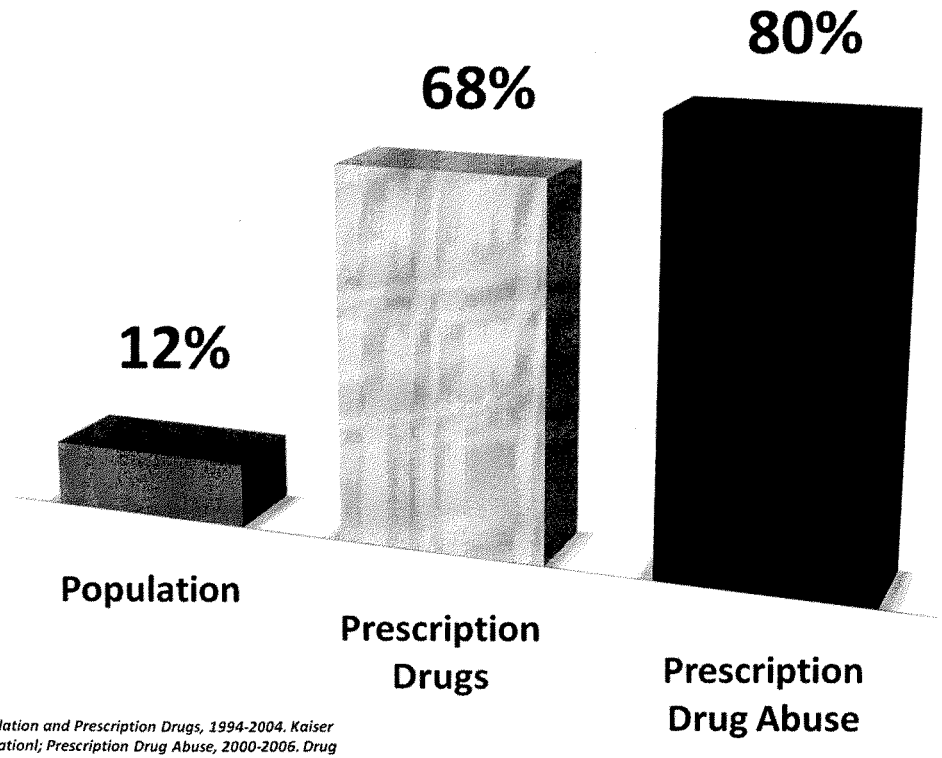
Rates of Growth



Source: Population and Prescription Drugs, 1994-2004. Kaiser Family Foundationl; Prescription Drug Abuse, 2000-2006. Drug Enforcement Administration

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The Senior Citizens League

Statement for the Record

on

Oversight Challenges in the Medicare Prescription Drug Program

Submitted to the

Committee on Homeland Security and Governmental Affairs
Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security

March 3, 2010

Washington, D.C.

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On behalf of the approximately 1.2 million members of The Senior Citizens League (TSCL), a proud affiliate of The Retired Enlisted Association (TREA), thank you for the opportunity to submit a statement regarding the oversight challenges in the Medicare Prescription Drug Program. TSCL consists of active senior citizens, many of whom are low income, concerned about the protection of their Social Security, Medicare, and veteran or military retiree benefits.

With the creation of the voluntary prescription drug benefit, known as Medicare Part D, many senior citizens gained access to prescription drug coverage they could not previously afford. However, TSCL feels that significant parts of the program are not getting the proper oversight. Because the Centers for Medicare and Medicaid Services (CMS) have been slow to develop estimates of improper payments or recovery plans for improper payments in Part D, this raises concerns for both beneficiaries and taxpayers that scarce program dollars are being misspent. For one, the sheer complexity of Part D may be causing many problems. The program relies on coordination between CMS, private contractors, plan providers and state governments.

The complexity is an open invitation to waste, fraud and abuse. It makes it especially difficult for beneficiaries to know when they are inappropriately charged, or denied coverage for prescriptions. TSCL surveys have found that beneficiaries have a very limited understanding of how Part D plans work, or what their costs should be. In a survey conducted by TSCL in the early part of 2009 about one-in-five respondents were uncertain about the new cost changes in their Part D plans for the year. Fully 60 percent said they did not know where to get free, unbiased Medicare counseling in their area to choose or switch drug plans.

Payments to Plans, Reconciliation and Audits

Many of the known problems in Part D oversight relate to the payment procedures. The plans must submit bids reflecting the estimated costs of providing the benefit by the first Monday of June of the previous year (June 2009 for plan year 2010). CMS reviews the bids before approving them. During the year, based on the plans'

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approved bids, CMS makes monthly prospective payments to the plans. CMS also enters into risk sharing agreements so that the federal government shares in the sponsors' unexpected profits and losses. The percentages of profits and losses that plan sponsors and CMS must share are based on defined risk corridors. Six months after the plan year, CMS then begins to reconcile the payments. It is during the reconciliation process that CMS collects any overpayments, and repays providers for any underpayments.

The Office of the Inspector General (OIG) of the Department of Health and Human Service (HHS) issued a report in October 2007 on the 2006 Part D reconciliation which found that plan sponsors owed CMS $4.4 billion.[i] In September 2009, the HHS OIG reported that CMS had reclaimed $4.37 billion of the money owed from the 2006 reconciliation, mostly by adjusting their prospective bids.[ii] Although this was a significant percentage that was recovered, as of September 2009 there were still five plans (three of which no longer participate in Part D) which owed CMS a total of $14 million for 2006. Thus, the plans had access to $4.4 billion of taxpayer dollars for over a year. In addition, they never had to return any cash funds to the government for the overpayments, because CMS simply adjusted the amount they would receive in future payments. The 2007 reconciliation resulted in plan sponsors owing CMS a net total of $18 million.

CMS does not appear to have a process to collect overpayments or to adjust prospective payments prior to the reconciliation process. The HHS OIG has recommended that CMS should seek authority to correct payments to plan sponsors at the end of the plan year, rather then wait until the reconciliation process. TSCL strongly supports this recommendation.

Failure to complete plan audits in a timely manner not only increases the potential for improper government payments to continue, but also results in plans overcharging beneficiaries for their premiums. An HHS OIG audit of the 2006 and 2007 plan bids stated that "if the bid amount was too high, then the Government, through its direct

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subsidy payments, and beneficiaries, through premium payments, would both end up paying too much for Part D coverage."[iii]

For 2007, through risk sharing agreements, many plans owe Medicare money because they overestimated their costs for providing benefits to recipients. Because of the overestimates, the monthly prospective payments Medicare made and beneficiary premiums were higher than they should have been. Following reconciliation, Medicare is able to get back some of the higher payments because of the requirements that come with risk-sharing. Of great concern to TSCL is that beneficiaries do not directly recover any of the money that they improperly paid in higher premiums.

The lack of oversight is undoubtedly contributing to a run-up in unsustainably high Part D premium increases. According to national surveys of drug plans by the Kaiser Family Foundation average monthly premiums weighted for enrollment have risen every year since 2006 for prescription drug plans. The survey found that since 2006, the average monthly premium has increased 50 percent.[iv]

Medicare Part D beneficiaries who pay more in premiums than they should will get especially hard hit this year, the first year since 1975 when they didn't receive a Social Security cost-of-living-adjustment (COLA).[v] Medicare Part B premiums will not increase for most beneficiaries, because of "hold harmless" protection. However, "hold harmless" does not apply to Medicare Part D. According to a new survey conducted by TSCL during late December 2009 through the end of February 2010, more than 52 percent of respondents said their Social Security payments in 2010 are lower than what they received in 2009.

Fraud & Abuse

Outside of payment system issues, there are other issues of fraud and abuse which affect the Part D program. A Government Accountability Office (GAO) report in July 2008 found that oversight of the fraud prevention programs of Part D plan sponsors was limited and that as of April 2008 no audits of plan sponsors' fraud programs had been

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conducted.[vi] Additionally, the HHS OIG has found that pharmaceutical companies have misreported pricing information; plans have conducted illegal marketing tactics; and pharmacies have switched drugs to maximize reimbursement.[vii]

Since CMS does not yet have a good figure as to how much is lost to waste, fraud and abuse in the Part D program, we do not know for certain how much is lost. However, the administration recently estimated that in 2009, Medicare fee-for-service and the Medicare Advantage program spent as much as 12.4 percent, or $47 billion, in improper payments. If the 12.4 percent also holds true for Part D TSCL estimates that in 2010 the estimated $68 billion program will improperly spend more than $8 billion.

Legislative Changes

In the Senate's pending health care overhaul legislation there are several sections which would increase the oversight abilities of CMS over the prescription drug plans. Section 6411 of the *Patient Protection and Affordable Care Act* would expand the Recovery Audit Contractor (RAC) program to Medicare Part D. According to CMS, the demonstration projects for the RAC resulted in over $900 million in overpayments being returned to the Medicare Trust Fund between 2005 and 2008.[viii] Section 6411 would also require the HHS Secretary to ensure that each Medicare Part D prescription drug plan has an anti-fraud plan and review the effectiveness of the plan. Additionally, the legislation would require increased penalties for knowingly making a false statement for items and services furnished under a Federal health care program (Sec. 6408); would strengthen the ability of CMS to conduct audits on Part D plans; and require a plan to notify CMS within 60 days if an overpayment is received and allow for increased data sharing between agencies (Sec. 6402). These provisions are common-sense solutions which Congress should consider.

Additionally, TSCL recommends that Congress give thought to the payment procedures for Part D plans through CMS. It appears that the current process needs a thorough review. Payments based on prospective bids appear to be inefficient and a problematic method of payment. Congress should appropriate adequate funds to CMS to

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conduct the reconciliation audits sooner to regain money overpaid to providers, or Congress should consider a more cost-efficient method of paying the providers.

Conclusion

CMS should take up more of the recommendations of the GAO and the HHS OIG to recover money more swiftly; and provide greater oversight of Part D plans' fraud programs. TSCL supports stronger oversight of Medicare spending and failure to do so is false economy. According to the most recent Annual Report from the Department of Justice (DOJ) on the Health Care Fraud and Abuse Control Program, enforcement efforts have yielded an impressive "return on investment" for the American taxpayer: for every dollar spent by the DOJ and HHS on federal health care enforcement, approximately $4 has been recovered and returned.[ix]

TSCL applauds this committee for its work to ensure that taxpayer dollars are not wasted through fraud, waste and abuse. This is an incredibly important topic for government accountability and the health of seniors.

Thank you.

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[i] OEI-02-07-00460 Medicare Part D Sponsors: Estimated Reconciliation Amounts For 2006, October 2007
[ii] OEI-02-08-00460 Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.
[iii] OEI-05-07-00560 Centers for Medicare & Medicaid Services Audits of Medicare Part D Bids, November 2008.
[iv] M-PartDPlan-KFF1009 "Part D Plan Availability in 2010 and Key Changes Since 2006," Kaiser Family Foundation, October 2009.
[v] SS-09TR-SST051209 2009 Social Security Trustees Report, May 12, 2009.
[vi] GAO-08-760 Medicare Part D Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited, July 2008.
[vii] Levinson, Daniel, "Health Care Reform: Opportunities to Address Waste, Fraud and Abuse," Testimony before the House Committee on Energy and Commerce, Subcommittee on Health, June 25, 2009.
[viii] "CMS Announces New Recovery Audit Contractors to Help Identify Improper Medicare Payments," CMS Office of Public Affairs, October 06, 2008.
[ix] M-HCF-HHS0909 The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program Annual Report For FY 2008, September 2009.

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Statement of:

The National Association of Chain Drug Stores

On:

Oversight Challenges in the Medicare Prescription Drug Program

To:

The United States Senate
Committee on Homeland Security and Government Affairs
Subcommittee on Federal Financial Management, Government Information,
Federal Services and International Security

March 9, 2010

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Chairman Carper, Ranking Member McCain and members of the subcommittee, the National Association of Chain Drug Stores (NACDS) is pleased to submit a statement on the Oversight Challenges in the Medicare Prescription Drug Program.

NACDS represents 154 traditional drug stores, supermarkets and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate 37,000 pharmacies and employ more than 2.5 million employees, including 118,000 full-time pharmacists. They fill more than 2.5 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States.

NACDS has worked closely with Congress and the Centers for Medicare and Medicaid Services (CMS) to improve the Medicare Part D program since its inception, and the active participation of pharmacies has been credited as one of the contributing factors to the program's success. As the subcommittee looks to address the oversight challenges in the Part D program, we ask that you consider the difficulties pharmacies encounter in complying with the fraud, waste and abuse training requirements under Part D. While we recognize the need for robust compliance programs under Part D, we urge Congress to consider our suggestions to ensure that these efforts do not place unnecessary burdens on healthcare providers and their patients.

Under Medicare Part D, pharmacies are required to train covered staff on fraud, waste and abuse control, in addition to meeting similar requirements under other public and private programs in which they participate. The multitude of training requirements place significant burdens on pharmacies and limit their ability to serve patients. In fact, CMS recently noted that the "current requirement for training for fraud, waste, and abuse of first tier, downstream, and related entities creates problems for pharmacies who may contract with dozens of Medicare Advantage and Part D Plan (PDP) sponsors, each of which is required by existing language, read literally, to provide the training to the pharmacy, or other provider, and its staff." *See* Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; 74 Fed. Reg. 54634, 54644 (proposed October 22, 2009). We agree. Pharmacies continue to struggle with the need to obtain multiple trainings and are under tremendous pressure from many Part D plans that insist on pharmacies completing the training mandated by the plans. We therefore urge Congress and CMS to consider the following suggestions on how to improve this requirement under Medicare Part D.

To alleviate the problem of pharmacies being required to take a different training program at the insistence of each plan, we have suggested that CMS include language in regulation permitting downstream entities to adopt any training program that meets CMS guidelines, without interference from sponsoring organizations. Under this approach, pharmacies could provide assurances to plans that they have complied with the training and education requirement by certifying compliance as part of their network contract process. Without such regulatory clarification, plans are reluctant to allow pharmacies to adopt their own programs that are perfectly appropriate and erroneously believe that pharmacies must take the training program demanded by the plan.

Congress should also direct CMS to target training to those who are directly involved in providing services under the Part D benefit. In pharmacies, required training should be limited

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to pharmacists and, at most, those employees who submit claims. Pharmacy technicians, cashiers and retail store clerks should not be required to undergo training if they are not involved in the delivery of the Part D benefit. Under current policy, pharmacies devote significant time and expense in training staff who have no direct involvement in providing care to Part D patients, which adds unnecessary expenses to the program without any benefit of reducing fraud, waste and abuse.

In addition, we question the benefit of mandating annual training on these individuals as CMS is currently requiring. The training of thousands of pharmacists on an annual basis demands a significant time investment that could otherwise be spent on providing prescription drugs and pharmacy services to Medicare beneficiaries and other patients. This duplicative requirement also adds unnecessary costs to pharmacies participating in the Medicare program and does very little to expand the knowledge about fraud, waste and abuse control for those who have previously completed the training. Therefore, training and education should be required at the time of initial hiring of covered employees of downstream entities and when there are significant changes in the laws and regulations related to fraud, waste and abuse necessitating a re-training.

