S. Hrg. 113–244

CURBING PRESCRIPTION DRUG ABUSE IN MEDICARE

HEARING

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

JUNE 24, 2013

Available via the World Wide Web: http://www.fdsys.gov/

Printed for the use of the
Committee on Homeland Security and Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE

82–571 PDF WASHINGTON : 2014

For sale by the Superintendent of Documents, U.S. Government Printing Office
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CURBING PRESCRIPTION DRUG ABUSE IN MEDICARE

MONDAY, JUNE 24, 2013

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 3:08 p.m., in room SD–342, Dirksen Senate Office Building, Hon. Thomas R. Carper, Chairman of the Committee, presiding.

Present: Senators Carper, Coburn, and Chiesa.

OPENING STATEMENT OF CHAIRMAN CARPER

Chairman CARPER. Well, a room as quiet as this one probably does not need me to call everyone to order, but this hearing will come to order, and I want to welcome our witnesses. I apologize for running a few minutes late, but thank you for being here and for your preparation and attendance today for an important hearing.

Our colleagues are coming in from across the country this afternoon, and we will be joined by a number of them as this hearing proceeds.

Today we are going to hear from several witnesses about the Medicare Prescription Drug Program and its vulnerability to waste, to fraud, and to abuse.

Medicare, as we all know, is a critical component of health care in our Nation, and the Prescription Drug Program, which we know as Part D, began about 7 years ago, in 2006. We are now in its seventh year. The overall reviews of the program have been generally positive, more than 31 million seniors participating. The lion's share of them like the program. However, Congress must ensure that the $60 billion a year program works effectively and efficiently. Unfortunately, Medicare, including Part D, is not as effective or efficient as it could or should be when it comes to preventing waste and fraud.

Each year, the Federal Government lists the estimates of overpayments, underpayments, undocumented expenditures, and other kinds of mistakes made by each agency. The total for fiscal year (FY) 2012 was more than $100 billion. Medicare has the largest reported share of that total at $44.3 billion, and the amount wasted in Medicare's Prescription Drug Program alone is approaching $1.6 billion.

In addition, health care is too often the focus of criminals who wish to take advantage of the system. Whether the care is provided through government programs or the private sector, attempts to

defraud the health care system are on the rise. There are estimates for Medicare fraud in the tens of billions of dollars.

We cannot afford to tolerate these levels of waste and fraud in our health care programs. As everyone in this room knows, we have faced record budget deficits in recent years, and while they are coming down, they are still way too large. Given the debt and deficit problems that our country faces and the tough work ahead of us as we attempt to address those challenges, we need to focus like a laser on the avoidable, expensive, and, frankly, unacceptable issues we will be discussing here today.

During a Subcommittee hearing that I chaired in the fall of 2011—and I might be mistaken, but I think Dr. Coburn was there as well. I am not positive. I think you were, because of your great interest. But the Government Accountability Office (GAO) that day testified that they identified about 170,000 beneficiaries who acquired the same class of frequently abused drugs, primarily hydrocodone and oxycodone, from five or more medical practitioners at a taxpayer cost of almost $150 million. In two egregious examples, individuals received prescriptions from 87 and 58 different medical practitioners. This followed a similar study by the GAO in 2009 showing the same problem in Medicaid.

This fraud technique, called "doctor shopping," involves recipients going to multiple doctors for the same type of drug. In these cases, beneficiaries are almost always either feeding an addiction or selling the drugs they do not use on the street. Drug dealers make the profits while the Federal Government foots the bill.

But the problem of prescription drug fraud is about more than just a loss of taxpayer dollars. It is also about the toll that drug abuse takes on people. It is of great concern that one out of seven high school seniors in America has abused, or is abusing, prescription drugs. In fact, more Americans abuse prescription drugs than the number who abuse cocaine, heroin, hallucinogens, Ecstasy, and inhalants combined.

The Department of—do we have a chart here anywhere?

The Department of Health and Human Services (HHS), specifically the Centers for Medicare & Medicaid Services (CMS), has established a set of oversight procedures to protect the Medicare Prescription Drug Program and its beneficiaries from fraud and waste. This is a team effort involving Medicare officials, law enforcement at the Federal, the State, and the local level, the Medicare prescription drug plans (PDPs), pharmacies and doctors, and the beneficiaries themselves. Unfortunately, based on today's testimony by the Health and Human Services Office of Inspector General (HHS OIG), there is still a lot more work to do.

On Thursday of last week, the Inspector General (IG) released a report detailing over 700 general care practitioners who had questionable Medicare Part D prescribing patterns. For example, while prescription drugs with a high abuse potential constitute on average only 2 percent of most general practitioners' prescriptions, they constituted 78 percent for one general practitioner identified in the report.

This physician prescribed a year's supply of three painkillers, such as morphine and codeine, for just one Medicare beneficiary.

Another general practitioner's prescriptions were filled at 872 pharmacies in 47 States, including Guam.

Today we will learn about an even more clear failure of oversight. The Inspector General is reporting that Medicare is paying for prescription drugs prescribed not by physicians or others authorized to prescribe those drugs, but by people with no authority to prescribe at all. Apparently, 400,000 prescriptions totaling some $31.6 million were prescribed by individuals who appear to be massage therapists, interpreters, music and art therapists, and contractors who perform health care-related home repairs. And you see the list[1] there to my left.

The most disturbing finding in the Inspector General's report is that 29,000 of the prescriptions were for controlled substances, including drugs with a high potential for abuse, such as oxycodone. One contractor alone wrote 79 prescriptions for commonly abused painkillers.

Obviously, these numbers and examples show clear indication of abuse and fraud. As a recovering Governor, I understand the unique challenges that come along with running a major program like Medicare. However, we simply have to do a better job in overseeing the Medicare Prescription Drug Program.

I will continue to work with Dr. Coburn and with our colleagues and the Administration to ensure that programs across the Federal Government are improving management functions, monitoring results, and finding ways to do more with less in almost everything that we do. A key part of these efforts will involve program managers sharpening their pencils and, in conjunction with our private sector partners, preventing expensive and harmful waste and fraud. We must use every tool available to make sure that our health care programs help those who need medications rather than feed drug addictions or fraudulent profiteering. By working together on this latest in a series of commonsense initiatives, we can take another important step forward in earning their trust once again.

And with that, let me turn to our Ranking Member, Dr. Coburn, for any comments he might like to make. Dr. Coburn, welcome.

OPENING STATEMENT OF SENATOR COBURN

Senator COBURN. Thank you, Senator Carper. Welcome to each of you.

This IG report is pretty revealing, and I am sitting here thinking about what we will be doing next year on the basis of the recommendations not being followed in the IG report, because that seems to be the case most often with CMS. And so my question is not is it happening. It is: What is wrong with the recommendations that the IG is making in this? It fits with common sense. And if we come back a year from now, Chairman Carper, and this stuff has not been done and the contractor is not either fired or made to do what they are supposed to do, what we ought to do is see about cleaning house everywhere at CMS. This is just another layer in a continuing saga of not applying common sense and OIG recommendations to fix problems.

[1] List referenced by Senator Carper appears in the Appendix on page 41.

And so I look forward to hearing the testimony. The problem is real. It is not just a problem of wasted dollars. It is wasted lives that Medicare is allowing through CMS, and the fact that people have identification in Medicare and we have a contractor that is not catching the fraud, not revealing the fraud, not prosecuting the fraud just says that we are wasting that contract money based on what we have seen in the IG report versus what the contractor has done.

So my hope is that we are not back here in a year, that we can say, "Way to go, CMS, you actually followed what the IG did, recommended," and they actually put it into action and we will not see this happening again.

Chairman CARPER. We have a new member on board. This is the first hearing he has joined us. He comes from the State of New Jersey. He is my neighbor across the Delaware River. Jeff, we are honored to have you join us here in the U.S. Senate and delighted that you have ended up on our Committee. Normally only the Chair and Ranking Member give an opening statement, but since this is a special day for you. And you come to it I think as the Attorney General of your State, if I am not mistaken. Is that correct?

Senator CHIESA. Yes, it is.

Chairman CARPER. If you would like to make just a brief statement, please feel free. We are happy to see you and happy to have you on our team.

OPENING STATEMENT OF SENATOR CHIESA

Senator CHIESA. Well, thank you so much for that warm welcome, Mr. Chairman. I would just say that we took a lot of steps in New Jersey because we recognize how catastrophic the prescription drug issue is.

I think the Chairman talked about the fact that we think about heroin and we think about cocaine as things that kill people, and we are realizing now that prescription drug abuse is killing more people than those drugs are. So while we live in a State that tells us that these drugs are safe, they are only safe if we use them exactly as we are supposed to and if the people that are giving us the drugs are doing it for the right reasons.

So I also look forward to this conversation today, a continuing conversation that is incredibly important to the safety of everybody who lives here.

Thank you, Mr. Chairman.

Chairman CARPER. Thank you very much. And, again, a warm welcome.

Our first witness is a witness whose name is probably frequently butchered, and I am going to try not to do it today, but is it "Rannazzisi"?

Mr. RANNAZZISI. That would be perfect.

Chairman CARPER. OK. I am not often perfect. Joseph T. Rannazzisi, Drug——

Senator COBURN. I second that.

Chairman CARPER. Pardon?

Senator COBURN. I second that.

Chairman CARPER. Dr. Coburn said he can second that. He sure can. [Laughter.]

Drug Enforcement Administration (DEA), Deputy Assistant Administrator of the Office of Diversion Control at the Drug Enforcement Administration. As the Deputy Assistant Administrator, he is responsible for overseeing and coordinating major diversion investigations, drafting and promulgating regulations, and working with the pharmaceutical industry, international governments, State governments and other Federal agencies, and with local law enforcement. He holds a B.S. degree in pharmacy from Butler University and a J.D. from the Detroit College of Law at Michigan State University. We are delighted to see you today. Thanks for joining us.

Jonathan Blum very nice to see you—Acting Principal Deputy Administrator and Director of the Center for Medicare at the Centers for Medicare & Medicaid Services. He is responsible for overseeing the regulations and payment of Medicare providers and plans, including the private plans that participate in the Medicare Prescription Drug Program. During the development of the Medicare prescription drug benefit, Mr. Blum was an adviser to the Senate Finance Committee working on prescription drugs and other Medicare policies. He was also a Medicare program analyst at the Office of Management and Budget (OMB). He has testified before this Committee before, as well as the Finance Committee before, and we welcome your appearance and testimony today.

I think I have to introduce the two OIG witnesses together, and I believe you are going to be splitting your testimony time. One is Gary Cantrell, Mr. Cantrell, nice to see you, and the other is Stuart Wright. We welcome both of you. They are from the Health and Human Services Office of Inspector General, where Mr. Cantrell serves as the Deputy Inspector General for Investigations. Mr. Cantrell has served in various leadership positions within the Office of Investigations where he advanced the office's use of data analysis in health care fraud detections. Mr. Cantrell has B.A.s in criminal justice from Georgia State and in computer and information science from the University of Maryland (UMD).

Mr. Wright is the Deputy Inspector General for Evaluations and Inspections. Mr. Wright joined the Office of Inspector General in 1987 and has held a variety of positions, including Chief of Medicare and Medicaid Branch and Director of the Program Evaluation Division, and is a graduate of the University of Rochester where he earned a B.S. in economics and political science and a master's in public policy. Thank you both for joining us today.

Finally, Alanna Lavelle from WellPoint is the last witness, Director of Special Investigations for WellPoint, a large health care company that also participates in the Medicare Prescription Drug Program. She joined WellPoint in 2004 after 24 months of service with the Federal Bureau of Investigations (FBI)—no, I am just kidding. [Laughter.]

Twenty five years of service with the FBI, including experience fighting health care fraud and bioterrorism. In addition to her duties at WellPoint, she also serves as the Chair of the National Health Care Anti-Fraud Association, which brings together the private and public sectors. Her resume suggests that she is eminently well qualified to testify, and we are grateful to you for being here today.

With that having been said, others of our panel are going to join us here throughout the afternoon. We start voting at 5:30. I expect we will be done by then. We appreciate your being here.

I am going to ask you to take about 5 minutes to summarize your testimony. If you want to go a little beyond that, that is OK. If you go way beyond that, it is not. So please proceed, Mr. Rannazzisi.

TESTIMONY OF JOSEPH T. RANNAZZISI,[1] DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE

Mr. RANNAZZISI. Good afternoon, Chairman Carper, Ranking Member Coburn, Senator Chiesa. On behalf of Administrator Michele Leonhart and the men and women of the Drug Enforcement Administration, thank you for the opportunity to appear today to discuss the epidemic of pharmaceutical controlled substance abuse and the diversion of pharmaceutical controlled substances.

The abuse of prescription drugs continues to plague the Nation at an alarming rate, crossing all age, gender, race, and socioeconomic boundaries. Studies show substantially high levels in the abuse of these drugs and the adverse consequences resulting from abuse. According to the most recent National Survey on Drug Use and Health (NSDUH), in 2011 there were approximately 6.1 million people over the age of 12 who used prescription-type psychotherapeutic drugs for non-medical reasons during the past month. The devastating effects of this statistic can be demonstrated by a report released in 2013 by the Drug Abuse Warning Network, which revealed a 153-percent increase in emergency room (ER) visits from 2004 to 2011 attributable to narcotic pain relievers. Oxycodone and hydrocodone were the two opiates most frequently implicated in these ER visits.

As these substances are increasingly diverted and abused, the number of pharmaceutical overdose deaths has correspondingly increased. A Centers for Disease Control (CDC) analysis revealed 38,329 people died from a drug overdose in the United States in 2010. Nearly 60 percent of the drug overdose deaths involved pharmaceuticals. Again, opioid analgesics, oxycodone, hydrocodone, and methadone were involved in about three of every four pharmaceutical overdose deaths. Oxycodone and hydrocodone, by the way, are the top two diverted drugs in the United States.

The diversion and abuse of pharmaceutical controlled substances is a problem that cannot be addressed through law enforcement action alone. A multidisciplinary approach is necessary to address the threat. The Office of National Drug Control Policy's 2011 Prescription Drug Abuse Prevention Plan has outlined a multipronged approach that includes education, prescription monitoring, disposal, and enforcement to comprehensively address the national epidemic. DEA plays an important role in education, disposal, and enforcement.

DEA participates in and hosts numerous education programs for registrants, health care providers, and community groups. In 2011,

[1] The prepared statement of Mr. Rannazzisi appears in the Appendix on page 43.

we began a program to educate health care professionals on the front lines of diversion, pharmacies and pharmacy techs, on diversion trends and their role in preventing diversion. These Pharmacy Diversion Awareness Conferences (PDACs), have been held in nine States thus far, providing continuing education to nearly 4,000 pharmacists and techs. We just finished a controlled substance manufacturer, importer, and exporter conference last week, training almost 400 corporate representatives. We also continue to present at State and local community meetings and law enforcement programs throughout the country.

The accumulation of unwanted and unused prescription drugs in the household medicine cabinet continues to provide easy access to non-medical users for abuse, accidental ingestion, and illegal distribution. This easy access to drug seekers, especially teenagers, has undoubtedly contributed to the increase in the abuse of these substances. DEA has responded by coordinating national take-back events with our law enforcement partners since September 2010. These events have resulted in the destruction of approximately 2.8 million pounds of unwanted prescription drugs. DEA is finalizing regulations implementing the Secure and Responsible Drug Disposal Act of 2010, which authorizes additional ways for Americans to dispose of their unwanted and expired controlled substance medications in a secure and responsible manner.

The diversion of controlled substances occurs at all levels of the supply chain, and we continue to identify, target, and investigate violators who cause millions of dosage units of controlled substances to be diverted due to noncompliance with the Controlled Substances Act (CSA) and its implementing regulations. Noncompliance is allowing dangerous pharmaceuticals to pour into the illicit market, posing an imminent danger to public health and safety.

Pharmaceutical diversion can be prevented if DEA registrants fulfill their obligations under the Controlled Substances Act. When the system breaks down, massive diversion occurs, as seen in domestic Internet drug distribution schemes a few years ago and the rogue pain clinics operating in Florida, Georgia, and Tennessee today. DEA rigorously pursues criminal, administrative, and civil actions against registrants who fail to comply with the CSA and their implementing regulations.

On June 11, 2013, Walgreens Corporation, the Nation's largest drug store chain, agreed to pay the largest civil fine in DEA history, about $80 million, resolving DEA's administrative actions and a civil investigation by DEA and the United States Attorney regarding the Jupiter, Florida, Distribution Center and six retail pharmacies in Florida. This is only the latest in a series of enforcement and regulatory operations focused on all levels of the registrant population within the drug delivery system. They were not complying with the CSA. All levels of the distribution chain, from manufacturing, wholesalers, retailers, pharmacies, and practitioners, are being closely scrutinized to ensure compliance with the act.

Controlled substance pharmaceuticals that are illegally obtained through health care fraud or abuse of the Medicaid program is yet another method of diversion that ultimately weakens the integrity

of the closed system of distribution. While these violations generally occur outside of DEA's jurisdiction, there are occasions when, while investigating violations of the Controlled Substances Act, DEA agents and investigators uncover violations involving health care fraud. This information is shared with investigators from the Department of Health and Human Services, the Federal Bureau of Investigation, and other State and local enforcement and regulatory bodies with relevant Federal and State authorities.

The importance of these cooperative and information-sharing relationships is reflected in the fact that HHS OIG and the FBI and others have investigated assigned or are working on an ad hoc basis with some of the Tactical Diversion Squads (TDSs) throughout the country. This collaborative effort facilitates information sharing between all the involved agencies and allows investigators to easily draw upon each other's expertise when conducting investigations and avoiding duplication of effort.

In conclusion, I want to assure you that DEA is working closely with our Federal, State, and local partners in combating drug diversion and, when encountered, health care fraud as part of the administration's comprehensive approach to combating prescription drug abuse. DEA is committed to balancing the need for diversion control and the enforcement with the need for access to these important medications by legitimate users.

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

Chairman CARPER. Thanks very much for that testimony.

Mr. Blum, you are recognized. Welcome.

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

Mr. BLUM. Chairman Carper, Ranking Member Coburn, Senator Chiesa, thank you for inviting CMS to testify at this hearing and for your focus on the Part D program. I want to assure this Committee that CMS takes very seriously the concerns being raised today. Not only does inappropriate prescribing weaken the fiscal integrity of the Part D program, but it places our beneficiaries in harm's way.

CMS sincerely thanks the OIG for its work, and we welcome further oversight to help us improve the Part D program. We have taken many steps to reduce waste, fraud, and abuse in the Part D program, but clearly we can and should do more to take further steps.

