S. Hrg. 112–455

# COSTS OF PRESCRIPTION DRUG ABUSE IN THE MEDICARE PART D 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

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

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TUESDAY, OCTOBER 4, 2011



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APPENDIX

# COSTS OF PRESCRIPTION DRUG ABUSE IN THE MEDICARE PART D PROGRAM

**TUESDAY, OCTOBER 4, 2011**

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 10:33 a.m., in Room SD–342, Dirksen Senate Office Building, Hon. Thomas R. Carper, Chairman of the Subcommittee, presiding.

Present: Senators Carper and Brown.

## OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. The Subcommittee will come to order—although this is not a disorderly gathering here this morning. It is good to see all of you. Thanks to our witnesses for joining us. Thanks to our Ranking Republican for joining us. Good morning.

Over the past several years, we have been engaged here in Washington and across the country in a conversation about our Nation's deficit and debt and the cost of Federal programs. The conversation has been serious and at times heated. Unfortunately, we have yet to reach a consensus on a plan to extract the country from the serious financial challenges that we face, but there is one thing, however, that I think we can all agree upon, and that is, we must stop the fiscal bleeding caused by waste, by fraud, and by abuse.

This is a small Subcommittee, but for years we have been almost singularly focused on how the Federal Government can get better results for less money or better results for the same amount of money. Whether the Chairman is Tom Carper or Tom Coburn, this has been our singular focus and continues to be.

Working together with partners such as the Government Accountability Office (GAO), the Office of Management and Budget (OMB), Inspectors General (IG) , and other Government watchdog groups, we have tried to maximize our oversight, and I believe that we have begun to make a real impact. We have drilled down on how the Federal Government wastes millions annually maintaining properties and buildings we neither want nor need. We have examined the billions that agencies waste, $125 billion, in avoidable improper payments made to contractors, to ineligible programs, to participants, and even to dead people. We have focused like a laser

on Federal information technology projects that have gone billions of dollars over budget without ever delivering any real benefit.

One issue we spent a lot of time taking a look at recently is the enormous amount of fraud and waste and abuse perpetrated within Medicare and Medicaid. These programs provide life-saving benefits, as we know, to millions of our Nation's most vulnerable citizens. Unfortunately, too often criminals have figured out how to use Medicare and Medicaid for their own gain.

Roughly 2 years ago, we held a hearing dealing with fraud and abuse in the Medicaid program in this room. At that hearing we learned that GAO had found tens of thousands of Medicaid beneficiaries and providers involved in fraudulent or abusive purchases of controlled substances through the program. After that hearing, we asked the Government Accountability Office to see whether or not something similar might be going on with the Medicare Part D prescription program. I was disappointed but not surprised to learn that GAO has found evidence that a number of Part D beneficiaries are likely abusing the system to obtain powerful drugs to fuel their own addictions or to sell them on the street.

As part of their analysis, GAO auditors looked at all of the prescriptions paid for by Part D in 2008. Combing through over 1 billion prescription records, they found that over 170,000 Part D beneficiaries apparently engaged that year in a practice commonly known as "doctor shopping." These beneficiaries have gone to five or more doctors to obtain prescriptions for the same drug.

In one case, GAO found a beneficiary who received prescriptions from 87 different medical practitioners in that one year, 2008. In another case, a beneficiary received 3 years' worth of oxycodone pills from 58 different prescribing doctors in just one year.

We need to be honest about what these findings mean. They mean that Federal dollars intended to address the health needs of the elderly and the poor are instead being used to feed addictions or to pad the wallets of drug dealers. This is clearly unacceptable.

According to GAO, the controls that the Centers for Medicare and Medicaid Services (CMS) has put into place to stop this sort of abuse have not done the trick. Under the plan CMS has put in place to combat doctor shopping, if a Part D plan sponsor suspects a beneficiary is doctor shopping, they send a letter to the doctors who have been visited. The letter is sent along with a self-addressed envelope in which the doctors can send a response to the sponsor's concerns. In some cases, the doctors will stop giving the doctor-shopping patients prescriptions. In other cases, they will not. Sometimes the letters go unanswered.

GAO has made several recommendations to CMS on how to tighten up controls of the program. Included among these recommendations is a suggestion that beneficiaries be limited to one doctor and one pharmacy, an approach that many States use in their Medicaid programs. I look forward to hearing more about this suggestion from our witnesses today.

In addition, I understand that just last week, perhaps as a result of GAO's work, CMS has issued new guidance to Part D plan sponsors. This guidance suggests that plans begin denying beneficiaries at the point of sale if they suspect abuse. This is an important change, and, again, I want to hear more about that today as well.

I have worked with Senator Tom Coburn, with Senator Brown, and with others on this panel to work on bipartisan legislation that curbs waste and fraud in both Medicaid and in Medicare. Our legislation, S. 1251, contains a set of important steps that will help rein in those trying to defraud our Federal health care programs. Our legislation has provisions that directly affect fraud in Medicare Part D, including strengthening the prescription drug monitoring programs (PDMP) and requiring closer coordination between CMS, their oversight contractors, Drug Enforcement Agency (DEA)—and State and local law enforcement. Our proposal also requires that the list of doctors who can prescribe controlled substances like painkillers be maintained up to date and accurate.

As many of you know, 12 of our colleagues are currently serving on a bipartisan, bicameral Joint Committee that has been tasked by the rest of us with coming up with a plan to begin to put our fiscal house in order. If at some point that Committee and Congress as a whole are to come to agreement on a meaningful plan for addressing our country's fiscal challenges, we will need to address issues like the ones we are talking about here today.

As I close this opening statement, I want to comment on prescription drug abuse. The dangers associated with the misuse of prescription drugs have become known in the past few years as celebrities and other public figures have succumbed to their lethal effects. However, less widely publicized are the millions of Americans, including children, who abuse the same drugs. Unfortunately, children are abusing prescription drugs at an alarming rate. One out of seven teenagers reportedly has abused or is abusing prescription drugs today. This is a drug problem that could impact any American home with a medicine cabinet.

As a father, I find this news especially troubling, and I want to make this point so that it is clear. While there is a financial cost to the fraud and abuse of controlled substances paid for by Medicare—and we are mindful of that—we cannot ignore the fact that there is a human cost as well. Prescription drug abuse is the fastest-growing addiction in the United States. The difference between a street drug like cocaine and a prescription painkiller is that in many cases, as this hearing and this Subcommittee's previous work show, the Federal Government is often paying to feed this addiction with taxpayer money.

Aside from our financial imperative, then, we have a moral imperative to ensure that our public health care system is not used or misused to further intensive and subsidize a public health crisis.

Before I turn it over to Senator Brown, I do not have the full list of the illegal drugs whose cost, if you add up their street sales, actually are still less than the value of the prescription drugs, the controlled substances that are being shopped and sold. But it includes cocaine, heroin, and others combined. So think about it. When we think about how big is this problem, add up heroin and cocaine sales and a number of other illegal drugs, and add them all up and the total is less than is involved in the sale of these controlled substances. It is a big problem. It is a problem that we are beginning to address. We are going to learn a lot more today about how we can further address it.

With that having been said, Senator Brown, you are on. Thanks.

## OPENING STATEMENT OF SENATOR BROWN

Senator BROWN. Good to see you, Mr. Chairman. Again, thank you, and thank you for holding this hearing. This is something, Mr. Chairman, I am not sure if you are aware of, that I was working on a task force back in Massachusetts on these types of abuses, especially just the rampant drug problem amongst our youth and others with these types of substances. We really did not get into the fraud part of it, but we certainly got into the issue itself, and Maine Senator Steve Tolman and I and others tried to tackle this very real problem. And I know that we are trying also to address these difficult decisions, and we are trying to put our Nation on a path of fiscal stability.

Folks, you all know what is going on. We are in a financial emergency and we are trying to find a way to do it better. It has been an honor to be on this Subcommittee and try to tackle a lot of these very real issues and try to find a way to do it better. And I do support, have very strong support for the Medicare prescription drug programs. They are important programs, we all know, that provide essential benefits to our seniors. That is why now more than ever, we must protect these programs because they are looking to be changed, and if we can weed out a lot of this fraud and abuse, we will have more money in the system, obviously, to give back to the people that need it the most.

This Subcommittee is releasing a GAO report that I think was asked to be done by Senator Carper which exposes the outrageous practice, that taxpayer dollars are potentially funding, through the Medicare Part D program, illicit prescription drug dealing. The findings in the GAO report highlight this problem.

As the Senator noted—I cannot remember if he said this, but one Medicare recipient, as you know, visited 58 different doctors to obtain 3,655 oxycodone pills equivalent to a 1,679 day supply. These prescriptions equate to a street value of almost $300,000. And many of these highly addictive prescription narcotics will find their way onto the streets, hurting communities, kids, families, and the doctor shopping is the primary way that these abusers get around the lawful use of these medications.

Only a very small percentage of Medicare Part D beneficiaries, approximately 1.8 percent, are engaging in this type of behavior. Though the percentage is small, we are still talking about approximately 170,000 people abusing the system according to the GAO, which costs the taxpayer approximately $148 million annually. That is real money, folks, and what I have tried to do since I have been here is to keep an open mind and try to find ways, without throwing bombs at all—you know, like where is the breakdown? And the key that we need to try to find out is where is the breakdown. Where can we try to fix it?

This not only wastes taxpayer dollars by paying for huge amounts of unneeded prescription drugs and unneeded doctor's visits, but it also take a very high human toll, and we all know what that involves. This prescription drug abuse is one of the Nation's fastest-growing drug problem and is now categorized by the Centers for Disease Control (CDC) as an epidemic. We must do everything we can do to create stronger oversight of these controlled substances.

In fact, in some cases our entitlement programs, which were established to benefit our country's most vulnerable, are instead being used to fuel addiction and abuse, and it is really, with all due respect, Mr. Chairman, unconscionable what is happening.

We have held several important hearings. Some I think have been really just fascinating, the things that I have learned through your leadership. I commend the Chairman for holding them, but this one, I do not think there are any that are more important than this one, quite frankly.

So I am looking forward to beginning with the hearing, and, Mr. Chairman, I appreciate you bringing it up. Thank you.

Senator CARPER. You bet, and thank you for your statement and for joining us today, Senator Brown.

Senator BROWN. I have not missed one yet, Mr. Chairman.

Senator CARPER. I know. You have a perfect attendance record here with me.

I asked my staff, I said, let me have the sentence from our briefing memo about just how big a problem the abuse of prescription drugs is, and here is just a sentence from our briefing memo. It was not in my statement. I wish it had been, but it says: "It is estimated that 7 million Americans abuse prescription drugs every year. That is more than the number who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants combined." Combined.

We welcome our witnesses. How many of you have testified before this Subcommittee before? All right. Well, thanks for continuing to come back, and we appreciate that.

Our first witness today, Greg Kutz, is Director of GAO's Forensic Audits and Special Investigations Unit. Mr. Kutz has spent over 20 years at GAO working to uncover abuse of government credit cards, abuse in the response to Hurricanes Katrina and Rita, problems with the U.S. border security, among many other issues. He has testified before this Subcommittee many times before, and I thank him for agreeing to be with us here today.

I hope you do not start charging us on a per visit basis. We have a very large deficit. But, seriously, we are grateful for your help.

Our next witness is Mr. Jonathan Blum, Deputy Administrator and Director at the Centers for Medicare & Medicaid Services. Mr. Blum is responsible for overseeing the Medicare prescription drug program and formerly worked as an adviser to one of our good friends and colleagues, Senator Max Baucus, on the Finance Committee staff. Thanks.

Our final witness is Louis Saccoccio, who is Executive Director of the National Health Care Anti-Fraud Association (NHCAA). Mr. Saccoccio and his group work to increase awareness and improve the detection and prevention of health care fraud. I also understand that Mr. Saccoccio is a former Navy JAG lawyer and a graduate of the U.S. Naval Academy, and I am told he served for 8 years, including a tour as a legal officer on the carrier the USS Kitty Hawk. Is that correct? Good for you. Bravo Zulu. I am an old Navy guy, I have a JAG guy here next to me, so we are in good company, I think. Thank you for that service and thanks for being here today.

Folks, the drill. I would ask that you take about 5 minutes for your statement. If you go a little bit over that, that is OK. If you go way over that, that is not OK, so we will rein you back in.

Mr. Kutz, why don't you lead us off? Thank you.

**TESTIMONY OF GREGORY D. KUTZ,[1] DIRECTOR, FORENSIC AUDITS AND INVESTIGATIVE SERVICE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE**

Mr. KUTZ. Mr. Chairman and Ranking Member Brown, thank you for the opportunity to discuss Medicare Part D. In 2009, I testified before this Subcommittee on doctor shopping in Medicaid. Today's testimony highlights the results of our investigation into doctor shopping in Medicare Part D. My testimony has two parts: first, I will discuss our findings; and, second, I will discuss our recommendations.

First, we found indications of doctor shopping for 14 classes of frequently abused prescription drugs, including Vicodin, Ritalin, and OxyContin as examples. Specifically, 170,000 beneficiaries acquired the same class of prescription drug from five or more prescribers during 2008. This represents about 1.8 percent of the beneficiaries acquiring these classes of drugs, and they showed indications, as I mentioned, of doctor shopping. The cost of these drugs was about $148 million, which excluded the cost of office visits. We referred 48 of the most egregious of these cases to the Medicare Drug Integrity Contractor (MDIC) for further investigation.

Our report documents the facts related to 10 individuals that were doctor shopping. Many of these individuals had prior criminal histories. This was not a random sample, and the results from these 10 cases cannot be projected to all 170,000 cases.

Examples that you both mentioned from our work for these 10 cases include:

A California man received a 1,758-day supply of fentanyl patches, which is a narcotic painkiller, from 21 different prescribers.

A Georgia woman received a 1,679-day supply of oxycodone, also a narcotic painkiller, and other drugs from 58 different prescribers and 45 different pharmacies.

And a Maryland woman received a 1,450-day supply of oxycodone from 11 different prescribers.

The graphic in your package, which I have in my hand here—it looks like this—illustrates an actual case from our investigation. As you can see, between September 8 and September 19, this individual received three 30-day supplies of the painkiller hydrocodone. These prescriptions were obtained from three different prescribers and filled at three different pharmacies. In cases like this, the prescribers told us that they were unaware that their patients were receiving the same prescription drugs from other prescribers.

Our recommendations to address doctor shopping are consistent with those used in the Medicaid program, as you mentioned, Mr. Chairman, and also in the private sector. First, we recommend that CMS consider the use of a restricted recipient program. This program would limit known system abusers to one prescriber, one pharmacy, or both. Since abusers generally face no criminal con-

[1] The prepared statement of Mr. Kutz appears in the appendix on page 39.

sequences and will not be removed from Part D, this lock-in program provides a valid mechanism to protect taxpayer interests.

Second, if a restricted recipient program is implemented, CMS should consider enhancing the sharing of information on these doctor shoppers between the drug plans. This is necessary to prevent abusers from circumventing controls by simply switching drug plans.

Third, and finally, because of CMS concerns about its legal authority to make these changes, we recommend that CMS consider seeking congressional authority as necessary to implement the recommendations.

In conclusion, as you both mentioned, Medicare dollars are being used to finance prescription drug abuse in our Nation. GAO is hopeful that Congress and CMS will use this report to improve the integrity and the safety of the Medicare Part D program.

Mr. Chairman and Ranking Member Brown, that ends my statement, and I look forward to your questions.

Senator CARPER. Thanks very much for that statement. Thanks very much for the work that backs it up. Mr. Blum.

**TESTIMONY OF JONATHAN BLUM,[1] DEPUTY ADMINISTRATOR AND DIRECTOR, CENTERS FOR MEDICARE & MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. BLUM. Chairman Carper, Ranking Member Brown, I would like to thank you and the Subcommittee for your focus to ensure that the Medicare Part D program is as strong as possible.

Today, the Medicare Part D program provides outpatient prescription drug benefits to more than 29 million Medicare beneficiaries. There are more than 3,400 Part D plans that provide drug benefits to Medicare beneficiaries, and Medicare beneficiaries may choose from a multitude of plans to deliver their benefits. The majority receives benefits in stand-alone Part D drug plans—that is, private plans that only provide outpatient drug benefits.

By many measures, the Part D program has been a great success. Overall, costs have risen more slowly than the original Congressional Budget Office (CBO) and the Office of the Actuary (OACT) projections, and a majority of beneficiaries report being satisfied with its benefits. But we know that the benefit is not perfect.

While the program is stronger today than ever before, we know there are vulnerabilities which must be addressed. I want to thank the GAO for its work highlighting the potential of fraud and abuse in the program specifically related to controlled substances. We have reviewed carefully the GAO's report and its recommendations, and we agree with the GAO that the misuse of controlled substances is a growing problem in the Medicare Part D program.

It is difficult to quantify the extent of the problem, but we agree the program can do more to curb potential fraud and abuse. At a time of scarce resources and significant budget deficits, we must ensure that every Federal dollar is spent as wisely as possible.

[1] The prepared statement of Mr. Blum appears in the appendix on page 51.

Since the Part D program is relatively new, to date our focus at CMS has been to ensure that Medicare beneficiaries receive the drugs they are entitled to. The Medicare Part D program pays private Part D plans a capitated payment and works to make sure that the Part D plans provide drugs consistent with the program's requirements.

Our compliance efforts in recent years have been focused on the underutilization of drugs. We have placed significant audit and oversight resources to ensure that beneficiaries receive the drugs they need at the point of sale. We have placed significant sanctions on Part D plans that have failed to deliver benefits consistent with the law and our regulations.

But the Part D program has reached a new state of maturity so that we now need to shift our oversight focus. We cannot just focus on the underutilization of Part D drugs. We must shift our focus on the overutilization of Part D drugs. To this end, we have recently taken the following steps:

First, last week CMS put out new guidance to plans to ensure they are putting into place more comprehensive drug utilization review programs to ensure they are screening for misuse of controlled substances and other drugs. If clinical reviews reveal misuse, we will expect our Part D plans to stop payment and report the fraud to law enforcement.

Yesterday, CMS proposed new proposed rules for the Part C and Part D programs that would ensure that the prescriber ID number is put on all Part D drug claims. This will ensure that we can produce more sophisticated data analyses and spot those prescribers that present vulnerabilities to the Part D program.

CMS also shares concerns over the high use of antipsychotic medications given to beneficiaries in nursing homes. There is evidence that the financial relationships between long-term-care pharmacies and drug manufacturers can lead to this overutilization. Our proposed rules put out last night suggest possible steps CMS could take to address this overprescribing.

CMS is also using data much more proactively. Again, our data analyses and data mining to date have been primarily focused on plans that may discourage the appropriate prescribing, denying our beneficiaries needed drugs. Our data analysis will also include proactively focusing on drug overutilization. The GAO report suggests that CMS should consider a program whereby it restricts prescribing of controlled substances to a single physician dispensed by a single pharmacy. CMS does not believe that such a measure, which has been employed by State Medicaid programs, would work well in the Part D program. Part D in its current form cannot restrict a beneficiary to a single physician or a single pharmacy. CMS believes that the responsibility to prevent Part D drugs rests with Part D sponsors.

We must also be very concerned that beneficiaries do not face undue restrictions to necessary medications. Beneficiaries seeing many doctors may have very complicated health care needs or may be victims to a dysfunctional health care delivery system. Any programs that are believed to curb overuse and misuse and overutilization must always involve strong clinical review and judgment to ensure that those in need do not go without or face arbitrary re-

strictions. CMS' response to this growing problem will continue to follow these principles.

Thank you for the opportunity to testify today, and I look forward to your questions.

Senator CARPER. And we look forward to your questions. Thanks very much for that testimony. We look forward to asking you some questions.

Mr. Saccoccio, please proceed.

## TESTIMONY OF LOUIS SACCOCCIO,[1] EXECUTIVE DIRECTOR, NATIONAL HEALTH CARE ANTI–FRAUD ASSOCIATION

Mr. SACCOCCIO. Thank you. Good morning, Chairman Carper, Ranking Member Brown.

The amount of health care dollars spend on prescription drugs in this country continues to grow. National health expenditure data reveal that in 2009 $250 billion was spent on prescription drugs, and that by the year 2020 that spending is projected to more than double, reaching more than $500 billion. NHCAA believes that the amount of health care dollars spent on prescription drugs continues—as that amount continues to grow, the problem of prescription drug diversion and fraud will also continue to grow as a segment of the total health care fraud problem.

While doctor shopping by patients is the primary focus of the GAO report released today, NHCAA believes it important to acknowledge that prescription drug fraud and diversion can take many forms. At its most complex, perpetrators of drug diversion undertake a multi-faceted criminal enterprise directed at reselling drugs in high volume and for large profit on the streets, with the cost of the drugs fraudulently billed to health insurers, both public and private.

Significantly, the money lost to prescription drug fraud through the payment of unnecessary or bogus pharmacy claims is only part of the financial impact of this problem. In the process of obtaining a prescription, a patient typically will generate claims for related medical services. Insurers often find that they have paid not just for unnecessary drugs but also for related emergency room visits, inpatient hospital stays, visits to physician offices and clinics, and diagnostic testing—all based on injuries, illnesses, and conditions feigned in order to obtain a prescription. Then there are the additional costs associated with treating the addictions and the overdoses arising from this behavior.

More importantly, the financial losses due to prescription drug fraud are compounded by instances of patient harm and sometimes death—insidious side effects of this fraud. The Office of National Drug Control Policy calls prescription drug abuse "the Nation's fastest-growing drug problem," and the Centers for Disease Control and Prevention classifies prescription drug abuse as an epidemic. Of course, prescription drug abuse in itself does not necessarily indicate fraud. Nevertheless, in many instances the drugs are obtained through fraud.

A cogent example of the human toll of this problem was all too clear in a recent case arising in Kansas. In October 2010, a Kansas

[1] The prepared statement of Mr. Saccoccio appears in the appendix on page 63.

physician and his wife, a licensed practical nurse who also acted as the office manager of her husband's pain management clinic, were sentenced to 30 and 33 years in Federal prison, respectively, for illegally distributing prescription pain medications to patients who overdosed. A 4-year investigation of this pill mill uncovered evidence of extensive overprescribing of controlled substances. More than 100 drug overdoses requiring visits to Wichita area emergency rooms and the deaths of at least 68 persons are linked to this case, as well as more than $4 million in Medicaid and private insurance claims. After an 8-week trial, the jury convicted the couple, finding that they directly contributed to the deaths of several patients. This case demonstrates that prescription drug fraud is a dangerous crime that can yield tragic results, including death.

Private insurers have acknowledged drug diversion and doctor shopping as a fraud trend for the last several years, and their antifraud efforts regularly identify dangerous prescription drug abuse by patients. In my written testimony, we provide examples of how two insurers, Humana and WellPoint, are using monitoring, letter notification to prescribers, and restricted recipient programs with success.

NHCAA also supports State prescription drug monitoring programs that help both to identify fraud and to ensure patient safety. NHCAA recommends that State investments in those monitoring programs be incentivized whenever possible. Also, NHCAA recommends taking full advantage of interoperability opportunities and information sharing among prescription drug monitoring programs for States sharing borders with one another.

For instance, in August 2011, Kentucky Governor Steve Beshear announced the formation of an interstate task force with border States Ohio, Tennessee, and West Virginia committed to targeting fraudulent or abusive prescription drug activities in those States.

NHCAA also is encouraged by the memorandum dated September 28th issued by CMS to Medicare Part D sponsors asking for their comments on how the Medicare Part D program can more successfully exert control over payment for inappropriate overutilization of drugs. In addition to responding to the ideas outlined in the memo, NHCAA suspects that many Part D sponsors will suggest that a restricted recipient program be considered to curb drug-seeking behavior due to drug abuse or diversion.

Thank you for the opportunity to testify this morning, and I look forward to any questions you may have.

Senator CARPER. Great. Thanks very much. That was great testimony, Mr. Saccoccio.