NACDS stands with Congress to eliminate fraud, waste and abuse from all healthcare programs. Pharmacies are already ahead of the curve in these efforts and continue to implement practices that improve quality and lower healthcare expenditures. As the most networked segment of the healthcare community, pharmacies offer all payors the efficiencies and safeguards provided by electronic real-time claims review and adjudication. Through widespread adoption of e-prescribing, pharmacies have also been one of the key players in the promotion of electronic healthcare systems. These accomplishments add to the value pharmacies already bring to the Medicare program through their status as a state-licensed healthcare provider. As Congress and CMS consider ways to improve the fraud, waste and abuse training requirement, we respectfully ask that these unique characteristics be given adequate consideration to minimize the burden on these legitimate healthcare providers.

Thank you for the opportunity to comment on this important aspect of the Medicare Part D program.

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Response to Post-Hearing Questions for the Record
Medicare Part D: CMS Oversight of Part D Sponsors' Fraud and Abuse Programs Has Been Limited, but CMS Plans Oversight Expansion

Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security
Committee on Homeland Security and Governmental Affairs
United States Senate
March 3, 2010

Questions for Kathleen King
Director, Health Care
U.S. Government Accountability Office

Questions for the Record Submitted by the Honorable John McCain

1. **Do you believe that CMS has adequate resources, capability, and authority to exercise robust oversight of Part D?**

We have not conducted an assessment of CMS's current level of resources, capability, or authority to exercise oversight of Part D. However, in 2008 we reported that offices within CMS with oversight authority cited resource problems in 2006, Part D's first year of operation, that either prevented audits from occurring or changed the audit strategy to use desk audits rather than on site audits.[1] Audits conducted by CMS are an activity that CMS acknowledged would be necessary to document that the agency had fulfilled its program oversight responsibilities. Moreover, in its comments on a draft of our report, CMS stated that insufficient resources had been one of the primary impediments to its implementation of a robust oversight strategy. Starting in FY 2009, CMS began receiving additional discretionary funds for activities performed under the Health Care Fraud and Abuse Control (HCFAC) program. In addition, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 included provisions for increased funding to fight fraud

[1] Our 2008 report focused on one type of program audit--audits of Part D sponsors' compliance plans. In addition to program audits, CMS is required to annually audit at least one third of all Part D organizations' financial records; however, these audits were outside of the scope of our 2008 report. GAO, *Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited,* GAO-08-760 (Washington, D.C.: July 21, 2008).

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and abuse. CMS's recent oral testimony before this Committee indicated that although the agency believed that it lacked the resources in the past to conduct sufficient oversight, increased funding through HHS's FY 2011 Budget Request would allow CMS to conduct sufficient oversight activities including audits. Specifically, CMS's written statement before this Committee indicated that CMS plans to direct $159 million toward Medicare C and D program integrity efforts.

In our written and oral statements before this Committee we reported that CMS had issued a proposed rule in 2009 to increase its oversight efforts that the agency expected to finalize in 2010. CMS's written statement indicated that this proposed rule contains approximately 70 proposed regulatory changes intended to strengthen its oversight of the Medicare program. However, the adequacy of the proposed rule cannot be assessed until it has been implemented, which CMS stated will not occur until 2011. Lastly, the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 establishes new program integrity provisions including new authorities for CMS and other federal agencies, such as the HHS OIG, to provide more oversight of Medicare. CMS's written statement before this Committee indicated that several of these new authorities would improve the Agency's oversight of Medicare; however, the effect of these authorities cannot be assessed until they are fully implemented.

2. What should be in CMS's expanded oversight strategy for Part D that isn't there now?

We have not assessed CMS's expanded oversight strategy. However, CMS has not fully implemented the oversight strategy it had developed prior to Part D's implementation. Our 2008 report found that CMS had not conducted audits, a key oversight activity it had detailed in its 2005 Part D Oversight strategy, and therefore we recommended that CMS conduct timely audits. In its comments on a draft of our report, CMS stated that it concurred with our recommendation and

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that it was prioritizing its oversight activities to ensure Part D sponsors' compliance with CMS's policies. At the time our report was issued, we concluded that the lack of CMS's oversight of Medicare Part D sponsors' implementation of programs to prevent fraud, waste, and abuse risked significant misuse of Medicare funds. CMS has not completed the development of a payment error rate for the Part D program; consequently, the agency does not know the relative risk of improper payments in Part D compared to other parts of the Medicare program.

3. Since GAO began looking at Medicare Part D oversight, what improvements have you seen CMS make to Part D program integrity?

As we previously testified, CMS's Medicare Drug Integrity Contractors (MEDIC) have completed 16 desk audits of selected Part D sponsors' fraud and abuse programs. Since the completion of these audits in 2009, CMS has revised its audit protocol and piloted on-site audits, rather than desk audits, to assess the effectiveness of sponsors' fraud and abuse programs more thoroughly. CMS expects to implement on-site audits in the spring of 2010. In addition, CMS issued a proposed rule in 2009 to increase its oversight efforts and ensure that sponsors have effective compliance programs in place. CMS does not expect to finalize the proposed rule until 2010 and the rule will not take effect until 2011. In a recent interview, a CMS official told us that the agency is undergoing a contractor-led assessment of the agency's programmatic oversight efforts to identify opportunities for improvement. In addition, CMS recently realigned the MEDICs to reflect the MEDICs' oversight strengths rather than giving them geographic assignments. For example, one MEDIC focuses on contract compliance activities for Medicare Part C and D programs while the other MEDIC focuses on pursuing fraud, waste and abuse activities. In its written testimony before this committee, CMS stated that this restructuring allows the MEDICs to gain efficiencies and expertise in their respective focus areas. CMS detailed other program integrity

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activities in its written and oral statements before the committee; however, we have not conducted an evaluation of these reported activities.

4. What additional enhancements should be made to MEDICs' oversight of Part D sponsors?

We have not assessed the effectiveness of the MEDICs' current oversight of Part D. Our previous work indicated that the MEDICs had been engaged to detect fraud, waste, and abuse in Part D and investigate reports from beneficiaries, sponsors, and other sources; conduct enrollment, eligibility, and marketing surveillance, and identify high risk sponsors requiring further investigation; and conduct audits of Part D sponsors' compliance plans. However, at the time of our 2008 report, the tasks performed by the MEDICs from their statement of work only included receiving fraud, waste, and abuse complaints from various sources including the MEDIC hotline. A CMS official told us that the expansion of the MEDICs' tasks to include other aspects of its scope of work was contingent upon increased funding.

The HHS OIG has conducted a more recent review of the MEDICs' oversight activities.[2] The OIG recommended that CMS ensure that MEDICs conduct more rigorous oversight, including proactive data analyses, and expand the MEDICs' legal authority.

5. In 2008, CMS launched the Zone Program Integrity Contractor (ZPIC) initiative to consolidate the work provided by Medicare Fee-For-Service benefit integrity contractors, and allocate it based on zones.

a. Do you believe that the current ZPIC strategy (regional vs. functional) employed by CMS is effective?

[2] OIG, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, October 2009.

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b. Should MEDICs be included in the ZPIC initiative?

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established the Medicare Integrity Program, which provided CMS with the authority to contract with specialists in program safeguards, separating these functions from the contracts for claims administration. This program enabled the improvement of the agency's program integrity efforts by, for example, permitting CMS to reduce the number of contractors conducting certain functions to increase efficiency and simplify oversight.[3] For some functions, such as identifying payments made by Medicare that might be the responsibility of another or a secondary payer, CMS has consolidated responsibility to one contractor that collects, manages, and reports on other health insurance coverage for Medicare beneficiaries and researches and conducts all such claim investigations.[4] For other functions, such as those performed by ZPICs, CMS uses multiple contractors. For example, CMS has a set of contractors aligned by region with the Medicare Administrative Contractors (MAC) that administer claims.[5]

We have not done the evaluation work necessary to assess the effectiveness of the current regional ZPIC strategy. In October 2008, CMS stated that once they were fully operational, ZPICs would be responsible for conducting benefit integrity activities for Medicare Parts A, B, C, and D, which include identifying and investigating potential fraud cases and referring to law enforcement. To facilitate coordination and communication between them, CMS established ZPIC zones to align with MAC jurisdictions that handle claims for Part A and Part B. MACs and ZPICs have complementary responsibilities for Part A and Part B. MACs are responsible for medical review of claims they have paid, identifying and

[3] GAO, *Medicare Integrity Program: Agency Approach for Allocating Funds Should Be Revised*, GAO-06-813 Washington, DC: September 6, 2006).

[4] GAO, *Medicare Integrity Program: Agency Approach for Allocating Funds Should Be Revised*, GAO-06-813 Washington, DC: September 6, 2006).

[5] CMS is still in the process of fully implementing the ZPICs and MACs, so in some jurisdictions other contractors are performing these functions. These include the Program Safeguard Contractors (PSC), which are being replaced by the ZPICs, and the fiscal intermediaries and carriers, which had paid Medicare Parts A and B claims respectively, and are being replaced by MACs.

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recovering overpayments, conducting provider audits, educating providers on appropriate billing practices, and screening beneficiary complaints related to alleged fraud.

On the question of whether the MEDICS should be included in the ZPICs' strategy, we also have not done the evaluation work necessary to answer that question. However, we note that although CMS had announced in 2008 that it was going to transition responsibilities from the MEDICs to the ZPICs, on March 30, 2010, CMS officials informed us that the agency has not decided whether to incorporate the program integrity functions of the MEDICs into the work of the ZPICs or maintain separate MEDICs. CMS officials informed us that they are currently in the process of examining their program integrity efforts as a whole, and developing a strategic plan for them.

6. **Last November CMS underwent a realignment of work dispersed between the MEDICs. Each MEDIC is now responsible for specific functions or duties, as opposed to oversight for a specific region. This seems to contradict the ZPIC approach of a regional dispersion. What strategy do you believe provides the most effective division of work among program integrity contractors – regional or functional – and why?**

We have not done the evaluation work to assess whether it would be more effective to have regionally aligned or functional MEDICs. CMS has said that its strategy was to have its ZPICs responsible for benefit integrity activities across all parts of the Medicare program, and CMS is doing this by creating regional zones for the ZPICs. Therefore, if CMS decides on a different strategy, it would be useful to have its rationale explained. In at least one case, CMS has found that consolidating a function into a single contractor has been more efficient—specifically, agency officials have stated that its coordination of benefits contractor is conducting its Medicare Secondary Payer functions much more efficiently than having each claims administration contractor conduct them in its

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jurisdiction.[6] There may be functions within the MEDIC statement of work that are also conducive to being consolidated into a smaller number of contractors than the seven ZPICs.

Question for the Record Submitted by the Honorable Tom Carper

1. **Your testimony focused on a key set of anti-fraud efforts that the Medicare drug plan sponsors are supposed to perform. These anti-fraud steps are called "compliance plans." I understand that the Centers for Medicare and Medicaid Services, along with their private sector contractors, the Medicare Drug Integrity Contractors, will soon re-start their compliance plan audits. Would the GAO take another look at the work by the MEDICs and CMS in auditing the compliance plans of Medicare Part D prescription drug sponsors at the appropriate time, updating the previous work of the GAO on this topic?**

   We have received your request letter and plan to complete this work.

[6] In GAO-06-813, we reported that the activities of the single COB contractor had a bigger return on investment than any other reported program integrity activities.

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QUESTIONS FOR RECORD
U.S. SENATOR JOHN MCCAIN
Hearing on "Oversight Challenges in the Medicare Prescription Drug Program"
March 3, 2010

For Mr. Robert Vito:

Question 1:

Beginning in late 2007, your office issued several reports regarding oversight of Part D. What improvements have you seen CMS make to Part D program integrity over the years?

OIG response:

CMS is responsible for safeguarding the Medicare Part D program against fraud, waste, and abuse. The OIG has identified concerns about limited oversight and implementation of program safeguards to prevent and detect fraud, waste, and abuse in Part D. OIG reviews indicate that some safeguards have been in place since the benefit's inception, others have been employed in a limited capacity, and some remain unimplemented.

Plan Sponsors' Compliance Plans. Since the inception of the Part D program, CMS has required that plan sponsors have comprehensive compliance plans in place to protect the integrity of Part D. Compliance plans are important because they include measures to detect, correct, and prevent Part D fraud, waste, and abuse. Our early review of sponsors' compliance plans indicated that many plans did not address all requirements, lacked detail, and provided only broad outlines of fraud and abuse measures. OIG has recommended that CMS conduct compliance plan audits to ensure that compliance plans are comprehensive and effective. As of December 2009, CMS has not issued a final report for any audits of plan sponsors' compliance plans. Without completion of compliance plan audits, there is no way to know if this key anti-fraud component is working at the plan level. According to CMS, it has authorized Medicare Drug Integrity Contractors (MEDIC) to conduct compliance plan audits in 2010.

Additionally, in an October 2009 Proposed Rule, CMS proposed to stress the importance of Part D sponsors' maintaining robust compliance programs by modifying current regulatory language to clarify what constitutes an effective compliance program. As of early April 2010, CMS has not issued a Final Rule.

MEDICs. According to CMS, one of the key aspects of their Part D safeguard strategy was MEDICs' use of innovative techniques for data analysis. However, OIG's October 2009 MEDICs report found that MEDICs identified most incidents of potential fraud through external sources, such as beneficiary complaints, rather than through proactive analysis of program data. This was due, in part, because MEDICs were delayed in receiving access to data. Now that CMS has given MEDICs have access to Part D records and Parts A and B claims, OIG expects MEDICs to

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increase their proactive data analysis and will consider performing follow-up work to ensure this is occurring.

Plan Sponsors' Identification of Fraud and Abuse. A crucial aspect of protecting the integrity of the Part D program is ensuring that plan sponsors have in place a comprehensive and effective program to detect and deter fraud and abuse. However, OIG found that CMS did not collect information that would describe the outcomes of plan sponsors' fraud and abuse programs. Outcome information includes measures such as the number of fraud and abuse incidents identified, the number of inquiries and corrective actions initiated, and the number of referrals made for further investigation. OIG recommended that CMS require plan sponsors to routinely report information related to the results of their fraud and abuse programs and that CMS should use this information in assessing the effectiveness of sponsors' fraud and abuse programs.

In its *2010 Medicare Part D Reporting Requirements*, CMS stated for the first time that plan sponsors may voluntarily report aggregate data related to their anti-fraud, waste, and abuse activities, and CMS provided sponsors with specific guidance on what to report. While OIG acknowledges CMS's effort, we believe that CMS should require reporting of these data. Without consistent and comparable outcome data from all Part D sponsors, CMS cannot effectively evaluate plan sponsors' fraud and abuse programs.

Part D Payments for Part A Stays. OIG's report issued in June 2009, *Medicare Part D Payments for Beneficiaries in Part A Skilled Nursing Facility Stays in 2006*, OEI-02-07-00230, found that Medicare Part D paid for drugs, amounting to $75 million, for beneficiaries in Part A skilled nursing facility stays in 2006 and that the majority of these payments were likely inappropriate. In response to our report, CMS began sending Part D sponsors reports of all the beneficiaries who resided in skilled nursing facilities and other institutions. CMS advised sponsors that they could use this report to conduct retrospective reviews to identify drugs that should have been billed under Part A. CMS also recently issued new guidance that clarified when it is appropriate for Part D to pay for drugs for beneficiaries in Part A skilled nursing facility stays.