To be sure, the Medicare Part D program is stronger than ever. It has dramatically lowered Medicare beneficiaries' out-of-pocket costs since 2006. Due to strong management by CMS and our plan partners, its total costs are lower than what the Congressional Budget Office (CBO) and our actuaries projected when the benefit was passed in 2003. In many respects, Part D sets the standard for all payers for cost containment measures. However, its statutory construct of operating the program through hundreds of Part D

[1] The prepared statement of Mr. Blum appears in the Appendix on page 56

plan sponsors presents vulnerabilities, and like all payers, public and private, Part D has seen rapid growth in payments for Schedule II pain medications.

We know that no one agency can solve these challenges, and that it will take resources from all levels of the government, Federal and State, and the private sector to solve this problem.

CMS sees its role as the following:

No. 1, to leverage CMS' data resources of complete Part D claims to spot outlier prescribing and share this information with our partners in as real time as possible.

No. 2, to hold sponsors, prescribers, pharmacies, and our contractors accountable for prescribing that is consistent with our goals and values. Those that violate our standards should expect to no longer have a relationship with the Medicare program.

No. 3, to support this Committee and the Congress in crafting further legislation to give the Federal Government more tools to address prescribing fraud.

Over the past several years, CMS has made some important changes to our policies and operations not reflective in 2009 claims files. Specifically, CMS has changed our rules to require all Part D drug claims to have a valid national provider number attached to it. Already in the first quarter of 2013, 99.6 percent of all Part D claims were compliant with this requirement. CMS now requires all claims for controlled substances to be checked for a valid DEA number.

CMS now requires all Part D plans to conduct more comprehensive drug utilization reviews for beneficiaries taking controlled substances. Part D plans must now verify that beneficiaries who exceed certain levels of prescribing are, one, being managed by a physician or, two, cutoff at the point of sale. To date, this program has cutoff 37 beneficiaries. We expect this number to grow, and we also expect to expand this program to other medications.

We have now begun to leverage the fraud prevention system (FPS) to identify outlier prescribers and pharmacies much earlier in the process. For example, last week, CMS provided to all Part D plans a comprehensive list of high-risk pharmacies for further review and scrutiny.

While we feel these actions will help curb Part D fraud, we also plan to take more action. For example, CMS is now considering proposing new regulations that would require all Part D prescribers be validated as Medicare providers.

CMS is considering new regulations that would expand the scope of our Part D fraud contract, the Medicare Drug Integrity Contractor (MEDIC), to provide greater access to Pharmacy Benefit Management (PBMs'), pharmacies', and prescribers' records at the physical premises. CMS will expand its Part D plan compliance reviews. Part D plans that submit claims for controlled substances greater than norms should expect further compliance actions and potential financial penalties.

In closing, I do believe further legislation may be needed to curb controlled substance abuse. Some plan sponsors have recommended locking in some patients to one pharmacy to receive controlled substances. We believe it is time for Congress to consider this potential

change. CMS stands ready to help this Committee to continue to make the Part D program as strong as possible.

Chairman CARPER. We are interested in exploring that and other ideas that require our action, because this is a shared responsibility, and it is an all-hands-on-deck initiative.

Mr. Cantrell, please proceed. Mr. Wright, you guys figure this out.

TESTIMONY OF GARY CANTRELL,[1] DEPUTY INSPECTOR GENERAL FOR INVESTIGATIONS; AND STUART WRIGHT, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. CANTRELL. Good afternoon, Chairman Carper, Ranking Member Coburn, and Senator Chiesa. We appreciate the opportunity to speak to you today about prescription drug diversion in the Medicare program.

In addition to the Medicare dollars stolen, there are few areas of health care fraud where we see such a direct and devastating impact to patients. The CDC has characterized prescription drug abuse as an epidemic, and too much of the time the bill is being paid by Medicare. This is a drug trade subsidized by the taxpayers. Bringing these criminals to justice is a top priority for OIG, and over the last 5 years, our prescription drug fraud investigations have nearly quadrupled.

Of particular concern are those prescription drug schemes that result in patient deaths. These are often associated with sham pain clinics or pill mills. One particular clinic was associated with the deaths of over 60 patients. The doctor and his wife, who was a nurse and the office manager, were sentenced to over 30 years in prison and ordered to pay back $114 million for their crimes.

Prescription drug fraud also often involves sophisticated criminal enterprises. One case involved a licensed pharmacist who owned 26 pharmacies. He was the mastermind of a scheme that enlisted physicians, pharmacists, and patient recruiters to defraud Medicare, Medicaid, and private health insurance. He paid kickbacks and other inducements to physicians to write bad prescriptions. The pharmacist responsible for this egregious scheme was sentenced to 17 years in prison and ordered to pay back $17 million.

Prescription drug schemes are not limited to controlled substances. OIG also investigates matters that involve expensive noncontrolled substances. In one example, a pharmacy billed for medically unnecessary and very expensive antipsychotic, respiratory, and cardiac drugs but never dispensed the drugs. The perpetrators of this scheme were sentenced to nearly 5 years in prison and ordered to pay $4.9 million.

These cases illustrate what happens when greed and profit trump patient care. And now my colleague Stuart Wright will discuss how better oversight will help curb these problems.

Mr. WRIGHT. Good afternoon. I am Stuart Wright, Deputy Inspector General for Evaluation and Inspections in the Office of In-

[1] The prepared statement of Mr. Cantrell and Mr. Wright appears in the Appendix on page 72.

spector General. I appreciate the opportunity to talk about our most recent work examining Medicare prescription drug billing as well as our body of work related to Part D. Our written statement outlines this work in more detail.

A basic safeguard in paying for medical care is ensuring that the care is ordered by an appropriate medical professional. A report that we released today shows that this safeguard is not always operating effectively. Nationwide, Medicare Part D paid more than $5 million in 2009 for prescriptions ordered by individuals who clearly did not have the authority to prescribe. These individuals included massage therapists, athletic trainers, dental hygienists, and contractors responsible for home repairs. We even found that interpreters, lodging companies, and veterinarians ordered prescriptions.

In addition, we reviewed 10 States in depth and found that Medicare inappropriately paid for drugs ordered by other types of unauthorized prescribers, such as counselors, social workers, and chiropractors. Medicare paid more than $26 million for these drugs. Senator Carper, as you indicated in your opening remarks, tens of thousands of these prescriptions were for controlled substances.

Vulnerabilities in Part D are not limited to unauthorized prescribers. In our report issued last week, we identified questionable prescribing patterns by 736 general care physicians. In total, Medicare paid $352 million for drugs ordered by these physicians in 2009. These physicians were extreme outliers and prescribed very differently than their peers. Some ordered extremely high percentages of certain controlled substances, such as oxycodone and morphine. In one example, Medicare paid $9.7 million for one California physician's prescriptions. This is 151 times more than the average prescriber. We also found 24 doctors who ordered more than 400 prescriptions for at least one of their patients.

In another review, we found approximately 2,600 retail pharmacies that billed far outside the norm. Medicare paid a total of $5.6 billion in 2009 to these pharmacies.

While some of these billings may be appropriate or may be due to billing errors, these patterns raise flags that warrant further review. This demonstrates that basic checks need to be done routinely by Medicare administrators and contractors.

In addition to conducting claims analysis, since the inception of Part D, we have examined CMS's oversight program and identified vulnerabilities. Notably, we found that some plan sponsors did not identify any fraud and abuse cases, and the MEDIC has not fully utilized data analytics to identify potential fraud and abuse.

Taken together, our findings consistently demonstrate the need to strengthen Part D monitoring and oversight. Our written statement highlights a number of recommendations, including: Require sponsors to verify that prescribers have the authority to prescribe drugs; strengthen the MEDIC's and sponsors' monitoring of prescribers and pharmacies; require sponsors to refer potential fraud and abuse incidents to CMS; develop a mechanism to recover payments for inappropriate Part D claims; and provide education and training for prescribers, including issuing reports to prescribers with information about their prescribing patterns.

In conclusion, more needs to be done to ensure patient safety and to prevent fraud, waste, and abuse. CMS, the MEDIC, and plan sponsors need to conduct rigorous oversight and monitoring. The OIG will continue to bring all of the oversight and enforcement tools at our disposal to protect Part D and its beneficiaries.

Thank you for your interest in this important issue and for the opportunity to present the results of our most recent work. We would be happy to answer any questions.

Chairman CARPER. Thanks, Mr. Wright, and we will have some, believe me.

Ms. Lavelle, welcome. Please proceed.

TESTIMONY OF ALANNA M. LAVELLE,[1] DIRECTOR, SPECIAL INVESTIGATIONS, WELLPOINT, INC.

Ms. LAVELLE. Thank you. Chairman Carper, Ranking Member Coburn, and Senator Chiesa, I am Alanna Lavelle, Director of Special Investigations for WellPoint. I also serve as the Chair of the National Health Care Anti-Fraud Association. Thank you for the opportunity to provide input and recommendations on prescription drug abuse in the health care delivery system.

One of the significant strengths that we and other health plans bring to the fight against prescription drug abuse is the data available from our integrated health care delivery systems. This allows the ability to see the entire health care spectrum and to spot trends and outliers, such as an overprescribing physician or a patient receiving several prescriptions from several providers or pharmacies.

To combat fraud and abuse, WellPoint has a dedicated fraud and abuse prevention team known as the Special Investigations Unit (SIU). I am one of their lead investigators, overseeing a team in the Southeast region. The SIU is staffed with former Federal and State law enforcement agents and medical professionals. We also have a data analysis team.

Today some of the top fraud and abuse schemes we currently see in prescription drug coverage include:

The practice often referred to as "doctor shopping," whereby individuals obtain prescriptions for frequently abused drugs from multiple prescribers and then fill them at different pharmacies. Oftentimes providers as well as pharmacies are involved in the scheme;

Bogus providers: these are the providers that, although they may have National Provider Identifier numbers (which are usually stolen or purchased), do not actually perform services for real patients but bill insurers;

And pain management doctors overprescribing pain medications.

WellPoint currently has 160 investigations open involving Medicare Part D. WellPoint refers every Part D case to the MEDIC, Medicare's Part C and D anti-fraud contractor, and WellPoint currently has the second highest number of referrals to the MEDIC nationwide.

Our goal at WellPoint is to prevent health care fraud and abuse for the benefit of our members' health. To meet this goal, we have developed a number of different programs.

[1] The prepared statement of Ms. Lavelle appears in the Appendix on page 82.

First we have our Controlled Substance Utilization Monitoring (CSUM) Program and Medicaid Restricted Recipient Program. Through these programs, we are helping identify those who are engaged in or contributing to prescription drug abuse or drug diversion.

For our Medicaid plans, we have implemented a Restricted Recipient Program. Through this program we identify a member who, within a 3-month period, visited three or more prescribing providers, three or more pharmacies, and filled ten or more controlled substance prescriptions without a confirmed underlying medically necessary condition.

To combat fraud and abuse of Schedule II narcotics, such as OxyContin, they are locked into using only one primary care physician, one retail pharmacy of their choice, and one hospital. Our case managers work directly with providers and members, and to date, this program has saved lives and many millions of dollars in emergency department visits alone for the drug-seeking behavior.

Second, we have a Prepayment Review Program to identify irregular provider practice patterns through data mining and analytics. WellPoint has implemented two such prepaid provider review programs in which the most egregious billers who, after being educated and refusing to modify their billing behavior, are placed on flagged prepayment review. In that case, providers must bill us with paper claims accompanied by paper medical records so that we can determine whether the procedures billed for are reflected in the records.

And, third, we have recently contracted with a vendor to do predictive modeling. This program uses advanced neural network technology from FICO to identify previously unknown and emerging fraud and abuse provider or member schemes. Suspect providers and claims are reviewed to identify potential fraud, waste, or abuse and investigated thoroughly. Since we began using this tool 6 months ago, the SIU has opened 200 investigations.

We will prevent this year, in 2013, over $13 million in inappropriate payments by having placed a system edit for urine drug testing abuse by providers, which is one of the largest collateral abuses spawned by the prescription drug abuse in the United States. The overall return on investment at this time is well over 15:1.

And, finally, we take a multifaceted approach to identifying bogus providers who do not actually perform services for real patients. Our provider database teams alerts the investigator to the presence of new labs, pharmacies, and durable medical equipment (DME) suppliers, and we perform a full background check as well as a drive-by of the provider's office space.

In just the last 6 months, we have identified and stopped payment to 63 bogus pharmacies through our collaboration with our PBM Express Scripts, resulting in a savings of $2.1 million.

Based on our experience in combating health care fraud and abuse, we offer the following recommendations:

First, we are supportive of giving CMS the authority to establish a Restricted Recipient Program in Medicare Part D for those beneficiaries displaying a pattern of misutilization.

Second, we recommend——

Chairman CARPER. Is that another way of saying the lock-in program?

Ms. LAVELLE. Yes, that is correct.

Chairman CARPER. OK.

Ms. LAVELLE. Second, we recommend that dually eligible beneficiaries with evidence of drug-seeking behavior should be locked into one managed care plan rather than continue to be allowed to switch plans on a monthly basis to evade detection.

Third, we support better coordination and cooperation among CMS, the Department of Justice (DOJ), and all stakeholders.

And, finally, all expenses for health insurer anti-fraud and abuse programs should be included as "activities that improve health care quality" in the medical loss ratio (MLR) calculation for both commercial health insurers as well as Medicare Advantage since they reduce waste, reduce the cost of health care, and enhance patient safety by helping identify and remove providers engaging in unsafe and fraudulent practices.

In conclusion, I would like to thank the Committee for the opportunity to testify today on behalf of WellPoint on this critical issue and pledge our support in any efforts to make the health care system financially viable and safer for our members.

Chairman CARPER. Thanks. Ms. Lavelle.

Just to put this in some context, Dr. Coburn and I focus on—and I will just say to our new colleague, whose name I believe is pronounced "Key-ay-sa," not——

Senator CHIESA. "Chee-ay-sa."

Chairman CARPER. Has it ever been mispronounced?

Senator CHIESA. Has it ever been? Never. [Laughter.]

Chairman CARPER. All right. Well, I will work on that.

To put this in context, our budget deficit is down. We are down from about $1.4 trillion maybe 4 years ago. We are told this year it is only going to be about $650 billion. It was $1.4 trillion about 4 years ago. That is an improvement. The biggest piece of our deficit—and we are going to actually get closer to a balanced budget—is health care costs, and the 800-pound gorilla in the room is probably Medicare. And rather than cutting benefits that people actually need that are doing a lot of good, what we have to do is to look for every bit of money that is just wasted, spent inefficiently, fraudulently, and that brings us to today's hearing.

We have some numbers up here on this board. These are 2009 numbers. It is money that Medicare paid apparently inappropriately for prescription drugs that year. About 417,000 prescriptions that year, some 29,000 controlled substance prescriptions, involving maybe 15,000 or so prescribers, cost a loss to taxpayers of $31.6 million. My fear is that this understates the situation.

We never conduct "gotcha" hearings here. We never do that, and we are not going to do that today. I just want to impart a sense of urgency. We do not have the money to be wasting, whether it is $31 million, $131 million, or $231 million. We do not have the money to spend wastefully.

I supported the Medicare Prescription Drug Program. I voted for it. Not many Democrats did. I voted for it. A lot of people were concerned it was not going to be a good benefit. They did not like the way the program was crafted. They were afraid it would run way

over budget and that the folks who would use it would not like it. As it turns out, it has not run way over budget. And what does it cost? About $60 billion a year or so, something like that, a little more than that. And I think about 85 percent of the folks who use it like it. Those are better, favorable numbers than I have at home, and probably for my colleagues as well.

Having said that, we have to figure out how to save some money in this program. We have to continue. Everything we do, we have to look at and say how do we save some money in this program.

Ms. Lavelle has just given us a little bit of a to-do list here. What was the first one? And what I am going to do is ask everybody on the panel just to react to it and figure out who is responsible for doing that. I think the first one may involve some responsibility for us on this side of the dais. But go ahead, Ms. Lavelle, just go through the first one, and then we will have some discussion on each of these.

Ms. LAVELLE. Sure. The first one was to establish a Restricted Recipient Program in Medicare Part D or a lock-in program.

Chairman CARPER. All right. OK. Don't we have that in Medicaid? Don't we have that in most States in Medicaid where you basically say to someone who is thought to be maybe an abuser, they say "You are going to have one doctor—one pharmacy, you are going to have one doctor, and that is it." And maybe that requires the assent of the Federal Government. I do not know that it does. It seems strange to me that we have that provision, a lock-in provision, in Medicaid but not in Medicare.

So let us just talk—start off with Mr. Rannazzisi, your reaction to that recommendation.

Mr. RANNAZZISI. Well, again, that is a little outside the scope of my authority, but——

Chairman CARPER. In that case, just be very brief.

Mr. RANNAZZISI. As far as diversion goes, I think it is a fantastic idea. If I am not mistaken, that lock-in program is being used in Ohio, if I am not mistaken, and the Ohio Board of Pharmacy, the investigators, the Ohio Board of Pharmacy believe in that program.

Chairman CARPER. I am told it is used in a number of States, not just Ohio but in a number of States, and we will find out how many.

Mr. Blum, please?

Mr. BLUM. I think that many State Medicaid programs do have a lock-in program. I do not believe that it is a Federal requirement, but I know that States on their own do put in place lock-in programs. The Part D program in its current construct runs the benefit through many different Part D plans, so I think this is an area that Congress would have to authorize. I do think it is time that Congress consider this change. I think the Congress would have to set out clear thresholds for which beneficiaries are required to be locked in, but we are happy to work with this Committee. And I think the Drug Utilization Review (DUR) Program that CMS put in place this year could serve as a model for which beneficiaries hit that threshold.

Chairman CARPER. All right. Mr. Cantrell.

Mr. CANTRELL. Yes, I think any legislation that would help us explore ways to prevent doctor shopping—and some of the patients

that we encounter in our cases actually are paid kickbacks to participate in these schemes. So in situations like that, I think we would be interested in exploring ways to prevent that kind of activity.

Chairman CARPER. Mr. Wright.

Mr. WRIGHT. I agree, and I think there may be two different kinds of lock-ins that are under discussion. One is to lock beneficiaries in a particular plan, and the other would be to lock them within a specific prescriber or pharmacy. We think that both of those should be considered.

Chairman CARPER. All right. Good.

What was your second point, Ms. Lavelle?