Let me start off by saying that one of the things that we focus most on in this Subcommittee is finding out results. We are not interested in process. We are interested in having the ability to actually measure results, and we focus on success and how do we measure success.

Senator Brown probably remembers me mentioning, not in this room but in the Finance Committee hearing room—a couple of months ago, we were having a hearing on deficit reduction. We had four or five really smart people there as our witnesses. One of them was Dr. Alan Blinder, who now teaches at Princeton. He used to be the Vice Chairman of the Federal Reserve when Alan Green-

span was Chairman. And he was before us to testify on deficit reduction, and he said in his testimony, he said, the 800-pound gorilla in the room in health care cost explosion—in deficit explosion is health care costs. And he said unless you do something about that, everything else is sort of window dressing.

And when it came around to my turn to ask questions, I said, Dr. Blinder, you talked about how health care costs is the 800-pound gorilla in the room with respect to the deficit and how it was imperative that we do something about that. And I said, "Do you have any advice for us today as to what we might do?" And he said, "I am not a health economist. I am not an expert in that stuff. Let me just say here is my advice: Find out what works, do more of that." That is all he said. "Find out what works, do more of that." And I said, "Well, is the corollary to that find out what does not work and do less of that?" And he said, "That would be true."

So in the spirit of finding out what works and do more of that, let us talk about what works, and I think, Mr. Saccoccio, you mentioned in your testimony about Humana and WellPoint, some of the steps that they are taking. We have the experiences in Medicaid where some States are saying one doc—if you are taking these controlled substances, use one doc, maybe one pharmacy, to try to control it. Talk to us about what is working and how we might take those ideas and incorporate them into whatever we might do in terms of legislation or a regulatory approach.

Mr. Kutz, would you lead us off?

Mr. KUTZ. Well, you mentioned restricted recipient. That has been successful in Medicaid. There are 30 to 40 States that have some variety of the one prescriber/one pharmacy or both or some different—some are two, actually. And that has been proven in those States to be successful in Medicaid.

Senator CARPER. Let me just interrupt for just a moment. Mr. Blum, in your testimony you said you did not think that the success that has been realized in Medicaid in addressing this problem would necessarily work in Medicare Part D. Just take a minute—and then I will come back to you, Mr. Kutz. Just take a minute and explain that.

Mr. BLUM. Sure. State Medicaid pharmacy benefits tend to work very differently than the Part D drug benefit. The State Medicaid program generally has one fee-for-service program where they can have a complete view of pharmacy benefits. The Part D program by statute works very differently than State Medicaid pharmacy benefits. We have 3,400 different Part D plans that provide the kind of day-to-day transactions of the pharmacy benefit. To our view, because of the wide diffusion to Part D benefits designed by statute, to our minds we have to have the Part D plans themselves provide the kind of review, the oversight to ensure that drugs are being dispensed consistent with the law.

Senator CARPER. OK. That is fine. Just stop right there.

Mr. Kutz, just briefly respond to what Mr. Blum has said on this point, if you would.

Mr. KUTZ. Well, we agree with Medicare that there needs to be a comprehensive fraud prevention plan in place, and their documents, their Chapter 7 and Chapter 9 of the regulations, state that. And to me that includes prevention, monitoring, and some

consequence at the end of the day for people that beat the system. So if you do not have a restricted recipient program in place, I see a hole in the comprehensiveness of their fraud prevention plan in that what are the deterrents to people actually doing this. Their belief is probably they are not going to get caught, and if they get caught, there are no consequences.

So I believe it is important that in any fraud prevention program—and I testify across Congress on these things—you have to have some consequences at the end of the day for people that might deter them.

Senator CARPER. All right. Thanks.

Go ahead. What else in terms of the spirit of what works?

Mr. KUTZ. One of the things we have seen in some of the States is the prescription drug monitoring plans have real-time data that doctors can actually access so that they could potentially know before they actually write the prescription that their patient is seeing other doctors or prescribers for the same thing. So if you think about the first step in the process, which is the writing of the prescription, you could perhaps prevent some of the prescriptions being written by having real-time data available for the prescribers to look at for their patients.

The next step is the point of sale at the pharmacy, and I know that CMS agrees with us on this, that it is very important to focus on information the pharmacist has before the drug is dispensed to see doctor-shopping activity. The issue really is, when they are getting alerts at the pharmacy, what are they doing with it? Are they actually using it to deny someone or is someone walking out with the drugs? Even though there was an indicator set, it is called a "soft edit," which can be overridden.

Senator CARPER. Called what? "Soft edit"?

Mr. KUTZ. "Soft edits," where basically they get an alert, but they do not have to do anything with it, and someone can walk out the door. So to me that is important.

I will just quickly mention a third thing, which is monitoring. Once you have—and, again, CMS promotes this—data mining and data matching, similar things we have done here but much more comprehensive is to me another important element of a comprehensive fraud prevention plan.

Senator CARPER. All right. Good. Mr. Blum.

Mr. BLUM. I totally agree with everything that Mr. Kutz said. We need to make sure that we are providing very strong guidance to our Part D plans to take a more complete and holistic picture of a beneficiary and that they are given the pain medication they need. I think to date we have systems that are set up that are much more transactional in nature at the point of sale, that there are edits in place, and we need to look—or to encourage the Part D plans to take a more complete picture so they can figure out whether or not beneficiaries are being prescribed medications that exceed good sound clinical judgment.

I think it is important to point out that a beneficiary who is seeing many physicians could have very legitimate needs. They also could be going to the ER. They could also be going to a clinic setting and just being bounced around the health care system, through no fault of their own. So to our minds, any system in place

that will stop doctor shopping and stop abuse needs to be based upon sound clinical judgment to make sure that we are stopping the bad behavior but also preventing harm to beneficiaries who have very legitimate needs who are being bounced around the health care system through no fault of their own.

Senator CARPER. All right. Mr. Saccoccio, go ahead. What is working? What is working out there?

Mr. SACCOCCIO. Well, I think it is a combination of several things. No single thing works by itself.

First, you need to analyze data. You need to take a look at what is happening out there. CMS in the fee-for-service Medicare area is moving towards predictive modeling. You need to be able to do that so you could figure out what is going on. Then you need to take some action. Now, the action should include notification to the physicians that are prescribing the drugs, also notification to the patients themselves, and then looking to those patients to see if they do have a problem, maybe trying to get them into programs that address the problem.

But I think the other big piece of it is a restricted recipient program, a lock-in program, where under certain circumstances, allowing for utilization for certain types of conditions that may need a lot of pain medication, that you lock those folks in. And that does not mean they do not have access to those drugs. For example, in the Humana example that we give, Humana may lock them into a pharmacy that has multiple locations, so it is not just, hey, you have to go to this one pharmacy down the street. You could go to different locations, but you are locked into that one pharmacy. So I think that should seriously be considered.

Given the right circumstances with the right patients that, hey, we are not making any dent in this, otherwise, we need to take that additional step.

Senator CARPER. All right. Good. Thanks very much. Senator Brown.

Senator BROWN. Thank you, Mr. Chairman.

Mr. Kutz, in your report you cite a case, amongst others, where in 2008 alone a beneficiary received 5,923 oxycodone pills after going to 11 different doctors. That is a 1,450-day supply in one year. I know as your report indicates that the beneficiary stated to his or her doctor that the pattern of abuse was a case of mistaken identity. But that, in fact, was not the case, and it is doubtful that the person could consume that amount of narcotics in that time frame. So what was really going on here?

Mr. KUTZ. Well, we did not interview all of these people, the reason being 8 of the 10 had prior criminal histories, and our criminal investigators do not carry weapons. So we do not go interview people that could potentially be dangerous. But certainly drug abuse is going on and potentially drug dealing is going on in that case.

Senator BROWN. Well, I agree because I hear the word "diversion," and diversion is drug dealing. It is clear what is happening. The person is shopping around, getting the drugs, and selling them, and taking advantage of basically a tax-free public benefit program and receiving government-funded health care. And as you can see from our chart,[1] Case 1, the street value is almost

$500,000. In Case 2, it is almost $300,000. Obviously, there is a breakdown.

I do not know about you, Mr. Chairman, but I have kids, and I remember those ear infections. You have to go get the Zithromax or whatever there was, and God forbid you left it somewhere. It was like getting Federal Bureau of Investigation (FBI) clearance to go and get another prescription of Zithromax for an ear infection. Yet you have instances where you have people like this that are going around doctor shopping. I mean, aren't these people paying co-pays or taking—I mean, isn't there like a system in place where there is a main record locator that says, hey, this person has been to 11 doctors for the same issue? Isn't there something in place like that?

Mr. KUTZ. There is, and as was mentioned by the other witnesses, there are prescription drug monitoring plans, and actually the plan sponsors that send letters—and we saw this in several of our cases—to the doctors. However, all the doctors can do really is kick the patient out. Some of them that even got the letters said, "Well, I know the person is in pain. I kept prescribing even though I know they were going to 10 other doctors."

Senator BROWN. That makes no sense.

Mr. KUTZ. That does not prevent it from continuing.

Senator BROWN. It makes no sense. A letter is sent out, and the doctor sees the letter, and yet he or she continues to prescribe the medication because the person is in pain. I mean, isn't there a realization that, gosh, these people are abusing drugs and they could potentially be dealing drugs? Isn't there an affirmative obligation for the doctors to find out what is going on? And isn't there an affirmative obligation once those letters are sent to take it a step further, call the doctor, refer it to law enforcement? I mean, a letter, I mean, gosh, they get so many papers every day. Is it really working?

Mr. KUTZ. I would say mixed results, but not really working to prevent it from happening. Several of them kicked the people out of their programs because they had violated their pain management agreement. Other ones kept prescribing. At the end of the day, Senator, we did not look at the culpability of the doctors because some of these doctors are potentially part of the problem in what they are doing, because if you look at the actual quantity of drugs that they were prescribing, it does raise questions. And it raises questions about the pharmacies, too. If you get the printouts at the pharmacy of how many drugs these people are getting, it was not just Medicare supplying it. They were going in with other prescriptions and paying cash for others and getting it from other sources. So typical doctor shoppers, they are looking for multiple sources, and as you said, that would indicate potential dealing.

Senator BROWN. The findings do not come as a surprise to CMS. In 2009, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) report cited that drug diversion by beneficiaries or drug dealing, as I referenced it, as the top type of potential fraud and abuse referred to the Inspector General's office. And in your investigation, what did you find with CMS' guidance

[1] The chart referenced by Senator Brown appears in the appendix on page 00.

to plan sponsors in response to a beneficiary who was doctor shopping?

Mr. KUTZ. Well, some of the sponsors—we mentioned a restricted recipient program. Some of the sponsors have actually asked CMS if they could to it, and it is right in CMS' Chapter 7 of the regulations that a lock-in program like that is prohibited at this point. Whether that is a legal or a policy issue, I think Mr. Blum could answer that question.

Senator BROWN. He is next.

Mr. KUTZ. I believe it still is a valid part of a comprehensive plan, and I agree with the other witness that said not one thing alone does it. You have to have stuff at the beginning, the monitoring at the end, and people have to believe there is a chance they will get caught, and if they get caught, that there will be consequences.

Senator BROWN. The thing I find amazing since I have been here is there is always an angle. Everyone has always got an angle to kind of screw the government, out of taxpayer money. Whether it is dealing with waste, fraud, and abuse in contracting, whether it is dealing with these sorts of things, whether it is selling government property or holding it back, we are just doing things so inefficiently it is mind-boggling.

Mr. Blum, just following up on you, knowing that according to OIG and GAO about the possible drug dealing as a result of the prescription drug abuse, CMS' primary response to a case where a beneficiary is found to have inappropriately obtained the abused drug is to have plan sponsors issue an educational letter to the doctor. And since issuing this guidance to plan sponsors to send an educational letter, have you seen a decline in cases of beneficiaries' doctor shopping or prescription drug dealing? And if so, what is the decline? What has the result been?

Mr. BLUM. I think quite honestly, Senator, we are hearing about an overall increase in potential overutilization and misuse of controlled substances.

Senator BROWN. So even though the letter has gone out, it has increased?

Mr. BLUM. I think that CMS fully agrees that our response must be stronger.

Senator BROWN. So the letter is not working.

Mr. BLUM. That is why we put out guidance——

Senator BROWN. Is the letter not working?

Mr. BLUM. I believe that we are seeing more complaints coming into our fraud and abuse contractor. We are having more reports——

Senator BROWN. So if the letter went out and the cases are increasing, then it is not working.

Mr. BLUM. I believe that we——

Senator BROWN. Yes or no. Is it working or not?

Mr. BLUM. I do not know, to be honest. What I do know is that there are more complaints coming into our MDIC of potential doctor shopping. Those cases get referred to law enforcement, and we are very concerned regarding the potential overuse of controlled substances.

Senator BROWN. Let me tell you, it is not working. OK? That is kind of the reason we are here, because it is not working. And I would encourage you to do more than just send a letter that is going to be lost in the shuffle.

Mr. BLUM. We are, Senator.

Senator BROWN. And if you need help or guidance or additional help from us, great, let us know. But sending a letter when we are talking about millions of taxpayer dollars just makes no sense to me.

Mr. Kutz, as you know, the DEA administers special licenses to doctors which enables them to prescribe these narcotic drugs. In preparing for this hearing, my staff talked with the DEA about their relationship with CMS and the effort to curb this real tragic abuse and found that the DEA had very little relationship with CMS and did not even know who the Medicare Drug Integrity Contractor was, much less share information with them. How important is it for CMS and the MDIC to be working with the DEA or sharing information about potential doctor shopping with the DEA?

Mr. KUTZ. I would hope someone in DEA knows who the MDIC is. Apparently the person you talked to did not, but there certainly would seem to be some relationship and coordination since DEA looks at large cases, and DEA is typically looking, I think, at Schedule I, which is not what we are talking about here—cocaine and marijuana and heroin and those types of things. But certainly better coordination with them, if it is not happening, is something that—some of these could be big cases. Even our individuals we found out of these 10, they might be part of some bigger network, and so sharing of information would seem to potentially be useful here.

Senator BROWN. We ran into problems about 10 years ago when we failed to share information. This is obviously different, but it still bears to learn the lesson that, we need to provide this information if the DEA and no one seems to be really putting their foot down, so I would encourage whoever is not communicating to start to do it.

I would like a second round, if we could.

Senator CARPER. We will have maybe three. All right. Thanks very much.

I want to come back to you, if I could, Mr. Blum. We talked a bit earlier about your office putting out a memo to the Medicare Part D plan sponsors that is intended to tamp down on doctor shopping in the program. I think it is probably in response to the GAO study that was released last week, and for the hearing that we are having today.

I am told that the memo that went out last week does not actually direct the plan sponsors to make changes. The memo, I am told, only asks for ideas and suggestions. I am also told that the memo left many potential experts and stakeholders out of the process. For example, I do not believe it was distributed to pharmacies or to law enforcement.

Let me just say, Mr. Blum, I think it is critical that we put into place concrete steps to stop this form of abuse and waste, to the extent that we can. When do you plan to complete the guidance by establishing a change of rules or other new procedures?

Mr. BLUM. I think it is a fair statement that we put out our guidance to plans as an opportunity to solicit comments, and I think we want to understand from our Part D plan sponsors themselves how best to implement the policy goals that we have to address and to respond very quickly, more quickly than in the past, to the overuse and the misuse of controlled substances and other drugs.

As I said during my testimony, we have to strike the careful balance, and so in stopping the behavior that Senator Brown points out in his chart, that is clear fraud, that needs to be stopped. But at the same time, there are legitimate beneficiaries who have legitimate pain needs, and so we need to find the right balance. We need to stop the egregious behavior that makes no clinical sense, but at the same time some beneficiaries who are seeing four and five physicians may have very legitimate health care needs.

We are open to all ideas, and your suggestion to share our guidance with others is a good one that we will follow up on, but we need to make sure that law enforcement best supports our work, that the pharmacists and the physician community are at the front line to these transactions; but I think it is fair to say we are open to every idea that strikes the right balance between stopping the behavior that is clearly fraudulent and illegal, but at the same time making sure beneficiaries have access to the medications they need. And it is not just controlled substances that we are concerned about. We are also concerned about antipsychotics and other drug classes. And to our minds, we cannot just focus only on controlled substances, but on all drug classes that could have potential misuse.

Senator CARPER. All right. I appreciate that response. In that case, it sounds like CMS is prepared to distribute that memo that you put out last week to others, including law enforcement and pharmacies.

Mr. BLUM. They are public documents, and so I think we have to do a better job to make sure that the entire public can see it. But they are public documents, and we will do our best to make sure that they are shared more widely than just our Part D plan sponsors.

Senator CARPER. I would encourage you to at least include those two areas, law enforcement and pharmacies.

Mr. BLUM. Absolutely.

Senator CARPER. Having said that, I also want to note that the Centers for Medicare & Medicaid Services I think just yesterday—finalized some new rules that take in——

Mr. BLUM. Proposed rules.

Senator CARPER. Is it proposed rules? OK. That take one important step to help curb fraud in Medicare prescription drugs. And I think starting next year Part D plan sponsors would have to confirm that a prescription was written by a valid physician, something we discussed at a similar hearing I think last year here. It is a good example, I think, of CMS taking action, and I hope that it can be repeated with many of the ideas that we are talking about here today. So that is good news.

A question, if I can, maybe for Mr. Kutz and Mr. Blum, if I could. I understand the Medicare Part D benefit is made up of two types of beneficiaries: those who are eligible because they are over 65 and

eligible for Medicare, and those who are eligible because of a disability or low income and they can be under the age of 65. I am told that the GAO found that nearly 70 percent of those Part D beneficiaries suspected of doctor shopping were low-income or disabled individuals. Is that correct?

Mr. KUTZ. Yes, it was 120,000 of the 170,000, and I want to make sure that those are indicators. They are not all necessarily doctor shopping, as Mr. Blum said, but they were disability. They were SSI and DI participants.

Senator CARPER. Just take a moment and let us drill down on that. What do you think those findings might mean? What are the implications of that?

Mr. KUTZ. Well, one of the things is it is not typically the over-65's that are doing this, which is something that one would look at Medicare and maybe assume that without digging into the numbers.

Senator CARPER. Is it true that for folks in the Medicare Part D program, if they are 65 and over, they are not there because they are disabled and unable to work, but they are there because they are 65 and over, traditional Medicare, they can only change their benefit plan—is it annually?

Mr. KUTZ. If they are not in the low-income subsidy (LIS), my understanding is they can only change annually.

Senator CARPER. Annually. But for the folks that are in the low-income category or population or those in the disabled population, they can change their plans monthly, can't they?

Mr. KUTZ. Right.

Senator CARPER. All right. That would seem to be ripe for abuse.

Mr. KUTZ. Right, and that is a risk here of, if you actually stop it happening in one plan, we recommended that sharing between the plans of the known abusers is something for CMS to consider.

Senator CARPER. Let me just ask you, Mr. Blum, if I could, does CMS believe the ability to change plans monthly for those particular beneficiaries is an idea that the Congress should revisit? Did we do that in the law? I presume that is in the actual law that we adopted 5 or 6 years ago.

Mr. BLUM. My understanding is that the ability for low-income beneficiaries to change plans month to month was through CMS guidance, not through the legislation. The history is that when CMS set up the new Part D program authorized by the Congress, there were lots of concerns regarding low-income beneficiaries being transitioned from pretty open drug formularies offered by State Medicaid programs over to more restricted Part D drug formularies that mirrored commercial formularies. As a beneficiary protection, the agency now allows low-income beneficiaries to change plans month to month. Given that they have oftentimes very complicated health care needs and very complicated drug regimens, the agency's goal is not to interfere with those health care needs.

That being said, this policy——

Senator CARPER. Could we have an unintended consequence here?

Mr. BLUM. I think that is one unintended consequence, potentially, that the operational framework that we operate under, those

who might be out to game the system could change plans month to month. I think we have to find the right balance between protecting consumer access and also stopping those that intend to defraud the program. But the current policy that the agency has is to permit low-income beneficiaries to change plans month to month.

Senator CARPER. As you consider this, just keep in mind—I am going to read the same statement I gave earlier. It is estimated that 7 million Americans abuse prescription drugs every year, more than the number who are abusing cocaine, heroin, hallucinogens, Ecstasy, and inhalants combined. And the point you had made, Mr. Kutz, did you say 70 percent——

Mr. KUTZ. Seventy-one percent were disability. They were in the program through disability, SSI and DI.

Senator CARPER. All right. Well, let us explore this a bit more and see if this is something that maybe has not worked as intended and if we ought to make some changes. Senator Brown.

Senator BROWN. Thank you, Mr. Chairman. I am going to go to the floor after this. This will be my last round. But I appreciate you holding this.

Mr. Blum, you said we have to strike a careful balance. I do not think we are—I think we are too careful, to be honest with you. I think that, we have 170,000 people abusing the system, according to my information. It could be more, it could be a little less. But, clearly, there is an issue, and I know that in a September 28 memo to Medicare Part D sponsors CMS admits that the MDIC contractor, the contractor responsible for identifying and investigating Medicare Part D fraud, has, in fact, identified excessive utilization of drugs, opioids and drugs, and that CMS considers these patterns highly indicative of drug abuse or diversion, a/k/a drug dealing.

Since the MDIC contractor has identified this outrageous fraud, how many cases have actually been referred by MDIC to the Inspector General for prosecution?

Mr. BLUM. I will have to defer to law enforcement, but my understanding is that every case that was revealed by the GAO of true patterns of illegal behavior—somewhere in the neighborhood of, I think, 50 to 60 cases—was referred to the MDIC. Those cases were all investigated. Some of those cases were referred to the IG, and the IG I think has decided to pursue a handful of those cases through law enforcement channels. But according to the data that I have from our MDIC, they continue to receive growing complaints regarding misuse, and they continue to fulfill their obligation to refer those cases to law enforcement.

I think it is also important to break down the 170,000 figure that you cite. There are four potential reasons for that number. One is that there is diversion or drug dealing going on. Two is that beneficiaries are fueling their own addiction. Three is they have a legitimate clinical need. And fourth is they are just the victims to a dysfunctional health care system. I do not believe the GAO report has broken down that 170,000 number into those four categories.

Senator BROWN. Can you just repeat that? What did you say, a dysfunctional health care system? What do you mean?

Mr. BLUM. Beneficiaries bouncing around from one ER to another ER, that we have a very uncoordinated health care system today

that we are working hard to reform. But beneficiaries who are seeing multiple physicians might be going to the ER, might be going to different physicians because they do not have a regular source of primary care. So that is not the fault of the beneficiary.

Senator BROWN. When are you going to implement edits that will capture if a beneficiary is acquiring more drugs that are actually clinically necessary? When will those safeguards be put in?

Mr. BLUM. Our strategy right now is to solicit comment, take that comment, and then work as far as we can to——

Senator BROWN. Here is a comment for you. Just fix it. We are talking hundreds of millions of dollars of taxpayer money. We need the money for other things, quite frankly.

Mr. BLUM. And my understanding is that some of the cases that have been pointed out by the GAO are true fraud and illegal behavior, and some of those cases are very legitimate health care needs. CMS has to find that right balance between——

Senator BROWN. Wait a minute. You just said fraud and illegal behavior, but you need to balance it with the health care needs. The people that need some care and coverage, I understand that. But we are talking clearly about taxpayer-funded Medicare prescription drugs that are probably being used to care for that individual, but the rest of it is being sold on the black market or, just being sold to friends or neighbors or whatever. So I get the fact we have to treat everybody, reasonably and make sure the care—but, obviously, if they are doing that, there is a deeper problem that I think supersedes the actual pain that they are in. And I think you have to take the gloves off a little bit. Instead of seeking and requesting, you have to dictate and actually come out with some suggestions of your own as to how to fix it. It seems pretty straightforward how to fix it. You have to have a check and balance. You have to have a top-to-bottom review of everything you are doing, have a check and balance, and when you have any indication that there is any type of abuse, you have to go right for the jugular and make sure that it does not happen. There has to be a sharing of information.