CMS Bid Audits. Each year, Part D plan sponsors' bid amounts are the basis for determining the payments Medicare makes directly to plan sponsors. The bid amounts also determine the monthly premiums that beneficiaries will pay. CMS's oversight is essential to reduce inaccuracies and errors in Part D sponsors' bids. Inaccuracies in sponsors' bids have resulted in Medicare paying higher payments and beneficiaries paying higher premiums than they should have. OIG has continually recommended that CMS strengthen its oversight and enforcement approach to hold plan sponsors accountable for their bids.

While CMS has not taken OIG's suggestions on how to hold sponsors more accountable for material findings identified in bid audits, it has taken some actions to strengthen the bid audit process. CMS has indicated that, starting with contract year 2011, the Office of the Actuary within CMS will evaluate plan sponsors' and certifying actuaries' compliance with bid instructions, CMS guidance, and the actuarial standards of practice. The Office of the Actuary

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will share the results of its evaluation and any material findings identified in the 2010 bid audits with CMS's Program Oversight and Evaluation Group.

CMS Financial Audits. CMS is statutorily required to conduct annual financial audits of at least one-third of Part D plan sponsors. Financial audits verify the accuracy of the financial data that plan sponsors submit to CMS with their bids. In a November 2008 report on CMS audits of Part D bids, OIG found that, as of April 2008, only 4 percent of the required number of Part D sponsor financial audits for plan year 2006 had begun. CMS reported that funding challenges prevented it from carrying out the statutory requirement to complete financial audits on one-third of plan sponsors annually. According to Mr. Blum's March 3, 2010 testimony, CMS has completed 58 percent of the required financial audits for the 2006 and 2007 plan years.

While CMS appears to be making progress with completing required financial audits, CMS needs to perform these audits more timely and establish mechanisms to hold plan sponsors accountable for problems identified. CMS's delays in conducting required financial audits of plan sponsors increases the risk that inaccuracies in the financial data underlying sponsors' bids will go undetected and affect future bids. OIG currently has work underway to obtain more information regarding CMS's financial audits of plan sponsors. Upon completion of our work, we will make it available to you.

Question 2:

What enhancements can be made to the MEDICs' oversight of Part D sponsors?

OIG response:

In our October 2009 MEDICs report, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse*, OEI-03-08-00420, we made four recommendations to CMS to improve MEDICs' oversight of the Part D program. Because of the data delays and the barriers that MEDICs described to us, our first recommendation is for CMS to ensure that the MEDICs have access to accurate and comprehensive data to assist them in identifying potential fraud and abuse and conducting proactive data analysis. Although MEDICs currently have access to Part D records, and Parts A and B claims data through CMS's integrated data repository, CMS stated that the new One PI data system would address the data concerns in our report and facilitate proactive fraud identification efforts. However, development of the One PI system is still underway. CMS reported to us, in December 2009, that it expects its contractors to have access to One PI by mid-2010. Full implementation of the One PI data system would assist MEDICs' in their oversight of the Part D program.

The second recommendation in our MEDICs report is that CMS authorize MEDICs to directly obtain information that they need to identify and investigate potential fraud and abuse from entities such as pharmacies, pharmacy benefit managers, and physicians even if statutory or regulatory change is required to do so. The structure of the Part D program is such that CMS's contract is with the Part D plan sponsor. The MEDICs reported to us that, because of this, they

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were only able to request the information they needed, such as hard copies of prescriptions, from the plan sponsors themselves. All three MEDICs indicated that not being able to obtain information directly from these entities was a barrier to investigating incidents of potential fraud and abuse. Allowing MEDICs to obtain this information directly would improve their ability to conduct investigations and identify fraud, waste, and abuse.

The third recommendation in our MEDICs report is that CMS require plan sponsors to report all potential fraud and abuse incidents that are referred to law enforcement agencies to MEDICs as well. This particular recommendation is not suggesting mandatory reporting of fraud to the MEDICs, but rather, to the extent such disclosures are made, that CMS require plan sponsors to report the information to the MEDICs as well. This would help MEDICs identify fraud and abuse trends and target problem providers. CMS concurred that when referring fraud and abuse incidents to law enforcement, plan sponsors should also report that same information to the MEDICs. CMS stated that those expectations are outlined in Chapter 9 of the *Prescription Drug Benefit Manual*. Ensuring that plan sponsors report this information to the MEDICs will help improve MEDICs' oversight of the Part D program.

The fourth recommendation in our MEDICs report is that CMS ensure that MEDICs have approval to conduct compliance plan audits for which they are responsible. We know that, as of December 2009, CMS had not issued any final reports for any audits of plan sponsors' compliance plans. CMS stated that it has made compliance plan audits a priority in 2010. Based on the recent MEDICs' restructuring it will be the Compliance and Enforcement MEDIC that will be responsible for conducting the compliance plan audits. Completion of compliance plan audits will help ensure proper oversight of plan sponsors. OIG will consider performing follow-up work in this area to ensure this is occurring.

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Question 3:

Based on work you've done on other parts of Medicare, what value does proactive data analysis provide in detecting fraud, waste and abuse?

OIG response

Both CMS and OIG have long recognized the importance of proactive data analysis. Although CMS has made proactive data analysis a requirement for its contractors, the contractors have not always produced a large number of investigations and case referrals as a result of proactive data analyses. We believe that contractors' ability to use of program data and innovative analytical methodologies is critical to the success of their program integrity efforts.

Proactive data analysis is the exploratory analysis of Medicare claims and payments to detect suspicious patterns, outliers, and aberrancies that may indicate system vulnerabilities and potential fraud. The results of proactive analyses can be used to identify targets for claim-processing edits and prepayment reviews. For example, a Medicare contractor may review Part B claims to identify physicians that billed Medicare for more patient office visits than legitimately could have been provided. In contrast to relying on complaints of potential fraud and abuse from external sources which typically occur after Medicare payments have been made, using proactive data analysis techniques for fraud detection can help to prevent improper payments quickly after they occur or, even in some cases, before they occur.

We in the OIG use proactive data analysis as an integral part of our Medicare Strike Force. The Strike Forces cases are data driven. Using proactive data analysis techniques, we are able to pinpoint fraud hotspots by identifying suspicious billing patterns as they occur. The Strike Forces have had impressive results. OIG and DOJ first launched their Strike Force efforts in 2007 in South Florida. Building on the success in South Florida, the Strike Force model has been expanded to Los Angeles, Houston, Detroit, Brooklyn, Tampa, and Baton Rouge.

Because OIG believes in the value of proactive data analysis, we have conducted numerous reviews of CMS's efforts to protect the integrity of the Medicare program through its use of proactive analyses. Since the mid-1990s, a number of these reviews have consistently found that CMS contractors conducted only limited proactive data analysis to identify potential fraud even though these contractors were responsible for using data analysis tools to detect fraud. For example, in OIG's 1998 report on Part A fiscal intermediary fraud units, we found that despite CMS's expectation that fraud units proactively identify fraud, half of the units did not open any cases proactively. In addition, as described in our 2007 report on Medicare's Part A and B program safeguard contractors (PSC), CMS expected PSCs to conduct innovative data analysis and to proactively identify fraud; however, we found most PSC's had minimal results from proactive data analysis. As recently October 2009, OIG found that the Part D MEDICs identified only 13 percent of potential fraud incidents through proactive methods despite the fact that proactive data analysis is touted as a key element of MEDICs' responsibilities.

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Question 4:

What impact does the lack of data have on MEDICs' oversight effectiveness?

OIG response

Previous OIG work has indicated that MEDICs' have relied mainly on external (i.e., reactive) sources to identify potential fraud and abuse rather than proactive methods. This was due, in part, because MEDICs were delayed in receiving access to the data necessary to conduct proactive data analysis. Complaints, by their nature, are reactive and tend to focus on a specific circumstance. In comparison, performing proactive data analysis can allow MEDICs, for example, to identify high prescribers of certain drugs to identify aberrancies. However, data is needed in order to conduct proactive analyses.

In our October 2009 report, MEDICs reported that they needed both Part D data and Part B data to effectively identify and investigate potential fraud and abuse incidents. However, MEDICs did not receive access to Part D data until August 2007 nearly a year after their contracts began. In addition, two MEDICs were not given access to Part B data until the fall of 2008 and the third MEDIC did not receive access to Part B data before its contract ended. MEDICs access to Part B data can allow MEDICs to see if a beneficiary had a corresponding doctor's visit which could help MEDICs determine whether a Part D prescription was appropriate. Without access to data, MEDICs' ability to perform comprehensive analyses that can identify trends, aberrancies, and outliers across the program is limited.

In addition, our MEDICs report found that MEDICs' lack of authority to directly obtain information, such as prescriptions and medical records from pharmacies, pharmacy benefit managers, and physicians hindered their ability to investigate potential fraud and abuse incidents. Allowing MEDICs to obtain this data directly would improve their ability to conduct investigations and identify fraud, waste, and abuse.

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Question 5:

In 2008, CMS launched the Zone Program Integrity Contractor (ZPIC) initiative to consolidate the work provided by Medicare Fee-For-Service benefit integrity contractors, and allocate it based on zones.

a. Do you believe that the current ZPIC strategy (regional vs. functional) employed by CMS is effective?

b. Should MEDICs be included in the ZPIC initiative?

OIG response

a. How to administer and implement Medicare's program integrity function among contractors is ultimately a CMS decision. However, OIG has work underway to review certain aspects of the ZPICs' performance.

CMS awarded the first two regional ZPIC contracts in September 2008 to Health Integrity and Safeguard Services and both contractors became operational in February 2009. Health Integrity is the Zone 4 ZPIC which includes Colorado, New Mexico, Oklahoma, and Texas. SafeGuard Services is the Zone 7 ZPIC which includes Florida, Puerto Rico, and the Virgin Islands. OIG will determine the extent to which these two ZPICs (1) identified potential fraud and abuse incidents through proactive methods and external sources, (2) took action to address potential fraud and abuse identified, and (3) encountered any issues or barriers in performing their contractual responsibilities. This review will focus on the ZPICs' results during their first year of operation (February 1, 2009 through October 1, 2009). OIG believes an examination of these two ZPICs will provide valuable information to CMS on ZPICs' efforts and results. OIG anticipates issuing a final report on this ZPIC review by mid-2011. Once our ZPIC review is completed, OIG will have data to help determine ZPICs' effectiveness.

b. Without knowing how CMS would integrate MEDICs' responsibilities within the ZPICs, it is difficult for us to answer whether or not it would be effective. However, housing the program integrity work for all parts of Medicare in a ZPIC would allow for information and data sharing in a way that no program integrity contractor has ever done. The ability to look at claims, beneficiaries, and providers across all Medicare parts would provide valuable information and allow for comprehensive data mining. However, the intricacies of each program would require ZPICs to maintain staff that has specific and detailed knowledge of Parts A, B, C, and D. Regardless of whether ZPICs have responsibility for Medicare Parts C and D, allowing ZPICs access to Part C encounter data and Part D prescription drug data would be beneficial in their program integrity efforts of Medicare Parts A and B.

With the restructuring of the MEDICs at the end of 2009, OIG has not had an opportunity to revisit the MEDICs under the new structure. There is now a Compliance and Enforcement MEDIC that focuses solely on compliance activities for the entire country including

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compliance plan audits and monitoring inappropriate agent/broker activity. The Benefit Integrity MEDIC is responsible for concentrating on fraud, waste, and abuse efforts for the entire country including investigating potential fraud and conducting data and investigative analysis.

Since OIG has not had an opportunity to revisit our work in this area since the MEDIC restructuring, we will consider reviewing MEDIC operations again in the future. Additionally, our current review looking at ZPICs activities to identify fraud and abuse will help determine ZPICs' effectiveness.

Question 6:

Last November CMS underwent a realignment of work dispersed between the MEDICs. Each MEDIC is now responsible for specific functions or duties, as opposed to oversight for a specific region. This seems to contradict the ZPIC approach of a regional dispersion. What strategy do you believe provides the most effective division of work among program integrity contractors – regional or functional – and why?

OIG response:

Regardless of the strategy – whether it is regional or functional – we believe that what is important is the effectiveness of each program integrity contractor. Previous OIG work that has examined the fraud detection and investigation activities of Medicare contractors, including Part A and B fraud units, PSCs, plan sponsors, and MEDICs, has found vulnerabilities in these contractors' efforts to combat fraud and abuse. In particular, these reviews have found that there is variation among the individual contractors' efforts and that their use of proactive methods has been limited.

With the transition of PSCs to ZPICs, and the realignment of the MEDICs, it will be helpful to determine if these changes have prompted an improvement in the use of proactive methods to identify fraud and abuse. Since the MEDICs were just restructured at the end of 2009, OIG has not had an opportunity to revisit our work in this area, but will consider reviewing MEDIC operations again in the future to help determine their effectiveness. Additionally, we believe our current review looking at ZPICs activities to identify fraud and abuse can help provide information to determine ZPICs' effectiveness.

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QUESTIONS FOR THE RECORD
U.S. SENATOR TOM CARPER
Hearing on "Oversight Challenges in the Medicare Prescription Drug Program"
March 3, 2010

Question for Mr. Robert Vito of the Inspector General

Question 1:

Mr. Vito, your testimony focused on a key set of anti-fraud efforts that the Medicare drug plan sponsors are supposed to perform. These anti-fraud steps are called "compliance plans." I understand that the Centers for Medicare and Medicaid Services, along with their private sector contractors, the Medicare Drug Integrity Contractors, will soon re-start their compliance plan audits. Would the OIG take another look at the work by the MEDICs and CMS in auditing the compliance plans of Medicare Part D prescription drug sponsors at the appropriate time, updating the previous work of the OIG on this topic?

OIG Response:

OIG often follows up on work we have completed to see if program vulnerabilities have been addressed. In our December 2006 report on compliance plans, we found that while all prescription drug plan sponsors had compliance plans, most plans did not address all of CMS's requirements. We recommended that CMS ensure that PDP sponsors' compliance plans address all requirements. In response to that report, CMS stated that it would conduct compliance plan audits beginning in January 2007 that would enable CMS to assess the effectiveness of compliance plans. In October 2008, OIG issued another report that found CMS had not conducted any routine audits of sponsors' compliance plans in 2007 and that by August 2008, no compliance plan audits had been conducted. We recommended that CMS conduct audits to verify that PDP sponsors' compliance plans meet requirements. However, as of December 2009, CMS had not finalized any audits of sponsors' compliance plans; therefore, there is no way to know if this key anti-fraud component is working at the plan level.

In addition, OIG is currently conducting an inspection entitled *Audits of Medicare Prescription Drug Plan Sponsors*, OEI-03-09-00330. This inspection focuses on seven types of Part D audits completed from January 1, 2006 through December 31, 2009. The audit types include compliance plan audits. However, since CMS had not issued a final report for any audits of plan sponsors' compliance plans, our report will not include information regarding any problems with sponsors' compliance plans or steps taken to address them.