Mr. LAVELLE. That was indeed the dual eligibles with evidence of drug-seeing behavior that bounce from one managed care plan to another on a monthly basis. And we at WellPoint are not allowed to tell Cigna or Aetna that someone that is coming from our plan is going to be a problem for them as well just because of the Health Insurance Portability and Accountability Act (HIPAA) requirements.

Chairman CARPER. All right. What can we do within the constraints of HIPAA? Anyone, please, what can we do?

Mr. BLUM. I think Congress can clearly provide greater authority for that data to be shared. I think there is always a balance between privacy and controlling payment, but this is another area that I would suggest that Congress can give more permission for that data sharing to happen.

Chairman CARPER. All right. Thank you.

What was No. 3?

Ms. LAVELLE. The third was we support better coordination and cooperation among CMS, DOJ, and all stakeholders.

Chairman CARPER. All right. Our friends from the OIG, react to that for us, if you would.

Mr. CANTRELL. We are very much in favor of better coordination and communication. We are coordinating very well. We have the Health Care Fraud Prevention Partnership that has been established. It is in its infancy, but we are very much supportive of private-public data sharing and public partnerships where we can.

Chairman CARPER. All right. No. 4?

Ms. LAVELLE. The last one was to recommend that all expenses for health insurance anti-fraud and abuse programs be included as activities that improve health care quality in the medical loss ratio. Right now they are not.

Chairman CARPER. Would you all react to that? Anyone. Who wants to react to that? Mr. Blum. Is it Dr. Blum? It is Mr. Blum, isn't it? I always want to call you "Doctor."

Mr. BLUM. Thank you, but it is Mr. Blum. CMS believes, and I think it is consistent with the State insurance commissioners, that strong fraud and abuse is part and parcel to what a plan should be doing, that it is not part of benefit costs but it is the cost to run a well-managed program. CMS in its rules does permit collections to count toward the MLRs. We think we have found the right balance between requiring plans to set up procedures that is part and parcel to running a plan, but we do allow plans to count the collections toward the benefit side of the MLR.

Chairman CARPER. OK. Well, Ms. Lavelle, you have given us a pretty good start on a to-do list from our side, and this is one of those deals where there is work to be done on both sides, and not just the Federal Government, not just the legislative branch, not just CMS, but a bunch of us, including folks that are not in Congress and not at CMS.

Dr. Coburn, thank you.

Senator COBURN. So, Mr. Blum, let me just kind of get you on the record a little firmer here. CMS supports the modification of the Part D program to establish a lock-in?

Mr. BLUM. What I can say to you, Senator, is that we have no official position, but I believe that it is time for Congress to consider this change.

Senator COBURN. CMS does not have a position on that?

Mr. BLUM. I am speaking for CMS, and I believe it is time for Congress to consider it, that it is not part of the President's 2014 budget submission, but I do think it is time for Congress to make this change.

Senator COBURN. So would your recommendation back up the chain at CMS that would go along with Congress writing the bill that would do that?

Mr. BLUM. Yes. And we are happy to support this Committee in that change.

Senator COBURN. The second point: Would CMS also go back up the chain and support a loosening of the HIPAA rules so that insurers can protect patients and their long-term well-being by allowing them to transfer data on drug-seeking behavior patients?

Mr. BLUM. I think one of the principles that CMS strongly believes is that we have to have greater data sharing to spot outliers, both beneficiaries, pharmacies, and physicians, and CMS would support that change.

Senator COBURN. So if I wrote a bill that would allow just a little bitty hole for the insurance industry that is managing this to share the data on drug-seeking behavior to the next managed care plan, there would not be an objection from CMS to that?

Mr. BLUM. We would have to see the details, obviously, but——

Senator COBURN. In principle.

Mr. BLUM. In principle, yes.

Senator COBURN. All right. Tell me, do you think that CMS gets $14 million worth of value a year from the MEDIC program?

Mr. BLUM. I think the MEDIC program can be improved, and I think we want the MEDICs to be active, we want the MEDIC to be proactive, and the MEDIC is just one piece of a strong CMS oversight practice. But I do think that the MEDIC process can be improved, and to be more proactive and to take more action.

I think data analysis is just one piece. It is what you do with the data. And we have to have action. We have to have many steps beyond just law enforcement action. But, I agree with you that we can improve the performance.

Senator COBURN. So they had 21 referrals last year for $14 million for prosecution, and you just heard WellPoint talk about the hundreds that they have done in the last 6 months. Explain to me why we are not getting more value out of the MEDIC program.

Mr. BLUM. Well, my understanding is that the way the program works today, once the referral is made, it has to meet certain thresholds for law enforcement to take action. And what I think we want to see is the same problem that we have in the Part B program. There are different levels. And so for behavior that does not meet the law enforcement prosecutable threshold but is still outlier behavior, that I believe that the program should suspend that physician, move to paper claims, and the same kinds of processes that WellPoint talked about, CMS will be holding our plans and our contractors to that standard. But I think one change that we can consider is rather than having prescribers self-declare what their backgrounds are, according to the chart that was shown, to have them formally be enrolled in the Medicare program similar to Part B, and that is a change that we plan to make.

Senator COBURN. When do you plan to make that change?

Mr. BLUM. Well, typically we put out rules in the fall, and that is in process right now.

Senator COBURN. So we are going to put out rules, so this time next year we might see a change?

Mr. BLUM. My hope and my promise to this Committee is that in data for 2012–13 we will see a lower number than what the OIG found, and CMS will continue to make changes to our rules to bring that number down close to zero. But my hope is that given the changes CMS has made that I talked about, including requiring the Medicare Provider Inventory (MPIs) to be on the Part D claim, to holding our contractors to higher degrees of accountability, we will see lower numbers. And that will continue through further policy change and operational details.

Senator COBURN. So I have no firm date. People are going to continue to die—right?—under this program. And we are going to put out rules in the fall. Why wouldn't we put out rules now based on the recommendations of the OIG?

Mr. BLUM. Well, I think we are taking action steps to respond to the OIG's findings. So, for example, we have shared those pharmacies that are outliers with all our Part D plans for action today. CMS needs to balance the burdens that are going to be placed on prescribers who are not part of the Medicare program today that need to come into the Medicare program for validation and further oversight, and that is a process we cannot turn on overnight. We have to go through proposed rulemaking. But that to me is one more step the agency can take to achieve better results.

Senator COBURN. You have plenty of paperwork to do; I understand that. Would you commit to this Committee, based on the recommendations of the OIG, to give us a report every 3 months for the next four quarters on where you are in complying with their recommendations since you readily accept that their recommendations are things you ought to do?

Mr. BLUM. Absolutely. My understanding is that we have, and we are happy to commit to whatever process would be helpful to this Committee.

Senator COBURN. And will you publish that report so that it does not just come to the Committee?

Mr. BLUM. We will defer to how you want the report published.

Senator COBURN. Well, if we get it, I will make it public, because I think, one of our problems in government is we see a problem, and then our rules of government make it to where we cannot save the lives of the next 1,600 people who are going to die from a prescription drug overdose because we are not managing the Medicare Part D program through CMS effectively. And that is really not a very good excuse for us to—and I am not talking about you. I am talking about us, too—to wait until tomorrow to start making these changes, when you are talking about lives, you are talking about money. And you are also talking about not just lives that are snuffed out, you are talking about lives that are destroyed and people going to prison because we have made it easy to game the system. So I hope your commitments will be there.

As you can tell from my opening statement, I am pretty disgusted with the MEDIC program because I do not think we are getting that much from it. And I plan on sending you a few letters and to the OIG to followup on that, because I do not think we are getting value out of the $14 million. And my hope will be that you will ride the contractors to where we actually get values and change the program to what it should be.

My time is up.

Chairman CARPER. Senator Chiesa.

Senator CHIESA. Thank you, Mr. Chairman, and thanks to all of you for your testimony here today.

I know from my experience as Attorney General what a catastrophic impact this epidemic has on the people that live in my State and I am sure throughout the country. What I do not appreciate as much is the impact it has on seniors and the different ways I think they are particularly vulnerable to people who are trying to game the system, as Dr. Coburn has talked about.

And what I would like to find out—and I open this question to any of you who feel competent to answer it—is: What are the particular focuses on a population that is clearly vulnerable to this? They trust their doctors. They want to get better. Some of them have long-term illnesses that they are dealing with, and in some cases, it is just easier to try to medicate your way out of those illnesses than it is to try to talk with the family and get to the heart of what is going on.

Are there relationships between, for example, assisted care facilities or nursing homes that are particularly problematic in this area that lead to this kind of abuse?

Mr. WRIGHT. I do not know that I can directly answer the question, but with regard to the vulnerable population of the elderly being in nursing homes and some of these drugs being very powerful, we did do a review of antipsychotic drugs as used in the nursing home setting, and we found that 88 percent of them were prescribed against the black box warning, clearly raising health concerns. And based on the medical record review, we found 51 percent of the claims should not have been paid by Medicare.

So when we did that kind of in-depth review in that vulnerable setting, we did, in fact, find substantial problems.

Senator CHIESA. OK. Ms. Lavelle, we talked about doctor shopping as a part of this problem, and I know, again, in my own experience seeing some of the typical populations that engage in this

behavior, is that a problem? Do we see that among the senior population as well?

Ms. LAVELLE. Frankly, when I speak of the doctor shoppers, the majority of what we are seeing are those that are under 65. They are dual eligibles, usually Social Security disability. We just referred eight cases last week, and all of them are under 65.

Senator CHIESA. OK. And do you have any statistics or information that is available to tell us what percentage, or in your experience that you see, are over 65 that are engaging in this behavior?

Ms. LAVELLE. I do not have any exact, but I can get that for you.

Senator CHIESA. OK. Pain clinics and pill mills. Mr. Rannazzisi, I know that you are experienced with the DEA. Again, talking about the senior population, are they being exposed to a greater extent in those settings than we find other patients are?

Mr. RANNAZZISI. I do not believe so. The pain clinic cases that I reviewed are generally a younger population of drug seekers that are going—remember, they are not going there, these rogue pain clinics, they are not going to get medical treatment. They are going to get medication to feed their addiction. So it is not really medical care. It is more of drug distribution illegally.

Senator CHIESA. OK. And, Mr. Blum, I would like to ask you about the enrollment process. What factors do you think provide the greatest deterrence to keeping out the kinds of physicians that we do not want involved in these programs?

Mr. BLUM. I think what we have learned from our fraud prevention system is that we have to do two things at the same time: We have to validate physicians' credentials, and that has to be periodic. And one of the most important changes that the Congress made is to direct CMS to require this process. That is not true in the Part D program. There are many prescribers who are legitimate but are not formally part of the Medicare system. For example, dentists are one of the most commonly—frequent prescribers of pain medications. So I believe that every physician who is writing scripts for the Part D program needs to be enrolled in the Medicare system so we can validate. We are not reliant on self-reported databases. We can verify those who are truly massage therapists versus those who are just self-reporting as massage therapists. That is a change that I believe that the program needs to make. It is going to place new burdens on physicians, and I am sure this Congress will hear pushback from the physician community that it is burdensome, that for those prescribers that do not provide medical services that they should not be enrolled. But I do believe that it is time that we move to a different framework.

Senator CHIESA. OK. Mr. Rannazzisi, we worked in New Jersey with the DEA to establish drop-box programs where people can take their unused prescription medications to those locations and get rid of them, no questions asked, in a secure location so that other family members cannot abuse them. In your experience, how effective do you think those programs have been at getting at the potential problem of the legitimately prescribed prescription drugs to a grandparent being then used inappropriately by one of the younger members of their household?

Mr. RANNAZZISI. Well, we have taken the position that those medications, once they are expired or unneeded, need to get out of

that household. That is why we have these nationwide take-back programs. In April, we took in almost 376 tons of pharmaceuticals, the last take-back program.

I think that we are in the process of drafting the final regulations for take-back, so we may have these drop boxes available across the country in certain authorized locations, and I think that will go a long way to preventing such tragedies as what we have seen in the past.

Senator CHIESA. And nationwide, what percentage of the States participate in these programs, the drop-box programs?

Mr. RANNAZZISI. Well, currently, the only drop-box programs that are allowed are ones in law enforcement facilities, either precinct houses or headquarters places. But I cannot tell you exactly how many because law enforcement agencies are exempt from the statute, so they could put their drop boxes in the facilities without reporting to DEA.

Senator CHIESA. OK. But, anecdotally—I know, for example, we have talked about it actively in New Jersey—do you get the sense that many States are getting involved in these programs or not?

Mr. RANNAZZISI. Yes. I believe quite a few States are getting involved in the program. Some States have their own program. I believe North Dakota has their own program now.

Senator CHIESA. OK. Well, thank you.

Thank you, Mr. Chairman.

Chairman CARPER. Thank you very much. Dr. Coburn.

Senator COBURN. [Presiding.] Mr. Blum, is CMS aware of actions by State medical boards and restricting of licensing or disciplinary procedures?

Mr. BLUM. To some degree, but I think one thing that we need to do is to improve that data sharing.

Senator COBURN. Does CMS share with providers—and I am talking insurance providers—when you have taken somebody off their eligibility to be able to prescribe, or treat Medicare patients?

Mr. BLUM. That is a vulnerability that I concede that we need to do a better job, but——

Senator COBURN. But do you do it?

Mr. BLUM. We will be doing it.

Senator COBURN. But you do not do it now?

Mr. BLUM. Not to the fullest degree.

Senator COBURN. Do you ever give the other providers a list of problematic providers—I am talking insurance providers—a list of problematic people that are under review or that are under suspicion of being a bad actor? Do you ever share that information, not just the ones that have gone off but the ones that you are suspecting of fraud?

Mr. BLUM. That CMS is?

Senator COBURN. Yes.

Mr. BLUM. One change that we have made, Senator, is that we now share those outlier pharmacies, for example, CMS will be expanding that list.

Senator COBURN. How about outlier physicians?

Mr. BLUM. That is going to be a change that CMS moves forward on.

Senator COBURN. You have to do a rulemaking on that? So there are some things that you can do immediately——

Mr. BLUM. Absolutely.

Senator COBURN [continuing]. To share with the other providers, the Part D providers as well as other insurers.

Mr. BLUM. And CMS pledges to this Committee that CMS will make those kinds of changes—certain changes require rulemaking, such as requiring all physicians to enroll in the Medicare program that prescribe through Part D. Some changes are management changes that CMS has and will continue to act on.

Senator COBURN. OK. Ms. Lavelle, we just had this conversation, and in your testimony you said that plan sponsors are rarely informed of the ultimate result of actions that are taken and information collected by the agency is rarely shared with the private payers and CMS does not share information on revoked Medicare providers with private payers. You just heard, I think, some good news and a commitment to this Committee.

WellPoint's Special Investigation Unit refers every Part D case to the MEDIC, and WellPoint has the second highest number of referrals to the MEDIC.

Ms. LAVELLE. That is correct.

Senator COBURN. What have you seen from that?

Ms. LAVELLE. That is one of the issues we have with the MEDIC. We are very collaborative with them, often refer cases over, but then we are never advised as to what type of action is ever taken.

Senator COBURN. So that is something that needs to be fixed as well.

Ms. LAVELLE. That would be very helpful to us.

Senator COBURN. Mr. Blum, what do you think about that?

Mr. BLUM. I think a small fraction of those cases that get referred to law enforcement are taken. Oftentimes there is a beneficiary who is complicit, and I think we all, the Federal Government, are hesitant to take action against beneficiaries who are complicit. I think it is time that we change, and I think it is time that we share that information. I think it is time that we hold the Part D MEDIC to a higher degree of accountability. And I think part of the issue is that the process now relies on that referral to be taken by law enforcement, but that is not sufficient.

Senator COBURN. Well, just because they choose not to prosecute does not mean somebody has not violated the law.

Mr. BLUM. Correct.

Senator COBURN. And it does not mean somebody should not be banned from having Medicare provider status. So you agree with that?

Mr. BLUM. I do.

Senator COBURN. How often do you see Medicare participants running in this program as far as pill mills? It was asked a little bit ago by my colleague from New Jersey, but how often are older patients used as part of the scam, not wanting the drugs but buying the drugs, using their Medicare number and their provider to get the drugs? How often are we seeing that?

Mr. CANTRELL. More and more we see that they are not even aware that this is happening. Through identity theft, their bene-

ficiary numbers are used to bill Medicare, and they are not even aware of it. So that is often the case.

Similar to the DEA and WellPoint's experience, we see lots of younger beneficiaries involved in some of the pill mill-type investigations who are interested in getting the drugs.

Senator COBURN. So all you have to have is a Social Security number, right?

Mr. CANTRELL. In essence and another letter that you tack on the end.

Senator COBURN. Yes, which you can fraudulently provide. So that is another reason why we should take Social Security numbers off the Medicare roll since that is what is at risk.

Mr. Chairman, thank you for this hearing. I have to be on the floor, but I would just tell you, we need, our staff needs to followup on this. We have a commitment from Mr. Blum in terms of quarterly reports on the OIG's recommendations. My hope is that they make great changes, and I look forward to working with you on two things that I think we can write very simple legislation and solve some problems.

Chairman CARPER. [Presiding]. You bet. Thank you, Dr. Coburn.

I want to back up just a little bit. We have been talking about what we can do in the legislative branch, what you all can do at CMS, what we can do in the law enforcement community. We have not talked at all about the roles of parents in this, and parents or family members, extended family members, talk a little bit about that. And are you aware of some States or some communities that are doing an especially good job in that kind of parental involvement or family involvement? Anybody know? Because it cannot just be the government. When it is all hands on deck, we mean all hands, including the hands of parents.

Mr. WRIGHT. When we did the work on antipsychotic drugs that I referenced earlier, we certainly made as part of that story that families needed to be more involved, especially when beneficiaries are in nursing homes and families are not necessarily aware of everything that is being prescribed on their behalf. We did very much make the point that this was something where everybody needed to contribute to correct.

Chairman CARPER. Others? Raise your hands. How many of you are parents? OK. Everybody. You can speak. You do not have to have your professional hat on. You can put on your parent hat if you want.

Mr. BLUM. I think from a Medicare perspective, Medicare beneficiaries take many drugs, and I think the average is 12 scripts per beneficiary right now. I think Part D plans do a lot to do polypharmacy reviews. That is not sufficient. Beneficiaries themselves, we encourage through the annual new wellness visit that Congress authorized in the Affordable Care Act (ACA) that medication be part of the annual wellness visit. And I think having the independent screen and check on the multitude of prescriptions beneficiaries take is one important step in the overall process.