I would encourage your Department and the people that are responsible. And I know there are good people over there, hard-working people. I get that. But, we have a real problem here. We would not be here—if we did not have a problem. Right, Mr. Chairman. So, I mean, we are all ears. I think out of probably all the Senators here, you have the two guys who work together the best in trying to find solutions. We are not just throwing bombs. We are trying to find out where the problems are and try to find a way to kind of get to the bottom of it to put money back into the system that can be used for people who legitimately care and respect the care and coverages that they are getting from the American taxpayer, because, quite frankly, there are other folks that do not have those luxuries and benefits and they are hurting and they need help, too.

So I do not want to preach. I think you know where I am at, and I know you know where the Chairman is at, too. We just have to do it better. We are in this together.

I appreciate your bringing this forward, Mr. Chairman. Once again, you are on it. So I appreciate it, and I am going to head to the floor.

Senator CARPER. And we appreciate very much the work of our staffs and certainly the work of GAO.

Senator BROWN. Yes, a great job, both of them.

Senator CARPER. We are very grateful for that.

We have a place at Rehoboth Beach called "Funland." I do not know if anybody in the audience—I see the audience reaction, people that have been there with their kids. It is great fun. Great fun for children of all ages, including our age. But one of the games they have at Funland is called "Whack-a-Mole." The idea is like if something pops up, you knock it down, and another one pops up.

Senator BROWN. It is all Republicans that come out and they——

[Laughter.]

Senator CARPER. In any event, in terms of whether the issue happens to be abuse of prescription drugs, feeding the drug trade and hooking people on controlled substances, or whether it happens to be surplus property or it happens to be waste in IT systems, you name it, there is plenty out there. We will stay busy in this Subcommittee for as long as I get to serve on it and continue to focus on these.

I want to come back, if I can, to Mr. Saccoccio. You mentioned Humana and WellPoint. Let us just come back and let us talk a bit more about what are they doing there to address these particular challenges?

Mr. SACCOCCIO. Well, they do several things. The first thing that they do is they take a look at their prescription drug claims in certain categories for the controlled type substances, and Humana, from has a three-three-three program, so it——

Senator CARPER. Has a what?

Mr. SACCOCCIO. A three-three-three program.

Senator CARPER. A lot of threes.

Mr. SACCOCCIO. A lot of threes. To the extent that you had three prescribers, three pharmacies, and three actual prescriptions filled over the course of a year, they will then take a closer look at that particular case and, if necessary, send out notifications to the physicians involved letting them know that there could be potentially abusive behavior going on here; and then after a further look at those cases, maybe putting those folks into a lock-in type program where they are restricted to one particular pharmacy in order to obtain those types of drugs. And they seem to have some success with that. Talking to Humana, they have seen a decrease in the amount of prescription drugs for these particular patients when they do that.

WellPoint had a similar program. They also have a program now where they will look at individuals that have 10 prescriptions over a 90-day period, and they carve out, again, when they are looking at that—going to Mr. Blum's point about, cases where patients do need those particular drugs, so they do carve out things like oncology or MS, and they carve those out. But then they look at those prescriptions over the 90 days, and, again, they notified the prescribers in those cases, and then they also put those individuals on a lock-in type program.

The other thing that they do is they look at geography, because even with the prescription drug monitoring programs that the States have, it is important folks that are living in States where

they can cross the border and avoid those types of programs that the States have, they will do that. If they need to travel outside a certain geographic area to go to other physicians to get drugs, they will do that. So one of the things that they do is they look at is the patient traveling a long distance in order to see a provider in order to get a prescription.

They also look at things like prescribers prescribing outside their area of expertise, so if you have, a certain type of doctor that is prescribing a lot of pain medication drugs that is not really working in an area where you expect that type of prescribing, they take a look at that.

I am sure CMS probably has similar edits, and to the extent that the sponsors in Part D have those types of edits, but, again, it gets back to a combination of things. And what we were told is that companies like Humana and WellPoint that are Part D sponsors would like to use those lock-in programs but are not allowed to in Medicare Part D.

Senator CARPER. OK. Mr. Blum and then Mr. Kutz, I am going to ask you just to react, if you will, to what Mr. Saccoccio just explained about what they are doing at Humana and WellPoint.

Mr. BLUM. I think what is encouraging about the examples that are raised in the testimony is the notion that Part D plans can look more comprehensively regarding the entire case of a beneficiary. That is very consistent with where we would like the program to go, our Part D sponsors taking into account much more comprehensive drug utilization reviews so they are seeing the history of the patient's care to make sure that the total drugs being dispensed over the course of a given benefit period are consistent with sound clinical judgment.

We understand that oncology patients and other patients have very legitimate care needs, and also many of our beneficiaries have very unique geographic circumstances that at this time we do not believe that a restrictive program would work well in the Part D program. To our strategy and our belief, we have to have clinical judgment, clinical review drive those behaviors, and when our Part D sponsors—our hope is that when our Part D sponsors see prescribing that cannot be justified by any means through clinical review and judgment, those payments are cut off. Our Part D sponsors do not carry guns. CMS does not carry guns. So we have to refer those cases to law enforcement. But our responsibility is, number one, to make sure there is good clinical judgment, and then two is to make sure that we are providing the necessary direction to our plans for clear cases to law enforcement for investigation and for follow-up.

Senator CARPER. Mr. Kutz, would you just respond to what Mr. Saccoccio has been saying?

Mr. KUTZ. Right, and I would agree that some of these 170,000, as we mentioned before, are not necessarily doctor shopping. Some are. And there are some people that go to two, three, or four that would meet the definition of doctor shopping. So that number is a soft number. You would have to really investigate all 170,000 to know what really is happening.

I think the sponsors told us the same thing, that they would like several to do a lock-in if they have the infrastructure in place. So,

again, I still think that CMS should at least consider this as a valid part of the back end of the process, which really, if you think about it, feeds into the front end, too. If you are only allowed to go to one pharmacy, it is kind of hard. We had people that went to 45 pharmacies. So if you are locked into one pharmacy—we are not denying you the drugs. We are just actually trying to better control your behavior. And, again, you have to have a safety net for the legitimate people so you do not lock legitimate people out of the program. We certainly agree with that.

Senator CARPER. All right. Mr. Blum, is it CMS' position that restricted recipient programs are a proven mechanism to minimize program issues in Medicaid but would not minimize program issues in Medicare Part D? We talked a bit about that. That seemed to be what you were saying. And in response to the request for comments from the plan sponsors that CMS put out, I believe last week, do you think that there is a chance that the plan sponsors would ask that a restricted recipient program actually be put into place? It sounds like some might be. And if so, would CMS' position change?

Mr. BLUM. We are certainly open to all ideas, and I think based upon the conversation and the testimony today, we will certainly take a second look to make sure that we are thinking about restricted programs correctly. If our Part D sponsors feel confident they can put these programs into place in a way that prevents fraud but does not restrict necessary care, we will consider being open to this idea. I think, again, our current judgment is that we think that more comprehensive drug utilization review is the best strategy right now, and we agree that broader data sharing, broader data analytics would give us new tools to help support law enforcement. But CMS will continue to stay open to all ideas, and we are very much committed to making sure that taxpayer dollars are being spent as wisely as possible.

Senator CARPER. All right. Thank you for that.

Back to Mr. Kutz, if I could. According to the report released by GAO today, the costs of drugs that were likely obtained through doctor shopping was close to $150 million. I think that was for one year?

Mr. KUTZ. 2008.

Senator CARPER. Yes, 2008. Could you talk further with us about that figure? How did GAO come up with it?

Mr. KUTZ. It really was using—I guess we had the 2008 claims data. We have information from the NPIs, the national identifiers for prescribers. We had Social Security data, national drug code information that we used for those 14 classes. Remember, it is limited to 14 classes of drugs. We simply went in and did the data mining to see who was going to five or more prescribers for the same class of drug, whether it was a generic brand or a name brand, within—like oxycodone, oxycodone versus OxyContin, they would be within that same class, is our understanding. So that was how we actually organized the data, and then the information was for five or more. And, again, we got that five or more. There are a lot of people that have used three, four, five, six. It seems that there is a consensus in the three to six area. We actually used six when we did Medicaid before, but other State audits, the PDMPs,

and the plan sponsors I think all would—five is in the ballpark for an indicator that there is a potential further review necessary.

Senator CARPER. OK. Is there any way to factor in those costs to arrive at the true taxpayer price of this abuse?

Mr. KUTZ. Well, it is not all taxpayer. This also affects the beneficiaries who are not doctor shoppers and are not abusing the program. That would presumably increase their share of paying for this. And then we did not include the office visit. I think it was mentioned that some of these people actually went to emergency rooms to get their drugs.

Senator CARPER. I think, Mr. Saccoccio, didn't you mention that?

Mr. KUTZ. Right, and we saw evidence of that also, and we saw it in Medicaid also, that in some cases they would go to the emergency room. It is just another way to doctor shop, is to go get several—they will not usually give you a full month, but they might give you enough to get you through a few days. Then I would assume Medicare has to pay for the cost of the emergency room visit in that particular case.

Senator CARPER. And talking about $148 million in 2008, does that include doctor's office visits? Does it include——

Mr. KUTZ. No, it does not include office visits or emergency room visits, no.

Senator CARPER. OK. Mr. Saccoccio, I have no idea how much that would add up to, but are we talking about several millions of dollars or maybe more than that?

Mr. SACCOCCIO. Yes, I think there is a ratio. Some information we had seen is for every prescription drug, say, that was obtained for abusive purposes, you may have as many as $14 behind that, and emergency——

Senator CARPER. Say that again.

Mr. SACCOCCIO. It is 14:1. Say the drug costs $20 to obtain. Between the office visits, emergency room visits, those kinds of things, you are talking about a ratio of, say, 14:1. So for every abusive drug that you may have seen, the cost could be that much higher.

Senator CARPER. Fourteen times higher?

Mr. SACCOCCIO. Well, because of those additional services that go along with obtaining that drug. So if you go to an emergency room and say, "I hurt my leg and I need to get the drug," I mean, there is the cost—either Medicare or Medicaid or commercial insurer is paying for that emergency room visit that goes along with that little prescription that you get as you walk out the door to go get that drug.

Senator CARPER. Even if it were four times higher, that would be a heck of a lot money. That would be like $600 million in a year.

Mr. KUTZ. We did not pick these drugs because of their cost, and as you mentioned, the cost in society in perhaps the bigger issue. We picked them because the street value of OxyContin is several thousand dollars for one prescription. So that gets into some of the other factors to consider here in why we picked them. But in working with you and your staff, we looked at the 14 drugs that we thought were the most dangerous and most highly abused in our country right now.

Senator CARPER. All right. Mr. Blum, if I could, as you know, I worked with Senator Brown and others, Tom Coburn, Senator Coburn, and others on our Subcommittee to try to write legislation that is aimed at curbing waste and fraud in both Medicare and Medicaid. We have introduced bipartisan legislation, S. 1251—I mentioned it earlier in my statement—the Medicare and Medicaid Fighting Fraud and Abuse to Save Taxpayer Dollars Act. That is a mouthful, isn't it? And there is no good acronym for that one, you will be pleased to know. But the legislation contains a number of ideas that I think directly impact the diversion of drugs from the Medicare prescription drug program.

For example, the legislation aims to help States establish and strengthen prescription drug monitoring programs. It also helps to stop identity theft of physicians who prescribe controlled substances. One of the terms I have learned this year is what is called the "Master Death File." People say, "Well, what is the Master Death File?" And I say, "That is the list you do not want your name to appear on because it means you are dead." And yet we have doctors whose names appear on the Master Death File because they are dead, and they are still writing prescriptions. And we have beneficiaries whose names paper on the Master Death File, and they are still receiving benefits even though they are dead. And we know that in reality that doctors cannot be writing prescriptions and the beneficiaries cannot be receiving benefits.

One of the cornerstones of our bill is to require closer coordination and better information sharing among Medicare officials and their staff, Medicare oversight contractors, or private partners such as the prescription drug plan sponsors, as well as local, State, and Federal law enforcement. And I would ask you, if I could, Mr. Blum, do you think that these provisions of our legislation would help to curb, at least to some extent, drug diversion from Medicare? And, second, do you believe that such steps as better communication and data sharing with law enforcement can prove beneficial?

Mr. BLUM. I had a chance to carefully review the legislation that you introduced, and I think there are some very good ideas that will improve both the Part D program and the Medicare program overall. And I think that it is fair to say that any barriers that can be taken down for data sharing and data analysis will prove very beneficial to the program. The program has been built in silos. We have physician data systems and hospital data systems and Part D data systems historically that have prevented very sophisticated data analysis. We do not always have the feedback loops between the program and law enforcement, and law enforcement back to the program. And those are barriers that we need to break down—that your legislation, I think, would be helpful to continuing that effort.

But now we have much more sophisticated data systems. We have Part A and Part B and Part D claims, the common data sets. We are moving to making sure that the prescriber's ID number is part of the drug claim so we can see where prescriptions start from much more easily. And I think any effort that we can use to be much more proactive in our focus and to put into place procedures up front will serve the program well, and also to facilitate the feedback between the programs and law enforcement and the oversight agencies to make sure that we are acting when we can.

I think the report that came to our attention through the great work of the GAO led us to take steps. The more that we can continue that feedback, the program will be better off.

Senator CARPER. Mr. Saccoccio, do you want to comment as well on that question, please?

Mr. SACCOCCIO. Yes, I think we have always stood for the proposition that information sharing is critical to being successful against health care fraud, whether that information sharing is between Federal agencies, between Federal agencies and State agencies, or between the private and public sector. So to the extent that the legislation endorses that idea and creates an environment where that type of information sharing could take place, I think that is critical.

Data analysis is important and looking at data and analyzing that is all well and good, but once you get that information, you need to do something with it. And it is important not only to just keep it in the little silo that it is in, but to share that information with others that are involved in the fight. So I think that is critically important.

Senator CARPER. OK. Well, as some of you know, when we hold these hearings, I describe the way I try to give speeches, and I like to tell people what I am going to tell them, and then at the end I tell them again what I have told them. It is almost like a diamond here. I do not do that as well as I ought to, but at least that is what I try to do. And at these hearings I like to give each of you a chance to make some comments at the end given what you may have learned or thought of or just want to react to. And I am going to do that here in a little bit.

Another question I oftentimes like to ask is: What implications flow from this hearing for those of us in the Legislative Branch? A lot of times we talk here about our responsibility to provide oversight, good oversight, and in many cases to work with GAO in order to find behavior that is financially wasteful and to put a spotlight on that. In some cases we like to put a spotlight on good behavior, too, and to positively reinforce that behavior.

Let me just ask each of you, in terms of what we are doing or are not doing, what should we maybe be doing more of on the legislative side or less of in order to get us to the point we are actually getting better results for less money? Mr. Kutz.

Mr. KUTZ. With respect to you, I think, having constructive hearings like this, talking about concrete solutions, this is a drill-down from the normal improper payment where you talk at a little bit higher level in general. Having drill-downs like this periodically I think is good to actually see what is really going on out there behind the numbers. This is a teeny little piece of your bigger fraudulent and improper payments story, and each one of those little pieces of that has concrete solutions that can be implemented. And so this is an example of that, and so I commend you for having this hearing. I think it is very good.

Legislatively, if it is determined that a restricted recipient is something they are considering, they may or may not need your assistance with legislation on that. That is just something from a standpoint of what you might need to help with.

And then just there is no one piece of a solution to the discussion today. It is a comprehensive solution. A fraud prevention program includes front-end monitoring and something happening at the back end, and all those things working together in a feedback loop so that if someone rips off the program, you utilize that so that they do not do it again at the front end.

So I think that there is a combination of things that could be done to address doctor shopping here.

Senator CARPER. All right. Thank you.

Mr. Blum, implications for us in the Legislative Branch, what can we do that would be helpful? What should we do more of or less of?

Mr. BLUM. Well, I think we as an agency overall, our strategy is to be much more proactive with data analysis and with more sophisticated monitoring and oversight to our data to find clues and to find trends that are troubling. We do not have all the resources that we could to do this kind of monitoring. The more that we can have outside experts and the oversight agencies sharing in that analysis to kind of bring things to our attention that our work does not necessarily highlight, but I think the more that we can have other analytic shops go into our data, mine our data, find relationships that are troubling, that is better for the program, and I think that is the best thought I have right now.

Senator CARPER. All right. Mr. Saccoccio, what can we be doing on our side over here?

Mr. SACCOCCIO. Well, the first thing with respect to this particular issue, again, gets back to the restricted recipient program. I do not know if there is some sort of statutory restriction with respect to that. If there is, then I would think, to the extent there is, a legislative fix may be the way to go in order to allow CMS—we believe that once CMS has now asked the sponsors. I think the sponsors are going to come back and recommend some sort of lock-in program. So, will CMS have the authority to do that?

But beyond that, on the broader question of health care fraud, I think one of the critical things is simply resources, the funding for the Inspector General's office, for the FBI, for CMS to implement the type of predictive modeling that they are doing now and to continue to fund them in such a way that allows them to do that job effectively, because it is an effort that you just cannot do in 1 or 2 years. It has to be an effort that continues over the course of many years if you are going to start driving this stuff down, because it is not going to happen overnight.

So I think, the funding, I think the Affordable Care Act provided some solid funding in the anti-fraud area for, again, the FBI Inspector General, both at the front end with respect to data analytics and preventing the money from going out the door in the first place, and then to the extent it has, to investigating that and taking the appropriate judicial and legal action on the back end.

Senator CARPER. All right. I sometimes use the example of my mom when we are talking about better outcomes for less money. My mom is now deceased. She died about 5 years ago, about the time that the Part D program was introduced. But for a number of years, she—she outlived my dad, but she lived down near Clearwater, Florida, and she had dementia in her later years. She had

dementia, arthritis, congestive heart failure, just a number of problems that sometimes happen to us when we get older. She was seeing about five or six doctors. My sister and I would take turns every other month going down to visit with her, and we had folks literally with her in her home around the clock near the latter part of her life. But we found out that five or six doctors were prescribing maybe as many as 15 different prescriptions, and none of the doctors ever talked to each other. They did not have electronic health records for my mom, people like in her situation, so no one was really monitoring to see which medicines were compatible with other medicines and, frankly, which ones were not.

We are at a point now—I was in a pharmacy, I actually visited Walgreen's, like pharmacy of the future. I was in Chicago a couple of weeks ago. And they are doing pretty amazing things in that pharmacy. And they, along with other pharmacies, especially the chain pharmacies, have gotten very good at being able, before they fill a prescription, to look at the other medicines that a person is taking and deciding which ones are compatible and which ones are not. And we are doing a better job, a lot better work now with electronic health records, some of which we funded through the stimulus act and some of which we are funding through the Affordable Care Act.

Talk to us a little bit, if you will, about how can we do a better job of using electronic health records as they become more common and more widespread. How can that help us in dealing with this particular issue?

Mr. KUTZ. I will just start. My team is the Forensic Audit Team in GAO. That is what we do. We deal with data, and so data is very powerful. Over the years we have identified hundreds of thousands of potential cases of fraud and abuse across the government, so I would just say data is a powerful tool not just for investigators but for management to actually oversee and manage a program, and in this particular case to prevent and identify fraud.

Senator CARPER. Aside from the fact that this stuff that is being done is illegal, aside from the fact that we are running out of money in the Medicare trust fund and are going to run out of money I think by about 2020, maybe even sooner, if we just sort of leave things on autopilot, but how do we—what is the interest, the financial interest, of the prescription benefit managers that are offering all these—what is their financial interest here in reducing the incidence of this kind of activity? Are they better off if it continues or not? For the doctors, who—I like to harness market forces rather than maybe pass legislation or to have regulations. How do we harness market forces in this situation to reduce this kind of illegal behavior? Or can we?

Mr. BLUM. I think one of our challenges of the Part D program is that most of the beneficiaries who are in the Part D benefit receive drug benefits from stand-alone drug plans that do not have the same financial relationships to other parts of the benefits. Beneficiaries who are in comprehensive health plans like the Medicare Advantage plans have a more comprehensive benefit structure. And I think the challenge for the program and the Congress is for us to think about ways to incent Part D plans, the stand-alone Part D plans, to think about consistent goals that the pro-

gram has. We know that care coordination not just for pharmacy benefits but for all of our health care benefits is the best strategy we have to reduce costs but also to improve care for our beneficiaries. We are trying to accomplish that through accountable care organizations and new payment reforms to provide stronger incentives for care coordination and primary care medical homes. But I think a challenge with that is the fact that we have stand-alone Part D plans providing the bulk of the benefits to our beneficiaries, and so we have to build much stronger relationships with our stand-alone Part D plans to ensure that they are providing benefits that are consistent with the overall strategies that we have for the Medicare program.

Senator CARPER. Mr. Saccoccio, in terms of harnessing market forces to incentivize, without regulations, maybe without laws, how might we do that in this instance?

Mr. SACCOCCIO. Well, I think, coordination of care is critical, and to Mr. Blum's point, to the extent that you have a stand-along Part D plan that is administering a drug benefit in Medicare and maybe using a PBM to do that, but is not at the same time—does not necessarily pay out anything or monitor any of the other care that the individual is receiving, then you have a disconnect between perhaps the prescription side of things and the actual medical care that the person is receiving, that may be receiving it through simple Medicare fee-for-service.

One of the advantages, I think, of the Part C program, Medicare Advantage, is that the person is in a health plan that can look at all aspects of what is happening and be able to control that. So, to the extent that—and what you see in the States with Medicaid is a lot of States moving away from Medicaid fee-for-service to managed care for Medicaid as well so that you get that coordination of care.

I think that coordination of care is critical, and I think maybe the ACOs under the Affordable Care Act are trying to move in that direction as well to try to put folks in situations where care is at least coordinated, where providers are speaking to each other. And your example about your mother, I know my mother as well now is on—we keep a list of all the medications she is on, because if she ever has to go to a hospital or anything, we show that list because it is up to about 10 or so. And she sees probably five or six different doctors.

Senator CARPER. Sounds familiar.

Mr. SACCOCCIO. And it is not clear to me that anybody is talking—that they are not really talking to each other. She is simply in Medicare fee-for-service.

Senator CARPER. All right. Mr. Kutz, talk to us a little bit about is there some way we can be harnessing market forces and using that as a way to reduce this incidence of abuse.

Mr. KUTZ. Well, I am not an expert at that issue, but, when we did our work, we did see some—we were not looking at it, but some of the pharmacies seemed somewhat culpable in what was happening in that if you actually got a printout of an individual who had gone to that pharmacy and all the different drugs they had gotten, all the different prescribers, and, in fact, they were going in with cash, because it was noted in the system that they got their

drugs with cash, they did not seem too concerned in some of the pharmacies with what was going on, and so perhaps it is because that would be a revenue source cut off if you kick someone out of your pharmacy.

Senator CARPER. So the financial incentives might be working just the opposite.

Mr. KUTZ. The opposite. It would seem the opposite. Now, again, I cannot say that. I am just saying it was an observation. We did not report on that, but it is just something we saw. When I looked at these printouts, it was pretty striking. You would think someone would have noticed.

Senator CARPER. Good point.

Mr. KUTZ. And the same thing with the doctors. Some of the doctors, even though they got the letters from the PDMPs and the drug sponsors that their patients were going to numerous other doctors for the same drug, they kept on prescribing and they did not do anything about it. So that was just another observation. I do not know what their incentives are, what their malpractice kind of liability is, but that was another observation.

Senator CARPER. All right. Good. Thanks.

We are getting close to the end, but I think before I ask you just to give a closing statement, I want each of you, if you will—we will start with you, Mr. Saccoccio. Given what you have heard—you bring a whole lot of knowledge and just great insights into these issues, anyway, but just tell us where you think there is consensus. One of the things I like to do is try to develop consensus at a hearing like this. But where do you think there is consensus on what is working now and next steps forward to address this problem? Where do you think the consensus lies in this arena?