According to Mr. Blum's testimony, 16 desk audits of sponsors' compliance plans were conducted in late 2008 and early 2009. However, CMS determined that these reviews were of limited value and chose not to issue final reports based on them. In late 2009, CMS restructured the Medicare Drug Integrity Contractors (MEDIC) and created a Benefit Integrity MEDIC and a Compliance and Enforcement MEDIC. The Compliance

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and Enforcement MEDIC focuses solely on compliance activities, including conducting compliance plan audits. CMS stated that it has developed new compliance plan audit protocols and expects to begin compliance plan audits in the spring of 2010.

Since our review of CMS audits of prescription drug plan sponsors, which should be finalized in early 2011, does not include a review of compliance plan audits CMS expects to conduct in 2010, OIG would consider conducting additional work in the area of CMS's oversight of Part D sponsors' compliance plans at the appropriate time.

Question 2:

Mr. Vito, the testimony by Mr. Blum described a reorganization of how CMS oversees its program integrity work. The Medicare Drug Integrity Contractors have been reorganized, and I believe we have gone from a geographic based alignment to a specialty based alignment. The idea is to make the structure as efficient and effective as possible, and ensure that we will see proactive data analysis by the Medicare Drug Integrity Contractors. Is this the first realignment of program integrity contractors by the Centers for Medicare and Medicaid Services? Wasn't a similar realignment of oversight contractors tried in the 1990s and in the last decade?

OIG response:

Historically, Medicare program integrity was a function of the claims-processing contractors, i.e., fiscal intermediaries' fraud units for Medicare Part A and carriers' fraud units for Medicare Part B. In the early to mid-1990s, CMS began using four Durable Medical Equipment Regional Carriers (DMERC) for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and five Regional Home Health Intermediaries (RHHI) for home health services. DMERCs and RHHIs were based on claim type and handled claims processing and program integrity functions.

In 1999, CMS began separating the major program integrity functions from all claims-processing contractors. CMS awarded benefit integrity task order contracts to Program Safeguard Contractors (PSC) for Medicare Parts A and B. In 2008, PSCs had 18 benefit integrity task orders for specific geographic areas. Of the 18, 13 had responsibility for Parts A and B, one had Part A only, one had Part B only, and three had DMEPOS only.

Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS is transitioning all Medicare administrative functions, i.e., claims processing and related functions, from fiscal intermediaries and carriers to 19 Medicare Administrative Contractors (MAC). In addition, CMS is transitioning the work of PSCs to Zone Program Integrity Contractors (ZPIC). The ZPICs will be divided into zones that align with the one or more of the MAC jurisdictions. The premise is that there will be a more concentrated effort of identifying fraud and abuse across claim types in each ZPIC zone. ZPICs will cover seven geographic zones and eventually all claim types, i.e., Parts A, B, C, and D. Two ZPICs handling Parts A and B became operational in February 2009, and CMS expects all seven ZPICs to be operational by the end of 2010. Currently,

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the Medicare Drug Integrity Contractors (MEDIC) are responsible for program integrity efforts in Medicare Parts C and D.

Under the Part D program, CMS originally awarded three regional MEDIC contracts to handle Part D program integrity. In November 2009, CMS restructured the MEDIC program. One MEDIC is now responsible for Parts C and D plan sponsors' compliance activities, including compliance plan audits and monitoring inappropriate agent/broker activity. The second MEDIC is responsible for Parts C and D benefit integrity efforts including investigating potential fraud and conducting data and investigative analysis related to fraud, waste, and abuse.

OIG has performed a number of reviews looking at the benefit integrity efforts of Medicare contractors since the mid 1990's. We issued a report on carrier fraud units in November 1996 and a report on fiscal intermediary fraud units in November 1998. Additionally, we issued a report in July 2007 that reviewed PSCs' activities to detect and deter fraud and abuse. Moreover, our October 2008 MEDICs report looked at the activities of the MEDICs to identify fraud and abuse and we have a review underway to review the ZPICs identification of fraud and abuse. Our past reviews have shown that there is variation among the individual contractor's efforts, regardless of whether those contractors have been fiscal intermediary fraud units, PSCs or MEDICs. Additionally, we have found the use of proactive methods has been limited. Regardless of the structure, we believe that what is important is the effectiveness of each program integrity contractor. OIG will continue to review Medicare contractor operations to ensure their effectiveness.

Question 3:

Mr. Vito, could you examine the testimony of the Medicare Drug Integrity Contractor panel? Their testimony describes improvements in a number of areas, including fraud reporting by the Medicare prescription drug sponsors and proactive data analysis. Will the Inspector General's office examine these figures, and any additional relevant figures that are available, and report back to the Subcommittee?

OIG Response

OIG's October 2009 MEDICs report, *Medicare Drug Integrity Contractors' Identification of Potential Part D Fraud and Abuse* (OEI-03-08-00420), focused on the MEDICs' second year of operations. We obtained MEDICs' data covering fiscal year 2008 including information regarding the number of (1) potential fraud and abuse incidents identified (2) incidents investigated, (3) cases referred to OIG, (4) immediate advisements to OIG, (5) referrals to State insurance commissioners, and (6) referrals to CMS for administrative action. We focused on whether MEDICs had used proactive methods or external sources to identify incidents of potential fraud and abuse.

In our October 2009 MEDICs report, we provided a table that presented the number and percentage of externally and proactively identified incidents and actions taken by all three MEDICs in fiscal year 2008. We have reproduced that table to provide you fiscal year

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2008 information specifically for SafeGuard Services and Health Integrity. Table 1 provides the information for SafeGuard Services and Table 2 provides the information for Health Integrity.

Table 1. Fiscal Year 2008 Data for SAFEGUARD SERVICES

Incidents Identified and Actions Taken	External		Proactive		Total
	Number	Percentage	Number	Percentage	
Incidents Identified	1179	93%	84	7%	1263
Investigations[1]	416	93%	30	7%	446
Cases Referred to OIG[1]	6	40%	9	60%	15
Immediate Advisements to OIG	7	88%	1	12%	8
Referrals to State Insurance Commissioners[2]					37
Referrals to CMS for Administrative Action	0	0%	0	0%	0

Source: OIG analysis of MEDIC's responses to data request for fiscal year 2008 data (report OEI-03-08-00420).

[1] Investigations and case referrals to OIG may have involved incidents identified prior to our FY 2008 timeframe.

[2] We did not ask MEDICs to indicate whether incidents referred to State insurance commissioners were identified through external sources or proactive methods.

In their testimony, both SafeGuard Services and Health Integrity describe their accomplishments; however, not all of their accomplishments can be compared to our fiscal year 2008 data. Particularly, SafeGuard Services' testimony provides some statistics on their accomplishments for a 3-year period, from December 1, 2006 through November 14, 2009, which does not make for a useful comparison to our data.

In their testimony, SafeGuard Services reported that they initiated approximately 1,100 investigations and referred over 120 instances of fraud and abuse to OIG and other law enforcement agencies between December 1, 2006 and November 14, 2009. As shown in Table 1, this is compared to SafeGuard Service's 446 investigations and 15 case referrals to OIG in fiscal year 2008.

In reference to proactive data analysis, SafeGuard Services did not provide data on the number of investigations or case referrals that were based on incidents identified proactively. However, they did describe that, in 2009, they conducted proactive data analysis of Part D prescription drug event data and Parts A and B data to identify, for example, instances where pharmacies and physicians were sharing beneficiaries.

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Conducting proactive data analysis utilizing all program data would be an improvement since MEDICs did not have access to all program data in fiscal year 2008. In addition, SafeGuard Services described that, as the Compliance and Enforcement MEDIC, they have referred 300 agent/ broker referrals to State Insurance Commissioners and Departments of Insurance since October 2009. This is an increase from the 37 referrals SafeGuard Services referred to State Insurance Commissioners in fiscal year 2008.

Table 2. Fiscal Year 2008 Data for HEALTH INTEGRITY

Incidents Identified and Actions Taken	External		Proactive		Total
	Number	Percentage	Number	Percentage	
Incidents Identified	1456	76%	467	24%	1923
Investigations[1]	647	97%	18	3%	665
Cases Referred to OIG[1]	39	93%	3	7%	42
Immediate Advisements to OIG	12	100%	0	0%	12
Referrals to State Insurance Commissioners[2]					160
Referrals to CMS for Administrative Action	33	100%	0	0%	33

Source: OIG analysis of MEDIC's responses to data request for fiscal year 2008 data (report OEI-03-08-00420).

[1] Investigations and case referrals to OIG may have involved incidents identified prior to our FY 2008 timeframe.

[2] We did not ask MEDICs to indicate whether incidents referred to State insurance commissioners were identified through external sources or proactive methods.

Health Integrity's testimony provided data on their accomplishments for 2009 which is more easily comparable to the fiscal year 2008 data from our MEDICs review. In addition, they provided data describing their proactive activities. Table 2 provides information regarding Health Integrity's fiscal year 2008 activities obtained during our MEDICs review. Additionally, Table 3 provides information on Health Integrity's 2009 accomplishments as provided in their testimony. Where applicable, Table 3 also provides a comparison to the fiscal year 2008 OIG received from our MEDICs review.

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Table 3. OIG's Fiscal Year 2008 Data for Health Integrity Compared to the 2009 Data Provided by Health Integrity in Written Testimony

	Fiscal Year 2008 Data from OIG MEDICs Review	2009 Data from Health Integrity's Testimony
Call Center Complaints Received and Processed	n/a	2,488
Requests Processed for Essential Case Data to Law Enforcement	n/a	138
Incidents Identified	1923	n/a
Investigations as a Result of Proactive Measures	18	267
Case Referrals to Law Enforcement	42[1]	121
Proactive Case Referrals	3	12[2]
Incidents referred from Plan Sponsors	232	396
Referrals to State Insurance Commissioners	160	157

Source: OIG analysis of MEDIC's responses to data request for fiscal year 2008 data (report number OEI-03-08-00420) and data provided by Health Integrity in their March 3, 2010 testimony.

[1] In fiscal year 2008, Health Integrity also had 12 immediate advisements to OIG

[2] This number represents proactive case referrals since January 2009.

In reference to proactive activities, Table 3 shows that in fiscal year 2008, Health Integrity had 18 investigations resulting from incidents identified proactively. This is compared to the 267 investigations in 2009 as a result of proactive measures as presented in Health Integrity's testimony. Additionally, in their testimony Health Integrity reports that 28 percent of their total investigations resulted from proactive analyses in 2009. This is compared to 3 percent of Health Integrity's investigations that were based on incidents identified proactively in fiscal year 2008 as shown in Table 2.

As shown in Table 3, Health Integrity referred 42 cases and made 12 immediate advisements to the OIG in fiscal year 2008. This is compared to 121 case referrals to law enforcement in 2009, as presented in Health Integrity's testimony. Additionally, as shown in Table 3, Health Integrity referred 3 cases that were based on incidents identified proactively in fiscal year 2008. Since January 2009, Health Integrity reports that they had 12 case referrals as a result of proactive analyses.

In reference to referrals from plan sponsors, Table 3 shows that in fiscal year 2008, Health Integrity had 232 incidents of potential fraud and abuse referred by plan sponsors. This is compared to 396 referrals from plan sponsors that Health Integrity reports for 2009. Additionally, Health integrity reports 244 referrals by plan sponsors in the first 2 months of 2010.

As requested, OIG has reviewed the information provided in the MEDICs' testimony and, where possible, has provided comparisons to the data from our MEDICs' review. However, OIG did not verify the data provided in MEDICs' testimony. Therefore, we cannot definitely confirm that these numbers are comparable nor can we comment on the quality of these MEDICs' fraud referrals or proactive data analyses.

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QUESTIONS FOR THE RECORD
Hearing on "Oversight Challenges in the Medicare Prescription Drug Program"
March 3, 2010

Senator Tom Carper

Question for Mr. Jonathan Blum of CMS

1) During the Senate floor debate over the health care reform bill, I wrote an amendment to require that Medicare sponsors report fraud. Oddly, the law is that sponsors are only asked to report, not required to report fraud. How will the Centers for Medicare and Medicaid Services ensure that sponsors report fraud? Should we require sponsors to report fraud?

   Answer: The Centers for Medicare & Medicaid Services (CMS) believes in a strong, comprehensive system that utilizes a variety of oversight tools to ensure that beneficiaries are protected and receive the benefits to which they are entitled and taxpayer dollars are not misused. Those tools include regular monitoring of plan performance, rigorous compliance plan requirements and audit protocols that hold plans accountable for their conduct and highlight areas for improvement and additional investigation by CMS. While receiving reports of fraud after it occurs is one strategy, CMS would not want to solely rely on such a strategy and is increasingly shifting our attention to approaches that maximize the use of resources by identifying potentially problematic plans and targeting them for comprehensive audits. We have recently revised our compliance plan audit protocols to improve our ability to identify plans that need closer scrutiny. We are improving communication channels between CMS, law enforcement agencies, and plans that will enable us to put the systems in place to stop fraud before it occurs.

   Under current policy, plans should report known instances where a pharmacy or provider is acting fraudulently. With regard to mandatory self-reporting, CMS has proposed rulemaking for this concept in the past, but CMS realized it would prove problematic for Part C and D plan implementation of mandatory self-reporting without further clarification and guidance. At this time, we are contemplating whether sub-regulatory guidance would make plans' responsibilities clearer in this area. I also note that a Part D sponsor faces potential liability under the False Claims Act, 31 U.S.C. section 3729, *et seq*, for knowingly submitting, or causing to be submitted, false or fraudulent claims to the government. This includes liability for knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay the United States. 31 U.S.C. 3729(a)(1)(G).

   I look forward to working with you to further examine appropriate tools to reduce waste, fraud, and abuse in the Part D program.

2) I am always trying to find ways to incentivize federal agencies, federal workers and our private sector partners to become more efficient and effective. The more I see of the important anti-fraud work of the Medicare prescription drug sponsors, I have to wonder if there is a way in incentivize their performance. For example, under the False Claims Act, whistleblowers can receive between 15% and 30% of the monetary proceeds of the action or settlement that are recovered by the government. The IRS has its own program rewarding

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those who report tax fraud. This is a powerful incentive for people to identify fraud. Are there similar ideas for incentivizing individuals or companies that we can pursue for the Medicare prescription drug program, or other elements of Medicare? Can we create a way to not just require the sponsors to successfully pursue anti-fraud action, but to reward the sponsors or their employees when they help identify or prevent fraud?

Answer: CMS' Incentive Reward Program (IRP) offers a monetary incentive up to $1000 for individuals to report suspected Medicare fraud, subject to certain conditions. Medicare beneficiaries and any individuals that are not immediate family members or officers of HHS, its contractors, or any other federal, state, or law enforcement agency are eligible to receive this reward. (See 42 CFR §420.405 (c)(2) for the complete list of individuals excluded from receiving a reward under the IRP). The IRP is outlined in the Medicare publication titled "Protecting Medicare and You from Fraud" (CMS Publication No. 10111). The IRP is also described in the "Medicare & You" handbook that is sent to all Medicare beneficiaries annually. We are currently reviewing the IRP and are looking for ways to further promote and expand this program.

One source of outreach in the beneficiary community is the SMP Program (formerly known as the Senior Medicare Patrol or Harkin Grantees), which educates and empowers people with Medicare to take an active role in detecting and preventing health care fraud and abuse. The SMP Program is another source of leads for investigation into Medicare fraud and CMS and its contractors actively partner with the SMP Programs across the country.