I do think there are voices here that should be at this table to speak to overprescribing, I think having the physician community to get much more engaged, I think having the pharmaceutical manufacturers getting much more engaged. One of the reasons that

payers are seeing so much growth in these medications is because the marketplace is being flooded, if you will, with these medications. And so payers can only do so much, beneficiaries can only do so much, Congress can only do so much. But there are other voices that I think need to be part of this conversation—the physician community, the pharmacy community, pharmaceutical manufacturers—to ensure that a multifaceted strategy is developed.

Chairman CARPER. I do not think I heard you mention parents.

Mr. BLUM. Parents, too. Absolutely.

Chairman CARPER. Go ahead, anybody else, please. Mr. Rannazzisi?

Mr. RANNAZZISI. I think one of the biggest problems we are encountering right now is that parents do not understand the dangers of these drugs, and they are not talking to their children about these drugs. Just 2 years ago, we attempted to do a parents program at the second largest school district in the country. We made sure that it was adequately marketed with e-mail blasts and news reports, and we had 11 parents—or 14 parents show up to a huge venue.

I am not so sure that they understand and I am not so sure parents are willing to understand how bad these drugs are and how bad the abuse of these drugs are. We work with community coalitions all the time. We partner with community coalitions on the take-back programs. We hand out literature. We try to go to every community meeting that we are invited to, to present. But in the end, I think you are right; if the parents do not get involved, we are going to see tragedy over and over again.

Chairman CARPER. All right. Others, please? Anybody else? Ms. Lavelle.

Ms. LAVELLE. I had a daughter who was a lacrosse player, tore her ACL. She had surgery, was sent home with a script for hydrocodone, and her first day back in school as a sophomore she had several students approach her and asked if they could buy her pills. So it is in our backyard, and it is very insidious.

So we went in the school and did some parent-teacher conferencing and we actually partnered with FBI and DEA agents and did some awareness type of workshops, because even if you have a babysitter over, they look in the prescription cabinet now, it is that pervasive out in society right now.

Chairman CARPER. Any other parents want to say anything on this one? Mr. Cantrell.

Mr. CANTRELL. Yes, I think it is education and outreach to parents, as Mr. Rannazzisi has mentioned before. I think we would welcome the opportunity to join them in some of these outreach efforts, whether they be parents or the prescriber community. I think that is the front line of defense in preventing these problems from happening in the first place.

Chairman CARPER. The good news here is that parents maybe do not have to worry as much about their kids being on heroin or maybe they do not have to worry as much about their kids being on cocaine or Ecstasy. The bad news is, as you say, this is pretty insidious.

One of the reasons why we are having this hearing is to figure out what we can do collectively, folks in law enforcement, CMS, in-

surance companies, providers, the PBMs, the legislative branch, what we can do. But we also need to send a message to parents. It is not good. It is not good for our kids. I say that as a father of three boys—men—and the parents just need to get their heads wrapped around this and understand what is going on here. And they have an obligation here as well. The government cannot just do it all. We have to be a partner, but they have to be a partner as well.

I want to go back to some of the steps that CMS has already taken, steps that you have taken, steps you are about to take, and then the third area would be steps that are called for in the President's 2014 budget proposal. Can you just briefly run through those? What have you already done that you think is helping? What are you about to do or are undertaking? And, finally, what would you like to do under the President's budget?

Mr. BLUM. So I think a couple of things. I think our focus so far has been to put in place our requirements for our Part D plans to do much more comprehensive drug utilization reviews, that it is not sufficient to just simply look at the point-of-sale pharmacy claim, you need to do the complete look over the course of a year to see the full spectrum of beneficiaries' uses.

For those beneficiaries that exceed a certain clinical threshold, we require the Part D plans to contact the patients' physicians to make sure they are being well managed. If they are not, then Part D plans are expected to put in place point-of-sale edits on those beneficiaries that could be doing drug-seeking behaviors.

CMS, consistent with changes in the law and changes that this Committee has urged, now requires every drug claim paid by any Part D plan to have the provider's number on it so we can track, we can do analyses, we can verify that those scripts are legitimate. We also hold our Part D plans to a higher degree of accountability. That is the current work that we are doing.

In addition to the outlier analysis that we are now sharing with our Part D sponsors and other stakeholders, CMS is moving to new areas. So I do believe that it is time for us to build a bigger universe of oversight on all prescribers, not just those that bill the Part B program but all prescribers in the Part D program as well. CMS will be upholding our MEDIC to a higher degree of accountability, but also giving it greater authority to do much more intensive reviews with PBMs, pharmacies, and physicians to do more comprehensive looks.

The President's budget has called for ways to promote greater Part D data sharing. I think one of the limitations right now with State monitoring programs is they are all separate systems that do not talk to each other. We know that drug-seeking behavior crosses State boundaries. We know that it crosses health insurance plans. Many are cash-paying customers, so Part D changes alone will not stop the cash-paying customers.

One proposal in the President's budget is to provide greater assistance to drug monitoring programs run by States to share data and build common data sets.

Chairman CARPER. Thank you.

A couple of questions, if I could, for Mr. Rannazzisi and Mr. Cantrell, and these pertain more to the law enforcement side, and

I know you and your agencies are doing a lot to identify, to investigate, and to try to bring to justice those that are defrauding Medicare.

But let me just ask you if you could comment on some of the challenges facing law enforcement and some of the steps that, whether it is Congress, whether it is the Centers for Medicare & Medicaid Services, or, frankly, others, steps that we could take, individually, collectively, that would help you and your colleagues in your work. So that would be the first question.

Second, the followup, can law enforcement alone curb the diversion and the abuse of prescription drugs? I think obviously not, and we have already talked about that. This is all hands on deck, and it includes not just you sitting at the table and others; it includes us and it also includes parents and families.

But let me just go back to the first question. What can those of us at CMS, those of us in the legislative branch, or maybe within the Administration do to provide some help for you in your work? It is a little bit like swimming against the tide, I think.

Mr. RANNAZZISI. As an investigator, one of the most frustrating things I see is when there are tools available to the registrant community, the prescribers and the dispensers, and they are not using them. They could help us in the long run by just using those prescription drug monitoring programs (PDMPs). If there is any way Congress could push the States to do that, because right now some very good programs have less than 15 percent of the prescribers using them.

Chairman CARPER. Why do you think that is?

Mr. RANNAZZISI. There are all sorts of reasons. One of the reasons I always hear is, "I do not have enough time." And that statement tells me you do not have enough time to provide patient care, because in the end this is just like another diagnostic tool. Wouldn't you want to know if your patient is seeing two or three or four different doctors? Wouldn't you want to know if you are prescribing methadone and you have two other doctors prescribing a depressant, a benzodiazepine, two drugs that might affect how the drug is distributed in the body, how it is eliminated? Wouldn't you want to know that?

It seems to me that if this tool is available—and in 49 States right now we have either PDMPs or an infrastructure in place, legislation in place to create a PDMP, that as a practitioner, be it a mid-level practitioner, a physician, or a pharmacist, you would want to know what your patient is doing.

Mr. Blum is absolutely right. It is not just payments through Medicare. These people might be getting payments through Medicare, and they are also paying cash. And if you are a true doctor shopper, you are going to go to five, six, seven doctors at a time for the same illness. If I was that practitioner, I would want to know exactly what that patient is doing. Yet in many States, with the exception, I believe, of New York, Kentucky, and I believe Tennessee now has mandatory review of the PDMP before prescribing. The other States, they are just not using them.

Chairman CARPER. OK. Anyone else? Mr. Cantrell, do you want to respond to that as well, please?

Mr. CANTRELL. Well, we certainly agree that we should explore increased utilization of prescription drug monitoring programs and even the potential for a lock-in to stop the overprescribing and the doctor shopping that is taking place. We have seen people leave the State, cross State lines in order to find places where it is easier to get the drugs. We see that fairly routinely in our investigations. And we are also very encouraged by some of the data sharing and additional data analytics that Mr. Blum has committed to today, and we think that is going to pay dividends down the road as well.

I would like to mention that our office, which is responsible for overseeing this huge program, is shrinking in the face of the growth in Medicare and Medicaid. Based on some expiring funding streams, we are set to lose roughly 400 bodies out of a total of 1,800 at our peak in 2012. And that is really limiting our ability to expand our oversight in some of these areas.

Chairman CARPER. That is a reduction from 1,200 to 400?

Mr. CANTRELL. Excuse me, 1,800 to around 1,400.

Chairman CARPER. And, again, the reason for that is what?

Mr. CANTRELL. Some expiring funding streams. Certainly sequestration has added to that. But before sequestration, we were already facing expiring funding streams through the Medicaid Integrity Program and others. So we are operating with a reduced budget in the face of the growing program, and just last year alone, our office closed down 1,200 complaints due to lack of resources. Those are complaints that came through the door that we did not have the resources to investigate further to determine whether it was a viable criminal case or not. And that number does not appear to be going down.

Chairman CARPER. OK. The next question I have is really for the entire panel, and it focuses on State efforts to combat prescription drug abuse and diversion. Some of you have mentioned in your testimonies today the serious efforts being made to combat prescription waste and fraud at the State level. We just talked about it here again. For example, the prescription drug monitoring programs established and operated by State governments have had a fair amount of success in rooting out fraud in Medicare as well as Medicaid and in the private sector. These monitoring programs track prescriptions filled by pharmacies across a State in order to help identify and prevent illegal diversion or abuse.

I was encouraged to hear from today's testimony that 46 States have operational monitoring programs and an additional 3 States have enacted legislation to establish one. I think when we first got into this issue a couple years ago, we found out that there are a lot more States that did not have this kind of monitoring program. One of them was my own State, and to the credit of our Governor and the legislature, they jumped all over it. But that is the good news. I think it was not that long ago, maybe 4 years ago, maybe two-thirds of the States, maybe about 33, 34 of the States had these programs operational.

Could each of you today just comment on the importance and effectiveness of the State-run prescription drug monitoring programs in combating prescription drug waste and fraud? And, also, what are some of the important next steps to ensure that the monitoring programs become, over time, even more effective?

Ms. Lavelle, do you want to go first?

Ms. LAVELLE. Sure. One of our biggest pain points in WellPoint is a little corner of the State of Virginia known as Roanoke. That——

Chairman CARPER. "Star city of the South?"

Ms. LAVELLE. Yes.

Chairman CARPER. Where I grew up.

Ms. LAVELLE. Really?

Chairman CARPER. In Danville and Roanoke.

Ms. LAVELLE. Oh, my goodness. We have pharmacies where we often see up to 15 license plates from outlying States. We know that they are pill mills. We know that they are impacting Part D and our commercial plans as well as our Medicaid plans. And we have been working with the State law enforcement agencies to get them prosecuted. We have been pretty successful in a lot of referrals, but it is, again, a major problem in that part of the State of Virginia, and we are really focusing on that.

Los Angeles County is our other hot spot and——

Chairman CARPER. Why do you suppose Roanoke, Virginia, would be a hot spot? I could see maybe L.A., but why——

Ms. LAVELLE. We have often asked that, and maybe the gentleman from DEA knows more than I. But I have often been told that it is a spillover from the coal mining days. It is hard to say, but we have a real pain point in that part of the world. So we are trying to lock in as many as we can in the Medicaid program and to refer all the pill mills for prosecution.

Chairman CARPER. And when you are referring them for prosecution, who do you refer them to? What entity do you refer them to?

Ms. LAVELLE. It depends. Usually the State troopers, Virginia State troopers will pick up those cases. The U.S. Attorney's Office has taken quite a few of the pain management providers, which we often refer to as "drug dealers in white lab jackets." Some very egregious. We have even had calls from the coroner's office advising us that the 14th body has come in from a particular prescriber, and they did not know who else to call, but they knew they had Blue Cross insurance. So it is that big of a problem there.

Chairman CARPER. OK. Thank you. Mr. Wright.

Mr. WRIGHT. In terms of next steps, we do plan additional evaluation work looking at Medicaid drug utilization review programs. That is not something that we have directly reviewed at this date, but we are planning on doing reviews that will determine how they operate, how they are reviewed, which ones are effective. We think this is an important place for us to go, building on the work that we have discussed today.

In addition to that, we continue to look at issues associated with Medicaid data overall. It is very important from a national standpoint that there be complete and accurate Medicaid data, which historically there have been difficulties in building. So we plan on continuing to work on that issue, hopefully getting to the point at a future date when we have a comprehensive Medicaid data set that will enable us to look at Medicaid holistically and not just State by State.

Chairman CARPER. OK. Thank you. Mr. Cantrell.

Mr. CANTRELL. I will just reiterate that we think that the prescription drug monitoring programs do serve in many States as a great deterrent to this type of activity, and if all States had a similar level of program, then we might prevent some of this crossing State lines in order to avoid them.

I will also just mention that we have the Medicaid Fraud Control Units, who we work with quite frequently, and their involvement in this effort is also important.

Chairman CARPER. Thank you. Mr. Blum.

Mr. BLUM. I think given the steps we are taking at CMS to reduce the probability that Part D is paying for inappropriate medications, I do not believe that is going to stop the problem. I think the drugs are very inexpensive, and if CMS takes further steps to bring the rate down to zero, those shift to cash-paying transactions, which means that other data sources will be necessary to spot drug-seeking behaviors, and I think that the State drug programs provide a tremendous resource. Data has to be shared. Data has to be cross-analyzed because beneficiaries and schemes do cross State lines. But just focusing on the Part D program will not solve the problem given the cost of these drugs. They are very inexpensive and they will just shift to cash.

Chairman CARPER. All right. Thank you. Mr. Rannazzisi.

Mr. RANNAZZISI. Again, going back to the PDMPs, one of the most important things involving the PDMPs is Internet connectivity between the States. If the States are not interconnected, you are not going to get a full picture of doctor shopping. The National Association of Boards of Pharmacy is currently connecting States. I think they have 15 States interconnected right now. That way it prevents these people from going cross-border. If you are going cross-border from Indiana to Kentucky, Kentucky to Ohio, it will show up on your PDMPs.

As far as why the pill mills are going into rural areas, it is because they are comfortable there. Pill mills, when they started in Florida, were very comfortable because Florida did not have a PDMP and they did not really have a regulatory infrastructure to prevent them from spreading. As soon as law enforcement, the regulatory infrastructure in the State of Florida started passing statutes, they felt heat and started to move. They moved up into Georgia, rural areas off I–75. Now Georgia is giving them heat, and they are up in Tennessee. They move to rural areas because they are comfortable because they do not believe that law enforcement and the regulatory bodies will find them in those rural areas. It is not that those areas have a lot of pain patients. It is that this is where they are comfortable. And you are absolutely right. If you look at a very active pain clinic, a rogue pain clinic, you are going to see license plates from all over the place. When we were doing the Florida pain clinics, there were license plates as far as Massachusetts down into Florida.

And you made one other statement before about heroin and parents not having to worry about heroin because of prescription drugs. The fact is that we are seeing more and more throughout the country where children, young adults, cannot afford the prescription drugs anymore, because, remember, the street value for hydrocodone is only $5 or $7, even the oxycodone combination prod-

ucts, $5 to $7 a tablet. But when you start talking about the single-entity, 30-milligram, immediate release oxycodone 30s or OxyContin or oxymorphone, you are talking between $30 and $80 a tablet. And once you are addicted, you cannot afford that, especially if you are on multiple tablets a day. So what we are seeing throughout the country in both rural and urban areas is kids moving to heroin, and that is well documented, both in the literature and by law enforcement reports. Heroin is going to be a problem if we do not get a handle on the opiate abuse in the United States.

Chairman CARPER. OK. Can I followup, Mr. Rannazzisi, with maybe another question? But before I ask this, I am going to telegraph a pitch, if I could here. One of the things sometimes I will do with a hearing of this nature is ask not only the witnesses to give an opening statement, but ask you to give a brief closing statement, not a 5-minute statement but just a brief closing statement. If there are some points you want to reiterate, that would be fine. If some of the other witnesses have said something that you think needs to be seconded or re-emphasized, or if there are some things, you have some advice for us on this side of the dais, again, we would welcome that, but just some closing thoughts that you think ought to be mentioned, either for the first time or re-emphasized, that would be helpful.

But, Mr. Rannazzisi, I am interested in learning a little bit more about the steps that DEA takes to ensure that its registry of practitioners authorized to prescribe controlled substances is accurate and up to date. A key preventive step for curbing fraudulent diversion of controlled substances such as OxyContin is, I am told, to maintain an accurate list of those physicians that are authorized to prescribe in the first place. But, obviously, there are some challenges.

For example, I understand that the DEA only has access to a less than complete list of people who have died. There is something called the Death Master File (DMF), and you have access to the public file but not the more complete file that is maintained by the Social Security Administration (SSA). And I would just ask what steps does the DEA take to ensure that the registry of controlled substance providers is accurate and up to date? And are there some additional steps that are under consideration, perhaps some that might need congressional support?

Mr. RANNAZZISI. I believe that we are bouncing our system off the Social Security death registry. I have to go back and look now because I thought we were looking at the complete system. But if we are looking at a partial system and not getting the information, I would like to get back to the Committee.

Chairman CARPER. If you would. I am told you have access to the public file, but not to the more complete file that is maintained by the Social Security Administration. So if you could followup on that, and we will ask you to respond in writing, if you would, please.

Mr. RANNAZZISI. Yes, sir.

Chairman CARPER. OK.

I have a short closing statement of my own, but before I offer that, I am just going to go back to our witnesses. And thank you for being here. Thank you for your work in these vineyards. This

is not an easy one, is it? It is not an easy one. And none of us has the solution or the ability to—there are no silver bullets here. A lot of silver BB's. And we have to make sure that we identify them and that we are putting them to good use.

Ms. Lavelle, do you want to give just a brief closing statement, just a minute or two?

Ms. LAVELLE. Sure. I appreciate Mr. Blum's words, and they give us great hope that we are going to have some changes in the future. I also appreciate the work that HHS and the Fraud Prevention Partnership has been doing. We have people in the room here that have been instrumental in bringing the privates and the publics and the agencies together, and I have great hope that we will have a very successful partnership going forward. There is a great deal of promise there, but we have work to do.

And, second, I wanted to reiterate and point out that the paradigm is changing for WellPoint. We no longer want to pay and chase. In doing so we get 20 to 30 cents back on the dollar. The paradigm for us is prevention and to stop the dollars from ever going out the door.

So, with that, I want to point out that with the medical loss ratio we are only allowed credit for collections, which is counterintuitive to our new paradigm of savings. So it actually encourages recoveries because that is the only credit we get. So with our new paradigm, we hope that there may be some changing activities in the MLR that will give us credit for some of the work we do and the tools that we use. Thank you.

Chairman CARPER. Thank you for that point. Thank you. Mr. Wright.