Mr. SACCOCCIO. Well, I think there is consensus that, first of all, there is an enormous problem. I think the problem may be even greater than what the GAO report reveals, especially since if you look at it from a national perspective, certainly Medicare Part D, looking at that piece. But from a national perspective, prescription drug fraud and diversion is an enormous issue, so I think there is consensus there.

I think there is consensus on the concept that you cannot go after this problem with just one solution. You have to be monitoring closely. You have to have up-front solutions to try to keep it from happening in the first place, and then to the extent that you have found the problem, you need to notify the prescribers, you need to notify the patient, you need to try to get that patient, if you think there is an addiction problem, the treatment that patient needs. And then you need to do something to control it, and I think the lock-in programs and restrict recipient programs are probably, again, what CMS is going to hear a lot of from the Part D sponsors.

So, I think you could do those lock-in programs in such a way that it does not interfere with the receiving of drugs that are needed by patients that actually need them.

Senator CARPER. Good. Mr. Blum, where do you think the consensus lies? And feel free to repeat almost verbatim what Mr. Saccoccio said if you agree with him, or add to that or take away.

Mr. BLUM. I do agree with the prior statement. I think there is consensus that we have a growing problem within the Part D pro-

gram of misuse and abuse. I think there is consensus within CMS and I think at this table that we need stronger responses.

I think there is consensus that we need to work with our plan sponsors to figure out the best strategies to put in place so we are not cutting off access to those beneficiaries who have need.

I think there is consensus that we need to explore some of the recommendations from the GAO more fully, but from CMS' perspective, there is no lack of concern that this is a growing problem for the Medicare Part D program, and hopefully, Mr. Chairman, there is no concern that we are not going to do everything we can to ensure that we are stopping the misuse and abuse while permitting those in need to have access to the drugs they need.

Senator CARPER. Thank you.

Mr. Kutz, where do you think the consensus lies?

Mr. KUTZ. That there is a problem; the problem is not just in Medicare Part D. This is a nationwide problem. You have pointed that out very clearly in some of the statistics so this goes beyond that. And we saw evidence of that. The sources of the drugs these people are getting was not just Medicare Part D.

That a comprehensive approach is necessary that includes more than just one type of activity, the importance of data mining and data to this and breaking down the silos we have in our government within the health care system so the data can more freely be shared.

And then with respect to the restrict recipient program, I do not think we have agreement on that, but we have agreement that if you have a program in place, you need to make sure you have a safety net for the individuals that have legitimate needs to make sure they do not get shut out of the program, and that is——

Senator CARPER. Give us an example of that.

Mr. KUTZ. Well, you would not want to put someone on a restricted recipient program if they are going to five or more doctors for legitimate reasons. You have to have proven the case that they are, in fact, doctor shopping in an abusive way. So I think that is what we are talking about. We all agree on that.

Senator CARPER. OK. All right. You all are welcome to take a minute or two just to help me with the benediction, a closing statement just as kind of a summary of what you are taking out of here and what you would have us take away from this hearing. It has been quite a good hearing, I think. Mr. Saccoccio.

Mr. SACCOCCIO. Well, again, I think that a hard look should be taken at restricted recipient programs. I think they could be done in such a way that they take into account the valid needs of folks that need those pain medications. I think we have come a long way with respect to treating folks, recognizing pain as a major issue and to be able to manage pain for patients with certain conditions. But at the same time, I think we could do it in such a way that cuts down significantly on the abuse. Obviously, you are not going to take away all the abuse, but you could cut down on it, and I think these types of programs have a lot of promise.

Senator CARPER. Mr. Blum.

Mr. BLUM. Just in closing, just to thank you and the Subcommittee for having this hearing. I think from our perspective at CMS oversight helps us understand vulnerabilities and where we

can improve the Part D program. I think the Part D program, to our belief, is stronger for beneficiaries than it has been during its 5- or 6-year history. But at the same time, there are vulnerabilities. We have to make sure those vulnerabilities are closed down while also maintaining the goals that we have for the Part D program to ensure that beneficiaries have drug benefits that will improve their health and to provide access.

So, in closing, thank you for the attention, and thank you for commissioning the GAO report. It was very helpful for us, and there are some definite to-do's for us to follow up on following this conversation. I look forward to working with you and your staff to report back on that follow-up.

Senator CARPER. Good. We will welcome that. Mr. Kutz.

Mr. KUTZ. Thank you for inviting us to this, and we enjoyed working in a bipartisan fashion with you and Senator Brown's staff, and I appreciate the constructive nature of the hearing.

Senator CARPER. All right. Thanks.

In closing, let me again thank each of you for joining us today, for your testimony, and for your responses. A special thanks to GAO for helping us with our oversight responsibilities. You are a great partner, and we are grateful to you and your colleagues on a broad range of issues.

It is hard to believe that 10, 11 years ago we had balanced budgets in this country. We had three or four of them in a row at the end of the 1990s, and it is hard to believe that we find ourselves looking, instead of at a sea of black ink where we were 10, 11 years ago, at a sea of red ink. And I think this year the deficit is expected to come in around $1.3 trillion and there is red ink for just about as far as the eye can see.

Some folks think that there may be two ways to reduce deficits. One of those is to cut spending and another is to raise taxes or increase revenues. I think there are at least two more, and one of them is just to grow the heck out of the economy, and we are actually going to do some good and, I think, thoughtful legislation in the next week or two which I think will help in that arena as we try to grow exports.

Another way is to look at every nook and cranny of the Federal Government and look at every program. I like to say, and you have all heard me say it before, that every thing I do I know I can do better. The same is true of all of us, and the same is true of Federal programs. Whether they happen to be Medicare, Medicaid, defense programs, entitlement programs, tax expenditures, everything we do we could do better, and we have to take that attitude, almost a culture change, moving from a culture of almost spendthrift to a culture of thrift. And this is just one more piece of that.

My boys are 21 and 23. They are pretty sure that Medicare or Social Security are not going to be there for them when they are 65, 67, or 69 years old. And, frankly, a lot of young people in their generation feel the same way. I think part of my responsibility is to make sure that those programs, those benefits are there and that they are most cost-effective and providing the safety net that we need as we advance in our years.

So I think there is a bit of a moral imperative here for us to get better results for less money, and we cannot continue to spend $1.3

trillion a year that we do not have. The rest of the world will stop lending us the money, and they are finding that in places like Greece.

So I appreciate the efforts that have begun at CMS, and we applaud those efforts. We want to do a whole lot better, and we want to help you do a whole lot better. I think we need to take a good look at Humana and WellPoint and some of those other outfits and see what we can learn from them.

I have never been very good at holding "gotcha" hearings. We always like to hold hearings on this Subcommittee, always bipartisan, but we always like to hold hearings where we are looking for an answer or a series of answers, and we are looking for a way to get to better results for less money, and today I think we have taken some good progress in that direction.

We thank you all, and let me ask our staffs, but I think our colleagues on the Committee, the Subcommittee, have a couple of weeks that they can still submit questions in writing, and I would just ask that you respond to them promptly.

We are not going to go away on this issue. We are going to stay on this issue. And I am encouraged to know that you will, too, and we look forward to making great progress on this front.

Thank you very much, and with that, this hearing is adjourned.

[Whereupon, at 12:17 p.m., the Subcommittee was adjourned.]

# APPENDIX



## Tom Carper, U.S. Senator for Delaware

WASHINGTON – Today, Sen. Tom Carper (D-Del.), Chairman of the Subcommittee on Federal Financial Management, and Sen. Scott Brown (R-Mass.), Ranking Member, released the results of recent investigation that reveals individuals defrauding the Medicare system to abuse and sell prescription drugs in Medicare Part D. The Government Accountability Office (GAO) found indications of "doctor shopping" in the Medicare Part D program for 14 categories of frequently abused prescription drugs, including hydrocodone, fentanyl and oxycodone. The investigation revealed that 170,000 Medicare Part D beneficiaries acquired the same class of frequently abused drugs from five or more doctors during 2008 at a cost of about $148 million. In a particularly egregious example, one individual received prescriptions from 87 different medical practitioners in 2008.

While the Centers for Medicare and Medicaid Services (CMS) relies on Part D plan sponsors to identify "doctor shopping" for prescription drugs, the federal government does not restrict beneficiaries' access to highly-addictive and highly-abused drugs. GAO recommends that CMS improve its efforts to curb the exploitation of Medicare Part D, and suggests that CMS implement a restricted recipient program for beneficiaries who "doctor shop" and seek congressional authority to limit those beneficiaries' access to highly-abused drugs, as appropriate.

**"Millions of Americans depend on Medicare Part D to purchase much-needed medication to help them go about their daily lives," said Sen. Carper. "Unfortunately, this vital program is not immune to exploitation. The abuse of prescription drugs purchased through the Medicare Part D program strains an already costly program, wastes taxpayer dollars and steals resources from seniors and the disabled who need the program's critical assistance. As prescription drug abuse rises across our nation, particularly among young people, it is disturbing to think that our public health care system could be subsidizing a major public health crisis. Moreover, at a time when we are focused on curbing our nation's overwhelming budget deficit, we need to do all that we can to prevent scarce resources from being lost to waste and fraud. I will continue to work with my colleagues in the Senate and the Administration to find solutions to curb the problem GAO has identified and to prevent similar instances of waste and fraud moving forward."**

"While seniors and Medicare Part D beneficiaries are struggling to pay for their legitimate prescription drug needs, there are people abusing the system to obtain, for example, the obscene amount of nearly 6,000 oxycodone pills a year," **said Sen. Brown**. "Beyond the fraud and abuse, taxpayer dollars are potentially being used to fuel the illicit prescription drug trade. In some cases, beneficiaries have seen more than 80 different medical practitioners to

obtain narcotic drugs. Incredibly, when faced with evidence of this so-called 'doctor shopping,' CMS's standard response is simply to send an educational letter to the doctors. CMS must immediately increase its oversight of this important program and begin notifying proper law enforcement agencies of potential abuses. CMS should work harder to ensure taxpayer dollars are used appropriately for Medicare beneficiaries."

Today, the Subcommittee on Federal Financial Management will hold a hearing to discuss the GAO report and examine the fiscal impact of fraud and abuse of prescription drugs in the Medicare Part D program. The Committee Members will hear testimony from witnesses on the taxpayer costs of such abuse and how it affects our public healthcare system overall. Witnesses, including officials from GAO and CMS, are also expected to discuss what government officials are doing to identify and prevent exploitation of the program. The hearing takes place today, Tuesday October 4 at 10:30 am in Dirksen 342. A webcast of the hearing, "Costs of Prescription Drug Abuse in the Medicare Part D Program," is available here.

###

Permalink: http://carper.senate.gov/public/index.cfm/2011/10/sens-carper-brown-release-report-on-prescription-drug-abuse-in-medicare-part-d

Opening Statement by Senator Scott P. Brown

October 4th, 2011

Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security

U.S. Senate Homeland Security & Governmental Affairs Committee

**"Costs of Prescription Drug Abuse in the Medicare Part D Program"**

Congress is addressing the difficult decisions that must be made to put our nation on a path to fiscal sustainability including ensuring the future vitality of critical entitlement programs for our nation's Senior's like Medicare. I would like to again state my strong support for the Medicare and the Medicare Prescription drug program. These are important programs that provide essential benefits to our seniors. That is why now more than ever, we must protect these programs and root out fraud and abuse in the system.

Today, this subcommittee is releasing a General Accountability Office (GAO) report which exposes the outrageous practice-- that taxpayer dollars are potentially funding, through the Medicare Part D program, illicit prescription drug dealing. The findings in the GAO report highlight this problem, for example -one Medicare recipient visited 58 different doctors to obtain 3,655 oxycodone pills equivalent to a 1,679 day supply. These taxpayer funded prescriptions equates to a street value of approximately $292,400. Unfortunately, many of these highly addictive prescription narcotics will find their way onto the streets, harming communities and endangering lives. The GAO report highlights that "doctor shopping" is the primary way these abusers get these highly addictive prescriptions such as hydrocodone and oxycodone. The GAO report

also indicates that only a very small percentage of Medicare Part D beneficiaries, approximately 1.8%, are potentially engaging in this type of unscrupulous behavior. Though a small percentage of beneficiaries, we're still talking about approximately 170,000 people abusing the system according to GAO, which the report states costs the taxpayer approximately $148 million annually.

This not only wastes taxpayer dollars by paying for huge amounts of unneeded prescription drugs and unneeded doctor's visits, but it also has a very high human toll. In fact, prescription drug abuse is the nation's fastest- growing drug problem and is now categorized by the Centers for Disease Control as an epidemic. We must do everything in our power to combat the suffering of those addicted to prescription drugs by enhancing the oversight of these "controlled" substances.

The fact that in some cases, our entitlement programs, which were established to benefit our country's most vulnerable, are instead being used to fuel drug addiction and abuse is unconscionable.

We have held some very important hearings over this last year, perhaps none more important than this one. I commend the Chairman for holding this hearing on this important topic and I intend to work on this bipartisan issue to ensure that Congress attacks the problem of taxpayer funded support for drug dealing. I came to Washington to ensure that taxpayer funds are spent wisely and simply put, the government needs urgent intervention to interrupt the flow of taxpayer funded narcotics to our streets and I welcome the opportunity to address the Center for Medicare and Medicaid Services (CMS) on how they will arrest this problem.

United States Government Accountability Office

GAO

Testimony

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

For Release on Delivery
Expected at 10:30 a.m. EDT
Tuesday, October 4, 2011

# MEDICARE PART D

# Instances of Questionable Access to Prescription Drugs

Statement of Gregory D. Kutz
Director, Forensic Audits and Special Investigations

U.S. Government Accountability Office
GAO 90 YEARS 1921-2011
ACCOUNTABILITY * INTEGRITY * RELIABILITY

GAO-12-104T

Chairman Carper, Ranking Member Brown, and Members of the Subcommittee:

Thank you for the opportunity to discuss the results of our investigation of fraud and prescription drug abuse in Medicare Part D. Prescription drug abuse is a serious and growing public health problem. According to the Centers for Disease Control and Prevention, drug overdoses, including those from prescription drugs, are the second leading cause of deaths from unintentional injuries in the United States, exceeded only by motor vehicle fatalities. Unlike addiction to heroin and other drugs that have no accepted medical use, addiction to some controlled substances can be unknowingly financed by insurance companies and public programs, such as Medicare Part D.

My statement today summarizes our report,[1] describing indications of doctor shopping in the Medicare Part D program for 14 categories of frequently abused prescription drugs.[2] The objectives of the forensic audit and related investigation were to (1) determine the extent to which Medicare beneficiaries obtained frequently abused drugs from multiple prescribers, (2) identify examples of doctor shopping activity, and (3) determine the actions taken by the Centers for Medicaid & Medicare Services (CMS) to limit access to drugs for known abusers. To meet the objectives, we analyzed Medicare Part D claims for calendar year 2008 to identify potential doctor shoppers. To identify examples, we chose a nonrepresentative selection of 10 beneficiaries based on a number of factors, including the number of prescribers.

We conducted this forensic audit from May 2010 to October 2011 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 that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. We conducted our related

[1] GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, D.C.: Sept. 6, 2011).

[2] According to the Drug Enforcement Administration, doctor shopping generally refers to visits by an individual to several doctors, each of whom writes a prescription for a controlled substance. The individual will visit several pharmacies, receiving more of the drug than intended by any single physician, typically for the purpose of abuse.

investigative work in accordance with standards prescribed by the Council of the Inspectors General on Integrity and Efficiency.

## Some Medicare Beneficiaries Received Prescriptions from Five or More Medical Practitioners to Obtain the Same Class of Frequently Abused Drugs

Our analysis found that about 170,000 Medicare beneficiaries received prescriptions from five or more medical practitioners for the 12 classes of frequently abused controlled substances and 2 classes of frequently abused noncontrolled substances in calendar year 2008.[3] This represented about 1.8 percent of the Medicare Part D beneficiaries who received prescriptions for these 14 classes of drugs during the same calendar year. These individuals incurred approximately $148 million in prescription drug costs[4] for these drugs,[5] much of which is paid by the Medicare program. We also found the following:

- Most of these 170,000 Medicare beneficiaries who were prescribed prescriptions from five or more practitioners were eligible for Medicare Part D benefits based on a disability. Specifically, approximately 120,000 Medicare beneficiaries (about 71 percent) were eligible for Medicare Part D benefits based on a disability.
- Of these 170,000 beneficiaries, approximately 122,000 beneficiaries (72 percent) received a Medicare Low-Income Cost-Sharing (LICS) subsidy.[6]

[3] We selected the 14 classes of drugs and the five or more prescribers threshold based on our review of drug diversion literature and prior GAO work and discussions with a criminal investigator whose recognized expertise is in drug diversion and with an official representing state prescription drug monitoring programs.

[4] Medicare Part D is financed from general revenues, beneficiary premiums, and state contributions for Medicare beneficiaries who are also eligible for Medicaid. A beneficiary premium is set to cover approximately 25 percent of the cost of standard drug coverage.

[5] The $148 million in prescription costs represents about 5 percent of total Medicare Part D prescription costs for these14 classes of highly abused drugs. The prescription drug costs included in this study do not include related costs associated with obtaining prescriptions, such as the corresponding visits to the doctor's office and emergency room. These costs are billed separately from the prescription drug claims.

[6] When Medicare Part D was established, it replaced Medicaid as the primary source of drug coverage for beneficiaries with coverage under both programs—referred to as dual-eligible beneficiaries. Part D provides substantial premium and cost-sharing assistance through the LICS for dual-eligible beneficiaries and other low-income beneficiaries. The amount of the subsidy for premiums, deductibles, co-payments, and catastrophic coverage varies depending on income and resources.

- Of the 14 classes of frequently abused drugs analyzed, hydrocodone and oxycodone were the most prevalent. These drugs represented over 80 percent of the instances of potential doctor shopping we identified.

In some cases, beneficiaries may have a justifiable reason for receiving prescriptions from multiple medical practitioners, such as visiting specialists or several prescribers in the same medical group. However, our analysis of Medicare Part D claims found that about 600 Medicare beneficiaries received prescriptions from 21 to 87 medical practitioners in the same year. In these situations, there is heightened concern that these Medicare beneficiaries may be seeking several medical practitioners to support and disguise an addiction.[7]

Our analysis of Medicare Part D claims did not focus on all prescription drugs, but instead targeted 12 classes of frequently abused controlled substances and 2 classes of frequently abused noncontrolled substances, as shown in table 1. Our analysis does have certain limitations based on the data. Specifically, for at least 5.8 percent of the Part D claims, the data submitted to CMS contained blank or invalid prescriber identification values. Because these claims were not included in our analysis, we potentially understated the total number of unique prescribers for each beneficiary who received a prescription for all the claims paid.

**Table 1: Fourteen Frequently Abused Prescription Drugs Classes**

| Prescription drug classes | Other names | DEA schedule[a] | Description |
|---|---|---|---|
| Amphetamine derivatives | Adderall | II | Non-narcotic stimulant |
| Benzodiazepines[b] (e.g., Diazepam, Alprazolam, Lorazepam, Clonazepam, Temazepam, and Triazolam) | Valium, Xanax, Klonopin, Ativan, Restoril, and Halcion | IV | Non-narcotic depressant |
| Carisoprodol | Soma | Not scheduled | Muscle relaxant |
| Codeine with Acetaminophen | Tylenol with Codeine | III | Narcotic painkiller |
| Fentanyl | Duragesic and Actiq | II | Narcotic painkiller |
| Hydrocodone combinations | Lorcet, Lortab, Norco, and Vicodin | III | Narcotic painkiller |
| Hydromorphone | Dilaudid | II | Narcotic painkiller |

[7] Our threshold of visiting five or more practitioners excludes those who successfully doctor shop by visiting fewer than five practitioners on a regular basis. For example, a Medicare beneficiary can regularly receive overlapping prescriptions of abused drugs by visiting as few as two practitioners.

| Prescription drug classes | Other names | DEA schedule[a] | Description |
|---|---|---|---|
| Meperidine | Demerol | II | Narcotic painkiller |
| Methadone[c] | Methadose and Dolophine | II | Narcotic painkiller |
| Methylphenidate | Ritalin, Concerta, and Methylin | II | Non-narcotic stimulant |
| Morphine | MS Contin, Roxanol, Avinza, and Kadian | II | Narcotic painkiller |
| Non-Benzodiazepine sleep aids (e.g., Zolpidem, Zopiclone, and Zaleplon) | Ambien, Sonata, and Lunesta | IV | Non-narcotic sedative |
| Oxycodone | OxyContin, Roxicodone, Percocet, Endocet, and Roxicet | II | Narcotic painkiller |
| Tramadol | Ultram and Ultracet | Not scheduled | Non-narcotic painkiller |

Sources: National Institutes of Health and Drug Enforcement Administration.

[a]The Drug Enforcement Administration (DEA) classifies controlled substances in schedules I through V. Schedule I drugs—including heroin, marijuana, and hallucinogens such as LSD—have a high potential for abuse and no federally accepted medical use. Schedule II drugs have a high potential for abuse and may lead to severe physical or psychological dependence but have a currently accepted medical use. Drugs on schedules III through V have medical uses and successively lower potentials for abuse and dependence.

[b]Part D plans are not required to cover benzodiazepines. However, some plans choose to cover these drugs as an added benefit.

[c]Methadone is also used for the treatment of narcotic withdrawal and dependence.

Table 2 shows the breakout by drug class for the approximately 170,000 Medicare Part D beneficiaries who were prescribed the same class of drug by five or more medical practitioners. Because Medicare Part D beneficiaries may be receiving multiple classes of prescription drugs from five or more medical practitioners, certain beneficiaries may be counted in more than one prescription drug class. As shown in table 2, hydrocodone and oxycodone were the two prescription drug classes that were most prescribed by multiple medical practitioners. According to the Department of Justice (DOJ), doctor shopping is the primary method to obtain highly addictive prescription opioids (e.g., hydrocodone and oxycodone) for illegitimate use.[8]

[8] DOJ, *National Prescription Drug Threat Assessment 2010 (NPDTA 10)* (Johnstown, Pa.: February 2010).

**Table 2: Number of Medicare Part D Beneficiaries Who Received 1 of 14 Prescription Drug Classes from Five or More Prescribers in 2008**

| | | Number of prescribers | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | DEA controlled | 5-10 | 11-15 | 16-20 | 21-50 | 51+ | Total | Total prescription cost |
| Amphetamine derivatives (e.g., Adderall) | Y | 881 | 9 | 3 | 2 | | **895** | $1,040,395 |
| Benzodiazepine (e.g., Valium and Xanax) | Y | 2,437 | 17 | 4 | 2 | | **2,460** | $372,822 |
| Carisoprodol (e.g., Soma) | N | 3,026 | 51 | 4 | 2 | | **3,083** | $592,751 |
| Codeine with Acetaminophen (e.g., Tylenol with Codeine) | Y | 1,500 | 21 | 4 | | | **1,525** | $244,930 |
| Fentanyl (e.g., Duragesic) | Y | 5,043 | 24 | 8 | 2 | | **5,077** | $19,124,853 |
| Hydrocodone (e.g., Vicodin and Lortab) | Y | 92,801 | 3,553 | 700 | 335 | 5 | **97,394** | $18,949,677 |
| Hydromorphone (e.g., Dilaudid) | Y | 2,453 | 77 | 13 | 8 | | **2,551** | $1,236,678 |
| Meperidine (e.g., Demerol) | Y | 149 | 8 | | | | **157** | $90,236 |
| Methadone (e.g., Dolophine and Methadose) | Y | 3,414 | 9 | | | | **3,423** | $859,208 |
| Methylphenidate (e.g., Ritalin and Concerta) | Y | 740 | 2 | 1 | | | **743** | $488,759 |
| Morphine (e.g., MS Contin and AVINZA) | Y | 6,354 | 33 | 4 | | | **6,391** | $9,311,773 |
| Non-Benzodiazepine sleep aids (e.g., Ambien and Lunesta) | Y | 4,496 | 15 | | | | **4,511** | $2,917,465 |
| Oxycodone (e.g., Oxycontin and Percodan) | Y | 54,183 | 1,974 | 440 | 235 | 5 | **56,837** | $91,681,281 |
| Tramadol (e.g., Ultram and Ultracet) | N | 4,346 | 134 | 33 | 14 | | **4,527** | $1,037,423 |
| **Total** | | **181,823** | **5,927** | **1,214** | **600** | **10** | **189,574** | **$147,948,251** |

Sources: GAO and DEA.