Additionally, individuals, employees, or companies can also pursue suspected Medicare fraud under the False Claims Act by filing a qui tam (whistleblower) lawsuit. Medicare qui tams, like other whistleblower lawsuits, are handled through the Department of Justice. CMS does not have access to data on Medicare-specific qui tam recoveries, but additional information may be available from DOJ.

3) Could you comment on the observations of the GAO and the Inspector General witnesses regarding two issues: the lack of data mining by the Medicare Drug Integrity Contractors and the lack of audits of the anti-fraud plans for Medicare sponsors, also called compliance plan audits? Specifically, how will the Centers for Medicare and Medicaid Services ensure that we see improvements in the work of the MEDICs in both of these areas?

Answer: In 2009, as part of our ongoing efforts to continue to improve and strengthen our oversight of Part D (and MA) sponsors, CMS changed the focus of the Medicare Drug Integrity Contractors (MEDIC) work from two regional contractors that performed similar work to a functional contracting approach. As a result, one MEDIC now focuses on contract compliance oversight activities for the entire nation, while the other MEDIC has a national emphasis on fraud, waste and abuse oversight activities. This change, which was effective October 2009, has already resulted in measurable improvements. For example, the Benefit Integrity MEDIC performed 47 proactive analysis projects during calendar year 2009, averaging approximately four per month. As of April 2010, the Benefit Integrity MEDIC has increased their monthly proactive data projects by over 50%, averaging seven per month.

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Also, CMS has contracted with a consulting firm, Booz Allen Hamilton (BAH) to conduct an evaluation of the MEDIC program. CMS anticipates using the results of this evaluation to inform our program management strategies and to assist the Agency with the development of performance metrics.

At the same time, CMS significantly revised our approach to conducting compliance plan audits. In 2009 CMS piloted our new audit protocols by conducting an on-site compliance plan audit with our largest MA and PDP sponsoring organization. As a result of lessons learned, CMS is making changes to the protocols. CMS is also preparing to incorporate into the audit protocols proposed measures to detect and prevent fraud, waste and abuse that were part of the proposed compliance plan regulations. CMS expects to begin these more comprehensive on-site compliance plan audits during the spring of 2010. In addition, CMS just published a final rule on April 15, 2010 that strengthens requirements for the compliance plans of MA and PDP sponsors.

CMS uses a risk-based methodology to evaluate our Part D sponsors and select plans for audits. While CMS has no plans to audit every Part D sponsor, the risk-based approach properly targets our resources to areas of vulnerability.

Compliance plan auditing is only a part of CMS' overall program integrity and audit strategy for monitoring Part D activities. The strategy also includes conducting both initial bid and post-payment bid reviews, review of plan sponsor contract requirements to assure there are adequate internal compliance and oversight plans, conducting risk-adjustment data validation audits, on-site evaluations of Part D plans, and proactive surveillance and monitoring tools that operate to protect beneficiaries and ensure the integrity of taxpayer dollars.

MEDIC analysis of the prescription drug event data (PDE) and other data housed in the Integrated Data Repository (IDR) results in leads for further investigation and referrals to law enforcement agencies including the OIG, FBI, DEA, and state law enforcement.

4) I understand that Health and Human Services reported about $36 billion in improper payments for Medicare in 2009. However, that figure did NOT include improper payments for the prescription drug component of Medicare. When will the Centers for Medicare and Medicaid Services have improper payments figures for Medicare Part D?

Answer: CMS is committed to reducing error rates in the Medicare, Medicaid, and CHIP programs. It is important to note that only a subset of improper payments are likely fraudulent.

For 2009, CMS is already reporting three components of a Part D payment error rate for calendar year 2007: (1) a Part D payment system error (0.59 percent); (2) a low-income subsidy payment error (0.25 percent); and (3) payment error related to Medicaid status for dual eligible Part D enrollees (1.06 percent). These rates were published on November 16, 2009, in the Department of Health and Human Services, FY 2009 Agency Financial Report, which can be found on the HHS web site at: http://www.hhs.gov/afr.

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CMS is also developing a method to calculate an error rate for 1) the validation of prescription drug claims, through an analysis of PDE data; and 2) Direct and Indirect Remuneration data, based on validation of plan-reported rebates from drug manufacturers and other price concessions, as reported to CMS.

Reducing the amount of improper payments in Federal government programs is a high priority for this Administration. Our error rate metrics are just one component of our overall Part D surveillance, oversight, and compliance activities, which as a whole ensure that our beneficiaries maintain access to appropriate prescription drugs and that taxpayer money is not wasted.

5) Outside of the oversight work that is being done by agencies and contractors on the federal level, there are serious efforts being made to combat prescription waste and abuse in the States. Namely, Prescription Drug Monitoring Programs, established and operated by State governments, have had a lot of success in rooting out fraud in Medicaid and Medicare Part D. However, as cash-strapped States take a look at their bottom lines; these monitoring programs are on the chopping block. Arizona, Mississippi, Minnesota and Washington have already publicly stated that they may terminate these programs in order to cut costs. The National All Schedules Prescription Electronic Reporting grant program, also known as NASPER, is a federal grant that helps States establish and upgrade these prescription monitoring programs. NASPER went without funding for nearly four years, before receiving $2 million last year. By all accounts, the money spent on this monitoring pays for itself. How effective are these programs in combating prescription drug fraud, waste, and abuse? If States are unable to fully fund these programs right now, does it make sense for the federal government to provide increased support?

Answer: The Administration, including CMS, is strongly committed to combating prescription waste and abuse in the States and at the federal level, including in the Medicaid and Medicare Part D programs. While CMS cannot speak directly to the effectiveness of Prescription Drug Monitoring Programs (PDMPs) and National All Schedules Prescription Electronic Reporting because they are not CMS programs, we do believe the monitoring programs under our authority are effective in combating prescription drug fraud, waste, and abuse and the Federal government has a role in assisting States in their ongoing monitoring activities. This is why the President's Budget for FY 2011 includes a CMS legislative proposal to require States to monitor and remediate high-risk prescription drug Medicaid billing activity to improve program integrity. However, beyond this proposal, we have several ongoing Medicaid monitoring activities to highlight.

For Medicaid, States are required to monitor drug utilization rates within their respective programs. Each State has a Surveillance and Utilization Review unit (SUR) that is responsible for conducting data analysis and monitoring the Medicaid claims processing system for indications of fraud and abuse, including utilization rates for prescription drugs. In addition to the SUR units, each State operates a Medicaid drug utilization review (DUR) program. The emphasis of the DUR program is to promote patient safety by generating an increased review and awareness of outpatient prescribed drugs. Under the law, one of the requirements of the DUR program is that each State must submit an annual report to CMS. The annual DUR report requirement provides a measurement tool to assess how well patient

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safety is being monitored. Currently, CMS is updating the survey instrument that States use as a tool to prepare their annual DUR reports. We have developed new questions relating to fraud and abuse and whether or not states use PDMPs. In addition, we plan in States to update the survey instrument to glean information about innovative and best practices with respect to the utilization of PDMP data.

The NASPER Act provides authority to set national standards for PDMPs. Uniform reporting and information transmission systems can accelerate interstate information sharing, or interoperability, a significant shortcoming of these State systems. In addition, NASPER information sharing requirements can accelerate the utility of PMPs, a concern noted in a recent GAO review. Finally, expanded PDMPs, coupled with ongoing physician education, can improve the identification and treatment of individuals who need substance abuse treatment interventions. With alarming rates of prescription drug abuse and mortality, these systems can help physicians screen, identify, treat, or refers those who need early treatment.

6) Do you need congressional authorization to extend the Recovery Auditing Contractor program to Medicare Part D?

Answer: When the Recovery Audit Contractor (RAC) program was first created, it focused on FFS Medicare claims. With the enactment of the Patient Protection and Affordable Care Act of 2010, CMS now has the statutory authority to expand the RAC program to Medicare Parts C and D.

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Senator Claire McCaskill

1) Why do we keep sponsors that don't follow guidelines? HHS OIG found few plans with compliance plans in 2007 (23 of 91 sponsors didn't have plans) and in 2008 the GAO found that there was still less than 100% compliance, yet CMS still lets these sponsors take part in the Part D program. Is there a penalty for not following the rules and if not, why not?

   Answer: All Part D sponsors are required to demonstrate during the application approval process that they have a compliance plan that meets the requirements contained at 42 CFR 422.503(b)(4)(vi) or 42 CFR 423.504(b)(4)(vi), including the requirement to have a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse. CMS has the authority to deny applications for entities that cannot make such a demonstration. Once the entity is approved for a contract, in order to be in substantial compliance with our requirements, entities must implement an effective compliance program that meets CMS' regulatory requirements.

   CMS takes these requirements seriously and monitors ongoing compliance with our requirements. If CMS learns that plan sponsors are not complying with program rules, depending on the nature and extent of non-compliance with our requirements, CMS may take a lower level compliance action, an enforcement action (such as suspension of marketing or enrollment or a civil money penalty) or terminate the entity's contract. CMS has a number of mechanisms beyond its routine account management and monitoring activities to ensure that sponsors continue to meet these requirements. These focused oversight activities include:

   - Compliance plan effectiveness audits;
   - Strengthened compliance plan regulations;
   - Focused account management outreach to sponsors;
   - Issuance of guidance reiterating requirements to plan sponsors.

2) CMS recommends that sponsors refer fraud and abuse incidents to MEDICs and MEDICs are asked to report fraud to CMS. This seems like a lot of parties involved. What is the reason that CMS is contracting this work out and not performing it internally? Are there any issues with performing this work internally? Was there a cost-benefit analysis performed? If so, please provide.

   Answer: CMS chose to use contractors to conduct certain MA and Part D program integrity oversight activities, such as audits, evaluations, and investigations as MEDICs are professionals who have education and training in complex data analysis, auditing, and backgrounds in state and federal law enforcement making them well-suited to the task of detecting and investigating potential fraud, waste, and abuse.

   In addition, resources provided under the Medicare Integrity Program (MIP), a primary funding stream for Medicare program integrity activities, have been required by statute to be spent on contractors since the program's inception. CMS was statutorily barred from using these funds to hire and train federal FTEs. Provisions in the health reform legislation

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address this problem by providing new flexibility for CMS to use MIP funding to hire and train federal FTE's, in addition to similar flexibility already available for MIP discretionary funding.

3) An OIG report from October 2009 indicated that plan sponsors are not required to report all fraud and abuse incidents to MEDICs that are referred to law enforcement. There is also indication from a 2008 OIG report that 24 of 86 plan sponsors did not have any potential fraud and abuse incidents, and of the 62 plan sponsors that did, not all of them conducted follow-up inquiries, initiated corrective actions, or made referrals for further investigation. If MEDICs are contracted to perform the audits and investigations for Part D, they need to have access to this information to better connect the dots, determine patterns, identify areas of interest, etc. CMS stated that they do not have the regulatory basis to require that plan sponsors report these incidents, but OIG disagreed and stated CMS has the ability to provide such reports. What can Congress do to make sure MEDICs have access to this information?

   Answer: The Administration is committed to a comprehensive program integrity strategy that gives our contractors the tools they need to proactively identify provider/plan misconduct, recover inappropriate payments, and ultimately reduce fraud and abuse in federal health care programs. CMS currently has tools in place that hold plans accountable for their conduct and highlight areas for improvement and additional investigation by CMS, including regular monitoring of plan performance, rigorous compliance plan requirements and audit protocols. While receiving reports of fraud after it occurs is one strategy, CMS would not want to rely solely on such a strategy and is increasingly shifting our attention to approaches that maximize the use of resources by identifying potentially problematic plans and targeting them for comprehensive audits. We have recently revised our compliance plan audit protocols to improve our ability to identify plans that need closer scrutiny. We are improving communication channels between CMS, law enforcement agencies, and plans that will enable us to put the systems in place to stop fraud before it occurs.

4) During your testimony you indicated that you felt that CMS did not have enforcement authority to require sponsors to report fraud. Could you elaborate on why you feel that you don't have enforcement authority? In contract law one party often cedes right to another such as audit authority, etc. Do the conditions of participation that sponsors agree to in order to participate in Part D include fraud reporting clauses and enforcement provisions for failure to report? If not, why not?

   Answer: Under current law, plans should report known instances where a pharmacy or provider is acting fraudulently. With regard to mandatory self-reporting, CMS has proposed rulemaking for this concept in the past, but CMS has decided not proceed with this requirement since there are currently no similar requirements in the Medicare FFS or Medicaid programs.

5) During your testimony the concept of "intelligent assignment" was raised regarding the assignment of dual eligible beneficiaries to Part D plans. Does CMS have any plans in place

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to work toward intelligent assignment? What hurdles to implementing exist and how much money could be saved by intelligent assignment?

Answer: In the fall of each year, CMS' current practice is to reassign Medicare beneficiaries with limited income and resources to another prescription drug plan to ensure they will not have to pay a monthly premium the following calendar year. Every affected beneficiary is mailed a letter notifying him or her of the new plan and giving them opportunity to either remain with their current plan or choose a new plan. In general, CMS aims to reduce the number of reassignments of beneficiaries for the purposes of minimizing disruptions in services provided. Although the Congressional Budget Office has previously scored intelligent assignment provisions with cost savings, research to date has not been sufficient to justify this type of policy shift. Therefore, additional analysis is required to better understand the pros and cons of implementing such a policy given the potential impact on beneficiaries.

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Senator John McCain

1) Medicare Part D is subject to significant risk of fraud, waste and abuse because of its size, complexity, and short implementation time. How does CMS allocate resources to ensure that risk is appropriately addressed?

   Answer: The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 created the Medicare Parts C and D benefits; however, additional funding to conduct fraud and abuse efforts was not provided in the authorizing legislation. In fiscal year (FY) 2006, CMS received one-time funding for Part C and D oversight in the Deficit Reduction Act. At that time, CMS began requesting discretionary Health Care Fraud and Abuse Control (HCFAC) funding in our annual budget request including funding within that account for Part C and D oversight. Because Congress did not provide funding in FY 2007 or FY 2008 for these oversight activities, CMS was forced to use a limited amount of our available mandatory Medicare Integrity Program funding, which has been frozen since FY 2003 (with the exception of the one-time DRA funding), to undertake a minimal level of Part C and D oversight. This lack of resources for Part C and D oversight was partially responsible for the problems identified by GAO and OIG in their reports on the program.

   Starting in FY 2009 Congress approved HCFAC discretionary funding for Part C and D oversight activities. The FY 2010 CMS HCFAC operating plan includes a stable funding stream to conduct Part C and D oversight activities. CMS believes we now have sufficient resources to undertake a robust Part C and D oversight program.

2) CMS awarded contracts to several MEDICS to support audit, oversight and antifraud and abuse efforts. What performance metrics has CMS put in place to ensure that MEDICs are exercising the appropriate oversight over Part D sponsors?

   Answer: CMS oversees the MEDICs performance through ongoing monitoring and annual contractor performance evaluations, in accordance with the requirements of the Federal Acquisition Regulations (FAR). On a monthly basis the MEDIC reports a number of statistics to CMS. These routine reports include, but are not limited to, the following measures: the number of requests for information from law enforcement agencies, the timeliness of response to law enforcement, the number of referrals made to law enforcement, and the number of complaints received from beneficiaries and others. Now that we have stable funding for the MEDICs, we are considering incorporating additional performance measures.