Mr. WRIGHT. In closing, I think I would like to make three points.

One, it is extremely important to follow through and implement the recommendations that have been made by our office. I would specifically mention recommendations aimed at the sponsors. For example, we have recommended that the sponsors be required to refer fraud and abuse cases to the MEDIC. Currently that reporting is only voluntary.

There are a series of recommendations aimed specifically at the MEDIC in terms of their ability to get information from sponsors, pharmacies, and prescribers that they do not currently have. There are recommendations pertaining to the MEDIC in terms of doing more proactive data analytics. And, last, I think just in general, revamping and strengthening the MEDIC function is really crucial to what we have been talking about today.

The second point that I would reiterate is the resource issues that Gary raised. Fully funding the office in terms of the President's budget request is crucial for our oversight activities. As Gary mentioned, we are slated to be down 200 staff by the end of the year and are on track to attrit 400 staff by the end of 2015. The office likes to point out that we return $8 for every dollar invested in us. To the extent staff leave, they will no longer be contributing to that return on investment.

And the third and final——

Chairman CARPER. Stop right there if you would. So the President's budget, you are urging us at least in this respect to support the President's budget?

Mr. WRIGHT. To fully fund the President's budget, correct.

Chairman CARPER. OK. Thank you. All right.

Mr. WRIGHT. And, last, conducting oversight hearings, as you have done today, is really crucial to shedding light on these problems and getting all the players aligned to actually do something about them.

Chairman CARPER. All right. Thank you. Mr. Cantrell.

Mr. CANTRELL. First, I want to thank you, Chairman Carper, for holding this hearing. I think it is a great opportunity for us all to talk and identify potential solutions. And Mr. Wright has already mentioned the resource issue, so——

Chairman CARPER. You can mention it again. Seriously. Repetition is good.

Mr. CANTRELL. Well, I will say real quick, you may have heard of the Health Enforcement Action Team (HEAT) and our strike force teams that have tackled Medicare fraud in nine cities across the country. It has been a very successful model in tackling all types of Medicare fraud. We would like to be able to expand that kind of focus in other areas of the country and other areas of the program. And I think with additional resources that are included in the President's budget, we would be able to do that sort of thing. And while prescription drug fraud and abuse is a top priority for OIG now, I know that there is more that we can do with more boots on the ground.

Chairman CARPER. OK. Thank you. Mr. Blum.

Mr. BLUM. I want to thank the Committee for holding this hearing. CMS welcomes the oversight. Oversight helps us build programs that better serve beneficiaries. And I think it is true that when the program was established back in 2006, the focus was on making sure beneficiaries got every drug they needed. And a lot of the oversight work that CMS has done was to make sure that beneficiaries get what they need at the point of sale, and that was appropriate at the time.

But now we are in a different time, and I think now the focus should be making sure beneficiaries get what they need, but stopping those payments for the prescribing that is inappropriate. And that will take some further steps—will build on current actions but take some further steps. It will create more friction that you will hear about from the physician community, from pharmacies, and from beneficiary themselves. I think that is something that, in addition to changes in law, I think the programs will need your support once that friction starts. To enroll all prescribers to the Medicare program will take a huge lift, and you will hear about it.

And I think one request that we do have is that Congress continue to support these changes, but we are going to have to create more friction in the system to kind of shift the paradigm from not just providing all drugs at the point of sale, but to hold everyone accountable, CMS too, to stopping those drugs that are not appropriate.

Chairman CARPER. All right. Thank you. Mr. Rannazzisi.

Mr. RANNAZZISI. Finally, Mr. Chairman, I want to thank you and Senator Coburn for your leadership in this area and to get the word out about the use of these drugs.

I also want to thank you for identifying education of parents and family members as being an important part of our overall strategy because, quite frankly, there are not too many people that understand that because it does not really affect them until it actually affects them, and then it is too late.

I look forward to working with colleagues at HHS, continuing to work in CMS as we move forward against these people who are basically gaming the system and doctor shoppers and people who are just diverting.

And, finally, when you talk about sequestration, it is problematic for us too. We are losing positions through attrition, and we cannot fill those positions right now, especially in my scientific staff and my regulatory staff and our special agents.

Thank you very much for this opportunity.

Chairman CARPER. Thank you, each of you, for those closing statements. I was not going to mention this, but I am going to. Dr. Coburn has put in a lot of time and energy over the last several years in helping to develop a comprehensive deficit reduction plan which involves roughly $1 of revenue, additional revenue for every $3 on the spending side, and it is a balanced plan put together under the auspices of Erskine Bowles and former Senator Alan Simpson, and it is something that I support as well, as do a number of my colleagues. The President's latest budget proposal for 2014 actually mirrors and looks a whole lot like the efforts of the Simpson-Bowles Deficit Commission.

One of the virtues that it would have if it were adopted, if something like that were to be adopted, is we would end sequestration. We would also put ourselves on a track to reduce the deficit by another roughly $5 trillion over the next 10 years. It does not balance the budget, but it gets us certainly a lot closer to where we need to be.

In response to your urging for us to be mindful of sequestration and what it does in terms of your abilities to do your jobs, I just want you to know, there is a pretty good plan out there, and the President actually seems to be lined up behind it now, and my hope is that we can before the end of this fiscal year actually do that or do something very close to that.

That leads me to this statement. I have already said it before. We still have huge budget deficits, about over $600 billion. That is better than $1.4 trillion, but we still have a ways to go, and it looks like the deficit might continue to go down for a while and then come back up again. The big driver of this is my generation, the boomers, and as we move into Medicare and other programs, we are needing greater Federal assistance.

As a result, if we are going to be serious on deficit reduction, it has to include Medicare, not in a thoughtless way, not in a way that savages older people or poor people, but in a way that actually saves some money. And it uses a lot of common sense, it uses technology, and saves these programs for my kids, for your kids, and for our grandchildren as well.

On the other side of that, Medicare is not running a big surplus these days. In fact, Medicare, given the tidal wave of boomers that are moving into a time in their lives when they are eligible for Medicare and other programs, is looking to eventually run out of money in the next decade, and that is not good.

So we attack on this Committee a lot of issues on a fiscal basis, and we look at why we are wasting money, it makes the deficit worse, it makes it hastens the day when Medicare runs out of money. But this issue has another more human side that we have heard here today. And when you talked, Ms. Lavelle, about your daughter, a lacrosse player, injured, going back to school, taking the controlled substance for pain control, and having other students in the schools saying they would like to buy some of her extra pills, that really brings it home.

And as good as you and the folks at WellPoint are in the work that you do in these vineyards, and our friends from the Inspector General's office and Jonathan Blum and the people at CMS and folks from DEA and our efforts here, it is not enough. Any one of us by ourselves cannot do it. This is, as I like to say, an old Navy guy, all hands on deck. It is a shared responsibility, and we have to all be part of this team.

We have the benefit of having some technology today that we did not have that many years ago, and I can remember—my mom is deceased now, but she passed away about 6 years ago. She lived down in Florida for most of the last 30 years of her life. She had I think about six different doctors that were prescribing 15 different medicines. None of them ever talked to each other. They did not know that the others were prescribing medicines for her. And, unfortunately, she was not unique, and that happened a whole lot.

But we figured out in that situation that a Medicare patient, was receiving medicines that were not compatible with one another. And we have just gone way beyond that in terms of our technology and our ability to know what is going on in those situations.

In this Committee we spend a fair amount of time on homeland security, the other piece of what we do, and there is a lot of discussion in the media and across the country about what the National Security Agency is doing in terms of telephone calls or electronic messages over the Internet, and in an effort to try to make sure bad people do not come in and do harm to us. And we have folks that are hacking into our systems as we gather here today, and there is a real tension between how do we protect our privacy, our rights as individuals, and how do we protect ourselves and our country from attacks, whether they be from terrorists or whether they be from cyber terrorists.

Having said that, the kind of tools that are available to protect our personal safety and our national security and protect us from cyber attacks, the technology is pretty amazing. And I think we are only scratching the surface in terms of what we can do in a way that is respectful to privacy rights to better harness technology, to identify whether it is a doctor, whether it is one of these pill mills, or whether it is a massage therapist—nothing against massage therapists—whether it is a dental hygienist—nothing against dental hygienists—but we want to make sure that they are prescribing

what is appropriate, what is lawful; and when they do not, that we have the ability to detect that and do something about it.

The last thing I want to say is this: Parents have to get their heads in the game. Most kids grow up in a home where they have at least one, oftentimes two parents that really care about them, love them, and want to make sure they are making the right decisions and the parents are setting the right kind of examples. The government cannot do this by itself. We need to be helpful. We need to be supportive. We need to play our role, and we have a big role to play. But so do parents and family members, and they need to get their heads in the game. And my hope is that holding a hearing like this not only helps to encourage all of us that have these responsibilities to work on these problems; my hope is that the word will get to a lot of homes across the country where parents are not as mindful as they need to be and remind them that they have a responsibility as well. They have a whole lot at stake as well.

We have a pretty good to-do list here for us on this side and for you on the other side of the table. Thank you for helping us put that together, for the work that is being done. And as I like to say, everything I do I know I can do better. And as I learned from my father as a little boy growing up in Roanoke, Virginia, I learned that if it is not perfect, make it better. That is what I learned: This is not a perfect situation. We are doing better in some respects, and we can do a whole lot better, and we need to.

With that, this hearing is almost adjourned, and I am told by this young lady over here on the left who is going to be retiring—in how many days? Four days. Trina is going to be retiring. She has been our chief clerk for a lot longer than you would imagine. Looking at her, it is hard to believe she is eligible to retire, but she is. And we appreciate very much her work. I do not know if we are going to have another hearing before you step down. I know we are going to have a business meeting here later today and try to put out some of the President's nominees. I just want to say in front of you and those who have admired your work for many years, Trina, how much we admire you and respect you and are grateful for your service not just to this Committee, not just to the Senate, but really to our country.

And with that having been said, the hearing record will remain open for 15 days—that is until July 9 at 5 p.m.—for the submission of statements and questions for the record.

And I would just say to our guests, three of us were here today. A number of staff were here as well. As I said earlier, we have a vote that starts at 5:30. Members are flying in from all over the country, from their own home States. And the fact that there are not more Members here, do not be discouraged by that. I am not. You should not be either. Dr. Coburn and I and our new Member from New Jersey, he is going to be good. I think he is in office until at least October or so. Maybe November. But we are going to get a lot of work out of him. He knows this stuff, and he is going to be a good addition to the U.S. Senate.

All right. I think that is it. It is a wrap, and with that this hearing is adjourned. Thank you.

[Whereupon, at 4:59 p.m., the Committee was adjourned.]

APPENDIX

Opening Statement of Chairman Thomas R. Carper

"Curbing Prescription Drug Abuse in Medicare"
June 24, 2013

As prepared for delivery:

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

Medicare is a critical component of health care in our nation. The prescription drug program, also known as Medicare Part D, began in January, 2006. We are now into the seventh year, and the overall reviews of the program have been positive, with more than 31 million seniors participating. However, Congress must ensure sure that the $60 billion a year program works effectively and efficiently. Unfortunately, Medicare – including Part D – isn't as effective or efficient as it could or should be when it comes to preventing waste and fraud.

Each year, the federal government lists the estimates of overpayments, underpayments, undocumented expenditures and other kinds of mistakes made by each agency.
The total for fiscal year 2012 was more than a hundred billion dollars. Medicare has the largest reported share of that total at $44.3 billion. And the amount wasted in Medicare's prescription drug program alone is $1.6 billion.

In addition, health care is too often the focus of criminals who wish to take advantage of the system. Whether the care is provided through government programs or the private sector, attempts to defraud the health care system are on the rise. There are estimates for Medicare fraud in the billions of dollars.

We simply cannot afford to tolerate these levels of waste and fraud in our federal health care programs. As everyone in this room knows, we've faced record budget deficits in recent years. Given the debt and deficit problems our country faces, and the tough work ahead of us as we attempt to address those challenges, we need to focus like a laser on the avoidable, expensive, and frankly unacceptable issues we'll be discussing today.

During a subcommittee hearing that I chaired in the fall of 2011, the Government Accountability Office testified that they identified about 170,000 beneficiaries who acquired the same class of frequently abused drugs, primarily hydrocodone and oxycodone, from five or more medical practitioners at a taxpayer cost of $148 million. In two egregious examples, individuals received prescriptions from 87 and 58 different medical practitioners. This followed a similar study by the GAO in 2009 showing the same problem in Medicaid.

This fraud technique is called 'doctor shopping.' It involves recipients going to multiple doctors for the same type of drug. In these cases, beneficiaries are almost always either feeding an addiction or selling the drugs they don't use on the street. Drug dealers make the profit, while the federal government foots the bill.

But the problem of prescription drug fraud is about more than just a loss of taxpayer dollars. It's also about the toll drug abuse takes on people. It is of great concern that one out of seven high school seniors in America has abused, or is abusing, prescription drugs. In fact, more Americans abuse prescription drugs than the number who abuse cocaine, heroin, hallucinogens, Ecstasy, and inhalants, combined.

The Department of Health and Human Services, specifically the Centers for Medicare and Medicaid Services, has established a set of oversight procedures to protect the Medicare Prescription Drug Program and its beneficiaries from fraud and waste. This is a team effort involving Medicare officials, law enforcement at the federal, state and local levels, the Medicare prescription drug plans, pharmacies and doctors, and the beneficiaries themselves. Unfortunately, based on today's testimony by the Health and Human Services Office of Inspector General, there is still a lot more work to do.

On Thursday of last week, the inspector general released a report detailing over 700 general-care practitioners who had questionable Medicare Part D prescribing patterns. For example, while prescription drugs with a high abuse potential constitute on average only 2 percent of most general practitioners' prescriptions, they constituted 78 percent for one general practitioner identified in the report.

This physician prescribed a year's supply of three painkillers, such as morphine and codeine, for just one Medicare beneficiary. Another general practitioner's prescriptions were filled at 872 different pharmacies in 47 states, including Guam.

Today, we will learn about an even more clear failure of oversight. The inspector general is reporting that Medicare is paying for prescription drugs, prescribed not be physicians or others authorized to prescribe drugs, but people with no authority to prescribe at all. Apparently, 400,000 prescriptions totaling $31.6 million were prescribed by individuals who appear to be massage therapists, interpreters, music and art therapists, and contractors who perform health-care related home repairs.

The most disturbing finding in the inspector general's report is that 29,000 of these prescriptions were for controlled substances, including drugs with a high potential for abuse, such as oxycodone. One contractor alone wrote 79 prescriptions for commonly abused pain killers.

Obviously, these numbers and examples show clear indicators of abuse and fraud. As a recovering Governor, I understand the unique challenges that come along with running a major program like Medicare. However, we simply have to do a better job in overseeing the Medicare prescription drug program.

I will continue to work with my colleagues and the Administration to ensure that programs across the federal government are improving management functions, monitoring results, and finding ways to do more with less in almost everything they do. A key part of these efforts will involve program managers sharpening their pencils and, in conjunction with our private sector partners, preventing expensive and harmful waste and fraud. We must use every tool available to

make sure that our health care programs help those who need medications, rather than feed drug addictions or fraudulent profiteering. By working together on this latest in a series of common sense initiatives, we can take another important step forward in earning their trust once again.

RANKING OF COMMONLY ABUSED DRUGS

1 MARIJUANA

2 PRESCRIPTION DRUGS

3 COCAINE

4 HALLUCINOGENS

5 INHALANTS

6 HEROIN

EXAMPLES OF UNAUTHORIZED PRESCRIBERS IDENTIFIED BY THE INSPECTOR GENERAL

Dieticians and Nutritionists

Audiologists

Massage Therapists

Athletic Trainers

Opticians

Dental Hygienists

Contractors (health-care related home modifications)

Home Health Aides

Interpreters

Transportation Companies

Music or Art Therapists

Nursing Technicians

Veterinarians

MEDICARE PAID FOR PRESCRIPTIONS

Made by Individuals

WITHOUT PRESCRIBING AUTHORITY

417,269	**Prescriptions**
29,212	**Controlled Substances Prescriptions**
15,484	**Prescribers**
$31.6 million	**Loss-to-Taxpayers**

Department of Justice

STATEMENT OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

FOR A HEARING ENTITLED

"CURBING PRESCRIPTION DRUG ABUSE IN MEDICARE"

PRESENTED ON

JUNE 24, 2013

Testimony of Deputy Assistant Administrator Joseph T. Rannazzisi
Office of Diversion Control, Drug Enforcement Administration
before the United States Senate
Committee on Homeland Security and Governmental Affairs
Monday, June 24, 2013

Introduction

Chairman Carper, Ranking Member Coburn, and distinguished Members of the Committee on Homeland Security and Governmental Affairs, on behalf of Drug Enforcement Administrator Michele M. Leonhart and the men and women of the Drug Enforcement Administration (DEA), I want to thank you for the opportunity to discuss the epidemic of pharmaceutical controlled substance abuse and the diversion of controlled substance pharmaceuticals.

Abuse of Controlled Substance Pharmaceuticals

The abuse of prescription drugs continues to plague the nation at an alarming rate, crossing all age, gender, racial and socioeconomic boundaries. Studies show substantially high levels in the abuse and misuse (non-medical use) of these drugs and the adverse consequences associated with such actions. According to the Substance Abuse and Mental Health Services Administration's (SAMHSA's) 2011 National Survey on Drug Use and Health (NSDUH)—the most recent NSDUH—the number and percentage of persons aged 12 or older who were current (past month) nonmedical users of psychotherapeutic drugs in 2011 (6.1 million or 2.4 percent) were lower than the estimates in 2010 (7.0 million or 2.7 percent) and 2009 (7.0 million or 2.8 percent). Psychotherapeutic drugs include prescription-type pain relievers, tranquilizers, stimulants, or sedatives, but not over-the-counter substances. Although the most recent statistics reveal a slight downward trend, the abuse of pharmaceutical controlled substances is still alarming.