Notes: The totals do not necessarily represent unique beneficiaries. A single beneficiary could have been prescribed more than one class of drug by more than one prescriber. The number of unique beneficiaries represented in this table is 170,029. The maximum number of prescribers from which a beneficiary received 1 of the 14 classes of prescription drugs was 87. The total beneficiary counts for oxycodone and hydrocodone represent 2.8 percent and 1.8 percent of all beneficiaries receiving that class of drug, respectively.

## Examples of Doctor Shopping in Medicare Part D

We obtained additional information on 10 of the Medicare Part D beneficiaries that showed indications of doctor shopping. In each of the 10 cases, we found evidence that the beneficiary was acquiring highly abused drugs through doctor shopping. We also found that in each example physicians were not aware that their patients were receiving drugs prescribed by other prescribers. DEA's definition of doctor shopping specifies an individual receiving more of a drug than intended by any single physician. In several examples physicians stated that they would not have prescribed the drugs if they were aware that the patient was receiving the same class of drugs from other sources. Table 3 highlights 3 of the 10 examples of doctor shopping for prescription drugs, including controlled substances, in the Medicare Part D program. We referred

these beneficiaries to the Medicare Part D fraud contractor, as appropriate, for further investigation.[9]

**Table 3: Examples of Doctor Shopping of Prescription Drugs in Medicare Part D**

| Example | State | Class of prescription drug(s) | Case details |
|---|---|---|---|
| 1 | CA | Fentanyl | • The beneficiary received prescriptions for a total of 1,397 fentanyl patches and pills (a 1,758-day supply) from 21 different prescribers in 2008.<br>• One physician who treated the beneficiary prescribed fentanyl for lower back pain. The beneficiary did not inform the physician that he was seeing other doctors. The physician stated that he would not have prescribed any controlled substances had he known they were being prescribed by other doctors.<br>• Another physician who treated the beneficiary from March 2008 through August 2008 stated that the beneficiary did not disclose that he was seeing other doctors and that she would not have prescribed any controlled substances had she known they were being prescribed by other doctors. In August 2008, the physician received an alert letter[8] from the state prescription drug monitoring program (PDMP) informing her that within a 4-month period the beneficiary had received 33 prescriptions for controlled substances from 10 different prescribers. After the PDMP alerted the physician of these multiple prescribers, the physician informed the beneficiary that she would no longer treat him as a patient. |

[9] CMS guidance directs Part D plans to refer cases of potential fraud directly to the Medicare Part D fraud contractor.

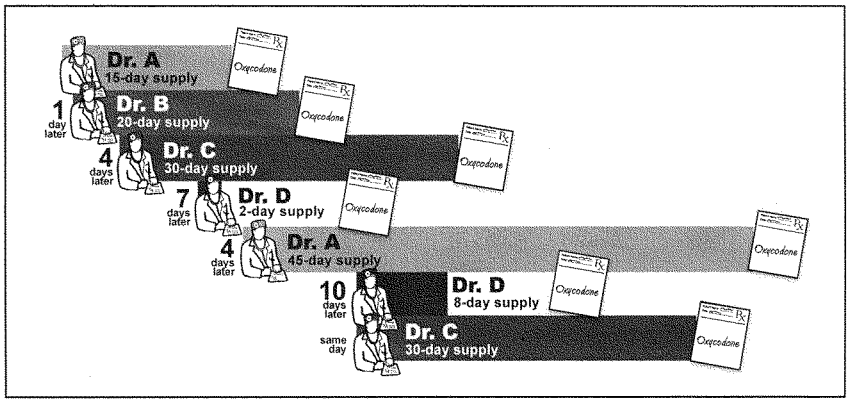
| Example | State | Class of prescription drug(s) | Case details |
|---|---|---|---|
| 2 | GA | Oxycodone | • The beneficiary received prescriptions for a total of 3,655 oxycodone pills (a 1,679-day supply) from 58 different prescribers in 2008. The beneficiary received a prescription for at least 1 of the 14 selected drugs from at least 66 different prescribers, and she filled her prescriptions at 45 different pharmacies in 2008.<br>• A pharmacy discovered that the beneficiary was forging a prescription from a physician. The pharmacy has noted in its system that its store and other pharmacies in the chain should refuse to fill controlled substances prescriptions for this beneficiary.<br>• Another pharmacy refused to fill a prescription for the beneficiary, after believing that the beneficiary tried to fill a forged prescription at the store. The beneficiary has not returned to the store since that refusal.<br>• A physician who frequently treated the beneficiary was repeatedly asked for early refills of Oxycontin prescriptions. After the physician would no longer prescribe Oxycontin, the beneficiary's medical visits to him ceased. The beneficiary did not inform the physician about seeing other physicians. The physician would not have prescribed any controlled substances had he known they were being prescribed by other physicians.<br>• Another physician stated that he was suspicious of the beneficiary's need for the drugs because (1) the beneficiary stated a desire for Oxycontin because of an allergy to other drugs and (2) the beneficiary refused to see a specialist despite his repeated directions. The beneficiary quit seeing the physician after the physician refused to prescribe any more narcotics. The physician was not aware of any attempted forgeries, but stated that he would not be surprised because it is easy to forge prescriptions in Georgia. The physician stated that Georgia has no requirements that prescriptions be written on any type of special security paper and that an individual can simply print or copy a prescription at home using a personal computer and regular computer paper. |
| 3 | TX | Hydrocodone | • The beneficiary received prescriptions for a total of 4,574 hydrocodone pills (a 994-day supply) from 25 different prescribers in 2008.<br>• A previous physician stated that the beneficiary was obligated to inform him about receiving other prescriptions for controlled substances. The physician stated that he did not know that other physicians were prescribing narcotics to the beneficiary. The physician stated that it was medically unnecessary, and possibly dangerous, to consume the amount of narcotics obtained by the beneficiary. Had he been informed that the beneficiary was receiving narcotics from other doctors, the physician would have ceased prescribing the drugs. |

Source: GAO.

[a]Prescribers can receive alert letters from state PDMPs and from Part D plan sponsors.

Figure 1 illustrates the doctor shopping activity from example 2. This beneficiary received a 150-day supply of oxycodone in just 27 days by obtaining seven prescriptions from four different prescribers.

**Figure 1: Medicare Part D Beneficiary Visits Four Doctors to Obtain Oxycodone**




Source: GAO analysis of Medicare Part D claims data for calendar year 2008.

## Systems Are in Place to Identify Inappropriate Drug Use, but Measures to Stop the Activity Are Limited

CMS requires Part D plans to perform retrospective drug utilization review (DUR) analysis to identify prior inappropriate or unnecessary medication use and provide education, such as alert letters, to the prescribers involved. By analyzing historical prescription claims data, the drug plans can identify individuals who are likely obtaining excessive amounts of highly abused drugs or potentially seeking such drugs from multiple medical practitioners. However, according to CMS Part D program officials, federal law does not authorize Part D plans to restrict the access of these individuals, leaving little recourse for preventing known doctor shoppers from obtaining hydrocodone, oxycodone, and other highly abused drugs.

Officials from the Part D plan sponsors we interviewed stated that controls in place in the Medicaid program and in some private sector plans could be used to better restrict the dispensing of abused drugs to individuals identified as doctor shoppers through detecting a pattern of abuse during retrospective analysis. Such programs employ a restricted

recipient program, or "lock-in" program, where prescription drug plans restrict beneficiaries who have been identified as drug abusers to one prescriber, one pharmacy, or both for receiving prescriptions. However, as mentioned, CMS Part D program officials' interpretation of federal law prevents such a program from being implemented.

Further, effective retrospective DURs require prescription drug plans to be able to share information about individuals identified as doctor shoppers with other Part D plans, as appropriate. Even if a restricted recipient program were implemented, according to CMS officials, Medicare Part D plan sponsors are not allowed to share beneficiary information with other plans. As a result, a Medicare Part D plan sponsor cannot forewarn another Medicare Part D plan sponsor when an identified doctor shopper has left its plan and enrolled in another. Because Medicare Part D beneficiaries can change prescription drug plans on at least a yearly basis, beneficiaries may be able to switch plans and continue their doctor shopping activity. Thus, to prevent known doctor shoppers from circumventing a restricted recipient program, a mechanism would also need to be established that allows CMS or its fraud contractor to inform the new plan of the doctor shopping activities of the beneficiary. Without such notification, beneficiaries will be able to bypass a restricted recipient program merely by switching prescription drug plans.

## Recommendations for Executive Action

In our report, we recommended that the Administrator of CMS should review our findings, evaluate the existing DUR program, and consider additional steps, such as a restricted recipient program for Medicare Part D that would limit identified doctor shoppers to one prescriber, one pharmacy, or both for receiving prescriptions. We stated that CMS should consider the experiences from Medicaid and private sector use of such restricted recipient programs, including weighing the potential costs and benefits of instituting the control. We also stated that along with a restricted recipient program, CMS should consider facilitating the sharing of information on identified doctor shoppers among the Part D drug plan sponsors so that those beneficiaries cannot circumvent the program by switching prescription drug plans. Finally, we stated that in considering such controls, CMS should seek congressional authority, as appropriate.

## CMS Comments and Our Evaluation

In response to a draft of our report, CMS agreed with our overall recommendation to improve efforts to curb overutilization in Part D, but disagreed that a restricted recipient program is necessarily the appropriate control for the Part D program. CMS also stated that it is

undertaking an additional evaluation of data on potential overutilization to identify potential solutions and that it will issue program guidance to Part D sponsors on any best practices and develop an internal monitoring strategy. We support CMS looking into both enhanced point-of-sale and retrospective controls and related actions to address overutilization and questionable access to specific drugs. We believe that a restricted recipient program should be part of CMS's assessment. It can be used for known abusers identified by retrospective DURs while not jeopardizing legitimate patient access to care.

CMS also stated that GAO provided no evidence that a restricted recipient program would be more effective than existing DUR requirements. Our intent was not to prescribe a restricted recipient program as the only solution, but instead for CMS to consider utilizing it along with other existing controls. As previously discussed, Part D plan sponsor officials we interviewed stated that a restricted recipient program could better restrict the dispensing of abused drugs. CMS also provided a written statement to this Subcommittee in 2009 asserting that a restricted recipient program, or "lock-in" program, is a proven mechanism in the Medicaid program to minimize misuse.[10] Thus, we continue to believe a restricted recipient program warrants further consideration.

Chairman Carper, Ranking Member Brown, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

## GAO Contact

For further information regarding this testimony, please contact me at (202) 512-6722 or kutzg@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement.

[10] *A Prescription for Waste: Controlled Substance Abuse in Medicaid, Before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security*, 111th Cong. (2009) (posthearing Questions for the Record Submitted to Penny Thompson, Deputy Director, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, from Senator Tom Carper).

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**Testimony of**
**Jonathan Blum**
**Deputy Administrator and Director, Center for Medicare**
**Centers for Medicare & Medicaid Services**
**On**
**"Cost of Prescription Drug Abuse in the Medicare Part D Program"**
**October 4, 2011**

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

The Administration is committed to reducing prescription drug abuse, as well as reducing waste, fraud, and abuse in Federal programs. Complementing those efforts, CMS is protecting our health care programs from waste, fraud, and abuse through new programs and technologies, such as enhanced Drug Utilization Review (DUR) procedures, increased use of health information technology (HIT), and improved collaboration between Medicare Part D stakeholders. We strongly believe that paying for prescription drugs that are not medically necessary is unacceptable and CMS is working aggressively to reduce abusive or fraudulent uses of the Part D benefit.

Prescription drug abuse is the nation's fastest-growing drug problem, and the Centers for Disease Control and Prevention has classified prescription drug abuse as an epidemic. Prescription medications have great potential for relieving suffering as well as great potential for abuse. For example, acute medical pain treatment for cancer patients would be impossible without prescription opioids; at the same time, opiate overdoses, once almost always due to heroin use, are now increasingly due to abuse of prescription painkillers.[1] These realities demand action, but we must approach any policy response thoughtfully, acknowledging that the policy must balance

[1] *Unintentional Drug Poisoning in the United States,* National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, July 2010.

our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use.

On April 25, 2011, President Obama outlined an action plan to reduce prescription abuse, titled "Epidemic: Responding to America's Prescription Drug Abuse Crisis."[2] A dramatic increase in prescription opioid use has occurred in recent years. From 1997 to 2007, the milligram per person use of prescription opioids in the U.S. increased from 74 milligrams to 369 milligrams, an increase of 402 percent.[3] In addition, in 2000, retail pharmacies dispensed 174 million prescriptions for opioids; by 2009, 257 million prescriptions were dispensed, an increase of 48 percent.[4] The Medicare program has felt this increase as well. In 2007, Part D sponsors provided nearly 46 million opiate prescriptions; by 2010, Part D sponsors provided nearly 57 million opiate prescriptions, an increase of 24 percent. As frequently abused drugs such as hydrocodone and oxycodone become more commonly prescribed, the likelihood that Medicare beneficiaries could abuse those drugs increases. As this crisis grows in size and scope, CMS is investigating the potential problem of Medicare beneficiaries obtaining frequently abused drugs through fraudulent means and determining the best policy to discourage abuse.

CMS appreciates the thoughtful work of this Subcommittee and the Government Accountability Office (GAO) who have provided information and recommendations to help CMS address this serious health problem.[5] Based on the information the GAO provided, CMS is undertaking an additional evaluation of our Medicare Drug Integrity Contractor's (MEDIC) data on potential prescription drug overutilization to identify policy solutions. Further, CMS issued program guidance to Part D sponsors on September 28, 2011 soliciting comments on how the Medicare Part D program can successfully exert control over payment for inappropriate overutilization of drugs. CMS is also helping Part D sponsors to use the wide variety of tools currently available

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[2] http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf

[3] Manchikanti L, Fellow B, Ailinani H, Pampati V. Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten-Year Perspective. *Pain Physician.* 13:401-435. 2010.

[4] Based on data from SDI, Vector One: National. Years 2000-2009. Extracted June 2010. Available at http://www.fda.downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM217510.pdf

[5] GAO, *Medicare Part D: Instance of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, D.C.: October 4, 2011). This GAO report found indications that doctor shopping could be occurring in the Medicare Part D program. The GAO recommended that CMS review GAO's findings, consider steps such as a restricted recipient program for identified doctor shoppers, and seek Congressional authority, as appropriate.

to them to ensure Medicare does not subsidize addiction to, or diversion of, prescription drugs. CMS is taking action to address the identified issues found in the GAO study.

**Background on Medicare Part D**

The Medicare Part D prescription drug benefit program was established under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108-173). Launched in 2006, Part D is designed to provide beneficiaries with drug coverage through private prescription drug plans. Unlike Parts A and B of the Medicare program, where Medicare acts as the payer and insurer and generally pays for items and services on a fee-for-service basis, the prescription drug benefit is based on a private market model. Under this model, CMS contracts with private entities—prescription drug plan (PDP) sponsors, Medicare Advantage (MA) organizations, as well as other types of Medicare health organizations—who then act as the payers and insurers for prescription drug benefits. These private entities are generally referred to as "Part D sponsors." CMS pays sponsors on a per enrollee basis, otherwise known as capitation, and the sponsors compete for enrollees based on premiums and coverage. In general, Medicare subsidizes about 75 percent of the average cost for basic coverage, with beneficiaries who choose to enroll in the voluntary Part D benefit paying the balance through monthly plan premiums.

Medicare beneficiaries who have limited income and resources may qualify for extra help to pay for prescription drugs costs. This low-income subsidy (LIS) Medicare program provides financial assistance for beneficiaries who have limited income and resources. Those who are eligible for the LIS program will get help paying for their monthly premium, yearly deductible, prescription coinsurance, and copayments, with no gap in coverage. Full benefit dual eligibles, Supplemental Security Income recipients with Medicare, and Medicare Savings Programs participants are automatically eligible for the LIS program. Other people almost always apply for the LIS program through the U.S. Social Security Administration (SSA) or through their State Medicaid programs.

*Medicare Drug Integrity Contractors (MEDICs)*

To discourage waste, fraud, and abuse in the Part D program, CMS contracts with private organizations, called Medicare Drug Integrity Contractors (MEDICs), to assist in the management of CMS' audit, oversight, and anti-fraud efforts in the Part D benefit. The main functions of the MEDICs include identifying and investigating potential Part D fraud and abuse, developing potential Part D fraud or abuse cases for referral to law enforcement agencies, acting as a liaison to law enforcement, collaborating with Part D sponsors on identification of potentially fraudulent schemes, and serving as an auditor of Part D sponsors' operations. MEDICs are also responsible for auditing the anti-waste, fraud, and abuse compliance programs detailed below that are a requirement for participation as a Part D sponsor in the Medicare program.

*Medicare Prescription Drug Benefit: Program Integrity Regulations*

On January 28, 2005, CMS published the final rule (CMS-4068-F) implementing the provisions of the Social Security Act that establish and regulate Medicare Part D. The regulation requires all Part D sponsors to have a comprehensive plan to detect, correct, and prevent waste, fraud, and abuse. The plan consists of written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards related to fraud and abuse. Sponsors must have a properly trained, effective compliance officer, and provisions for internal monitoring and auditing, as well as other requirements. These requirements help ensure that sponsors track and identify potential beneficiary or provider abuse. Chapter 9 of CMS' Prescription Drug Benefit Manual recommends that Part D sponsors generate and review reports, such as the following:

- **Payment Reports** which detail the amount paid by the Part D sponsor, the pharmacy provider, and the beneficiary, and a description of the drug provided, including dosage and amount. Part D sponsors use these reports to identify over- and under-payments, duplicate payments, timely payments, and pricing aberrances, and, also, to help verify correct pricing.
- **Drug Utilization Reports** which identify the number of prescriptions filled by a particular enrollee, and in particular numbers for suspect classes of drugs such as narcotics to identify possible therapeutic abuse or illegal activity by an enrollee.

Enrollees with an abnormal number of prescriptions or prescription patterns for certain drugs can be identified in reports and the enrollee and their prescribing providers should be contacted and explanations for use should be received by the Part D plan sponsor.

- **Prescribing Patterns by Physician Reports** which identify the number of prescriptions written by a particular provider and typically focus on a class or particular type of drug such as narcotics. Part D sponsors generate these reports to identify possible prescriber, provider, or pharmacy fraud.
- **Geographic Zip Reports** which identify possible doctor shopping schemes or script mills by comparing the geographic location (zip code) of the patient to the location of the provider that wrote the prescription, and should also include the location of the dispensing pharmacy. These reports generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (i.e., 30 miles). "Normal distance" should take into account where the beneficiary resides (i.e., beneficiaries in rural areas would typically have longer trips to a doctor or pharmacy than beneficiaries living in urban areas).

**Medicare Prescription Drug Benefit Program Integrity Activities**

To combat prescription drug waste, fraud, and abuse more effectively, CMS evaluates Part D sponsors' operations to ensure that they are compliant with the regulations detailed above, as well as aware of the recommendations in the Prescription Drug Benefit Manual. CMS also develops new methods and technologies designed to get ahead of people who would abuse the Part D program and identify their patterns of behavior early. CMS takes a variety of specific actions to identify, stop, and prevent drug abuse, which are detailed below.

*Drug Utilization Review Reports*

As mentioned earlier, CMS believes that drug monitoring and drug utilization reviews are effective in preserving program integrity, promoting safety, providing quality care, and preventing prescription errors. Part D plan sponsors must have concurrent and retrospective DUR programs in place. Concurrent DUR programs ensure that a Part D sponsor performs a review of the prescribed drug therapy at point-of-sale. Retrospective DUR programs ensure that Part D plan sponsors conduct ongoing periodic examination of claims data, to identify patterns of

inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs. A concurrent DUR program must include the following checks each time a prescription is dispensed:

- Screening for potential drug therapy problems due to therapeutic duplication,
- Over-utilization and under-utilization,
- Incorrect drug dosage or duration of drug therapy, and
- Clinical abuse/misuse.

The DUR programs generally produce online edits to perform the checks listed above and/or reports to describe the data found through the reviews. These online edits and/or reports provide an excellent measurement tool to assess efforts to fix patient safety and provider prescribing issues. In addition, the DUR reports identify dollars saved by avoidance of problems, such as drug-drug interactions, drug-disease interactions, therapeutic duplication, and over-prescribing by providers.

Prescriptions undergo DUR-related analysis both before they are dispensed (concurrent DUR reports) and after they are dispensed (retrospective DUR reports). Concurrent DUR reports take place by automatically prescreening the prescription prior to its being approved and dispensed. The retrospective DUR program is a broader analysis of prescribing patterns and may focus on a specific provider or specific drug use in individual patients. The Part D sponsor could examine DUR-related analysis, claims data, and other records to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicare recipients. The Part D sponsors can also look for suspicious patterns associated with specific drugs or groups of drugs. This examination could involve pattern analysis, using predetermined standards of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies.

The GAO report provided an example of the DUR process preventing potential prescription drug abuse. Two physicians received alert letters from a Part D sponsor listing all of the medications that were dispensed to a beneficiary over a 9-month period. Both physicians no longer prescribed narcotics to the beneficiary after they became aware that the beneficiary saw multiple

doctors and obtained additional narcotics. Part D sponsors regularly send alert letters to providers when they identify, usually through retrospective DUR analysis, suspicious patterns of drug-seeking behavior. The GAO report also identified some cases where DUR procedures did not appear to work. CMS is working with Part D sponsors to implement best practices so that all sponsors become more effective at identifying and preventing fraud and abuse.

*Health Information Technology and Electronic Health Records*

The Obama Administration is supportive of information technology (IT) efforts and the use of IT to improve quality of care and clinical outcomes. CMS strongly supports Part D sponsors' anti-waste, fraud, and abuse measures and wants sponsors and providers to be aware that e-prescribing can reduce instances of unauthorized, improperly altered, and counterfeit prescriptions. Part D sponsors must establish and maintain an electronic prescription drug program that is consistent with the uniform e-prescribing standards adopted in the E-Prescribing and the Prescription Drug Program final rule (CMS-0011-F).

E-prescribing is an effective tool to detect and prevent fraud and abuse. For example, in the Medicare Part D program, an e-prescribing system could show the clinician the patient's real-time medication history across all providers. The e-prescribing tool may indicate if a prescription was filled, what the dosage was, who prescribed it and when. This data may indicate if the patient is doctor shopping for pain medications or other misused drugs. Hospital emergency department doctors appreciate e-prescribing for this reason, as they often struggle to identify what is an attempt to get medications fraudulently, versus what is a true medical complaint.

E-prescribing is a function of an electronic health record (EHR) being meaningfully used. An EHR with an e-prescribing function provides a more complete picture because it offers the service utilization history, diagnoses, lab results, and other data that can help clinicians determine the best course of treatment and if there is potential fraud or abuse involved. E-prescribing of controlled substances is under the purview of the Drug Enforcement Administration (DEA). CMS worked with the DEA on their proposed rulemaking and adjudicating the public comments. On March 31, 2010, DEA published an Interim Final Rule in

the Federal Register. This interim rule allows for the utilization of e-prescribing for controlled substances.