   Annually, during the contract performance period, each MEDIC undergoes an evaluation that covers the following elements: quality of services and deliverables, timeliness of performance and deliverables, business relations, and cost control. The MEDIC's scores and supporting comments by the Agency on each of these elements are recorded in the National Institute of Health Contractor Performance System. In the event of Agency concerns about contractor performance between annual evaluations, CMS may perform (informal) program evaluations more frequently than the above-mentioned annual evaluation.

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3) According to an October 2009 HHS Inspector General's report, MEDICs were not given access to Part D data until August 2007, nearly a year after their contracts began. Additionally, Part B data, which is vital to effectively identifying and investigating instances of potential Part D fraud and abuse, was not granted until fall of 2008. Why were there one to two year delays in providing necessary data to the MEDICs? How has this issue been addressed?

   Answer: CMS acknowledges that there was a delay in providing the MEDICs access to Part D data. Since both Part B and D data are used by law enforcement, as well as for MEDIC proactive data analysis, CMS needed to resolve the data integrity issues associated with the Part D data submissions. This included a review of the Part B data that would be matched with the Part D data submissions. However, the MEDICs now have access to Part A and B claims data back to January 1, 2006 and PDE records date back to January 1, 2006 through the IDR.

4) In 2008, CMS launched the Zone Program Integrity Contractor (ZPIC) initiative to consolidate the work provided by Medicare FFS benefit integrity contractors, and allocate it based on zones.
   a. How successful has this initiative been in protecting Medicare's program integrity?

      Answer: CMS foresaw the need to change its contracting strategy for uncovering fraud, waste and abuse in the FFS benefit. The new ZPIC contracting strategy permits each contractor to conduct its benefit integrity responsibilities across all claim types (Medicare Parts A and B, durable medical equipment, home health and hospice) and across its geographic zone, as opposed to a piecemeal review of specific claim types which is the way the jurisdictions were previously organized. Using the zone strategy, the ZPICs can identify common ownership across lines of business and can identify migrating patterns of fraud from one benefit type to another. The daily downloads of shared systems claim data has identified cases of identity theft within days of the provider's or the beneficiary's number being compromised, so CMS can take prompt action. In addition, the efforts of the ZPICs have enabled CMS to initiate specific anti-fraud initiatives in geographically high risk areas of the country; one such example is the Fraud Hotline in South Florida. The ZPIC in this area established a special fraud hotline in 2007 to protect Medicare beneficiaries in South Florida from fraudulent providers of infusion therapy. Once the fraudulent infusion therapy providers were identified, the ZPIC was able to make links to other fraudulent lines of business for these providers. As a result of the hotline's early success, CMS has now expanded the scope of this infusion therapy fraud hotline to handle all Medicare fraud-related calls in South Florida. The fraud hotline number is now included on monthly Medicare Summary Notices sent to all beneficiaries in Miami-Dade, Broward and Palm Beach counties. Since the inception of the Fraud Hotline, more than 450 cases have been investigated.

      Feedback from the Healthcare Fraud Prevention and Enforcement Action Team taskforce and other law enforcements partners has been favorable to the new strategy

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as it ensures a more coordinated approach to fraud detection and limits the points of contact for law enforcement when conducting investigations and receiving data.

b. It seems that almost all Part D claims are tied to either doctor visits or hospital visits, as that is the primary means to get a valid prescription. Why was Part D oversight excluded from ZPIC?

Answer: Part D oversight is included in the ZPIC statement of work. However, at this time, the Agency is still in the procurement process for the ZPIC program.

c. Do you plan to include Part D oversight into ZPICs for zones in which contracts have not yet been awarded?

Answer: CMS is still gaining experience with the Part D program. The Part D program is structured so CMS contracts with Part D plans who under S 423.505(i) of 42 CFR, retain ultimate responsibility for adhering to all terms and conditions of our contracts, rather than downstream entities, such as contracted physicians or hospitals. The targets of fraud may be the same but the entity CMS holds accountable is not. While the ZPIC SOW includes an option for Part D oversight, CMS is still developing the strategies to effectively oversee the Part D program. As a result, Part D oversight may be part of the overall ZPIC strategy in the future.

5) Last November CMS underwent a realignment of work dispersed between the MEDICs. Each MEDIC is now responsible for specific functions or duties, as opposed to oversight for a specific region. This seems to contradict the ZPIC approach of a regional dispersion.

a. Is the ZPIC approach so unsuccessful that CMS shifted MEDICs to a functional alignment? Why were the MEDICs realigned?

Answer: The ZPIC strategy has been successful. However, the FFS program and the Parts C and D program are inherently different, and as a result, they require different oversight. One of the key differences is that with the Part C and Part D programs, Medicare is not the insurer. Instead, Medicare has contracted with MA organizations and Part D sponsors to provide services to Medicare beneficiaries. The geographic (regional) approach has worked well in the Medicare FFS program where the majority of the work is region-specific and locally-focused. However, Part C and D sponsors, unlike FFS providers and suppliers, typically operate nationally, and the majority of Part C and Part D sponsors conduct business and manage operations in areas all across the country that subvert any geographic boundaries. Based on these significant differences in the programs, we have instituted different oversight strategies.

With the previous MEDIC approach, one of three MEDICs was assigned to monitor all potential fraud and noncompliance activities within a given geographic region. CMS thus realized that the prior alignment of the MEDICs was an ineffective means of ensuring proper compliance and oversight. The new MEDIC strategy, employing two MEDICs on a national level, corrects this inefficiency and is a more efficient approach considering the unique structure of the Part C and D programs.

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The MEDIC program uses elements of both the PSC and the ZPIC strategies and has evolved over time. As referenced earlier, the first MEDIC task order was awarded in 2005 to Health Integrity to investigate enrollment and eligibility issues associated with allegations of fraudulent and abusive marketing activity during the initial Part D enrollment period. This contractor looked at these issues nationwide. Subsequently, CMS awarded task orders to two additional MEDICs to establish the regional MEDIC oversight. Each MEDIC was responsible for Part D compliance and identification and prevention of fraud waste and abuse in the Part D program in their respective jurisdictions. In 2009, CMS modified the MEDIC program to functionally address different vulnerabilities that were emerging in the Part C and D programs. As a result, the current oversight strategy allows one MEDIC to solely focus on potential fraud in the Parts C and D programs, while the other MEDIC is focused on developing national policies for compliance program oversight. One example of this is the effort underway to provide compliance guidance on CMS' requirement that Part D plans provide fraud, waste and abuse training to all Part C and D downstream entities.

b. Why is CMS employing two different strategies for Medicare program integrity contractors?

Answer: CMS uses contracting strategies that are tailored to the different types of providers in the program, the different operational structures in FFS Medicare and Parts C and D, and the different types of potential fraud or vulnerabilities that develop in the programs.

c. Doesn't employing two different strategies increase the complexity of oversight CMS has over Medicare program integrity contractors?

Answer: CMS maintains separate and dedicated teams to oversee the ZPICs (and outgoing PSCs) in the Medicare FFS program and the MEDICs in the Medicare Parts C and D programs. This ensures that appropriate staff and resources are dedicated to the oversight of each program and all contractors. It also allows the parallel ZPIC and MEDIC oversight teams the flexibility to accommodate the unique needs of each program. As outlined above, the Medicare Parts C and D programs operate on a national level and, thus, a regional approach to Parts C and D program integrity efforts is not the most efficient way to monitor these parts of the Medicare program. The MEDIC realignment also streamlines oversight of the MEDIC contractors by simplifying workload assignment and reporting, as each MEDIC is now responsible for one national functional body of work.

The MEDIC and ZPIC oversight teams within CMS have a specialized understanding of the context under which each program (ZPIC versus MEDIC) operates. Where there are opportunities for cross-program anti-fraud efforts, CMS ensures collaboration among ZPICs and MEDICs.

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6) In mid to late 2008, CMS did not renew SAIC's contract as a MEDIC, citing performance issues.
   a. What criteria was used in determine SAIC's capabilities to perform when it was originally awarded a contract in FY 2007?

      Answer: The evaluation criteria used for the West MEDIC (awarded to SAIC) was defined in the Request for Proposals. Specifically, the proposals were evaluated in the following areas: strategy for managing complaints and fraud case development, Part D audit, the knowledge and experience of key personnel, quality assurance of their work, public relations and outreach activities, physical and information technology security, past performance, and any subcontracting arrangements.

   b. Where did SAIC fail to perform?

      Answer: In 2007, CMS conducted a midyear performance evaluation of SAIC. However, according to FAR 42.1503(b), any information regarding a contractor's performance evaluation may only be released to other Government personnel and the contractor being evaluated. We would be happy to meet with the Committee to discuss this situation more.

   c. How did SAIC's ethics issues from other government contracts impact the decision to award a contract originally in FY 2007 and during consideration of its renewal the following year?

      Answer: The nonrenewal of SAIC's contract was not the result of performance issues. Rather, in 2008, CMS learned that SAIC was found liable for violating the False Claims Act for work performed under contract with the Nuclear Regulatory Commission. CMS believed that it was improper to have a contractor that was found liable of False Claims Act violations performing integrity oversight activities in the Medicare program. Therefore, CMS decided not to renew SAIC's MEDIC contract.

   d. What impact did SAIC's failure to perform proactive data analysis have on its performance evaluation?

      Answer: This was not a major issue in their performance evaluation.

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QUESTIONS FOR THE RECORD
U.S. SENATOR TOM CARPER
Hearing on "Oversight Challenges in the Medicare Prescription Drug Program"
March 3, 2010

Question for Mr. Apple

I understand that both of the MEDICs companies perform program integrity work for Medicare in addition to your Medicare Drug Integrity Contractor work. So you both have a fairly broad understanding of the anti-waste, fraud and abuse work for the Medicare – not just the prescription drug program, but the fee for service and Medicare Advantage.

- Are there steps that Medicare or Congress could take to increase your effectiveness?
- Are there steps that the Medicare program could take to increase your access to quality data, and increase your effectiveness?

Response

SGS firmly considers the Zone Program Integrity Contractor (ZPIC) strategy as the optimal solution to combating Medicare Program Integrity. Although relatively new, under our ZPIC Contract for Zone 7 (Florida, Puerto Rico, and the U.S. Virgin Islands), we have experienced the success that comes from a familiarity with geographic schemes and demographics; providing law enforcement with "one-stop shopping" for supporting data; and providing consistency in investigative products.

While SGS no longer conducts fraud and abuse investigations, our experience indicates that the lack of Part C encounter data prevents an investigator or data analyst from gaining a complete picture of the beneficiary's medical history. Currently, the Medicare Advantage Organizations (MAOs) maintain data related to their members but there is no central repository for all Part C encounter data to compare things, such as office visits and diagnoses that support the Part D prescription drug events. MAOs should be required to provide encounter data to CMS for use by the responsible MEDIC for conducting proactive data analysis to assist in uncovering fraud and abuse schemes. Expanding the data elements CMS may collect from MAOs for Part D prescription drug events should also improve the proactive detection of fraud and abuse schemes. SGS also recommends that CMS capture all iterations of Part C and D submissions to include denied and adjusted submissions as these often provide indicators of fraudsters "testing" the system to determine vulnerabilities to get claims paid.

Additionally, legislative authority to permit the sharing of all program data with those agencies charged with the responsibility of investigating program fraud and abuse will facilitate the pooling of investigative resources to successfully root out, attack and prevent fraud and abuse in all programs. This would further allow agencies to identify common subjects or perpetrators across all federal and state health insurance programs.

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QUESTIONS FOR RECORD
U.S. SENATOR JOHN MCCAIN
Hearing on "Oversight Challenges in the Medicare Prescription Drug Program"
March 3, 2010

For Mr. Howard Apple:

Question

1) The HHS Inspector General found that in FY 2008, 87% of potential fraud and abuse incidents were identified by MEDICs through external sources – primarily complaints. The remaining 13% of potential fraud and abuse incidents were identified through proactive methods, such as data analysis. Of the actual investigations conducted by MEDICs, 96% of them were identified through external sources.
   a. What data analysis are you conducting that identifies Part D fraud and abuse? On what basis do you launch an investigation? Why is there such a high percentage of investigations that were initiated from external sources?
   b. Is there additional information or data that would enhance your data analysis that you do not receive?
   c. What are the barriers to you getting that information?

Response

1.a In October 2009, CMS assigned the responsibilities for initiating and conducting all Part D fraud and abuse investigations to the Benefit Integrity MEDIC, Health Integrity, LLC. SGS is now responsible for conducting Compliance Plan audits of Part C and Part D parent organizations to ensure they have effective Compliance Plans in place and to handle agent/broker and marketing misrepresentation issues, such as the violation of CMS' marketing guidelines.

Prior to October 2009, SGS had developed a detailed data analysis plan to ensure data analysis projects are effectively and efficiently identified, prioritized, and deliver useful outcomes for further fraud case development. Examples of SGS' proactive projects included:

- Seven Day Supply: SGS reviewed pharmacies with the highest earnings of prescriptions under a 7-day supply. This project resulted from a lead identified from a law enforcement request for proposal (RFI) that a pharmacist had received monthly prescriptions but dispensed the medication in 7-day supplies in order to increase his dispensing fees. SGS focused on 10 pharmacies with over $5M in prescriptions under a 7-day supply.
- Zip Code Project: The Zip Code project targets areas with high volume of medications dispensed. This project started in 2008 and yielded results until we ceased work on fraud, waste, and abuse activities. The project was initiated as a result of excessive

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Medicare expenditures within specific areas of New York City and expanded into Chicago, California, and Michigan.

- Compounded Drugs: When billing for a compounded medication, the pharmacy needs to bill the higher cost National Drug Code regardless of the amount. This project compared the billed cost of compounded drugs to the individual medications. Additionally, compounded medications are not to include more than 20 percent of Schedule II drugs without the pharmacy obtaining additional credentials. This category of drugs was targeted specifically in the review of compounded drugs.
- Beers List: The Beers List (or Beers Criteria) applied to drugs that are generally considered inappropriate when given to elderly people. For a wide variety of individual reasons, the medications listed tended to cause side effects in the elderly due to the physiologic changes of aging. The SGS data team coordinated with SGS pharmacy technicians to identify the top 12 drugs by name for review.
- Fraudulent Drug Enforcement Administration (DEA) Registration Number Usage: This project was opened when Data Analysts observed a frequent use of DEA numbers that looked suspicious in conducting analysis in other unrelated projects. SGS focused on DEA numbers that did not pass the DEA logarithm test and evaluated those that have the greatest impact to the Medicare Trust Fund, such as the top 5 suspect DEA numbers.

Although SGS is no longer tasked with investigating Part C and D fraud and abuse of the , historically our investigations originated from either an allegation of fraud from an external source, or from proactively mining the data for aberrant patterns of behavior. SGS launched investigations into all allegations of potential fraud received from external sources. Proactive investigations were launched on the basis of either a known aberrant pattern of behavior or upon the identification of potential vulnerabilities in the program benefits, the submission process, or the limitations of the prescription drug event data.