An estimated 8.0 million people aged 12 or older (3.1 percent of the population) were current users of illicit drugs other than marijuana in 2011; the majority of these users (6.1 million persons, or 2.4 percent of the population) were non-medical users of psychotherapeutic drugs. In 2011, 2.3 million persons aged 12 or older used psychotherapeutic drugs non-medically for the first time within the previous year, which averages to around 6,400 initiates per day. The number of new non-medical users of psychotherapeutic drugs in 2011 was similar to the 2010 estimate (2.4 million), but lower than the 2004 estimate (2.8 million). Of the total number of non-medical users of psychotherapeutic drugs in 2011, the number of new non-medical users of pain relievers (1.9 million) was lower than the numbers in 2002 through 2005 and in 2008 and 2009 (ranging from 2.2 million to 2.5 million). In 2011, the number of initiates of other psychotherapeutic drugs was 1.2 million for tranquilizers, 670,000 for stimulants, and 159,000 for sedatives.[1] The non-medical use of prescription drugs is the second-leading category of illicit drug use among Americans 12 and older—second only to

1 Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

marijuana use.[2] Among this population, the number of new initiates who used narcotic pain relievers is second only to the number of new initiates who used marijuana.[3]

This data is particularly disturbing because prescription opiate abuse by teens and young adults can lead to heroin abuse. DEA intelligence has shown that the "street" cost of prescription opiates - as high as $80.00 per tablet or more in the case of OxyContin 80 mg, and $30.00 to $40.00 per tablet for 30 mg oxycodone single entity immediate release - makes it difficult for teens and young adults to purchase the drugs to continue use in support of their addiction. As a result, intelligence indicates that some users of prescription opiates turn to heroin, a much cheaper opiate that provides a similar "high" and keeps the drug seeker/abuser from experiencing painful withdrawal symptoms. This cycle has been confirmed by police agencies throughout the country, who are now reporting an increase in heroin use by teens and young adults who began their cycle of abuse with prescription opiates. In 2011, 178,000 persons aged 12 or older used heroin for the first time within the previous 12 months. Although this number was similar to the estimates in 2010(142,000) and 2009 (187,000), the 2011 estimate was higher than the estimates during 2005 to 2007 (ranging from 90,000 to 108,000 per year). A special analysis by NSDUH researchers indicates that 81 percent of heroin initiates in 2008-2010 had previously used pain relievers non-medically.[4] Among recent initiates aged 12 to 49, the average age for first-time heroin use was 22.1 years, which was similar to the 2010 estimate (21.4 years).[5]

This cycle of abuse can be traced to the mistaken belief among teens and young adults that prescription medications are safer than other drugs of abuse such as heroin, cocaine, marijuana, and methamphetamine, combined with, at least initially, easy access to prescription medications. The 2012 Partnership Attitude Tracking Study (PATS) noted that 43 percent of teenagers believe that prescription medications are "easier to obtain" than illegal drugs.[6] Because prescription medications are manufactured by pharmaceutical companies, prescribed by physicians and other medical professionals, and dispensed by pharmacists, teens and young adults often have a false sense of security regarding these potent and dangerous medications. In fact, according to the same 2012 PATS, 27 percent of teens mistakenly believe that misusing or abusing prescription drugs is "safer" than using street drugs.[7] Other key points revealed in the 2012 PATS are that 1 in 4 teens (24 percent) admitted to having misused or abused a prescription drug at least once in their lifetime; 33 percent of teens said they believe "it's okay to use prescription drugs that were not prescribed to them to deal with an injury, illness, or physical pains;" and 23 percent of teens said their parents don't care as much if they are caught using prescription drugs without a doctor's prescription, compared to getting caught with illegal drugs.[8] Sixteen percent of teens said they discussed the misuse or abuse of prescription pain relievers with their parents.[9]

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2 Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

3 Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

4 Gfroerer, Joe and Muhuri, Pradip. Associations between nonmedical pain reliever use and heroin initiation. Presentation at ONDCP Interagency Meeting on Heroin. June 28, 2012.

5 Substance Abuse and Mental Health Services Administration, Results from the 2011 National Survey on Drug Use and Health.

6 Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Full Report, Page 10.

7 Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.

8 Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.

9 Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.

As one would expect, this abuse leads to increased diversion, and, in turn, increased enforcement activity. The National Forensic Laboratory Information System (NFLIS) collects results of drug chemistry analyses conducted by Federal, state, and local forensic laboratories across the country. As such, NFLIS can provide detailed analytical results of drugs seized by law enforcement, including trends in the diversion of pharmaceutical controlled substances into illegal markets. As of June 14, 2013, 47 state laboratory systems, 94 local laboratory systems, and one territorial laboratory system were participating in NFLIS. In 2010, approximately 1.7 million drug analysis records were reported to NFLIS. The increase in opiate pain medication analyses conducted by NFLIS-reporting laboratories from 2001 to 2010 is staggering: 322 percent for oxycodone; 240 percent for hydrocodone; and 253 percent for morphine.

Drug abuse is a problem that cannot be addressed through law enforcement action alone. We will never be able to "arrest our way" out of this problem. The Office of National Drug Control Policy's 2011 Prescription Drug Abuse Prevention Plan, a multi-pronged approach that includes education, monitoring, proper medication disposal, and enforcement is a science-based and practical way to address this national epidemic. One role of DEA, in addition to enforcing the Controlled Substances Act (CSA), is to educate the registrant population—including health care providers—on their obligations under the CSA, as well as to educate parents, community leaders and law enforcement personnel regarding diversion trends, the scope of the problem, and how to best address prescription drug diversion in communities throughout the United States.

One of the factors that contribute to the abuse of pharmaceutical controlled substances is the perception by some members of the public that it is safer to abuse prescription substances than to abuse illicit substances. Additionally, black-market sales for prescription controlled substances are typically at five to ten times the retail value. Profits generated from these street sales provide a strong incentive for continued diversion. Another factor that contributes to the increase of prescription drug diversion is the availability of these drugs in the household. In many cases, dispensed controlled substances remain in household medicine cabinets well after medication therapy has been completed, thus providing easy access to non-medical users for abuse, accidental ingestion, or illegal distribution for profit. Accidental ingestion of medication, including a controlled substance, by the elderly and children, is more likely when the household medicine cabinet contains unused medications that are no longer needed for treatment. The medicine cabinet also provides ready access to persons, especially teenagers, who seek to abuse medications. The 2012 PATS noted that 56 percent of teens indicated that it's easy to get prescription drugs from their parent's medicine cabinet and, in fact, 49 percent of parents say "anyone can access their medicine cabinet."[10] Furthermore, the 2011 NSDUH indicates that 71 percent of individuals in 2010-2011 who used pain relievers nonmedically in the past year obtained them from a friend or relative.[11]

DEA has responded to this problem by coordinating, every six months, National Prescription Drug Take-Back events with our Federal, state, local, and tribal law enforcement partners. Since September 2010, DEA has held six National Prescription Drug Take-Back Days, resulting in the collection of approximately 2.8 million pounds (1,409 tons) of unwanted prescription drugs. Removing household medication that is unwanted or no longer needed is a key component to limiting the availability of and access to these drugs by children and drug seekers for non-medical purposes. DEA is fully engaged in ensuring proper disposal of controlled substances and is

10 Partnership for a Drug-Free America, 2012 Partnership Attitude Tracking Study, Key Findings.
11 Substance Abuse and Mental Health Services Administration. Results from the 2011 National Survey on Drug Use and Health.

currently finalizing regulations implementing the Secure and Responsible Drug Disposal Act of 2010, which authorizes additional ways for Americans to dispose of their unwanted or expired controlled substance medications in a secure and responsible manner.

Means by Which Pharmaceutical Controlled Substances Are Diverted

Understanding the means by which controlled substances are diverted is critical in determining appropriate regulatory controls. Diversion of pharmaceutical controlled substances can occur in a number of ways, including, but not limited to, the following:

- Prescription pads are stolen from practitioners' offices by patients, staff, or others, and illegitimate prescriptions are written and forged.
- Legitimate prescriptions are altered to obtain additional amounts of legitimately prescribed controlled substances.
- Drug-seeking patients may falsify symptoms or obtain multiple prescriptions from different practitioners for their own use or for resale. In some cases, organized groups visit practitioners with fake symptoms to obtain prescriptions, which are filled and resold. Some patients resell their legitimately obtained drugs to earn extra money.
- Prescription pads containing legitimate practitioner information (e.g., name, address, DEA registration number) are printed with a different call-back number that is answered by an accomplice to verify the prescription.
- Computers and scanning or copying equipment are used to create prescriptions for non-existent practitioners or to copy legitimate practitioners' prescriptions.
- Pharmacies and other locations where pharmaceutical controlled substances are stored are robbed or burglarized.

Diversion from within the practitioner's practice or pharmacy may also occur, such as in the following situations:

- Prescriptions are written for other than a legitimate medical purpose.
- Pharmaceutical controlled substances are stolen from pharmacies by pharmacy personnel. Legitimately dispensed prescriptions may be altered to make the thefts less detectable.
- Pharmacists are not exercising their coordinating responsibility to ensure that prescriptions are valid.

Recent Schemes to Divert Controlled Substances

Over the past several years, DEA Diversion Investigators and Special Agents have uncovered two types of illegal schemes used to divert powerful and addictive controlled substance pharmaceuticals. Florida was the epicenter of many illegal operations whereby hundreds of millions of dosage units of controlled substances were diverted into the illicit marketplace across the United States. Between 2005 and 2009, the diversion of millions of dosage units of Schedule III hydrocodone products was

facilitated by rogue internet pharmacies and unscrupulous prescribers who provided prescriptions to drug seekers utilizing these sites.

The *Ryan Haight Online Pharmacy Consumer Protection Act* that took effect in April 2009 responded to the explosion of domestic rogue internet pharmacy diversion. This law, combined with intensified law enforcement and regulatory actions, virtually eliminated domestic-based rogue internet pharmacies that were involved in internet controlled substance distribution. Internet traffickers have adapted to the law, for example by selling legend drugs and Fioricet (containing butalbital, a Schedule III controlled drug), which is exempt from administrative regulations but not criminal sanctions under the CSA.

As the number of domestic, internet-based pharmacies began to decline in 2008, law enforcement observed a significant rise in the number of rogue pain clinics, particularly in Florida. Instead of hydrocodone, the practitioners in these clinics dispensed millions of dosage units of oxycodone, a Schedule II controlled substance that is just as dangerous as hydrocodone when taken for a non-medical use. There was a sharp increase in pain clinics located in the tri-county area of South Florida (comprised of Broward, Miami-Dade, and Palm Beach Counties) in 2009. According to data provided by the State of Florida, by 2010, Broward County alone was home to approximately 142 rogue pain clinics. Federal, state and local law enforcement investigations identified thousands of drug seekers that routinely traveled to Florida-based rogue pain clinics to obtain pharmaceutical controlled and non-controlled substances, such as oxycodone, hydromorphone, methadone, tramadol, alprazolam, clonazepam, and carisoprodol. They then would travel back to their home states and illegally distribute the drugs that ultimately flooded the illicit market in states along the entire East Coast and the Midwest.

In response to this problem, state legislation in Florida was implemented to restrict a physician's ability to dispense oxycodone and other controlled substances from a pain clinic. However, dispensing controlled substances from these clinics was a huge source of income for clinic owners. Some clinic owners moved operations out of Florida to avoid increased law enforcement and regulatory pressure and the new legislation. Federal, state, and local law enforcement agencies have tracked the expansion of these clinics to other states, including Georgia, Tennessee, Ohio, Missouri, Texas, California, and Pennsylvania. Other rogue pain clinic owners and practitioners adapted to the new laws by issuing illegitimate prescriptions for oxycodone and other controlled substances rather than dispensing directly to the "customer." DEA and other law enforcement agencies saw an immediate and significant increase in the volume of oxycodone dispensed from various pharmacies across the State of Florida.

Seeing their profits going to dispensing pharmacies across the State, clinic owners began purchasing pharmacies and locating them at or near the pain clinics. The purchase of pharmacies is part of the scheme by rogue pain clinic owners to circumvent Florida laws: if a pain clinic cannot lawfully dispense drugs directly to a "customer," then the pain clinic will issue illegitimate prescriptions to "customers," and the pain clinic pharmacy will dispense drugs based on those illegitimate prescriptions. As a result of this scheme, there was a sharp increase in the number of new pharmacy registration applications in the State of Florida. The rise in the number of new pharmacy applications in Florida lead DEA to initiate on-site investigations of all pharmacy applications in Florida,[12] rather than rely upon state licensure to ensure that the applicants have the requisite skill

12 On-site investigations of registrant applicants are conducted by DEA pursuant to its authority under 21 U.S.C. 822(f) and 21 CFR 1301.31.

and experience to safely and responsibly dispense controlled substances, sufficient knowledge of applicable federal law and regulations, and that the applicants intend to comply with Federal laws and regulations.

Further investigation of pharmacy applicants revealed "straw purchases" of pharmacies that had ties to established rogue pain clinics. During the on-site investigations, DEA personnel interviewed numerous applicants with backgrounds such as drywall installer, truck driver, bartender, lawn service owner, and spouse of a pain clinic owner. Many of the applicants had little or no experience with pharmacy operations. To date, this initiative has conducted five deployments to Florida. As a result, 132 retail pharmacies and one distributor have withdrawn their applications. The majority of these withdrawals, including the distributor application, were located in South Florida. As a result of this and other initiatives in Florida, 154 existing retail pharmacies have surrendered their registrations (again, the majority of which were in South Florida). Preventing these pharmacies from conducting business undoubtedly prevented millions of dosage units of controlled substances from entering the illicit market and closed an avenue of distribution and source of income for the rogue pain clinics. This initiative is on-going and has been expanded to other states where DEA has seen an unexplained increase in pharmacy applications.

DEA-registered pharmacies are generally supplied by DEA-registered wholesale distributors. Rogue pain clinics, pharmacies that fill illegitimate prescriptions for pain clinic "patients," and the wholesale distributors who supply these pharmacies have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted. Consequently, the registrants involved—practitioners, pharmacies, and wholesale distributors that do not comply with the CSA and its implementing regulations—are allowing millions of dosage units of controlled substances to pour into the illicit market, posing an imminent danger to the public health and safety. The damage to society is evident from the number of pharmaceutical overdose deaths reported recently by the Centers for Disease Control (CDC). CDC analysis revealed that 38,329 people died from a drug overdose in the United States in 2010. Nearly 60 percent of the drug overdose deaths (22,134) involved pharmaceutical drugs. Opioid analgesics, such as oxycodone, hydrocodone, and methadone, were involved in about 3 of every 4 pharmaceutical overdose deaths (16,651), confirming the predominant role opioid analgesics play in drug overdose deaths.[13]

Registration and Information Sharing

The level of control mandated by Congress for pharmaceutical controlled substances far exceeds that for other prescription drugs. This level of control is commensurate with the potential for physical and psychological dependence and abuse properties associated with controlled substances and is necessary to help prevent abuse and diversion of these substances.

One of the most effective tools to ensure legitimate use of pharmaceutical controlled substances is the registration requirement. The following individuals and entities are required to be registered with DEA: any business that imports or exports a controlled substance, or that manufactures or distributes a controlled substance; pharmacies that dispense controlled substances; practitioners that prescribe, administer, or dispense controlled substances; and any person that conducts research or chemical analysis with a controlled substance. Currently, there are more than 1.4 million registrants registered with DEA, and the vast majority are practitioners (i.e., registered medical professionals

13 Centers for Disease Control and Prevention, Press Release "Opioids drive continued increase in drug overdose deaths." (Feb. 20, 2013).

who prescribe, administer, or dispense pharmaceutical controlled substances). Once registered, each individual or business is issued a unique DEA registration number. DEA maintains over 2 million registration records in a database that includes historical and current regulatory action(s) taken against a registrant.

DEA provides an electronic means by which registrants can check the validity of another registrant's DEA registration number free of charge. DEA also provides access to state agencies that have a responsibility to investigate health care fraud. DEA provides daily access to the registrant database to 41 states, Guam, and D.C., which have requested the data. DEA provides this data to agencies such as the New York State Medicaid Inspector General's Office; the Illinois Office of Inspector General Health and Family Services the Illinois Department of Human Services Bureau of Pharmacy and Clinical Support Services; the North Carolina Medical Board; and the Texas Department of Public Safety, Controlled Substances Registration section. Additionally, DEA provides a listing of current DEA registration numbers to the National Technical Information Service (NTIS), an agency of the U.S. Department of Commerce, on a weekly basis. NTIS collects and disseminates technical information produced by and for Federal agencies. It operates on a self-sustaining basis and makes this information widely available to those who need it on a subscription basis at no cost to the Treasury. DEA currently receives the Social Security Death Master List, and cross-checks that information with DEA registration records to better reconcile these two databases and thereby curb potential avenues of healthcare fraud.

The CSA and DEA Regulations Pertaining to Prescriptions for Controlled Substances

In enacting the CSA, Congress sought to control the diversion of pharmaceutical controlled substances into illicit markets by establishing a closed system of distribution for controlled substances. The CSA requires that a prescription for a controlled substance may be issued only by a practitioner who is registered with DEA, or exempt from registration, and who is also authorized to prescribe controlled substances by the state in which they are prescribing. The CSA and its implementing regulations help maintain the integrity of this closed system of distribution by requiring registrants to adhere to specified security, recordkeeping, and reporting requirements, as well as controlling and limiting legitimate transfers of controlled substances by and between specified registrants. When DEA registrants adhere to the CSA and its implementing regulations, diversion of pharmaceutical controlled substances from the closed system of distribution is prevented.

The closed system is specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain as well as the registrants within the health care delivery system. All registrants must adhere to specific security, recordkeeping, monitoring, and reporting requirements that are designed to identify or prevent diversion. Adherence to these requirements at every level of the delivery and supply chain will reduce the opportunities for diversion.

Practitioners, such as prescribers and pharmacists, must adhere to additional requirements when prescribing or dispensing controlled substances. For example, an individual practitioner such as a physician, dentist, veterinarian, or mid-level practitioner may only dispense or prescribe a controlled substance for a legitimate medical purpose while acting in the usual course of professional practice. 21 CFR §1306.04(a); *United States v. Moore*, 423 US 122 (1975). While the vast majority of practitioners act in accordance with the law, requirements such as this are disregarded at rogue pain

clinics operating throughout the United States. Rather than providing medical care, they utilize the façade of medical care as a front for illegal controlled substance distribution activities. The "physicians" that operate in rogue pain clinics are feeding the addiction of drug seekers. These clinics have minimal physician-patient interaction and generally provide the medication requested by the patient (patient-directed prescribing) without question. There is no attempt to determine the underlying cause of pain and the standard accepted medical practice is disregarded. Most of the practitioners that write prescriptions in these facilities are committing criminal and civil violations of the CSA. If the practitioners in these clinics were to abide by the requirement to issue a prescription only for a legitimate medical purpose and in the usual course of professional practice, drug seekers would not have the opportunity to feed their addiction or to distribute pharmaceutical controlled substances into the illicit market.