*Sharing Data to Fight Abuse*

The Affordable Care Act requires the centralization of certain claims data from Medicare, Medicaid and CHIP; the Department of Veterans Affairs; the Department of Defense; the Old-Age, Survivors, and Disability Insurance program; and the Indian Health Service. Sharing data makes it easier for agency and law enforcement officials to coordinate and identify criminals and prevent fraud on a system-wide basis. CMS is building the Integrated Data Repository (IDR), a data warehouse to integrate Medicare and Medicaid data so CMS and our partners can access data from a single source. The IDR provides a comprehensive view of Medicare and Medicaid data including claims, beneficiary, and drug information. The IDR provides greater information sharing, broader and easier access to data, enhanced data integration, and increased security and privacy of data, while strengthening our analytical capabilities. The IDR makes fraud prevention and detection efforts more effective by eliminating duplicative efforts to identify and prevent waste, fraud, and abuse by agency and law enforcement officials.

The IDR is currently populated with five years of historical Medicare Parts A, B, and D paid claims, and CMS is actively inputting pre-payment claims data. This additional data may allow us to analyze previously undetected indicators of aberrant activity throughout the claims process. Along with the IDR, the One Program Integrity (PI) web-based portal shares data with our contractors and law enforcement. The portal provides a single access point to the data within the IDR, as well as analytic tools to review the data. CMS is working closely with law enforcement to provide training and support in the use of One PI for their needs.

In their report, the GAO recommended that CMS consider facilitating the sharing of information on identified doctor shoppers among the Part D drug plan sponsors. In CMS' recently issued guidance, we ask Part D sponsors to provide suggestions on what would be required in terms of resources to address excessive utilization. We will consider the GAO recommendations, along with the Part D sponsors' responses to our guidance, when exploring approaches that could help

Part D sponsors monitor beneficiary-level utilization reports and the beneficiaries' medication histories in order to identify unusual patterns of drug use.

*Collaborating with Part D Sponsors*

CMS shares the best practices Part D sponsors have cultivated to address prescription drug abuse in the Part D program. CMS is distributing the GAO report to Part D sponsors and issuing guidance to address the problem of beneficiaries abusing the Part D program. CMS regularly promotes best practices and information sharing among the Part D sponsors. For example, on August 2 and 3, 2011, CMS hosted the "Part C and Part D Program Integrity National Conference" with the following goals:

- Enhancing stakeholders' understanding of MEDICs' roles, responsibilities, and capabilities;
- Discussing best practices in preventing, deterring, and detecting waste, fraud, and abuse in the Part C and Part D programs; and
- Providing opportunities for collaboration between CMS, the MEDIC team, and other key stakeholders, including Part D sponsors, in combating waste, fraud, and abuse.

Part D sponsors such as Humana, Cigna, and CVS Caremark hosted panels dedicated to sharing best practices for preventing and reducing waste, fraud, and abuse. CMS and the MEDICs also host quarterly Part C and Part D Working Groups during which sponsors share their experiences with fraud schemes.

For example, one case discussed at the August workgroup showed the value of information sharing and collaboration between Part D sponsors, pharmacies, the Office of Inspector General (OIG) in the U.S. Department of Health and Human Services (HHS), and MEDICs. Teamwork between those groups led to an invoice and billing audit focused on the purchase and distribution of 40 high-dollar medications in six pharmacies across various States. This example showed how comparing claims and billing information across several purchasers could uncover fraudulent activities, even if the pharmacy's claims under one plan may not seem suspicious. CMS continues to bring these stakeholder communities together to conduct this important dialogue and strengthen our cooperative efforts across the Federal government and with the private sector.

CMS also sends letters to Part D sponsors about fraud schemes that are being perpetrated across the country. The letters summarize the schemes and explain how they are perpetrated, and encourage Part D sponsors to contact the appropriate MEDIC if they have encountered a similar scheme. This collaboration and information sharing allows CMS, Part D sponsors, and MEDICs to identify potential fraud and stop it before payment is made.

*Collaborating with the States*

States began to address the issue of prescription misuse and abuse more than 60 years ago by creating programs to monitor the dispensing of prescription drugs. Many States have established State Prescription Drug Monitoring Programs (PDMPs) and they are quite diverse in features.[6] The Substance Abuse and Mental Health Services Administration (SAMHSA) within HHS actively collaborates with the States and communities on the prevention and treatment of prescription drug abuse and specifically with States and the Department of Justice (DOJ) on implementing and improving PDMPs.

Beginning in fiscal year 2002, Congress appropriated funding to the DOJ to support the Harold Rogers Prescription Drug Monitoring Program (U.S. Department of Justice Appropriations Act; P.L. 107-77). The purpose of the program is to provide support to States in an effort to enhance regulatory agencies and health care providers' capacity to collect and analyze controlled substance prescription data. The program focuses on providing help for States that want to establish new or enhance existing programs.[7] Currently, 48 States have enacted legislation that authorizes PDMPs, and 36 States have operational PDMPs. PDMPs aim to detect and prevent the diversion and abuse of prescription drugs at the retail level by tracking controlled substances prescribed by authorized practitioners and dispensed by pharmacies. To improve State PDMPs, the Administration and CMS are evaluating the utility of State PDMPs for reducing Medicare and Medicaid fraud. This step is called for in President Obama's prescription drug abuse prevention action plan mentioned previously. To build on these State efforts, the President's Fiscal Year 2012 Budget Request includes a proposal to require States to monitor high-risk

[6] www.dpt.samhsa.gov/doc/NASPER%2009142007.doc
[7] www.dpt.samhsa.gov/doc/NASPER%2009142007.doc

billing activity in the Medicaid program to identify prescribing and utilization patterns that may indicate abuse or excessive utilization of certain prescription drugs. This proposal, if enacted, would ensure that all States have efforts in place to track high utilizers, and is estimated to save $3.45 billion over 10 years.

*Restricted Recipient Program*

CMS agrees with the GAO that we must address the problems of excessive drug use and doctor shopping in the Part D program. CMS is improving and increasing efforts to curb overutilization in Part D. We are implementing solutions that curb not only the Federal costs of excessive prescription drug use, but improve the overall health and safety of Medicare beneficiaries taking Part D prescription drugs. CMS is undertaking a thoughtful approach that balances the need to combat waste, fraud, and abuse and the need to ensure our beneficiaries have adequate access to medically necessary prescription drugs. We recognize that one potential way to address the problem of drug abuse is to restrict a beneficiary's access to only certain providers, as the GAO recommends to CMS to consider. However, this approach is problematic in the Part D program because the Part D program is statutorily designed such that beneficiaries choose their drug coverage from a market of multiple private prescription drug plans. This multipayer design creates some challenges for implementing a traditional restricted recipient program model. For example, individuals in the Part D LIS program are permitted to change plans at any time. Further, a restricted recipient program may also create a barrier between a beneficiary and needed care. CMS is unsure that a restricted recipient program would be more effective in preventing prescription drug abuse than the enhanced DUR procedures that CMS will be implementing to better prevent overutilization as well as clinical abuse and misuse. CMS supports the DUR requirements for Part D sponsors and is currently taking action to improve and enforce those requirements.

**Moving Forward**

CMS is strongly committed to protecting taxpayer dollars and ensuring the sound financial management of the Medicare program. As evidenced by my testimony today, CMS is improving its procedures to address the serious issues raised by the GAO. CMS is making progress in

overseeing the management of Part D, and remains committed to rooting out waste, fraud, and abuse in the Part D program.

CMS appreciates the Subcommittee and GAO's efforts and is seriously considering their recommendations. We are evaluating the GAO's data on questionable overutilization to develop and implement program changes that prevent beneficiary abuse of the Part D program. Those changes will supplement the DUR programs, while ensuring that the policy does not jeopardize a patient's access to care. In addition, CMS is undertaking an additional evaluation of MEDIC data and findings on overutilization and questionable access to certain covered Part D drugs. This evaluation will help us better understand the problem of overutilization of the Part D program and identify solutions tailored to the Part D program's unique design. CMS issued program guidance on new DUR requirements for Part D sponsors' consideration. CMS will consider those sponsors' comments, as well as our evaluations of the MEDIC and GAO's data, to identify best practices that address excessive prescription drug utilization in the Medicare Part D program. CMS will continue to work with Congress and this Subcommittee in protecting taxpayer dollars, beneficiary health, and the integrity of the Medicare program.


Statement of Louis Saccoccio
Executive Director
National Health Care Anti-Fraud Association

on

"Costs of Prescription Drug Abuse
in the Medicare Part D Program"

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

October 4, 2011


Testimony of:

Louis Saccoccio

Executive Director

National Health Care Anti-Fraud Association

Good morning, Chairman Carper, Ranking Member Brown and other distinguished Members of the Subcommittee. I am Louis Saccoccio, Executive Director of the National Health Care Anti-Fraud Association (NHCAA).

In October 2010, a Kansas physician named Stephen J. Schneider and his wife, Linda K. Schneider, a licensed practical nurse who also acted as the office manager of her husband's pain management clinic, were sentenced to 30 and 33 years in federal prison, respectively, for illegally distributing prescription pain medication to patients who overdosed. A four-year investigation of this "pill mill" uncovered evidence of extensive over-prescribing of controlled substances by Dr. Schneider. More than 100 drug overdoses requiring visits to Wichita-area emergency rooms and the deaths of at least 68 persons are linked to this case, as well as more than $4 million in Medicaid and private insurance claims. A 34-count indictment charged the Schneiders with health care fraud resulting in death, unlawfully dispensing controlled substances resulting in death, conspiracy, submitting false claims and money laundering. After an eight-week trial, the jury convicted Stephen Schneider on 19 counts and Linda Schneider on 32 counts, finding that the couple directly contributed to the deaths of several patients. Presiding U.S.


District Judge Monti L. Belot offered a bleak and succinct summary of the case calling it "an avoidable tragedy motivated by greed."[1]

As demonstrated by the Schneider case, prescription drug fraud is clearly a dangerous crime that can yield tragic results, including death, and I appreciate the opportunity to discuss the problem with you.

The National Health Care Anti-Fraud Association (NHCAA) was established in 1985 and is the leading national organization focused exclusively on combating health care fraud in all its forms. In my testimony today, I draw upon our organization's 25-plus years of experience focusing on the fraud issue. Health care fraud is a serious and costly problem that affects every patient and every taxpayer in America. The extent of financial losses due to health care fraud in the United States, while not entirely known, is estimated to range in the tens of billions of dollars or more. Extrapolating to apply those estimates to prescription drug spending suggests that billions of dollars may be lost to fraud annually in that area alone.

NHCAA is uncommon among associations in that we are a private-public partnership—our members comprise more than 85 of the nation's most prominent private health insurers, along with nearly 90 federal, state and local government law enforcement and regulatory agencies that have jurisdiction over health care fraud who participate in NHCAA as law enforcement liaisons.

[1] http://www.justice.gov/usao/ks/PressReleases/2010/oct/Oct20a.html


NHCAA's mission is straightforward: To protect and serve the public interest by increasing awareness and improving the detection, investigation, civil and criminal prosecution and prevention of health care fraud. The weight of this mission is the same regardless of whether a patient has private health care or prescription coverage as an individual or through an employer, or is covered by a public program such as Medicare, Medicaid, or TRICARE.

**Prescription Drug Fraud and Diversion**

NHCAA believes prescription drug fraud will continue to grow as a segment of the health care fraud problem based on three factors: 1) projected increases in spending for prescription drugs, 2) the expansion of health coverage envisioned by the Affordable Care Act, and 3) our experience and insight about health care fraud trends. National Health Expenditure Data reveal that in 2009, $250 billion dollars were spent on prescription drugs and by 2020, that spending is projected to more than double, reaching $513 billion.[2] It is notable that in 2014 an estimated 18 million Americans will become newly insured under Medicaid and through Exchange plans,[3] significantly influencing the 10.7 percent annual increase projected for prescription drug spending in that year alone.[4] Private and public insurers underwrite 78 percent of all spending on prescription drugs in the U.S., while consumers pay roughly just one-fifth of the cost.[5] This means insurers shoulder the bulk of exposure, risk and ultimately financial losses resulting from drug diversion and other prescription drug fraud schemes. It is notable that while year-to-year

[2] https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf
[3] http://www.cbo.gov/budget/factsheets/2011b/HealthInsuranceProvisions.pdf
[4] https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf, Table 11
[5] https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf, Table 11


increases in spending on prescription drugs is predicted, the Office of the Actuary within the Centers for Medicare and Medicaid Services (CMS) observes that these consistent increases are tempered somewhat by the anticipated loss of patent protection for many brand-name drugs.[6]

The financial losses due to health care fraud are compounded by instances of patient harm and sometimes death—unfortunate and insidious side effects of health care fraud. As shown by the Schneider case, the nature of prescription drug fraud, with its risks of overdoses and unsafe drug interactions, often leads to patient harm. The Office of National Drug Control Policy calls prescription drug abuse "the Nation's fastest-growing drug problem,"[7] and the Centers for Disease Control and Prevention classifies prescription drug abuse as an epidemic. The 2011 National Drug Threat Assessment report produced by the Department of Justice National Intelligence Center says that the abuse of controlled prescription drugs "constitutes a problem second only to the abuse of marijuana in scope and pervasiveness in the United States."[8] Of course, prescription drug abuse in itself does not necessarily indicate fraud. Abuse (resulting in overdoses and deaths) can certainly occur in situations where the prescription drugs were legitimately obtained for legitimate purposes. Nevertheless, fraud likely plays a role in many instances.

I had the opportunity to review the Government Accountability Office (GAO) report released publicly today, "Medicare Part D: Instances of Questionable Access to Prescription Drugs" and concur with many of the report's findings and recommendations. It is my understanding that the

[6] https://www.cms.gov/NationalHealthExpendData/downloads/proj2010.pdf, Forecast Summary
[7] http://www.whitehouse.gov/ondcp/prescription-drug-abuse
[8] http://www.justice.gov/ndic/pubs44/44849/44849p.pdf


GAO was requested to examine the drug-seeking behaviors of Medicare beneficiaries under the Part D program, focusing on those who obtain prescriptions for frequently abused drugs from multiple prescribers and then fill them at different pharmacies. This practice is frequently referred to as "doctor shopping" and represents one form of a broader prescription drug fraud scheme commonly referred to as drug diversion.

While doctor shopping by patients is the primary focus of the GAO report, NHCAA believes it is important to acknowledge that prescription drug fraud and diversion can take many forms and be extremely complex. For example, doctor shopping isn't always perpetrated by beneficiaries alone. Sometimes prescribing physicians, as well as pharmacists, are complicit or even drivers in the scheme. Patients also may be involved with the forging of prescriptions using prescription pads that have been stolen from legitimate physicians. Other schemes include unscrupulous physicians selling prescriptions to abusers or street dealers. Still another has perpetrators taking part in a criminal enterprise directed at reselling drugs in high volume (and for large profits) on the street. Regardless of the form drug diversion takes there is usually a common thread—the drugs are obtained and paid for by filing false insurance claims.

Significantly, the money lost to prescription drug fraud through payment of bogus pharmacy claims is only a part of the financial impact of this problem. In the process of obtaining a prescription, a patient typically will generate claims for related medical services. Insurers often find that they have paid not just for unnecessary medications but also for related emergency room visits, in-patient hospital stays, visits to physician offices and clinics, diagnostic testing and rehabilitation—all based on phantom injuries, illnesses and conditions feigned in order to obtain


a prescription. Then there are the additional costs associated with treating the addictions and overdoses arising from this behavior.

To offer some perspective, a 2007 study produced by the Coalition Against Insurance Fraud titled "Prescription for Peril," states that WellPoint, Inc. found that it "paid $41 in related medical claims for every $1 it paid in narcotic prescriptions for suspected doctor-shopper plan members."[9] That is an astonishing ratio and a significant waste of medical resources.

A survey conducted by the Substance Abuse and Mental Health Services Administration's Office of Applied Studies (SAMHSA/OAS) titled "The Drug Abuse Warning Network (DAWN) Report," finds: "The estimated number of emergency department (ED) visits involving nonmedical use of narcotic pain relievers rose from 144,644 in 2004 to 305,885 in 2008, an increase of 111 percent."[10] While we can't assume that all of those emergency room visits were the result of prescription drug fraud and abuse, we can reasonably assume that many of them were and therefore the cost of some of those visits constitute fraud losses.

**Private Insurer Programs**

NHCAA insurer members have acknowledged doctor shopping as a fraud trend for the last several years and anti-fraud efforts by our members regularly identify dangerous prescription drug abuse by patients. Most often, it's the insurer that is best able to connect the dots and

[9] http://www.insurancefraud.org/downloads/drugDiversion.pdf
[10] http://oas.samhsa.gov/2k10/dawn016/opioided.htm


identify overprescribing by physicians and prescription drug abuse by patients based on review of claims data. Many insurers use pharmacy benefit managers (PBMs) to carry out pharmacy functions, tasking them also with claims integrity. However, because a PBM's responsibility is typically limited to prescription claims it is often unable to detect the larger scheme that takes into account the related medical services.

In order to meet the growing threat of prescription drug fraud, particularly doctor shopping, several NHCAA members are devoting significantly increased resources to the problem, developing policies to quickly detect suspected doctor shopping and drug diversion, and implementing programs to stop it.

The Humana Example

National insurer Humana currently has 24 investigative anti-fraud staff members dedicated exclusively to prescription drug fraud, equating to nearly a quarter of its entire anti-fraud investigative manpower. By January 2012, Humana plans to increase its pharmacy anti-fraud team by an additional 10 to 12 investigators.

To try and identify possible doctor shopping the Humana special investigations unit (SIU) has developed what it calls the 333 report. It is a data mining report that searches across the company's nationwide claims data to identify insureds who over the last year have gone to three or more prescribing doctors, have filled prescriptions at three or more pharmacies and have received three or more prescriptions for schedule III or IV controlled substances. The SIU then


takes a closer look at the report results to try and identify members who appear as if they might be engaging in doctor shopping (it's not uncommon to find members who have seen 10+ doctors, received 10+ controlled substance prescriptions, and filled them at 10+ pharmacies). For Humana's commercial health insurance business they are able to look at the member's medical history and this will often help the investigator determine if the suspected fraud is being perpetrated by the member alone or if a prescriber or pharmacy is likely complicit. For example, Humana may see that several oxycodone prescriptions have been written by a physician and filled by the patient, but the member's record may show that no correlating medical claims were submitted. Or the member has received prescriptions for similar drugs from numerous doctors but has filled them all at the same pharmacy. In this case, the investigator might question if the pharmacist is turning a blind eye.

When an investigator is reasonably confident that doctor shopping is taking place Humana reaches out to the member to acknowledge the suspicion and offer help, including an offer to get the member into a treatment program. A letter is also sent to each prescribing physician making him/her aware that the patient has sought similar prescriptions from multiple doctors. The member receives a copy of each letter as well. Humana continues to monitor the member to see if behavior changes; for example, is there a switch to new doctors or are there suddenly visits to the emergency room based on ailments that might yield narcotic prescriptions?

When Humana determines that doctor shopping has occurred the member may be required to participate in a restricted recipient program or "lock-in" program whereby the member is limited to filling prescriptions at one pharmacy (a lock-in program could also require a patient to receive


prescriptions from just one doctor, but Humana's program only applies the restriction to pharmacy). Humana often will try to select a chain pharmacy as the single option so that the member can visit any location of that chain, thus maintaining convenience and a level of freedom. This lock-in program was put in place for Humana's commercial business two years ago and the results have been extremely positive. While Humana is not permitted to use a lock-in program for its Medicare Part D members, it does run 333 reports for Part D claims data and reports suspected doctor shopping to Health Integrity, the Medicare Drug Integrity Contractor (MEDIC).

Humana also does Medicaid business in the state of Florida, which is administered through Florida's Agency for Health Care Administration (AHCA). A year ago, Humana was granted permission by AHCA to establish a pharmacy lock-in program for Medicaid members who meet certain criteria indicating a high probability of prescription drug fraud. This program also utilizes a 333 report, albeit with slightly different criteria: the Medicaid beneficiary has filled three controlled substance prescriptions at three different pharmacies within a three month period. The agreement with AHCA allows Humana to lock-in a Medicaid enrollee for a one year period.

The WellPoint Example

Another national health insurer, WellPoint, Inc. has in place what it terms as a "pain management" program to address behavior that indicates possible doctor shopping. Like Humana, WellPoint had in place a 333 reporting program for its commercial business. Then a couple years ago, a new program was developed within WellPoint's State Sponsored Business


division called the Controlled Substance Utilization Monitoring (CSUM) program. The CSUM program was built as an automated program and was adopted for use by WellPoint's Medicare Part D, commercial and state sponsored business.

The parameters used by WellPoint's CSUM program to identify drug seekers include:

- CSUM will only look at members who are 18 years of age or older (no minors).
- There must have been 10 or more claims for controlled substances (narcotics, benzodiazepines, hypnotics) within a 90-day period.
- There must not be any claims for multiple sclerosis or oncology medication (otherwise the 10+ claims for controlled substances may be appropriate).
- Members may be re-identified every three months.

The list of members that results from running the CSUM program based on the above criteria will serve as the basis for monthly mailings to prescribing doctors, aimed at making them aware when one of their patients has been going to several providers seeking similar prescription drugs. Here is an example of the type of language used in the letter sent to physicians: "Prescription claims suggest this patient has filled 10 or more prescriptions for controlled substances within 3 months. Multiple providers may have prescribed these medications, as seen in the Patient Profile. Regular monitoring is needed to treat pain, ensure patient safety, and minimize opioid dependence. If you have not reviewed this patient's medications recently, please review them soon."


The Patient Profile, which is mailed together with the letter, lists the controlled substances filled during the three-month period and includes information like dispensing date, the drug name and strength, the quantity prescribed and the prescriber name.

In 2009, analysis was done of the CSUM program for WellPoint's Medicare Part D program. In total, 35,246 members met the intervention criteria. Of those, 17,151, or a remarkable 49%, decreased controlled substance utilization following the intervention, showing great promise for this program.

Between November 2010 and January 2011, 23,472 letters were sent to prescribing physicians under WellPoint's Medicare Part D business and 29,372 letters were sent involving members under WellPoint's commercial health insurance business (including their California state sponsored business). Utilization outcomes resulting from those mailings are not yet available.

As with Humana, WellPoint employs a restricted recipient program for its commercial business but is not authorized to lock-in any Medicare Part D members. Alanna Lavelle, WellPoint Director of Investigations and NHCAA Board member says that the restricted recipient program "has been a very effective program, has saved lives (addicts who have gone for assistance and thanked us), has saved millions in facility fees and is something we can use to better manage care."

WellPoint also applies other investigative and data mining techniques to try and detect prescription drug fraud. Some of these include utilizing geo-mapping technologies to identify


members who appear to be traveling long distances to obtain controlled substances from physicians or pharmacies, identifying prescribers who are writing prescriptions that fall outside their scope of specialty, and looking closely at large concentrations of claims coming from a single pharmacy.

Humana and WellPoint are just two examples of insurers that are using monitoring, notifications, and restricted recipient programs with success. With these promising models it is understandable that the GAO has recommended that CMS consider use of a restricted recipient program for Medicare Part D.

NHCAA is encouraged by the memorandum dated September 28th issued by CMS to Medicare Part D sponsors asking for their comments "on how the Medicare Part D program can more successfully exert control over payment for inappropriate overutilization of drugs." In addition to responding to the ideas outlined in the memo, NHCAA suspects that many Part D sponsors will suggest that a restricted recipient program be considered to curb drug-seeking behavior due to drug abuse or diversion.

**State Prescription Drug Monitoring Programs (PDMP)**

Thirty-seven states now have prescription drug monitoring programs (PDMP) which are electronic databases that collect data on dispensed substances in that state. Each PDMP is hosted by a state agency (regulatory, administrative or law enforcement) and each respective authorizing state law dictates who is eligible to receive program information.


NHCAA sees promise in state prescription drug monitoring programs for helping to identify fraud and saving finite health care resources. Even more important are the opportunities PDMPs offer to help ensure quality of care and patient safety, and even save lives. NHCAA recommends that state investments in these monitoring programs be incentivized whenever possible. Until every state has a PDMP in operation there will continue to be incentives for drug seekers to travel to states without a PDMP. NHCAA members have told us that their claims data often reveals that enrollees living in a state with an operational PDMP will travel to a state without a PDMP to get their prescription drugs. National insurer Humana tells us that they had often seen Kentucky-based members traveling to Florida for prescriptions, which until this year had no PDMP. Florida's new program went into effect on September 1.