The high percentage of investigations that were initiated from external sources were the results of three factors. First, the MEDICs did not have access to Part D data until August 2007. In August, 2007, the MEDICs received limited access to the data. Only two data analysts from each MEDIC had direct access to only a limited number of Prescription Drug Event (PDE) fields within the data. Additionally, we did not have access to Part A and Part B data until November 2008 which would have been used to complement or supplement Part D data for a more effective analysis. Second, SGS had developed outstanding working relationships with law enforcement agencies within our jurisdiction. These relationships resulted in receiving over 100 requests from law enforcement for PDE data to support their ongoing investigations which consumed a major portion of the data analysts' time in 2008. The third factor was the sheer volume of external complaints received by SGS. In 2008, SGS alone handled over 2,200 telephone calls via the 877-7SafeRx hotline, which resulted in initiating over 1,300 complaints and investigations from reactive sources. Many of these complaints and investigations required the use of data to confirm or refute the allegations.

1.b-c. While SGS no longer conducts fraud and abuse investigations, our experience indicates that the lack of Part C encounter data prevents an investigator or data analyst from gaining a

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complete picture of the beneficiary's medical history. Currently, the Medicare Advantage Organizations (MAOs) maintain data related to their members, but there is no central repository for all Part C encounter data to compare things, such as office visits and diagnoses that support the Part D prescription drug events. MAOs should be required to provide encounter data to CMS for use by the responsible MEDIC for conducting proactive data analysis to assist in uncovering fraud and abuse schemes. Expanding the data elements CMS may collect from MAOs for Part D prescription drug events should also improve the proactive detection of fraud and abuse schemes. SGS also recommends that CMS capture all iterations of Part C and D submissions to include denied and adjusted submissions as these often provide indicators of fraudsters "testing" the system to determine vulnerabilities to get claims paid.

Question

2) How has the lack of authority to directly obtain information from pharmacies, pharmacy benefit managers, and physicians hindered your ability to investigate potential fraud and abuse?

Response

While SGS no longer investigates fraud and abuse, having to go through the Part D parent organizations for data, caused delays in the investigations, and could compromise and denigrate any investigation involving suspected fraud and abuse activity by the parent organization that provides the data. In addition, situations may arise when a Part D parent organization may have no contractual relationship with the provider who wrote a given prescription, which presents a challenge in obtaining information from a physician.

Question

3) What improvements in program integrity have you seen in the Part D program since you were awarded a contract in FY 2007?

Response

The receipt of access to Part D prescription drug event data in August 2007 and the permission to access Part A and Part B data in the fall of 2008 were the most effective improvements. These enhancements significantly improved our ability to respond to requests for information from law enforcement, support reactive complaints and investigations, and initiate proactive investigations based on known or suspected fraud and abuse schemes.

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Question

4) In November 2009, CMS realigned how work was dispersed between the two remaining MEDICS. Previously, they were assigned cover a geographical area, but now they are assigned specific functions to cover (i.e., audit vs. investigation) for the entire country. This realignment is contrary to the Zone Program Integrity Contractor (ZPIC) approach that shifted from a functional strategy to a regional strategy, yet both MEDICs and ZPIC look to strengthen Medicare program integrity.
    a. How effective do you think this strategy is to shift MEDICs' work from a regional to a functional one? What impact does this realignment have on your company in terms of ensuring you have enough employees with the right skill sets and relocating employees to cover parts of the country you didn't cover before the realignment?

Response

4a. SGS considers the ZPIC strategy as the optimal solution to strengthening Medicare Program Integrity. Under our Program Safeguard Contracts, we have experienced the success that comes with a familiarity of geographic schemes and demographics; providing law enforcement with "one-stop shopping" for supporting data, and providing consistency in investigative products. While it is too early to determine the effectiveness, we believe the November 2009 realignment has advantages and disadvantages. The advantages include breeding familiarity with the contractor among partners and stakeholders and providing a consistency in the approach in investigating compliance, fraud, or abuse issues.

However, the disadvantages include the difficulty it presents CMS when it attempts to compare best practices among contractors for determining the most effective approach. SGS also feels that the lack of competition towards a common goal could create the potential risk of complacency in a contractor's work activities. Additionally, the use of one contractor for the entire nation creates a risk to the program if it became necessary to remove the sole contractor due to a conflict of interest or if it failed to provide adequate service to the program. Lastly, rapid changes to the functions can lead to loss of employees and delays in hiring staff qualified to meet the new scope of work.

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Post-Hearing Questions for the Record
Submitted to Howard Apple and Dr. Christian Jensen
From Senator Claire McCaskill

"Oversight Challenges In The Medicare Prescription Drug Program"
March 3, 2010

Question

1. MEDICs are using complex programs and data mining to catch fraud that would otherwise go undetected. However, the statistics for the number of potential and investigated cases of fraud in 2008 were from old-fashioned complaints, not from computer programs. Even without many cases detected with these computer programs, MEDICs only investigated about a third of the potential cases in 2008. a. Can you explain why so few of the potential fraud cases make it to an investigation stage (1,320 investigated out of 4,194 potential cases in 2008)? b. Are you limited in the number of cases you can follow? c. More importantly are the leads detected by these programs somehow better than outside complaints?

Response

1.a. The MEDIC program was still relatively new to Medicare beneficiaries in 2008. Many beneficiaries still had difficulty understanding the difference between a customer service issue and a fraud or abuse issue. Therefore, many calls the MEDICs received via the 877-7SafeRx hotline were customer service-related. Some examples included issues such as, "I did not receive my card" or "my Viagra should be covered." The MEDICs were not tasked with resolving customer service issues, and therefore, these types of complaints did not result in initiating an investigation. The MEDICs worked with CMS to educate beneficiaries through 1-800- Medicare and various beneficiary advocacy groups, which decreased non-fraud related calls received from beneficiaries, and, as the program matured, generated a higher percentage of calls that resulted in the initiation of an investigation.

1.b. Adequate manpower would be the only barrier to the number of cases the MEDICs could work and complete. While SGS had adequate manpower to work the cases, additional manpower would always enable SGS to even quicker.

1.c. Although a pattern of reactive complaints may indicate a widespread problem, proactive investigations, based on an aberrant pattern of behavior determined using prescription drug event data, is more indicative of a pervasive problem that could have a greater impact on the program.

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Question

2. During your testimony, you stated it was too difficult to quantifiably determine how much money MEDICs are saving the American taxpayers through Part D fraud audits and investigations. By what metrics other than just the number of complaints you handle can we best track your measurements of performance and measurements of effectiveness?

Response

SGS believes the current process used by CMS to evaluate the quality of a contractor's work product or service. the ability to control the cost of the contract, the timeliness of the contractor's performance and the quality of their business relations are the ideal means to measure performance and effectiveness.

Question

3. The role of MEDICs has changed in the rather brief life of Part D. First we had only one MEDIC during the startup period, then we went to three MEDICs with full responsibility each in their own distinctive region of the U.S., and now we have two with nationwide purview, but with each MEDIC being responsible for only one aspect of fraud and abuse detection. a. Have we found the right model? b. Does having responsibility for only one aspect of oversight make it easier to do your job or easier to pass the buck in terms of responsibility?

Response

SGS considers the Zone Program Integrity Contractor strategy as the optimal solution to strengthening Medicare Program Integrity. Under our Program Safeguard Contracts, we have experienced the success that comes with a familiarity of geographic schemes and demographics; providing law enforcement with "one-stop shopping" for supporting data, and providing consistency in investigative products. While it is too early to determine the effectiveness, we believe the November 2009 realignment has advantages and disadvantages. The advantages include breeding familiarity with the contractor among partners and stakeholders and providing a consistency in the approach in investigating compliance, fraud, or abuse issues. However, the disadvantages include the difficulty it presents CMS when it attempts to compare best practices among contractors for determining the most effective approach. SGS also feels that the lack of competition towards a common goal could create the potential risk of complacency in a contractor's work activities. Additionally, the use of one contractor for the entire nation creates a risk to the program if it became necessary to remove the sole contractor due to a conflict of interest or if it failed to provide adequate service to the program. Lastly, rapid changes to the functions can lead to loss of employees and delays in hiring staff qualified to meet the new scope of work.

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Question

4. During your testimony, you mentioned that requiring sponsors to submit fraud information to MEDICs and allowing MEDICs to directly obtain information from pharmacies, pharmacy benefit managers, and physicians would enhance MEDIC's ability to investigate potential fraud and abuse incidents. What else can we do to make sure the audit and investigation teams have access to the information they need to perform effective audits?

Response

While SGS no longer conducts fraud and abuse investigations, our experience indicates that the lack of Part C encounter data prevents an investigator or data analyst from gaining a complete picture of the beneficiary's medical history. Currently, the Medicare Advantage Organizations (MAOs) maintain data related to their members but there is no central repository for all Part C encounter data to compare things, such as office visits and diagnoses that support the Part D prescription drug events. MAOs should be required to provide encounter data to CMS for use by the responsible MEDIC for conducting proactive data analysis to assist in uncovering fraud and abuse schemes. Expanding the data elements CMS may collect from MAOs for Part D prescription drug events should also improve the proactive detection of fraud and abuse schemes. SGS also recommends that CMS capture all iterations of Part C and D submissions to include denied and adjusted submissions as these often provide indicators of fraudsters "testing" the system to determine vulnerabilities to get claims paid.

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Responses of Christian Jensen, M.D., to
Questions for the Record from

U.S. SENATOR CLAIRE McCASKILL

Regarding the Hearing on
"Oversight Challenges in the Medicare Prescription Drug Program"

April 23, 2010

Question 1: *MEDICs are using complex programs and data mining to catch fraud that would otherwise go undetected. However, the statistics for the number of potential and investigated cases of fraud in 2008 were from old-fashioned complaints, not from computer programs. Even without many cases detected with these computer programs, MEDICs only investigated about a third of the potential cases in 2008.*

Can you explain why so few of the potential fraud cases make it to an investigation stage (1,320 investigated out of 4,194 potential cases in 2008)? Are you limited in the number of cases you can follow? More importantly are the leads detected by these programs somehow better than outside complaints?

Dr. Jensen's Response:

The MEDIC Statement of Work defines complaints, investigations, and cases as the following:

> *"A complaint is a statement, oral or written, alleging that a provider, Part D Plan, RDS, MA Plan, beneficiary, etc., received a Medicare benefit of monetary value, directly or indirectly, overtly or covertly, in cash or in kind, to which he or she is not entitled under current Medicare law, regulations, or policy. An investigation is the analysis performed on both proactive and reactive leads (e.g., complaints, data analysis, newspaper articles, etc.) in an effort to substantiate the lead or allegation as a case. However, not all investigations will result in cases. A case exists when the MEDIC has referred a fraud allegation to law enforcement..."*

Complaints may be received from many external sources: beneficiaries, providers, pharmacies, law enforcement, plans, and other affiliated contractors. All complaints are reviewed and assigned a complaint category such as "Potential Over-Prescribing Provider", "Drug-Seeking Beneficiary", etc. Not every complaint that was received in 2008 was related to potential fraud, waste, and abuse and not every complaint rises to the level of an investigation. Complaints that do not rise to the level of an investigation are worked by a team of Nurse Investigators, a Complaint Specialist, or are closed.

An example of a complaint that would be worked by a Nurse Investigator would be a beneficiary that reports a medication on their Explanation-of-Benefits (EOB) that they did not receive. The

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Nurse Investigators work with plan sponsors to obtain a resolution. There are some instances after the EOB has been reviewed when it is determined that there is no evidence of potential fraud, waste, or abuse. It may have been the result of a misunderstanding (e.g., the beneficiary did not recognize the name of the medication listed on the EOB because it was generic instead of brand), or the beneficiary misunderstood a formulary listing change.

Although there were 4,194 complaints reported in 2008 and 1,320 were elevated to investigations, the remaining complaints were either worked by Nurse Investigators, a Complaints Specialist, or were closed.

The MEDICs also receive a number of complaints that are considered "inappropriate complaints." Examples of such complaints include beneficiaries that contact the MEDIC regarding the status of a claim, and/or beneficiaries that desire to be enrolled into a different plan. These beneficiaries are referred to other agencies such as 1-800-Medicare or the Centers for Medicare & Medicaid Services' (CMS) Regional Office for assistance.

The MEDICs are not limited in the number of investigations we pursue. If a complaint rises to the level of an investigation, the investigation is prioritized using a priority scoring system and assigned to an investigator. An example of a complaint that would rise to the level of an investigation would be a beneficiary that forged a physician's signature on a prescription or a pharmacy that was billing for services not rendered. The investigators utilize a variety of methods to conduct their investigations. Some of those methods include reviewing Prescription Drug Event (PDE) data and review of proactive analysis.

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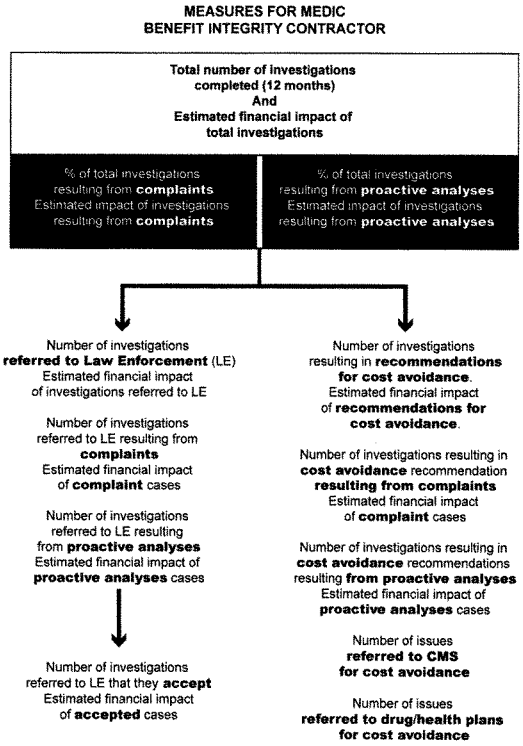
HEALTH integrity LLC

Question 2: *During your testimony, you stated it was too difficult to quantifiably determine how much money MEDICs are saving the American taxpayers through Part D fraud audits and investigations. By what metrics other than just the number of complaints you handle can we best track your measurements of performance and measurements of effectiveness?*

Dr. Jensen's Response:

The flowchart below provides an overview of the metrics Health Integrity considers critical for tracking the performance and effectiveness of the Medicare Part D Benefit Integrity Contract.



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Question 3: *The role of MEDICs has changed in the rather brief life of Part D. First we had only one MEDIC during the startup period, then we went to three MEDICs with full responsibility each in their own distinctive region of the U.S., and now we have two with nationwide purview, but with each MEDIC being responsible for only one aspect of fraud and abuse detection. Have we found the right model? Does having responsibility for only one aspect of oversight make it easier to do your job or easier to pass the buck in terms of responsibility?*

Dr. Jensen's Response:

Health Integrity believes opportunities still exist to improve the model. Working with plan sponsors in both compliance and fraud issues may be more effective because sometimes overlapping issues and gray areas exist in determining potential fraud.

For example, agents and brokers may be signing up beneficiaries inappropriately for Part C and Part D. In some cases this is a compliance education issue, but if the agents are falsifying documents, it becomes a fraud issue. Pricing of services is another area deserving coordination between compliance and benefit integrity functions. Trends should be examined to differentiate between billing mistakes and a broader issue of inappropriate pricing. Multiple compliance issues may be a flag for potential fraud and should be investigated.