A legitimate prescription may be filled only by a pharmacist acting in the usual course of professional practice who is employed in a DEA-registered pharmacy. Except under limited circumstances, a pharmacist may dispense a schedule II controlled substance only upon receipt of a valid electronic prescription or an original written prescription manually signed by the practitioner. A pharmacist may dispense a schedule III or IV controlled substance only pursuant to a legitimate oral, written, or electronic prescription from an individual practitioner. The elements of a prescription that identify the practitioner (i.e., the practitioner's name, address, DEA registration number, and signature) also serve to enable a pharmacy to authenticate the prescription. If a pharmacy is unfamiliar with the practitioner identified on the prescription, it can use the registration number to verify the identity and prescriptive authority of the practitioner.

Ultimately, the last line of defense against diversion is the pharmacist that receives the prescription for medication dispensing. The pharmacist is obligated to ensure that a prescription for a controlled substance is legitimate before dispensing the medication to the patient. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription . . . and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 CFR §1306.04(a). The pharmacist is the "drug expert" in the healthcare delivery system and is well equipped to review a prescription to determine if it is legitimate. If more pharmacists questioned the validity of prescriptions issued by rogue pain clinic physicians and refused to fill the prescriptions based upon their professional judgment, diversion would be significantly decreased. The exercise of their "corresponding responsibility," in many instances, is an opportunity for pharmacists to save lives.

DEA regulations require registered pharmacies to maintain records of dispensing activities for two years from the date of dispensing of the controlled substance. However, some states require that these records be maintained for longer periods of time. These records must be made available for inspection and copying by authorized employees of DEA. This system of records is unique in that the prescribing practitioner creates the prescription, but the dispensing pharmacy retains the prescription as a record of dispensing. DEA does not have authority to require pharmacies to report their controlled substance dispensing activities to DEA. However, DEA does have an administrative authority to access these records stemming from the authority to inspect registered premises.

Prescription Drug Monitoring Programs

Prescription drug monitoring programs (PDMPs) are typically electronic database systems used by practitioners, pharmacists, medical and pharmacy boards, and law enforcement. These programs are established through state legislation and are tailored to the specific needs of a particular state. DEA strongly supports PDMP programs and encourages the use of these programs by medical professionals in detecting and preventing doctor shopping and other forms of diversion. Currently, 46 states have an operational PDMP; 3 more states have enacted PDMP legislation, but do not have operations programs; and 1 state (Missouri) and the District of Columbia do not have legislation. Additionally, DEA makes its registrant database available to any state, without a fee, for use in their PDMP or other state agency charged with investigating health care fraud or controlled substance diversion. These programs, however, are only as good as the data that is in each system and the willingness of practitioners and pharmacists to use such systems on a consistent basis.

Medicare and Medicaid Fraud

Federal investigations of health care fraud are conducted pursuant to the authority of Title 18 U.S.C. §§ 287 and 1001, 18 U.S.C. § 1347, 18 U.S.C. §1518 and Title 42 U.S.C. § 1320a-7b. State agencies also have authority to investigate Medicaid fraud within their jurisdictions. While these violations are outside DEA's jurisdiction, there are occasions when, while investigating violations of the Controlled Substances Act, DEA agents and investigators uncover violations involving health care fraud. This information is shared with investigators from the Department of Health and Human Services (HHS), the Federal Bureau of Investigation (FBI), and other investigative agencies with relevant Federal or state authorities.

The importance of these cooperative and information sharing relationships are reflected in the fact that HHS Office of the Inspector General, the FBI, and others have investigators assigned or are working on an ad-hoc basis with some of our Tactical Diversion Squads. This expertise and contact facilitates information sharing between all of the involved agencies, and allows investigators to easily draw upon each other's expertise when conducting an investigation.

The Drug Enforcement Administration Response to the Prescription Drug Abuse Crisis

Just as illicit drug traffickers and organizations adapt to law enforcement methods, pharmaceutical traffickers adapt to and circumvent laws that attempt to stop the flow of controlled substance pharmaceuticals into the illicit market. As such, law enforcement efforts to prevent, detect, and reduce the diversion of controlled substance pharmaceuticals continue to evolve. DEA has taken action on several fronts over the past few years to help reduce this growing problem.

Restructuring

In October 2008, the then-Acting Administrator authorized a two-pronged reorganization of the Diversion Control Program. The first prong involved a substantial expansion in the number of Tactical Diversion Squads (TDSs) and their deployment throughout the United States. This approach provided a significant increase in the number of Special Agents and Task Force Officers who possess the requisite law enforcement authorities needed when conducting criminal investigations, i.e., the ability to conduct surveillance, make undercover purchases, make arrests, and execute search warrants. The second prong of the reorganization plan called for a renewed

focus on DEA's regulatory oversight of more than 1.4 million DEA registrants. With more Diversion Investigators available to concentrate on the regulatory aspects of the Diversion Control Program, DEA increased the frequency of compliance inspections of specific registrant categories such as manufacturers (including bulk manufacturers); distributors; importers; exporters; narcotic treatment programs; practitioners waived under the Drug Addiction Treatment Act to prescribe certain controlled substances to treat opioid addiction and dependence without obtaining a separate registration to do so; researchers; and chemical handlers. This renewed focus on oversight has enabled DEA to take a more proactive approach to educate registrants and ensure that DEA registrants understand and comply with the Controlled Substances Act and its implementing regulations.

Expansion of Tactical Diversion Squads

Tactical Diversion Squads (TDS) investigate suspected violations of the CSA and other Federal and state statutes pertaining to the diversion of controlled substance pharmaceuticals and listed chemicals. These unique groups combine the skill sets of Special Agents, Diversion Investigators, and a variety of state and local law enforcement agencies. They are dedicated solely towards investigating, disrupting, and dismantling those individuals or organizations involved in diversion schemes (e.g., "doctor shopping," prescription forgery rings, and practitioners or pharmacists who divert controlled substance pharmaceuticals).

As of June 14, 2013, 66 TDS groups have been approved throughout the United States, of which 51 are operational. With the expansion of TDS groups across the U.S., the number of diversion-related criminal and administrative cases has increased significantly. For example, between fiscal year (FY) 2008 and FY 2012, regulatory inspections increased from 1,192 to 4,675 (a 392% increase). Between FY 2008 and FY 2011, administrative actions, including Orders To Show Cause and Immediate Suspension Orders, increased from 70 to 131 (a 87% increase). An Order To Show Cause, which commences administrative action against a registrant, is an order from DEA that provides notice to a registrant that the registrant may show cause, at an administrative hearing or through submission of documentary evidence, as to why the DEA should not revoke their registration or deny their application for a DEA registration on the basis of any of the enumerated statutory factors. An Immediate Suspension Order is an administrative action in which the DEA Administrator simultaneously suspends the registrant's DEA registration with the commencement of Order to Show Cause proceedings because their continued registration pending the administrative proceeding would pose an imminent danger to the public health or safety.

Between FY 2008 and FY 2013 as of June 13, 2013, these TDS groups have also increased the number of diversion-related Priority Target Organization (PTO) investigations from 243 to 595 (a 141% increase). PTO investigations focus on those criminal organizations or groups that significantly impact areas of the country. On October 1, 2011, DEA began tracking non-criminal PTO investigations, which encompass regulatory, civil, and administrative investigations. Since then, there have been 75 designated non-criminal PTO investigations.

The restructuring of the Diversion Control Program has allowed investigative efforts to focus on specific problem areas. For example, DEA, working with its state and local partners, put forth a substantial investigative effort towards rogue clinics, dubbed *Operation Pill Nation I*. This operation involved the mobilization of eleven TDSs from across the United States to marshal with the Miami TDS and other state and local agencies in a concerted effort to attack and dismantle the hundreds of rogue pain clinics that continued to plague South Florida. On February 23, 2011, DEA,

as part of *Operation Pill Nation I,* conducted a coordinated effort with more than 500 state and local law enforcement officers in a massive takedown. As of June 14, 2013, *Operation Pill Nation I* resulted in 47 arrests, including 27 doctors; the issuance of 34 Immediate Suspension Orders against 63 DEA registrations; 92 DEA registrations being surrendered for cause; and the seizure of more than $18.9 million in assets.

DEA conducted a similar operation in the central Florida area, dubbed *Operation Pill Nation II.* As of June 6, 2013, *Operation Pill Nation II* has resulted in 58 arrests, including 9 doctors and 4 pharmacists; the issuance of 4 Immediate Suspension Orders; 7 DEA registrations being surrendered for cause; and the seizure of approximately $311,995 in assets.

Renewed Oversight

DEA uses its regulatory authority to ensure that DEA registrants comply with all aspects of the CSA and its implementing regulations, particularly maintaining effective controls against diversion, and monitoring for and reporting suspicious orders. One way DEA attempts to accomplish this is through our Distributor Initiative Program. This program was implemented in late 2005 and is designed to educate wholesale distributors who were supplying controlled substances to rogue Internet pharmacies and, more recently, to rogue pain clinics and rogue pharmacies. The goal of this educational program is to increase distributor awareness and vigilance so that they cut off the source of supply to these and other schemes. As stated above, wholesale distributors are required to design and operate a system that will detect suspicious orders and report those suspicious orders to DEA. Through the Distributor Initiative Program, DEA educates distributors about their obligations under the CSA, as well as provides registrants with current trends and "red flags" that might indicate that an order is suspicious, such as the type of drug(s) ordered, orders of unusual size, orders that deviate from a normal pattern, frequency of orders, breadth and type of products ordered, and the location of the customer.

DEA vigorously pursues criminal, administrative, and civil actions against registrants who fail to comply with all aspect of the CSA and its implementing regulations as required. DEA has identified various distributors who failed to adhere to their regulatory responsibilities to maintain effective controls against diversion, resulting in administrative action and referral for civil action. These investigations resulted in record-breaking civil penalties ($13.25 million against McKesson Drug Corporation in April 2008 and $34 million against Cardinal Health in October 2008). More recent examples include, but are not limited to, actions against wholesale distributors such as Harvard Drugs, Keysource, and Sunrise.

In February 2012, the DEA Administrator again used her authority under the CSA to immediately suspend the registrations of Cardinal Health's Lakeland, Florida, facility and two Sanford, Florida-based CVS pharmacies (stores 219 and 5195) after making a determination that the continued operation of these facilities (with respect to controlled substances), while pending administrative proceedings to revoke their registrations posed an imminent danger to the public health or safety. A Memorandum of Agreement has been reached between DEA and Cardinal Health regarding their conduct, which includes a suspension of their Lakeland facility registration for a period of two years. On August 31, 2012, the DEA Administrator issued a Final Order revoking the registrations of both of the CVS pharmacies.

On March 29, 2013, as a result of an eight-year investigation of illegal Internet pharmacies, United Parcel Service, Inc. (UPS) agreed to forfeit $40 million, which was alleged to be the profits earned

from conducting business with illegal Internet pharmacies, to the U.S. Government and entered into a non-prosecution agreement. This agreement requires the world's largest package delivery company to implement a comprehensive compliance program prohibiting illegal Internet pharmacies from using their services.

On June 11, 2013, Walgreens Corporation, the nation's largest drug store chain, agreed to pay $80 million in civil penalties, resolving DEA's administrative actions and a civil penalty investigation by the United States Attorney's Office regarding the Jupiter Distribution Center and six retail pharmacies in Florida. The settlement, the largest in DEA history, resolved the allegations that Walgreens committed an unprecedented number of record-keeping and dispensing violations under the Controlled Substances Act. The Settlement and Memorandum of Agreement also includes the suspension of the Jupiter Distribution Center registration until September 14, 2014, and the registrations of the six pharmacies until May 26, 2014.

Education

DEA, along with state regulatory and law enforcement officials, and in conjunction with the National Association of Boards of Pharmacy, hosts Pharmacy Diversion Awareness Conferences (PDACs) throughout the country; to date, 16 separate PDACs have been held in 8 states. Each one-day conference is held on a Saturday or a Sunday for the convenience of the pharmacy community. The conference is designed to address the growing problem of diversion of pharmaceutical controlled substances at the retail level. The conference addresses pharmacy robberies and thefts, forged prescriptions, doctor shoppers, and illegitimate prescriptions from rogue practitioners. The objective of this conference is to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on methods to prevent and respond to potential diversion activity. In addition, since FY 2012, the Office of Diversion Control has separately conducted more than 100 presentations to the public, educators, community-based organizations, registrants, and their professional organizations, industry organizations, and law enforcement agencies regarding the diversion and abuse of pharmaceutical controlled substances.

Conclusion

Minimizing the availability of pharmaceutical controlled substances to non-medical users and maintaining the integrity of the closed-system of distribution are priorities for the Drug Enforcement Administration. As such, DEA will continue to work in a cooperative effort with other Federal, state, and local officials, law enforcement, professional organizations, and community groups to address this epidemic.

STATEMENT OF
JONATHAN BLUM

ACTING PRINCIPAL DEPUTY ADMINISTRATOR AND DIRECTOR,
CENTER FOR MEDICARE
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

CURBING PRESCRIPTION DRUG ABUSE IN MEDICARE

BEFORE THE

U.S. SENATE COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

JUNE 24, 2013

Statement of Jonathan Blum on
Curbing Prescription Drug Abuse in Medicare
U.S. Senate Committee on Homeland Security and Government Affairs
June 24, 2013

Chairman Carper, Ranking Member Coburn, and members of the Committee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services' (CMS) work to improve the Medicare Prescription Drug Program, also known as Medicare Part D, to ensure that all Medicare beneficiaries are receiving the medicines they need while also reducing and preventing prescription drug abuse.

The Medicare Part D prescription drug benefit program has been very successful by several measures. In its eight years of operation, Part D has made medicines more available and affordable for Medicare beneficiaries, leading to improvements in access to prescription drugs, better health outcomes, and more beneficiary satisfaction with their Medicare coverage. In addition, the drug benefit is helping beneficiaries avoid the need for other services that would otherwise be covered under Medicare Parts A and B; the Congressional Budget Office (CBO) recently estimated that a one percent increase in the number of prescriptions filled by beneficiaries causes Medicare's overall spending on medical services to fall by roughly one-fifth of one percent.[1]

The Medicare Part D program provides outpatient prescription drug benefits to about 37 million Medicare beneficiaries[2] through a wide range of plan choices, with an average of 31 plans per region[3] competing to provide drug benefits to Medicare beneficiaries at the average monthly premium of about $30.[4] According to surveys, 95 percent of Part D enrollees are satisfied with their drug coverage and confident that the level of coverage meets their needs.[5]

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[1] http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf.
[2] MedPAC. "Status Report on Part D." March 1, 2013. http://www.medpac.gov/chapters/Mar13_Ch15.pdf.
[3] 2013 Prescription Drug Plan Landscape available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/index.html.
[4] http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/PartDandMABenchmarks2013.pdf.
[5] MedPAC. "Status Report on Part D." March 1, 2013. http://www.medpac.gov/chapters/Mar13_Ch15.pdf.

Meanwhile, the overall costs for the Part D program have risen more slowly than originally projected. According to CBO's data, Part D is on track to cost 45 percent less than projected for the initial 2004-to-2013 forecast period,[6] and as we announced earlier this year, Part D's per capita costs will only rise 1.83 percent for 2013 — the lowest growth rate in the history of the program.[7] Additionally, the deductible and out-of-pocket limit for Part D will be lower in 2014 than in 2013, and beneficiary costs will be further reduced as coverage in the prescription drug coverage gap, or "donut hole," continues to expand in 2014. To date, 6.3 million beneficiaries have saved over $6.1 billion on prescription drugs through the Affordable Care Act's discounts, rebates, and additional coverage.[8]

While beneficiaries are saving money on prescription drugs, the quality of Part D plans is improving. The average star rating among standalone Part D sponsors, weighted by enrollment, in 2013 is 3.3 stars out of five, compared with 2.96 for 2012.[9] These ratings are based on quality measures including patient safety and appropriate medication use metrics. Sponsors have incorporated the Medication Therapy Management Programs into their plans' benefit structures to ensure optimum therapeutic outcomes through improved medication use and a reduced risk of adverse outcomes.

While the Part D program is strong, CMS knows it must continually improve the program and address vulnerabilities. CMS appreciates the thoughtful work of this Committee[10] and the Department of Health & Human Services (HHS) Office of the Inspector General (OIG)[11] that highlights the potential for fraud, waste, and abuse in Part D. We agree that CMS can do more to reduce fraud and abuse in order to ensure that beneficiaries receive high-quality, appropriate care, while also making sure that we spend every federal dollar as wisely as possible.

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[6] http://www.cbo.gov/sites/default/files/cbofiles/attachments/44205_Medicare_0.pdf
[7] Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter . http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/RateNotice.pdf
[8] http://www.hhs.gov/news/press/2013pres/03/20130321a.html
[9] MedPAC. "Status Report on Part D." March 1, 2013. http://www.medpac.gov/chapters/Mar13_Ch15.pdf
[10] http://www.hsgac.senate.gov/subcommittees/federal-financial-management/hearings/costs-of-prescription-drug-abuse-in-the-medicare-part-d-program
[11] HHS OIG has a large body of work examining Part D billing including: OEI-02-09-00603, OEI-02-09-00608, OEI-02-09-00140, OEI-03-11-00310, OEI-07-09-00150, OEI-07-10-06004

As the program matures, CMS is broadening its initial focus of ensuring beneficiaries have access to prescribed drugs to also ensure that Part D sponsors implement effective safeguards to prevent fraud and drug abuse, and provide coverage for drug therapies that meet standards for safety and efficacy. Based on the lessons learned from activities in fee-for-service Medicare and input from this Committee, the HHS OIG, and the Government Accountability Office (GAO), we have enhanced our data analyses and improved coordination with our law enforcement partners to get a more comprehensive view of activities in the Part D program.

Prescription drug abuse is the Nation's fastest-growing drug problem, and the Centers for Disease Control and Prevention (CDC) has classified prescription drug overdose as an epidemic.[12] In 2010, more than 100 people died from drug overdoses every day in the United States,[13] and drug overdose death rates have more than tripled since 1990.[14] Between 1997 and 2008, the rate of hospital admissions for conditions related to prescription medication interactions and illicit drug use rose by 96 percent among people ages 65 and 84, and for people 85 and older, admissions grew 87 percent.[15]

In response to this growth in prescription drug misuse and abuse, the Administration released its "Prescription Drug Abuse Prevention Plan" in 2011.[16] This plan includes four pillars: education, monitoring, proper disposal, and enforcement. National survey data indicate that the number of people in the United States currently abusing prescription drugs decreased from 7 million in 2010 to 6.1 million in 2011,[17] a promising trend.