Also, NHCAA recommends taking full advantage of interoperability opportunities among state prescription drug monitoring programs for states sharing boundaries with one another. For instance, in August 2011, Kentucky Governor Steve Beshear announced the formation of an interstate task force with border states Ohio, Tennessee, and West Virginia committed to targeting fraudulent or abusive prescription drug activities in those states. Governor Beshear explains: "This problem is destroying a lot of our families in Kentucky. We think together we can be a lot more effective."

The idea, espoused by PDMP advocates, of sharing information in order to be more effective in identifying prescription drug fraud and abuse resonates with NHCAA. Since our founding, NHCAA has been a facilitator of information sharing and our experience has taught us that


sharing investigative information is critical in combating health care fraud. The Schneider pill mill case discussed early in my testimony offers a perfect illustration of private-public partnership and information sharing. The investigative team in that case included private-sector investigators working with federal and state agency investigators.

**Emerging Prescription Drug Fraud Trends**

Health care fraud, whether it relates to prescription drugs or other aspects of our health care delivery system, is an exceptionally complex crime that manifests in countless ways. Fraud trends and schemes are constantly changing, developing, shifting, migrating and morphing and the task for anti-fraud professionals to stay ahead of the threat is daunting. Detecting health care fraud often requires the knowledge and application of clinical best practices, as well as knowledge of medical terminology and specialized coding systems, including CPT and CDT codes, DRGs, ICD-9 codes, and the forthcoming ICD-10 codes. Prescription drug fraud detection demands specialized knowledge of drug classification systems like the American Hospital Formulary Service (AHFS), National Drug Codes (NDC) and Generic Code Numbers (GCN).

Consider some of the following emerging trends in the prescription drug fraud arena:

- Drug seekers who are aware that their doctor shopping behaviors are being monitored are making several visits to emergency rooms in order to gain access to drugs.
- A new drug combination has emerged known as "Holy Trinity" which consists of opiate agonists, benzodiazepine, and muscle relaxants that produces a heroin-like high. Insurers are data-mining for that combination of drugs, whether prescribed together or as

individual prescriptions from three different physicians. This drug combination presents a high overdose risk; therefore, detecting abuse is a means to managing quality of care.

- Physician self–prescribing of schedule II controlled substances is seen as a growing problem.
- Some insurers are finding that diagnoses are being altered so that human growth hormone (HGH) will be a covered benefit, when in reality it is being used for body-building and youthfulness.
- Recurrent early refills, self-escalation of dosage without a documented change in medical condition, and a patient repeatedly claiming that medications were lost, stolen or spilled are often signs of drug diversion.
- Requesting brand name only prescription drugs may be an indicator of drug diversion. The "secondary market" or street value of brand name prescription drugs is significantly higher than generic drugs.

Hopefully, these few examples of emerging prescription drug fraud trends help provide a bit of perspective of how broad the array of fraud schemes is and the challenge investigative professionals face in trying to identify and then effectively address new fraud threats.

**Conclusion**

Prescription drug fraud is a serious issue with severe patient harm risks. Overdoses resulting from the abuse of prescription drugs are sadly commonplace and in many cases the drugs taken were obtained by filing false claims. In meeting their obligations to provide coverage and make


prompt claims payments, health insurers, including government programs and private health care payers, often pay for the unnecessary prescription drugs as well as the related medical services. Insurers are devoting increased attention and resources to this problem, devising new and innovative ways to detect possible drug diversion and taking appropriate steps to stop it, while also trying to help patients in need of intervention and treatment.

In the last two years CMS has demonstrated a commendable determination to ferret out fraud, waste and abuse in the Medicare, Medicaid and CHIP programs. The Center for Program Integrity of CMS has made it one of its goals to move from a pay and chase mode of fraud-fighting to one based on prepayment detection and prevention, focusing significantly on predictive modeling and data analytics. Great strides have already been made, including implementation of a predictive modeling program for Medicare fee-for-service that launched July 1. Increased emphasis on stopping prescription drug fraud and diversion in Medicare Part D program should be part of these efforts.

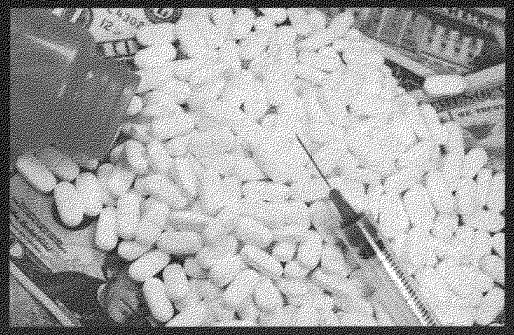
Today's GAO report findings certainly indicate that Part D is vulnerable to prescription drug abuse. The September 28 memo from CMS giving Medicare Part D sponsors the opportunity to comment on how to best address the problem of "inappropriate overutilization of drugs," will surely yield some good ideas worthy of consideration. In addition, some state Medicaid programs and private health insurers have implemented innovative programs, including overutilization reports, letter campaigns making prescribers aware of possible drug-seeking


behavior, and restricted recipient programs, that CMS may want to consider adopting for the Part D program.

Thank you for allowing me to speak to you today. I would be happy to answer any questions that you may have.

# IS THIS TAXPAYER FUNDED DRUG DEALING?

Case 1:
5,923 Oxycodone Pills



Street Value ($80/pill) $473,840

Case 2:
3,655 Oxycodone Pills

Street Value ($80/pill) $292,400

*Source GAO Report: GAO-11-699

GAO
Accountability * Integrity * Reliability
**United States Government Accountability Office**
**Washington, DC 20548**

November 18, 2011

The Honorable Tom Carper
Chairman
The Honorable Tom Coburn
Subcommittee on Federal Financial Management, Government Information, Federal Services and International Security
Committee on Homeland Security and Governmental Affairs
United States Senate

Subject: *Medicare: Posthearing Responses on October 4th, 2011, Hearing on Costs of Prescription Drug Abuse in the Medicare Part D Program.*

On October 4th, 2011, we testified before your subcommittee at a hearing entitled *Costs of Prescription Drug Abuse in the Medicare Part D Program.* This letter responds to your request that GAO provide answers to a number of post-hearing questions. The questions and our responses are provided in the enclosure. The responses are generally based on work associated with previously issued GAO products, which were conducted in accordance with generally accepted government auditing standards and investigative standards from the Council of the Inspectors General on Integrity and Efficiency. We did not obtain comments from Centers of Medicare & Medicaid Services or the Drug Enforcement Administration.

If you have any further questions or would like to discuss these responses, please call me on (202) 512-6722.

Gregory D. Kutz
Director
Forensic Audits and Investigative Services
Enclosure-1

**Post-Hearing Questions for the Record**
**Submitted to Gregory D. Kutz**
**From Senator Tom Coburn**

1. **In the past GAO identified 65,000 Medicaid beneficiaries that were visiting 6 or more doctors to obtain prescriptions for abused controlled substances. Under this "doctor shopping scheme", these individuals incurred $63 million in Medicaid costs for prescription drugs.[1] The Drug Enforcement Agency (DEA) supports Prescription Drug Monitoring Plans (PDMPs) and encourages their use by medical professionals.[2] The Medicare and Medicaid FAST Act I cosponsored with Sen. Carper supports the use of state-based Prescription Drug Monitoring Program (PDMP), an electronic reporting system of distribution of controlled substances to end users by each state. (40+ states already have PDMPs). The FAST Act encourages the establishment and use of a by giving states an increased share of recoveries that are attributable to data contained in an electronic PDMP as a financial incentive. The PDMP must be certified by the Attorney General to be in compliance with specific PDMP requirements.**
    - **Do you think this is a useful approach?**
    - **How can we encourage the use of PDMPs?**
    - **How can PDMPs advance program integrity within Medicare?**

Prescription drug monitoring programs (PDMP) can advance program integrity within Medicare by helping to prevent and detect the diversion and abuse of pharmaceutical controlled substances at the retail level. States that have implemented PDMPs have the capability to collect and analyze data on filled and paid prescriptions, including those from the Medicare Part D program, more efficiently than those without such programs, where the collection of prescription information can require a time-consuming manual review of pharmacy files. We have previously reported that states with PDMPs have realized benefits

[1] GAO, *Medicaid: Fraud and Abuse Related to Controlled Substances Identified in Selected States*, GAO-09-957, Sept. 9, 2009.
[2] Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration Before the Subcommittee on Federal Financial Management, Government Information, Federal Services, and International Security; Committee on Homeland Security and Governmental Affairs, United States Senate. "*A Prescription for Waste: Controlled Substance Abuse in Medicaid,* Sept. 20, 2009.

in their efforts to reduce drug diversion.[3] Further, according to the Department of Justice (DOJ), in states that have implemented PDMPs, doctor shopping has decreased. However, since determined doctor shoppers can travel to nearby states to bypass a PDMP, DOJ has also reported an increased need for information sharing between neighboring states to facilitate the interstate exchange of PDMP data.[4] Our review of indications of doctor shopping in the Medicare Part D program did not evaluate methods for encouraging the use of PDMPs.

2. **GAO says in its report that "CMS has systems in place to identify individuals with doctor shopping behavior; however, according to CMS policy officials, federal law may not authorize them to restrict these individuals' access to drugs, including highly abused drugs."**
    - **Can you please explain for the Committee if CMS does or does not have the necessary legal authority to restrict access?**

CMS Part D policy officials we spoke with stated that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) did not authorize CMS to establish restrictions on the dispensing of abused drugs, such as hydrocodone and oxycodone, to individuals identified as doctor shoppers. As such, Part D plan sponsors are prevented from implementing these controls on specific individuals to prevent doctor shopping.

3. **A recent HHS OIG report found that, for the year 2008, Part D sponsors received $6.5 billion in rebates, yet some sponsors *might* be allocating rebates across their plans in order to maximize reconciliation payments.[5] According to the same OIG report, most PBMs did not pass the full amount of rebates onto beneficiaries, and only 4 out of 258 sponsors provided rebates to beneficiaries at the point of sale. The OIG also found that sponsors underestimated rebates in 69% of their bids and 78% of Part D beneficiaries were enrolled in plans that underestimated rebates. These underestimations can lead to higher premiums for Part D beneficiaries and overpayments by CMS.**

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[3] GAO, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, GAO-02-634 (Washington, D.C.: May 17, 2002).
[4] DOJ, *National Prescription Drug Threat Assessment 2009 (NPDTA 09)* (Johnstown, Pa.: April 2009).
[5] Department of Health and Human Services, Office of the Inspector General, *Concerns with Rebates in the Medicare Part D Program*, Daniel R. Levinson, March, 2011, OEI-02-08-00050

- **Does GAO believe that this high percentage of underestimates may indicate some PBMs underestimate their rebates, while passing increased costs along to CMS and seniors?**
- **Does GAO have any concerns regarding the automatic shipping of large amounts of Part D drugs to beneficiaries via PBM mail order pharmacies that in some cases the plan sponsor themselves own?**
- **What else might you recommend Congress consider?**

We did not evaluate whether pharmacy benefit managers (PBMs) underestimate their rebates as part of this review and the effects of those underestimates. As such, we can make no recommendations on this matter.

**Post-Hearing Questions for the Record**
**Submitted to Gregory D. Kutz**
**From Senator Tom Carper**

**I understand that GAO faced some data limitations with the report released at our hearing. I also understand that this could have resulted in a potential understatement of the number of doctor shoppers. Can you detail any of data issues your team faced and this may have mean for the findings of the final report?**

Our analysis of Medicare Part D claims that found that 170,000 Medicare beneficiaries received prescriptions from five or more medical practitioners may be understated. First, our analysis only covered 14 classes of drugs, 12 of which are controlled substances, Thus, our analysis did not cover other classes of drugs which a Medicare beneficiary may have received prescriptions from five or more medical practitioners. In addition, the data submitted to CMS did not identify the prescriber for many Part D claims because of blank or invalid prescriber identification values. At least 5.8 percent of the prescription claims for the 14 classes of drugs contained blank or invalid prescriber identification values. These claims were not included in our analysis. Our threshold of visiting five or more practitioners also excludes those who successfully doctor shop by visiting fewer than five practitioners on a regular basis. For example, a Medicare beneficiary can regularly receive overlapping prescriptions of abused drugs by visiting as few as two practitioners. Beneficiaries who may have successfully doctor shopped by visiting fewer than five practitioners were not included in our analysis. Finally, some duplication may have occurred in our estimate of doctor shoppers because the Medicare Part D prescription claims identify prescribers using either their own identifier or a group practice identifier. However, our analysis showed that the extent of claims with group level identifiers was insignificant.

**Post-Hearing Questions for the Record**
**Submitted to the Honorable Mr. Jonathan Blum**
**Deputy Administrator and Director, Centers for Medicare and Medicaid Services**
**"Costs of Prescription Drug Abuse in the Medicare Part D Program"**
**October 4, 2011**

**From Senator Tom Carper**

**1. I understand that the Medicare Part D benefit is made up of two types of beneficiaries, those who are eligible because they are over 65 years of age and those who are eligible because of a disability or low income. I'm told that the GAO found that nearly 70% of those Part D beneficiaries suspected of doctor shopping were low income or disabled individuals. I also understand that these particular beneficiaries can change their plan every month. Some have argued that this is a tremendous administrative burden for CMS, while the GAO believes this could allow some beneficiaries to simply switch plans if they are found to be doctor shopping. Does CMS have any plans to revisit this particular policy? If so, what are the steps that are being taken and when can we expect a decision to be made?**

**Answer:** Medicare Part D is a voluntary prescription drug benefit available to all Medicare beneficiaries, which include those who are eligible due to age or disability status. CMS regulations now permit beneficiaries who receive the Part D low-income subsidy (LIS), including Medicare-Medicaid enrollees, to change plans at any time. This policy is intended to address the fact that these individuals are auto-enrolled into plans and the universe of plans that receive auto-enrollment--those with premiums at or below the LIS benchmark--changes each year. The current enrollment flexibility is designed to allow LIS beneficiaries to change plans during the course of the year if they decide the plan in which they were auto-enrolled does not suit their needs. CMS does not plan to revisit this policy at this time.

Instead, CMS plans to address overutilization of prescription drugs by beneficiaries within the Part D program by working with Part D plan sponsors to improve our controls at the beneficiary-level. CMS issued program guidance to Part D sponsors on September 28, 2011, soliciting comments on how the Medicare Part D program can successfully exert control over payment for inappropriate overutilization of drugs. Currently, the controls that are in place address overutilization though claim-level edits, edits that restrict access to particular drugs but may fail to curb a beneficiary's inappropriate access to a range of controlled substances. New, beneficiary-level (in contrast to claim-level) controls could be an option to help Part D sponsors take a broader perspective on utilization. These controls would establish clinical upper thresholds, create and monitor beneficiary-level utilization reports, assign clinical staff to review reports and medication histories to determine individual medical necessity, and deny any payment for claims determined to be medically unjustified. CMS is also encouraging Part D sponsors to use a wide variety of drug utilization management tools currently available to them to ensure Medicare does not subsidize abuse of, addiction to, or diversion of, prescription drugs.

**Post-Hearing Questions for the Record**
**Submitted to the Honorable Mr. Jonathan Blum**
**Deputy Administrator and Director, Centers for Medicare and Medicaid Services**
**"Costs of Prescription Drug Abuse in the Medicare Part D Program"**
**October 4, 2011**

**From Senator Tom Coburn**

1. **When Peter Budetti, head of Program Integrity was last before our Subcommittee, he was lauding CMS' adoption of predictive analytics in the payment system – the pre-pay examination of claims to reduce fraud and abuse. At that time system had been in place for 3 weeks, and Dr. Budetti could not tell me how many claims had been stopped before they were paid.**

**Since then, how many/what percentage claims have been identified as potentially fraudulent before they were paid? How many/what percentage investigated?**

**Answer:** CMS does not analyze or track individual claims, rather it analyzes claim lines and tracks system alerts at the provider level. CMS adopted the strategy of building alerts on the claim-line level to enable the system to perform more targeted and nuanced analyses of billing activity; tracking alerts at the provider level streamlines the investigation process by providing a comprehensive overview of all suspect provider activity.

As of September 21, 2011, zone program integrity contractors (ZPICs) reviewed 1,474 detailed alert summary records (ASRs). ASRs identify claims flagged for suspicious behavior, and consolidate the alerts based on several factors – either beneficiary, provider or service location. These reviews have resulted in a host of investigative activity, and all of the highest priority alerts have been reviewed and investigated. The investigative activity includes additional data analysis and beneficiary and provider or supplier interviews. The ZPICs developed 220 new investigations and supplemented 209 existing investigations from leads generated by the fraud prevention system (FPS) to date, and are continuing to work through the additional ASRs.

**How many claims/ what percentage was confirmed fraudulent before they were paid?**

**Answer:** Because fraud is a legal definition requiring, among other items, proof of intent, neither CMS nor the ZPICs can determine that a claim is fraudulent prior to a law enforcement investigation and judicial decision. CMS is currently using the Fraud Prevention System to identify aberrant and suspect behavior, and has taken administrative action against inappropriate billing in 155 instances. ZPIC analysts who suspect that a provider has committed fraud

forward the cases to the appropriate law enforcement entity, which most often is the HHS Office of Inspector General (OIG). There have been 9 referrals to law enforcement.

Recognizing the opportunity for more inter-Agency coordination, CMS is working closely with the OIG and the Federal Bureau of Investigation (FBI) leadership to streamline the referral and investigation process to ensure swift and decisive action against providers suspected of committing fraud. To date, CMS has held several separate multi-day training and collaboration sessions with both the FBI and the OIG. The Center for Program Integrity (CPI) is also hosting an OIG leadership detail dedicated to coordinating investigative efforts and administrative actions between CMS and the OIG.

**Please explain what additional training ZPICs have received for their new support role in predictive analytics.**

**Answer:** CMS has ensured that the ZPICs have been involved in training and system updates since before the FPS was fully implemented. Although CMS administers and manages the system, the program would not be successful without the coordinated efforts of the ZPIC investigators and analysts who are using the system to build and manage their caseloads.

Several weeks prior to implementing the FPS, CMS hosted a day-long workshop to acquaint ZPIC users with CMS's National Fraud Prevention Program, provide an introductory training on the Fraud Prevention System, and address ZPIC concerns and suggestions with the changes presented by the new system.

Each ZPIC is also participating in two rounds of an intensive three-day rotation in CMS's interim Command Center. Five ZPICs have already completed the first round, with the remainder of the first round scheduled before the end of 2011. During these training sessions, CPI leadership, ZPIC representatives, CMS contracting officer technical representatives (COTRs), predictive modeling experts, and clinicians discuss the FPS algorithms and ASRs in great detail. The sessions are designed to be mutually beneficial: ZPICs get the opportunity to work side-by-side with CMS leadership and FPS experts are able to learn the details of the new system and the models generating their investigative leads while CMS is able to solicit candid feedback and suggestions for process improvements, system enhancements, and model updates.

CMS also holds regular conference calls with ZPICs to discuss performance metrics, systems issues, and predictive models. After the initial system launch, ZPICs met with CMS twice each week to triage implementation issues; in response to a decrease in the number of time-sensitive issues raised by ZPICs, CMS now holds these meetings biweekly. ZPICs also participate in a monthly Vulnerabilities and Models Workgroup to collaborate on developing and refining FPS algorithms. ZPICs may also participate in real-time online trainings, of which 53 have been offered since the system was launched.

**Does CMS yet have a complete work plan for the enhancement and refinement of the predictive analytics program? Please explain. What specific metrics and milestones does CMS have in place to ensure the predictive analytics program is a success?**

**Answer:** Because the predictive modeling and system upgrades are interdependent, CMS developed integrated model governance and systems development plans.

The FPS is governed by three bodies: the Steering Committee, the Operations Board, and the Change Control Board. The Steering Committee is compromised of senior CPI leadership who will meet quarterly to set high-level priorities. The CPI Deputy Center Directors and Group Directors sit on the Operations Board, whose main directive is to review and approve model research and development. The Change Control Board is the technical arm of the governance process: CPI leadership, modelers, and system developers review and prioritize change requests approved by the Operations Board. CMS selects for production models that target high-fraud sectors, such as home health and durable medical equipment, without creating alerts on low-risk activity. CMS is working closely with ZPICs and law enforcement to develop and refine models to ensure that the FPS generates useful leads and data that contribute to the investigative process.

The FPS is on approximately a quarterly enhancement schedule, which provides sufficient time for models and enhancement requests to complete the development, testing, and governance processes.

2. **Related, if I recall correctly, during the same last hearing before our Subcommittee referenced above, Dr. Budetti said there was a new program integrity process in place for addressing suspected fraud in situations where a beneficiary has Medigap coverage. Currently, when a Medigap plan suspects fraud, the plan must still pay the bill.**
    - **Is CMS/CPI taking steps to ensure Medigap plans are warned of suspected fraud?**
    - **Has CMS/CPI contemplated how to ensure Medigap plans are not paying fraudulent claims, which drives up overall costs in the system?**
    - **Has CMS/CPI developed a feedback loop or other mechanism for Medigap plans to alert CMS/CPI in a timely manner before a claim is paid when they suspect fraud?**

**Answer:** CMS has developed a process for sharing information on providers subject to a Medicare payment suspension with Medigap plans. This is a new process, and CMS is carefully working through all legal and technical issues to ensure the information sharing is implemented correctly and efficiently. Please note that the Medigap plans' use of this information will be strictly voluntary – CMS has no authority to require these private payers to use this information and cannot direct any of their internal fraud related activities and policies. However, CMS is also currently in the process of creating a Fraud Prevention Partnership with the private sector in order to provide a collaborative forum to voluntarily share data, analytics, and best practices in a trusted environment for the purposes of detecting and preventing healthcare fraud.

3. **GAO says in its report that "CMS has systems in place to identify individuals with doctor shopping behavior; however, according to CMS policy officials, federal law may not authorize them to restrict these individuals' access to drugs, including highly abused drugs."**
    - **Can you please explain for the Committee if CMS does or does not have the necessary legal authority to restrict access?**

- **Does CMS believe additional legal authority in this area would be constructive?**

**Answer:** We do not think that a restricted recipient program would necessarily be an effective tool in the Part D program as compared to other options we are currently considering. We continue to believe that much of the overutilization in Part D is a result of inefficient or uncoordinated care. By improving drug utilization controls to identify at risk beneficiaries and having clinical staff at the Part D plan sponsor work with these beneficiaries and their health care providers, we can provide better healthcare without reducing access to the Part D benefit. The Part D plan sponsor is in the best position to identify therapeutic duplication from multiple prescribers and can work with the prescribers to find the most efficient treatment therapy.

As for the few beneficiaries that are abusing the Part D benefit, the beneficiary-level drug utilization controls and clinical intervention could be used to deter and identify the abusers. Once identified, Part D plan sponsors have the authority to restrict access through other drug utilization controls such as quantity limits and safety edits and can refer appropriate cases to the appropriate law enforcement authorities.

We believe that our existing authority provides CMS and Part D sponsors with the appropriate tools to control overutilization while maintaining physician and pharmacy access for beneficiaries with complex healthcare issues.