A better model may be the Zone Program Integrity model that is organized by geographic regions and looks across all payer types to identify and pursue fraud investigations. Health Integrity currently is responsible for Zone 4 (Texas, Oklahoma, Colorado, and New Mexico) and has been fully operational since February 2009. Combining the ZPIC and the MEDIC functions would enhance the effectiveness of both programs, because having one contractor to data mine all Medicare claims would provide a faster and more robust approach to identifying the connections and fraud patterns across provider types.

This ZPIC regional approach provides a much higher return on investment than past approaches that were "siloed" by separate provider types. There are often Durable Medical Equipment (DME) supplier and provider connections as well as DME supplier and DME pharmacy connections that are currently not being investigated in the same manner because of the current division of workload between the ZPICs and MEDICs.

If the benefit integrity MEDIC functions were to be rolled into the ZPIC contracts it would be imperative to form a national panel with representation from each ZPIC MEDIC Task that would work together on national plan issues. The Plans for Part C and D are national and regional so if there are issues with a national plan this would cross Zones and communications between the ZPICs would need to be open and ongoing. Additionally, if the ZPIC approach was decided upon it would be necessary that the ZPIC employees were trained in Part C and Part D extensively because these payer types are very different from the traditional fee-for-service Medicare payer types.

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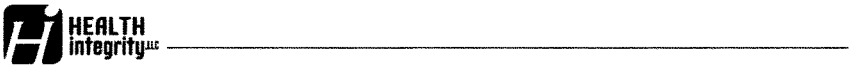

Question 4: *During your testimony, you mentioned that requiring sponsors to submit fraud information to MEDICs and allowing MEDICs to directly obtain information from pharmacies, pharmacy benefit managers, and physicians would enhance MEDIC's ability to investigate potential fraud and abuse incidents. What else can we do to make sure the audit and investigation teams have access to the information they need to perform effective audits?*

Dr. Jensen's Response:

Obviously, access to more information regarding potential fraud issues would enhance our ability to perform our duties and achieve our mission. Since the Office of Inspector General's (OIG) evaluation of the MEDIC program, our access to data has been greatly enhanced, allowing us to do more than we were able to do before. Having said that, however, if it were possible for us to have real-time access to PDE data, we could do more to stop fraudulent payments in some circumstances.

For example, a recent referral to OIG by the National Benefit Integrity (NBI) MEDIC based on real-time data obtained from a Part D plan resulted in identifying a fraud scheme amounting to nearly $1 million. Because of the quick identification of the fraud scheme, none of the fraudulent claims were paid and no loss to the Government occurred.

Within days of the referral, OIG was able to arrest the subjects of the investigation. It is our belief that direct access to real-time Part D PDE information would enhance our ability to increase our successes in this area.

This ability would help reduce the amount of Program dollars lost to those defrauding the system.

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Responses of Christian Jensen, M.D., to
Questions for the Record from

U.S. SENATOR TOM CARPER

Regarding the Hearing on
"Oversight Challenges in the Medicare Prescription Drug Program"

April 23, 2010

Question 1a: *I understand that both of the MEDICs companies perform program integrity work for Medicare in addition to your Medicare Drug Integrity Contractor work. So you both have a fairly broad understanding of the anti-waste, fraud and abuse work for the Medicare – not just the prescription drug program, but the fee for service and Medicare Advantage.*

a. Are there steps that Medicare or Congress could take to increase your effectiveness?

Dr. Jensen's Response:

The Centers for Medicare & Medicaid Services (CMS) and Health Integrity are committed to the success of program but have been hindered due to lack of statutory and regulatory authority. Health Integrity suggests the following changes to grant the necessary authority for MEDICs to gain direct access to pertinent records needed to effectively perform audits of first-tier, downstream, and related entities. The regulations require that sponsors and downstream entities reach an agreement on the method of document production for CMS or its designees but do not address direct access to these entities.

Under the Part D regulations at 42 CFR 423.505(i)(2)(i), Part D sponsors agree to require all first-tier, downstream, and related entities to agree that: the Department of Health and Human Services (HHS), the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, including medical records and documentation of the first-tier, downstream, and related entities involving transactions related to CMS's contract with the Part D sponsor.

CMS and its designees can reach pharmacies and other first-tier, downstream, and related entities only through CMS's contractual relationship with Plan D sponsors. This does not provide sufficient access to all potentially relevant materials or ensure that pharmacies engaged in potentially fraudulent behavior have not edited or concealed documents prior to providing them to a plan sponsor. We believe that a revision to the Social Security Act to allow the Secretary and her designees to audit first-tier, downstream, and related entities, in addition to Prescription Drug Plan (PDP) sponsors, would strengthen these fraud and abuse efforts.

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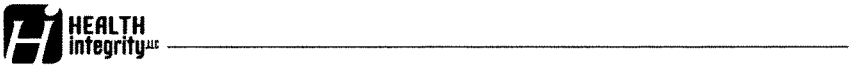

Health Integrity also suggests changes be made to the Part D Data Rule 73 Federal Register 30,664, which is based upon § 1860D-12 of the Social Security Act. The current regulation requires entities outside of HHS to work through Research Data Assistance Center (ResDAC) to obtain Part D Prescription Drug Event (PDE) Record data.

We suggest that the Data Rule be expanded to permit the direct release of Part D PDE Record data from the MEDIC to any federal or state integrity contractors under circumstances in which the addition of such data would bolster their case. This would likely require changes to §1860D-12 of the Social Security Act and 73 Federal Register 30,664 to expand the conditions under which the data could be released.

Question 1b: *I understand that both of the MEDICs companies perform program integrity work for Medicare in addition to your Medicare Drug Integrity Contractor work. So you both have a fairly broad understanding of the anti-waste, fraud and abuse work for the Medicare – not just the prescription drug program, but the fee for service and Medicare Advantage.*

b. Are there steps that the Medicare program could take to increase your access to quality data, and increase your effectiveness?

Dr. Jensen's Response:

Health Integrity suggests two changes that would enhance our ability to combat fraud, waste, and abuse in the Medicare Parts C and D programs.

1. CMS does not currently collect Part C data from plan sponsors. This lack of aggregated data severely limits the ability of CMS and its contractors to fight fraud, waste, and abuse within the program through proactive data analysis and support of law enforcement requests for data.

   Health Integrity suggests that CMS build and maintain a Part C claims data warehouse to bolster program integrity efforts within that program. This aggregated data would support analysis needed to identify trends and outliers within the Part C program.

2. Efforts to combat fraud, waste, and abuse could further be bolstered with access to real-time Part D data. This is currently submitted by plan sponsors on a regular basis but we often find that the submission of data lags at least one month (and sometimes several months) from the date of service.

   Developing a warehouse containing real-time Part D data would allow swifter identification of patterns of fraud, which would dramatically increase the ability to implement pre-pay edits against these patterns and decrease the program's vulnerability to fraud.

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In addition to the suggestions above, we recommend enhancing the Office of Inspector General (OIG) Exclusion Database to bolster program integrity efforts. The Exclusion Database does not currently capture the National Provider Identifier (NPI), or any unique identifier, associated with the providers contained in the database. We understand they may be working on this enhancement. We would recommend expediting this project.

As with all federal programs, there is an inherent risk that excluded providers will continue to attempt to evaluate and treat beneficiaries enrolled in those programs. This lack of a unique identifier prevents the identification of excluded providers who are the cause of claims in a program from which they have been excluded.

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Responses of Christian Jensen, M.D., to
Questions for the Record from

U.S. SENATOR JOHN McCAIN

Regarding the Hearing on
"Oversight Challenges in the Medicare Prescription Drug Program"

April 23, 2010

Question 1: *In your written statement, you include as 2009 accomplishments for Health Integrity, 267 investigations as a result of proactive measures. What do you mean by "proactive" measures? Does this include data analysis or other activities? What proactive activity has yielded the most results for you?*

Dr. Jensen's Response:

Health Integrity employs various methods to proactively identify subjects that may be engaging in fraudulent activities. These methods include proactive data analysis, review of news articles, and Internet searches.

Of the proactive methods applied, proactive data analysis has yielded the largest number of targets for investigation. This type of analysis supports the application of statistical methodologies used to identify outliers in the data. One recent example includes identifying pharmacies that were filling prescriptions for beneficiaries living long distances from the pharmacy. Another recent example was our pharmacy claims volumes analysis that used pattern recognition algorithms to analyze abnormal pharmacy prescription volume distributions.

Both of these studies have provided many new targets for investigation. As the program matures the data provides a richer source of information that can be used to identify targets for investigation.

Question 2: *Plan sponsors are not required to refer potential fraud and abuse, so MEDICs may not be aware of all incidents. What measures within your authority are you taking to get the most comprehensive report of potential fraud and abuse? Have you or can you be proactive in seeking the information from plan sponsors?*

Dr. Jensen's Response:

Since its inception, Health Integrity has developed and maintained strong working relationships with plan sponsors to encourage the reporting of potential fraud, waste, and abuse.

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Health Integrity conducts quarterly Parts C and D workgroups with plan sponsors to identify current trends in emerging fraud schemes and to discuss proactive edits that plans can put in place to prevent fraudulent billing. Our investigative and data analysis team conduct presentations at national conferences such as the National Health Care Anti-Fraud Association in an effort to encourage plan sponsors to report potential fraudulent issues.

The Health Plan Management System (HPMS) is a system the Centers for Medicare & Medicaid Services (CMS) uses to communicate with plan sponsors. Health Integrity has developed and submitted HPMS alerts regarding fraudulent schemes such as infusion therapy and pharmacies billing for services not rendered. These alerts encourage plan sponsors to evaluate their internal systems for potential fraudulent claims and to notify the MEDICs if they identify possible exposure in their system.

All of these methods have proven effective as Health Integrity has seen an increase in the number of plan sponsors that "self-report" potentially fraudulent incidents. The referrals that we have received from plan sponsors went up from 90 in 2007 to 396 in 2009 and we have already had 244 in the first two months of 2010.

Question 3: *What additional tools do you believe are necessary for MEDICS – and CMS – to effectively implement and monitor an anti-fraud and abuse program for Part D?*

Dr. Jensen's Response:

While we believe that we are doing a very good job on our anti-fraud/waste/abuse (FWA) efforts in the Part D arena with the tools currently available to us, we recognize that any program can be improved. Towards that end, we believe that we could enhance our capabilities by increasing our efforts in the area of outreach and communications both to the general public and the Part D plans.

One tool we currently employ that can be expanded upon is the Part D working group sessions that we have organized. By working to bring the Part D plans together regularly, we have increased the amount of communication among the attendees regarding common fraud schemes and problem areas. As the National Benefit Integrity (NBI) MEDIC, we have a vast amount of experience in the area of FWA. As such, we would be able to provide training in these areas to the various Part D plans around the country. The ability to work more closely with these plans sharing information and providing edits to help identify fraudulent patterns could only help to combat the problem.

Another tool that would increase our effectiveness is access to real-time data. While we have access to Part D data, there is a time lag in what information we can obtain. A recent referral to the Office of Inspector General (OIG) by the NBI MEDIC based on real-time data obtained from a Part D plan resulted in the identification of a fraud scheme amounting to nearly $1 million. Within days of the referral, OIG was able to arrest the subject of the investigation. Upon the subject's arrest and interview he confessed and provided information leading to two additional arrests.

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It is our belief that direct access to real-time Part D Prescription Drug Event (PDE) information would enhance our ability to increase our successes in this area.

Question 4a: *In November 2009, CMS realigned how work was dispersed between the two remaining MEDICS. Previously, they were assigned cover a geographical area, but now they are assigned specific functions to cover (i.e., audit vs. investigation) for the entire country. This realignment is contrary to the Zone Program Integrity Contractor (ZPIC) approach that shifted from a functional strategy to a regional strategy, yet both MEDICs and ZPIC look to strengthen Medicare program integrity.*

a. How effective do you think this strategy is to shift MEDICs' work from a regional to a functional one?

Dr. Jensen's Response:

There are pros and cons to the approach of shifting from a regional MEDIC to a functional MEDIC.

On the positive side, the Health Integrity team is very strong in benefit integrity matters and has strong working relationships with law enforcement and plans across the country due to our initial work as the national Enrollment and Eligibility MEDIC in 2006. The functional approach allows the MEDIC to concentrate on just Part C and D benefit integrity efforts. On the other hand, Health Integrity is a successful Zone Program Integrity ZPIC for Zone 4 (Texas, Colorado, Oklahoma, and New Mexico) and has been fully operational since February 2009. We have seen that the zone-based approach enhances the identification and investigation of potential fraud across Medicare Parts A, B, Durable Medical Equipment (DME), Home Health, and Hospice.

This new Zone approach, which is organized by regional geography and looks across all payer types, effectively and efficiently identifies and pursues fraud investigations. There are connections and fraud patterns across provider entities and having all of the claim types available in one region provides a faster and more robust way to pursue fraud. Examples where efficiencies would be gained if the MEDICs were combined with the ZPICs include investigations of DME suppliers with DME pharmacies; Part B and Part D duplicate billing investigations and provider referrals; investigations of billing Part D while a beneficiary is in a Part A institutional stay; and investigations involving overlap of Part C and other types of service (i.e., duplicate billing).

This ZPIC regional approach provides a much higher return on investment than past approaches that were "siloed". If the benefit integrity MEDIC functions were to be rolled into the ZPIC contracts it would be imperative to form a national panel with representations from each ZPIC MEDIC Task that would work together on national plan issues. The plans for Part C and D are national and regional so issues with a national plan would cross Zones, therefore,

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communications between the ZPICs would need to be open and ongoing. This same type of coordination currently occurs with ZPICs in issues related to national DME companies.

Question 4b: *In November 2009, CMS realigned how work was dispersed between the two remaining MEDICS. Previously, they were assigned cover a geographical area, but now they are assigned specific functions to cover (i.e., audit vs. investigation) for the entire country. This realignment is contrary to the Zone Program Integrity Contractor (ZPIC) approach that shifted from a functional strategy to a regional strategy, yet both MEDICs and ZPIC look to strengthen Medicare program integrity.*

b. What impact does this realignment have on your company in terms of ensuring you have enough employees with the right skill sets and relocating employees to cover parts of the country you didn't cover before the realignment?

Dr. Jensen's Response:

Our company has 15 offices located throughout the country. We have successfully ramped up for this NBI effort by opening offices in Plymouth Meeting, Pennsylvania, Boston, Massachusetts, and McAllen, Texas and by hiring home-based investigators in the Northern and Western states (New Jersey, Illinois, Michigan, Washington, and California).

Health Integrity has a successful track record of hiring former OIG and FBI agents who are familiar with fraud investigations. Additionally, we have re-organized our management structure and hired a new Program Director, formerly a Special Agent in Charge of the OIG, and appointed three Deputy Directors. Additional nurses and data analysts with the necessary skills have been hired as well and all new positions are currently filled (except for three positions that will be filled in the next month). We have also recently added additional employees that have extensive Part C backgrounds.

In all, a total of 40 additional employees and subcontractor employees were hired in the last six months for this NBI effort. Orientation and training sessions have been conducted for all staff types and the contract is fully operational.

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