4. **There was media coverage earlier this year when the CEO of IBM alleged he offered the Administration free software program that he claimed would cut Medicare/Medicaid fraud by almost a trillion dollars. According to his version of the story, the Administration declined – twice. When my staff checked with CMS about why the gift was declined, CMS said that they did not have the legal ability to accept the gift. I am aware that agencies need express statutory authority to accept "gifts" from private sources. The rule comes under the scope of the "unlawful augmentation of appropriations" rubric, to prevent government agencies operating on private funds and gifts outside of congressional budget control. It is not uncommon for an agency or the Secretary of a Department to have specific statutory authority to accept gifts for certain programs, or even generally. However, several entities or representatives of the federal government do have the ability to legally accept gifts on behalf of the government.**
    - **In a time of increased billing to Medicare and increasingly complex fraud schemes, does CMS believe it would be helpful to have legal authority to accept free gifts of technology and related support services for the purposes of program integrity? Why or why not?**

**Answer:** CMS believes that the procurement process is the most appropriate strategy for acquiring the innovative technology and knowledgeably supporting an undertaking as technical and complex as predictive modeling and systems integration. Reviewing proposals allows CMS to gauge an entity's experience, technical skill, and familiarity with the existing CMS systems. Additionally, CMS would not be willing to implement technology into our claims processing system if CMS were not able to oversee and participate in the development process, as the

potential for major disruptions to CMS' existing fraud and claims processing work would be too great. Disruptions to claims processing could delay payment to legitimate providers and jeopardize beneficiary access to necessary and appropriate medical care.

**5. A recent HHS OIG report found that, for the year 2008, Part D sponsors received $6.5 billion in rebates, yet some sponsors *might* be allocating rebates across their plans in order to maximize reconciliation payments.[1] According to the same OIG report, most PBMs did not pass the full amount of rebates onto beneficiaries, and only 4 out of 258 sponsors provided rebates to beneficiaries at the point of sale. The OIG also found that sponsors underestimated rebates in 69% of their bids and 78% of Part D beneficiaries were enrolled in plans that underestimated rebates. These underestimations can lead to higher premiums for Part D beneficiaries and overpayments by CMS.**

- **What is CMS' opinion of the findings from the OIG?**
- **Does CMS believe that this high percentage of underestimates may indicate some PBMs underestimate their rebates, while passing increased costs along to CMS and seniors?**

**Answer:** As stated in the January 2005 final rule (70 *Federal Register* 4244), CMS has interpreted section 1860D-2(d)(1)(B) of the Act as requiring Part D sponsors to pass through some, but not necessarily all, rebates and price concessions to Part D beneficiaries at the point of sale. Section 1860D–2(d)(1)(B) of the Act specifically requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations...'' This interpretation is based on the assumption that Congress would not have used the phrase ''take into account'' if it intended to include all price concessions in the negotiated prices made available to Part D beneficiaries at the point of sale. This interpretation aligns with industry practice of determining certain rebates and price concessions after the point of sale purchase, which makes it difficult for Part D sponsors to always apply these amounts to the negotiated price at the point of sale.

Further, CMS believes that it is important to put the OIG findings in context. The OIG used data collected for the 2008 calendar year (CY). Since CY2008, CMS has taken several actions to ensure that Part D beneficiaries and the Federal Government receive the highest possible benefit from negotiated rebates. In regulations published on January 12, 2009 (74 *Federal Register* 1505-1515), CMS compelled (effective for CY2010) greater pharmacy benefit manager (PBM) transparency by requiring Part D sponsors to base beneficiary cost sharing and price reporting to CMS on the price ultimately received by the pharmacy or other dispensing provider, which is also known as the pass-through price. In addition, CMS has required more detailed reporting of direct and indirect renumeration (DIR) in order to better evaluate how DIR is allocated by sponsors to Part D.

When developing their Part D bids, Part D sponsors are required to include their best *estimate* of the rebates they expect to receive during the contract year. Given the variability in plan enrollments, drug utilization, and rebate contracts, it can be difficult for Part D sponsors to

[1] Department of Health and Human Services, Office of the Inspector General, *Concerns with Rebates in the Medicare Part D Program*, Daniel R. Levinson, March, 2011, OEI-02-08-00050

accurately estimate their rebates in the Part D bids. In addition, overestimating rebates in the Part D bids can result in a Part D sponsor receiving less revenue than necessary to provide the Part D benefit, putting the Part D sponsor at risk. As a result, Part D sponsors are generally conservative in their rebate estimates, underestimating their Part D rebates. However, we believe that the competitive nature of the Part D program provides a disincentive for Part D sponsors to significantly underestimate their rebates in the Part D bids as this would increase their beneficiary premiums and make their plans less competitive.

Section 6005 of the Affordable Care Act established new reporting requirements to promote transparency of financial transactions involving Part D sponsors and PBMs. One of these new reporting requirements is the PBM spread, which is the amount a sponsor pays the PBM and the amount the PBM pays retail and mail order pharmacies. Starting in CY2010, CMS required reporting of the PBM spread on the DIR report.

With respect to the issue of PBM ownership of mail order pharmacies, CMS notes that the issues of concern here have been documented in the commercial private employer group market, not in Medicare Part D. In the commercial employer group market, many employer sponsors actually require the use of mail order pharmacy to dispense maintenance medications used to treat chronic conditions. It is also commonplace for commercial employer group plans to significantly discount their member co-payments to incentivize use of mail-order pharmacy. By contrast, CMS does not have policies that promote mail-order over retail pharmacy. Indeed, in Medicare Part D the inclusion of mail-order pharmacies in Part D plan networks is optional and network mail-order pharmacies do not count toward meeting the Part D retail pharmacy access requirements. Moreover, Part D sponsors with mail-order pharmacies must permit their enrollees to receive benefits, which may include an extended supply of covered Part D drugs (for example, a 90-day supply), through a network retail pharmacy rather than a network mail-order pharmacy, if they so choose. Preliminary analysis of CY 2010 Part D claims indicates that the vast majority of prescriptions, or estimated days supply of Part D drugs, are provided by retail, not mail-order, pharmacies. In conclusion, CMS does not believe that PBM ownership of mail-order pharmacies has been detrimental to Medicare beneficiaries.

- **What is CMS' position regarding the automatic shipping of large amounts of Part D drugs to beneficiaries via PBM mail order pharmacies that in some cases the plan sponsor themselves own?**

**Answer:** While many Part D sponsors own mail order pharmacies, we believe that the ownership of mail order pharmacies by Part D sponsors is not a contributing factor to prescription drug abuse in Part D. Part D sponsors must apply the same drug utilization management controls for prescriptions filled by mail order pharmacies as they do for prescriptions filled by retail pharmacies. Part D sponsors cannot automatically enroll beneficiaries into a mail order program; the beneficiary must opt in to a mail order program for any prescription.

Although CMS does not have any restrictions against Part D sponsors establishing automatic shipments programs as part of their mail order benefit, we are concerned with the potential for large amounts of frequently abused drugs being shipped without beneficiary confirmation of the

clinical need. We are considering a number of actions to help mitigate this issue in the Part D program. Although we do not have the authority to require prescribers to write prescriptions in less than 90-day supply for mail order, we are considering sending educational notices through our Part D sponsors to prescribers encouraging them to write prescriptions in less than 90-day supply for mail order and less than 30-day in the community retail setting, if appropriate, for opioid prescriptions. We agree that the automatic shipping of frequently abused drugs creates the opportunity for both waste and abuse, and we will consider implementing this and other utilization controls in the Part D program.

**Post-Hearing Questions for the Record**
**Submitted to the Honorable Mr. Jonathan Blum**
**Deputy Administrator and Director, Centers for Medicare and Medicaid Services**
**"Costs of Prescription Drug Abuse in the Medicare Part D Program"**
**October 4, 2011**

**From Senator Mark Pryor**

1. **In your testimony you identified a number of integrity activities that are currently being used by CMS to combat waste, fraud and abuse. What is the current rate-of-return for these integrity activities?**

**Answer:** The historical return-on-investment (ROI) for the Health Care Fraud and Abuse Control (HCFAC) program, from 1997 through 2010, is $4.90 returned to every $1.00 expended. The 3-year average (2008-2010) ROI is $6.80 to $1.00, which is $1.90 (39 percent) higher than the historical average. In total, as of the end of FY 2010, the HCFAC program has returned more than $18 billion to the government since the inception of the program in 1997.

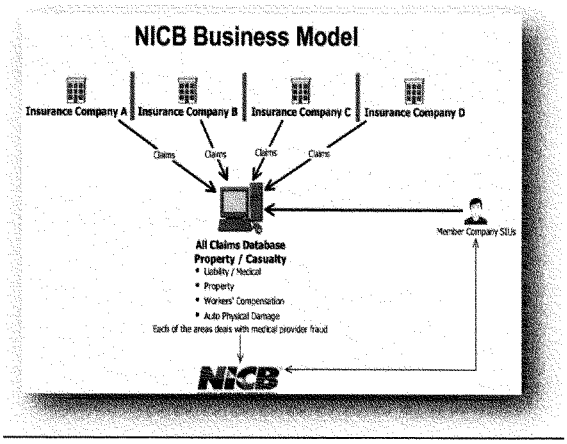
Specifically, the Medicare Integrity Program (MIP) averages an ROI of $14.00 to $1.00. MIP activities have yielded an average of almost $10 billion annually in recoveries, claims denials, and accounts receivable over the past decade.

2. **What steps is CMS taking to set up processes by which physicians can report individual cases of suspected abuse of Medicare Part D?**

**Answer:** CMS is working with our Part D sponsors to improve the detection of drug abuse and how they can act on cases of suspected abuse more effectively. Physicians can report individual cases of suspected abuse either directly to 1-800-Medicare or to their Medicare Advantage or Part D plans. Plans that receive this information can report it to their MEDIC. We are also working with other HHS organizations to help promote the use of prescription drug monitoring programs (PDMPs). PDMPs are statewide electronic databases that collect designated data on substances dispensed in the state. The PDMP is housed in a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession. CMS is investigating how to make Part D prescription data more readily available to PDMPs in order to help identify patterns of abusive behavior.

**Louis Saccoccio, National Health Care Anti-Fraud Association**

1. **My understanding is National Insurance Crime Bureau is an independent entity similar to your organization that is focused on preventing fraud and abuse in the property and casualty insurance industry. My staff have had conversations with their leadership and their model intrigues me. As I understand it, insurance companies submit their claims to the NICB's all claims database, and then NICB runs analysis to help root out fraud and abuse – following up as needed with law enforcement and insurance companies. Under this model, there is a one-way flow of claims information that protects the proprietary data of individual member companies.**
    - How is your association's model different from the NICB?
    - Would the health insurance industry benefit from a model like NICB where claims data is collected, aggregated, analyzed, and trends in fraud schemes, utilization, etc. are shared with law enforcement and other PI partners? What promises and challenges do you envision?




**Response:** The National Health Care Anti-Fraud Association (NHCAA) was founded in 1985 as a private-public partnership. We believe that government entities, tasked with fighting fraud and safeguarding our health system, and private insurers, responsible for protecting their beneficiaries and customers, can and should work cooperatively on this critical issue of mutual interest. Our experience has taught us that investigative information sharing works in combating health care fraud, and NHCAA dedicates itself to providing venues in which the sharing of relevant information can take place.

One of the primary tools NHCAA offers its members to facilitate investigative information sharing is our Special Investigation Resource and Intelligence System (SIRIS), a web-based searchable database. To be clear, SIRIS is not a claims database, but rather an investigations database where our members can document and share information about active health care fraud investigations, any one of which could involve dozens, hundreds or even thousands of individual health insurance claims.

NHCAA is very familiar with the National Insurance Crime Bureau (NICB). In fact, in 2008, NHCAA and NICB jointly launched (along with a third organization) the Consortium to Combat Medical Fraud. The Consortium aims to

create a more open and collaborative environment between different segments of the insurance industry to heighten the detection and prevention of health care fraud.

Our understanding is that through the database ISO ClaimSearch (owned by ISO, A Verisk Analytics Company), NICB has access to what is considered to be an all-claims database for property and casualty lines of insurance. It is important to understand, however, that claims in the property and casualty (P&C) arena differ from those in health care. For example, P&C claims are filed by the policy holders, while in health care nearly all claims are filed by the providers of health care. As a result, the focus of anti-fraud inquiries in P&C claims often is on the extent of the injury or disability claimed by the policy holder arising from an auto accident, workplace injury or other accident. There may be fraud on the part of the provider of medical services involved with the claim (e.g., in supporting the claimant's misrepresentation of the extent of the injury or disability), but the focus is on the overall nature of the claimant's extent of injury or disability. Additionally, the costs of the medical services involved in treating the injury or disability are all tied into a single claim, the claim filed by the policy holder. This single claim also may involve property damage as in the case of an auto accident. This contrasts with the manner in which claims are generated and processed in the health care arena.

The complexity and size of our nation's health care system present unique challenges not present in the P&C arena. Health care fraud is a crime that can manifest in countless ways. There are numerous variables at play. The sheer volume of health care claims makes fraud detection a challenge (Medicare alone pays 4.4 million claims per day to 1.5 million providers nationwide). Add to that the fact that fraud can conceivably be committed by anyone in the system, and that those committing fraud have the full range of medical conditions, treatments and patients on which to base false claims. Plus, detecting health care fraud often requires the knowledge and application of clinical best practices, as well as knowledge of medical terminology and specialized coding systems, including CPT and CDT codes, DRGs, ICD-9 codes, and the forthcoming ICD-10 codes. Moreover, in the process of seeking medical care a patient may see several providers, have numerous tests, examinations and procedures performed, and involve multiple prescriptions for drugs and durable medical equipment and supplies. Additionally, in some cases more than one payer may be involved, as with Medicare and Medicare supplemental policies where both public and private dollars are at stake.

Nevertheless, an all-claims database for health insurance could improve fraud detection. The vast majority of providers of medical services and products bill multiple payers, both private and public. For example, a health care provider may be billing Medicare, Medicaid, and several private health plans in which it is a network provider, and may also be billing other health plans as an out-of-network provider. However, when analyzing claims for potential fraud, each payer is limited to the claims it receives and adjudicates, which limits the effectiveness of anti-fraud claims analysis. The absence of a single repository of health care claims also demonstrates the importance of anti-fraud investigative information sharing among all payers of health care.

Pursuing an all-claims database for health insurance is not without its challenges. The volume of data involved is enormous as are the logistical challenges involved in compiling data from many disparate systems. Because personal medical information is involved, confidentiality issues also come into play. In addition, there are conceivably anti-trust and other business-related considerations when discussing the idea of compiling claims information from several private companies who are competitors in the marketplace. But regardless of the challenges, NHCAA supports further examination of an all-claims database for health insurance.

NHCAA is encouraged by the expanded data matching provisions provided for by the Affordable Care Act, mandating an expanded "Integrated Data Repository" at CMS that will incorporate data from all federal health care programs. The law stipulates that inclusion of Medicare data into the Integrated Data Repository "shall be a priority," and data from the other federal programs shall be included "as appropriate." As a result, this provision establishes the ability to create an "all claims" database, albeit limited to government programs, with the purpose of conducting law enforcement and oversight activities. This is a major step in the right direction for analyzing claims data in a way that will stem potential losses and identify emerging schemes at the earliest possible time.

Another intriguing development to consider is a new effort launched in September called the Health Care Cost Institute (HCCI). The Health Care Cost Institute (HCCI) was launched as "an independent, nonprofit entity committed to creating the nation's most comprehensive source of information on health care costs and utilization." Led by a Governing Board comprised of economists and researchers from across the country the HCCI mission is to promote independent research and analysis on the causes of rising health spending; to provide policy makers, consumers, and researchers with better, more transparent information on what is driving health care costs; and to help ensure that, over time, the nation is able to get greater value from its health spending. Four major health insurers (all NHCAA members)—Aetna, Humana, Kaiser Permanente and UnitedHealth Group—have agreed to provide HCCI information on what amounts to more than five billion medical claims, which will be compiled in a database for research purposes. To be clear, the HCCI project is focused on cost and utilization and not anti-fraud efforts. Nevertheless, it clearly establishes the feasibility of compiling the health care claims.

2. **Currently, the DEA has approximately 1.3 million registrants for the prescription or distribution of controlled substances. This data is available for confirmation by other registrants and various states and agencies, including CMS. DEA currently matches its database of controlled substances prescribers on a monthly basis against the death records maintained by SSA in order to reconcile these databases and curb healthcare fraud. According to testimony in 2009, DEA is working to improve this process.[1] However, conducting a DEA to SSA data match on a daily basis would prove beneficial. Further, while the DEA has some access to individual state's medical licensing information, the DEA could improve its access through the Federation of State Medical Board's national-level data.**

    - To strengthen controls over prescribing of controlled substances, the Medicare and Medicaid FAST Act requires that on a daily basis, DOJ shall update the database of the DEA of persons registered to manufacture, distribute, or dispense a controlled substance to reflect any changes in the information in the Death Master File of the Social Security Administration (SSA). Do you think this is a helpful requirement? What else might you recommend Congress consider?

**Response:** Timeliness is perhaps the most important factor in effectively thwarting health care fraud. In the health care fraud world, phantom providers represent one common scheme. They will set up shop and then begin brief, yet intense periods of claim filings, often submitting hundreds or thousands of claims. The majority of those claims will be auto-adjudicated by the payer and if no red flags are raised that indicate possible fraud, payments will be made quickly to meet prompt payment requirements. In many of these cases, by the time the insurer or law enforcement investigates, the phantom provider has stopped billing, has collected hundreds of thousands of dollars or more in payments on false claims, and has closed up shop, leaving no trace. A month's delay in receiving useful data that could alert investigators to suspected fraud can result in significant financial losses.

[1] IBID, Statement of Joseph T. Rannazzisi.

NHCAA constantly espouses the importance and value of sharing health care fraud scheme and trend information in a timely manner among health care payers, whether they are private insurers or public programs. NHCAA was founded as a private-public partnership in 1985 and remains dedicated to effective and timely information sharing as a means to protect the public interest. Identifying a fraud trend or scheme is useful, but waiting to share that information with other interested parties only enables the perpetrators to continue their nefarious crimes and perpetuates the damage they cause.

Any effort to improve the speed at which pertinent data is compiled and compared and the results shared with interested parties is worthwhile in our view. So, assuming the hurdles involved in establishing a daily data match between the DEA registrant list and the death records maintained by the Social Security Administration are surmountable, this requirement would be a positive step.

Along those lines, NHCAA also urges the examination of the security of sensitive information that can be used to commit health care fraud. This is something NHCAA addresses in an October 2010 white paper, "Combating Health Care Fraud in a Post-Reform World: Seven Guiding Principles for Policymakers."

For example, the National Provider Identifier (NPI), established under HIPAA, is a unique identification number for covered health care providers. NPIs are used in claim submissions, remittances, eligibility and enrollment determinations, referrals and authorizations. This powerful, unique identifier should be considered sensitive information, yet NPIs are readily available online to anyone with internet access (https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do). In short, NHCAA believes health care provider identifier numbers should be made more secure.

Submitted November 30, 2011 by:

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**Question for Mr. Saccoccio**

**In your testimony you cite a number of emerging trends you see in healthcare fraud in the private sector. Can you detail those further and describe how the federal government might help stay ahead of the curve on them as we try to rein in costs in the public sector?**

**Response:** In my testimony for the October 4th hearing before your Senate Subcommittee, I highlighted several emerging trends in the area of prescription drug fraud. Beyond the realm of prescription drugs, the National Health Care Anti-Fraud Association (NHCAA) tracks schemes and trends involving many aspects of health care fraud.

As with prescription drug fraud, the schemes and trends emerging from other areas of health care are constantly changing, developing, shifting, migrating and morphing. Geography also plays a prominent role. It is typical to see a fraud scheme established in one geographic region migrate to a different region once the insurance and law enforcement communities in the original region react to the scheme.

The geographic nature of health care fraud was the driving force behind the decision by the Health Care Fraud Prevention & Enforcement Action Team (HEAT) (an inter-agency effort between the Department of Justice and Department of Health & Human Services) to adopt a strike force model in selected metro areas across the country. Medicare Fraud Strike Forces are inter-agency teams of federal, state and local investigators designed to combat Medicare fraud through the use of Medicare data analysis techniques and an increased focus on community policing. The strike forces have been very successful and currently operate in Baton Rouge, Brooklyn, Detroit, Houston, Los Angeles, Miami-Dade, Tampa Bay, Dallas and Chicago.

While there is always a creative criminal out there trying to come up with something new, the broad categories of health care fraud remain somewhat static. Some of the more common health care fraud schemes include:

- Billing for services that were never rendered
- Billing for more expensive services or procedures than were actually provided or performed, commonly known as "upcoding"
- Performing medically unnecessary services solely for the purpose of generating insurance payments
- Misrepresenting non-covered treatments as medically necessary covered treatments for purposes of obtaining insurance payments
- Falsifying a patient's diagnosis to justify tests, surgeries or other procedures that aren't medically necessary
- Unbundling, which is billing each step of a procedure as if it were a separate procedure
- Accepting kickbacks for patient referrals
- Failing to provide necessary services pre-paid under a health plan

- Billing a patient more than the co-pay amount for services that were prepaid or paid in full by the benefit plan under the terms of a managed care contract

Based on NHCAA's experience and listening to what our members tell us, the areas of health care that seem to be indicating the greatest uptick in or susceptibility to fraud include:

- Organized criminal enterprises (could invoke several types of schemes but seem to depend significantly on medical identify theft—theft of patient and provider identities)
- Infusion Therapy
- Pain Management (office-based opioid therapy (OBOT))
- Pharmaceutical/Drug Diversion
- Durable Medical Equipment (involves significant medical identity theft)
- Behavioral health and community mental health centers
- Medical Identity Theft (Medical ID theft is often an element of a broader health care fraud scheme)
- Home Health Care
- Cardiology
- Ophthalmology
- Physical therapy and occupational therapy (medical necessity, spa vacations)
- Transportation (ambulatory)

As to how the federal government might "stay ahead of the curve" on fraud trends, NHCAA would submit that CMS, HHS-OIG and DOJ are very much on the right track. The investment and commitment being made to prepayment fraud detection using predictive analytics is a very positive development. The heightened attention given to the fraud problem as demonstrated by the Strike Forces also shows renewed commitment. Additionally, the increased funding and fraud-fighting tools enabled by the Affordable Care Act certainly bolster fraud-fighting efforts.

A reoccurring theme in any discussion we have about how best to combat health care fraud is investigative information sharing. Since our founding in 1985, NHCAA has remained a private-public partnership. We believe that government entities, tasked with fighting fraud and safeguarding our health system, and private insurers, responsible for protecting their beneficiaries and customers, can and should work cooperatively on this critical issue of mutual interest. Our experience has taught us that investigative information sharing works in combating health care fraud, and NHCAA provides venues in which the sharing of relevant information can take place.

Consistent with this focus on information sharing, we believe that as CMS identifies fraud schemes and trends as a result of its Fraud Prevention System which uses predictive modeling, that information should be shared with other payers who could be affected by the detected schemes. Health care fraud does not discriminate between types of medical coverage. The same schemes used to defraud Medicare migrate over to private insurers, and schemes perpetrated against private insurers make their way into government programs. Additionally, many private insurers are Medicare Parts C and D contractors or provide Medicaid coverage in the states, making clear the intrinsic connection between private and public interests. As a means to protecting our health care system and the millions of patients it serves, it just makes sense to share what we know about health care fraud.

The Department of Justice has developed guidelines for the operation of the Health Care Fraud & Abuse Control Program (HCFAC) established by HIPAA that provide a strong basis for information sharing. The "Statement of Principles for the Sharing of Health Care Fraud Information between the Department of Justice and Private Health Plans" recognizes the importance of a coordinated program, bringing together both the public and private sectors in the organized fight against health care fraud. Likewise, CMS has recognized the value of greater information sharing. During a September 22, 2010, Congressional subcommittee hearing, Peter Budetti, M.D., J.D., Deputy Administrator and Director of the Center for Program Integrity, stated: "Sharing information and performance metrics broadly and engaging internal and external stakeholders involves establishing new partnerships with government and private sector groups. Because the public and private sectors have common challenges in fighting fraud and keeping fraudulent providers at bay, it makes sense that we should join together in seeking common solutions."

NHCAA continues to work closely with the HHS-OIG, CMS, and DOJ to identify the barriers, both actual and perceived, to effective anti-fraud information sharing with the goal of increasing the effectiveness of this critical tool in the fight against health care fraud.

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