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[12] Paulozzi, L. et al. (2012). CDC Grand Rounds: Prescription Drug Overdoses—a U.S. Epidemic. *Morbidity and Mortality Weekly Report*, 61(01):10-13, January 13.
[13] CDC/Wonder, extracted February 11, 2013, showed 38,329 deaths in 2010.
[14] http://www.cdc.gov/homeandrecreationalsafety/rxbrief/.
[15] Based on analysis by the Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistic and Quality. http://www.samhsa.gov/grants/2011/sm_11_009.aspx#f4
[16] *Epidemic: Responding to America's Prescription Drug Abuse Crisis.* Executive Office of the President of the United States. 2011. http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf.
[17] *Results from the 2011 National Survey on Drug Use and Health: Mental Health Findings*. Substance Abuse and Mental Health Services Administration, NSDUH Series H-45, HHS Publication No. (SMA) 12-4725. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012. http://www.samhsa.gov/data/NSDUH/2k11MH_FindingsandDetTables/2K11MHFR/NSDUHmhfr2011.htm.

The growth of prescription drug abuse has touched providers, pharmacies, and beneficiaries in the Part D program. CMS recognizes that Part D plan sponsors face unique challenges in administering the Medicare prescription drug benefit. Part D plan sponsors can manage the benefit only at the beneficiary level, because they do not have access to Part D prescriber and pharmacy data beyond the transactions they manage for their own enrollees, which makes it more difficult to identify prescribers or pharmacies that are outliers in their prescribing patterns or are filling patterns relative to the entire Part D program. Unlike Medicare Advantage plans offering Part D, stand-alone plan sponsors face additional challenges because they manage only the drug benefit, which leaves plan sponsors without a direct relationship with the prescriber, while CMS manages the medical benefit. These plan sponsors operate under a different legal and regulatory framework than the traditional Medicare fee-for-service benefit. The ability of Medicare providers, pharmacies, and beneficiaries to abuse the Medicare prescription drug benefit is one symptom of the complex health care delivery system that must be addressed through broader reforms that result in better-coordinated care.

By focusing on stringent plan compliance and increased use of data analytics to identify outliers and suspicious prescribing patterns, we can provide Part D plans with the tools needed to prevent abuse, improve care, and ensure federal dollars are spent appropriately. As this public health challenge grows in size and scope, CMS is protecting our beneficiaries through new programs and technologies, such as enhanced Drug Utilization Review (DUR) procedures, increased use of analytics on prescriber and pharmacy data, and improved collaboration between Medicare Part D stakeholders. In addition, we are looking at ways we can leverage the administrative authorities we have to oversee fee-for-service providers and apply those same principles and techniques in the Part D program, where possible. Any policy response to Part D drug abuse must balance our desire to minimize prescription drugs abuse with the need to ensure access to prescription drugs for legitimate clinical use.

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 access to drug coverage through private prescription drug plans.

In Part D, CMS contracts with private entities—stand-alone prescription drug plan (PDP) sponsors, MA organizations, and other types of Medicare health organizations—who then act as the payers and insurers for prescription drug benefits. CMS pays sponsors on a per enrollee basis 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 for beneficiaries who choose to enroll in the voluntary Part D benefit, and those beneficiaries pay the balance through monthly plan premiums. Additionally, some beneficiaries qualify for "extra help" through the Part D low-income subsidy program.

All Part D sponsors are required to have a comprehensive plan to detect, correct, and prevent waste, fraud, and abuse. This 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's Prescription Drug Benefit Manual[18] recommends that Part D sponsors generate and review reports, such as the following:

- **Prescription Drug Event (PDE) Payment Reports** which detail for every prescription filled: (1) the amount paid by the Part D sponsor; (2) the pharmacy and provider identification numbers; (3) the beneficiary; and (4) a description of the drug, 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.
- **DURs** which identify the number of prescriptions filled by an individual enrollee, and, in particular, the number of prescriptions for certain classes of drugs, such as narcotics, to identify potential therapeutic abuse or illegal activity by an enrollee.

[18] Chapter 9 of CMS' Prescription Drug Benefit Manual: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/PDBManual_Chapter9_FWA.pdf

- **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.

CMS also contracts with a private organization, called the Medicare Drug Integrity Contractor (MEDIC), to assist CMS in managing its Part D audit, oversight, and anti-fraud efforts. The MEDIC's main functions 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, and collaborating with Part D sponsors on identification of potentially fraudulent schemes. The MEDIC is also responsible for auditing the anti-waste, fraud, and abuse compliance programs detailed above that are requirements for participation as a Part D sponsor.

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 the guidance in the Prescription Drug Benefit Manual. As part of program oversight, CMS uses the Fraud Prevention System (FPS) in Medicare fee-for-service to target investigative resources to suspicious claims and providers and swiftly impose administrative action when warranted. Lessons learned from the FPS are providing insights into new methods and technologies to get ahead of people who would abuse the Part D program and identify their patterns of behavior early. CMS is now considering implementing similar strategies and administrative actions into its management of the Part D program and its sponsors to ensure a more systematic analysis of the claims data to prevent and detect abuse.

Improving Data Analysis to Address Opioid Overutilization and Questionable Prescribing Patterns

An individual beneficiary's behavior, such as "doctor shopping" to obtain frequently abused prescription drugs from multiple prescribers, may indicate fraud, waste, or abuse, and might also signal troubling patterns that endanger the beneficiary's health or indicate illegal selling of

prescription drugs. DUR programs can help preserve program integrity, while also promoting safety, improving the quality of care, and preventing prescription errors. Part D plan sponsors must in place concurrent DUR programs for reviewing prescribed drug therapies at point-of-sale, as well as retrospective DUR programs for conducting ongoing, periodic examinations of claims data to identify patterns of inappropriate or medically-unnecessary prescription, dispensing, or use of prescription drugs. A concurrent DUR program must include screening for the following problems each time a prescription is dispensed:

- Screening for potential drug therapy problems due to therapeutic duplication
- Age/gender-related contraindications
- Drug over-utilization and under-utilization
- Drug-drug interactions
- Incorrect drug dosage or duration of drug therapy
- Drug-allergy contraindications
- Clinical abuse/misuse of drugs

Examining DUR-related analyses, claims data, and other records allows Part D sponsors to identify questionable utilization patterns that may indicate fraud, abuse, gross overuse, or inappropriate or medically-unnecessary prescription, dispensing, or use of prescription drugs. The Part D sponsors can also look for suspicious patterns associated with specific drugs or groups of drugs. Part D sponsors can then refer suspected fraud to CMS, the MEDIC, or a law enforcement agency, as appropriate.

A 2011 GAO report[19] found examples of potential egregious overutilization of medications by Part D beneficiaries who were obtaining opioid medications from multiple prescribers, with the vast majority of these beneficiaries receiving medications from between five and ten providers. Through discussions with the industry, CMS determined that sponsors need to employ more effective concurrent and retrospective DUR programs to address overutilization of medications to protect beneficiaries, and to reduce fraud, waste, and abuse in Part D.

[19] GAO-11-699 "Medicare Part D: Instances of Questionable Access to Presciption Drugs" http://www.gao.gov/assets/590/585424.pdf

CMS, through its Final Calendar Year 2013 Call Letter and subsequent guidance,[20] outlined an approach to reduce potential opioid overutilization in the Part D program. Under this approach, Part D plans ensure safe dosages are dispensed through the improved use of concurrent claim edits and formulary utilization management design. CMS's guidance clarified that sponsors should clinically analyze cases for unsafe cumulative dosing that DUR programming has identified through patterns that suggest potential overutilization of drugs.

The effective DUR program should include case management, outreach to providers, and, if necessary, beneficiary-level controls to prevent overutilization of opioid therapy and ensure beneficiary safety. During case management, clinical staff should communicate with prescribers and beneficiaries to understand the beneficiaries' medical needs. This clinician-to-clinician communication should result in beneficiaries receiving appropriate levels of medication through improved care coordination.

If prescribers are non-responsive after multiple attempts, or prescribers concur that the current level of medication is unnecessary, a sponsor may implement beneficiary-level claim edits, but they must inform the beneficiary and their prescribers of those restrictions, and allow beneficiaries to appeal these restrictions. If a Part D sponsor implemented a point-of-sale edit for a beneficiary based on retrospective review, and that beneficiary then voluntarily changed to another plan, the initial sponsor should share this information with the subsequent sponsor so it can immediately implement similar beneficiary-level edits. CMS is monitoring Part D sponsors' implementation of the opioid overutilization policy, and if warranted, CMS will issue additional guidance to Part D sponsors identified from our oversight of the implementation of these measures.

Additionally, CMS undertook a communication and educational campaign about medication overutilization, particularly opioids, for physicians and pharmacies in the fall of 2012 to support sponsors' strengthened efforts to address this issue in the Part D program. In November 2012, as

[20] Final Calendar Year 2013 Call letter: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2013.pdf and August 31, 2012 HPMS memo "Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D".

part of the annual Medicare "Dear Doctor" letter (*e.g.*, the "Announcement About Medicare Participation for Calendar Year 2013"), CMS encouraged prescribers to work with Part D sponsors on overutilization case management. To encourage further dialogue between CMS and Part D sponsors about overutilization, we also offered a session on overutilization at the Medicare Advantage and Part D Spring Conference in April 2012.

Monitoring Prescribers and Pharmacies

Part D is potentially vulnerable to fraud at the prescriber and pharmacy levels, as well. Providers and pharmacies may participate in drug diversion by participating in a "pill mill" scheme. This typically involves a pharmacy or other entity that pays kickbacks to a physician to write prescriptions for an illegal or inappropriate purpose so the pharmacy can bill for a Part D drug that is ultimately never dispensed. The HHS OIG, through a series of investigations, identified questionable Part D billing in 2009, including instances where PDE data contained invalid prescriber identifiers[21] and where pharmacies billed extremely high dollar amounts or a high number of prescriptions per beneficiary, prescriber, or per type of drug.[22]

Over the last few years, CMS has taken a series of steps to ensure that valid prescriber identifiers accompany Part D claims and that the MEDIC and plan sponsors are monitoring pharmacy billing patterns. In 2011, to enhance then existing practice and in collaboration with the Drug Enforcement Administration (DEA), we directed Part D sponsors to ensure that the prescriber identifier submitted on a PDE was active and valid starting in the 2012 coverage year, whether it be a national provider identifier (NPI), DEA number, unique physician identifier number, or state license number. Additionally, we began validating the format of all prescriber identifiers on PDEs that were coded as an NPI and excluded from payment reconciliation PDEs with invalid NPIs. We began assessing each sponsor's performance regarding NPI use and validity and notified them of their performance. We also directed Part D sponsors to check that all prescriptions for controlled substances under Part D were associated with DEA numbers that indicated there was appropriate authority to prescribe the controlled substance.

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[21] This refers to two upcoming reports. OEI-02-09-00603 "Prescribers with Questionable Patterns in Medicare Part D" and OEI-02-09-00608 "Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority"

[22] OEI-02-09-00600 "Retail Pharmacies with Questionable Part D Billing" https://oig.hhs.gov/oei/reports/oei-02-09-00600.pdf

Through rulemaking finalized in 2012,[23] CMS required Part D sponsors to submit PDEs with active and valid individual prescriber NPIs, beginning January 1, 2013. CMS, through the annual Medicare "Dear Doctor" letter, explained the NPI requirement to prescribers. CMS began to deny any PDE without an active and valid individual NPI beginning on May 6, 2013. We have continued to assess each sponsor's performance regarding NPI use and validity of submitted NPIs and notified sponsors of their performance in preparation for this deadline. Based on this assessment, we found that 99.6 percent of the 2013 PDEs received during the first quarter of the coverage year reported the prescriber's NPI; all but 0.002 percent of the reported NPIs were valid and currently active or active within a year of the date of service. We also examined the taxonomy codes, which are self-reported by the providers to identify their specialty. We found 0.7 percent of these codes would be unreasonable for a prescriber. As a result, we have initiated a review of the PDEs reporting these NPIs to determine what drugs were prescribed, if any are controlled substances, and if the prescriber has a valid individual DEA number.

These actions ensure improved sponsor compliance with the PDE reporting requirements, enhance CMS's ability to review claims data to identify possible fraud and abuse, and help determine whether prescribers of controlled substances are writing prescriptions in accordance with their DEA registration.

CMS has increased its monitoring of prescribers through the Part D Recovery Audit Contractor (RAC), with which CMS has contracted to identify and recover Part D improper payments. In 2011, CMS implemented the RAC program for Medicare Part D, and overpayment recoupment began in November 2012. The Part D RAC recently completed an analysis of PDE data to determine if any claims were prescribed by individuals or entities on OIG's List of Excluded Individuals and Entities (LEIE) for contract year 2007, and is currently reviewing LEIE data for contract years 2008 through 2011.[24]

[23] 77 FR 54664: http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf
[24] More information about Part D RACs is available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Part-D-Recovery-Audit-Contractor.html

Additionally, in response to the concerns identified by recent HHS OIG reports and this Committee, we are currently exploring whether to use the Secretary's authority under section 6405 of the Affordable Care Act to require Medicare enrollment of the prescribing provider in order for the Part D program to cover the provider's prescriptions. This is similar to the Medicare fee-for-service rule that was finalized in April 2012. Based on CMS's experience with the FPS in Medicare fee-for-service and the critical reviews conducted by the HHS OIG, GAO, and this Committee, we have stepped up our efforts to take a cross-sectional look at our data to identify outliers or questionable patterns, particularly with respect to pharmacies. MEDICs are currently analyzing pharmacy data to detect anomalies, trends, patterns, and spikes to identify and refer to law enforcement pharmacies that present a fraud risk. We also plan to share this pharmacy data with Part D plan sponsors and will work with them to ensure they understand what actions they can take when conducting their own reviews of the outlier pharmacies.

CMS also sends letters to Part D sponsors about fraud schemes that are being perpetrated across the country at the beneficiary, prescriber, and pharmacy levels. 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.[25] Part D sponsors may deny or reverse claims when they confirm such fraud schemes.[26] Sponsors may also terminate their contracts with indicted pharmacies, as contractually appropriate. This collaboration and information sharing allows CMS, Part D sponsors, and MEDICs to identify potential fraud and stop it before payment is made.

Sharing Data to Fight Abuse

The Affordable Care Act requires the centralization of certain claims data from CMS (Medicare, Medicaid, and the State Children's Health Insurance Program); the Department of Veterans Affairs; the Department of Defense; the Social Security Administration; and the Indian Health Service. Data-sharing makes it easier for agency and law enforcement officials to coordinate and

[25] To see an example of a fraud alert, please visit: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/FraudAlert.pdf

[26] Guidance to sponsors about fraud alerts is available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/FraudAlertGuidance122211.pdf

identify criminals and prevent fraud on a system-wide basis. CMS has an 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 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 agency and law-enforcement efforts to identify and prevent waste, fraud, and abuse.

The IDR is currently populated with seven years of historical Medicare Parts A, B, and D paid claims, and pre-payment claims data. These additional data may allow us to analyze previously undetected indicators of aberrant activity throughout the claims process. The One Program Integrity ("One PI") web-based portal shares data with our contractors and with law enforcement by providing a single access point to IDR data as well as analytic tools for reviewing the data. CMS is working closely with law enforcement to provide One PI training and support.

Information technology also can help prescribers share data while improving the quality of care and clinical outcomes, while also reducing fraud, waste, and abuse in Part D. E-prescribing can reduce instances of unauthorized, improperly altered, and counterfeit prescriptions. For example, in Part D, 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, and who prescribed it and when. These 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 distinguish between an attempt to get medications fraudulently, versus a true medical complaint. An electronic health record 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, and is part of the meaningful use requirements.

Collaborating with Part D Stakeholders

CMS's approach to program integrity once involved stand-alone programs with siloed communications that did not engage other Federal partners or allow for shared best practices. Now, however, thanks to a variety of efforts, Federal, state, and local law enforcement health care fraud activities are being coordinated to a greater extent than ever before. CMS is also engaging with the private sector in new ways to better share information to combat fraud.

CMS has established collaboration between program officials and law enforcement as a critical cornerstone in improving health care fraud detection and investigation. As a natural progression from early collaborative meetings, on July 31, 2012, CMS opened the Command Center, which provides the advanced technologies and collaborative environment for a multi-disciplinary team of experts and decision makers to more efficiently coordinate policies and case actions, reduce duplication of efforts, and streamline fraud investigations for more immediate administrative action. Since its opening, the Command Center has supported 61 missions that included over 450 unique participants from CMS and our partners, including the HHS OIG and the Federal Bureau of Investigations (FBI). Earlier this month, the Command Center held an all-day collaborative workgroup about prescription drug fraud; participants included CMS, the MEDIC, a representative from Florida's Medicaid Program Integrity Unit, a Medicaid Fraud Control Unit, and the HHS OIG. They outlined current efforts to prevent and fight prescription drug fraud, discussed barriers and gaps, shared analysis results, and presented new trends.

In addition to CMS's commitment to collaboration, the sustained success of the Health Enforcement Action Team (HEAT) demonstrates the effectiveness of the Cabinet-level commitment between HHS and the Department of Justice (DOJ) to prevent and prosecute health care fraud. Since its creation in May 2009, HEAT has played a critical role in identifying new enforcement initiatives and expanding data sharing to a cross-government health care fraud data intelligence-sharing workgroup. A key component of HEAT is the presence of Medicare Strike Force Teams, interagency teams of analysts, investigators, and prosecutors, who target emerging or migrating fraud schemes such as criminals masquerading as healthcare providers or suppliers.

Medicare Strike Force Teams coordinated three major takedowns in 2012, and CMS took administrative action against 160 providers and suppliers associated with those law enforcement activities. One major takedown included a Miami pharmacy owner who was sentenced to 14 years in prison for a $23 million health care fraud scheme involving illegal kickbacks to physicians in exchange for prescription referrals, which the pharmacies ultimately billed to Medicare.[27]

In addition to collaborating with other agencies, CMS is partnering with the private sector in anti-fraud efforts. Last year, HHS and DOJ announced the creation of a voluntary, collaborative Healthcare Fraud Prevention Partnership, involving the Federal Government, state officials, private health insurance organizations, and other health care anti-fraud groups.[28] The goal of this collaboration is to improve fraud detection and prevent payment of fraudulent health care billings by finding and stopping schemes that cut across public and private payers. CMS and the MEDICs also host quarterly Part C and Part D Working Groups, during which plan sponsors share their experiences with fraud schemes.

Finally, CMS works with the states to address prescription drug abuse. States began to monitor and prevent prescription misuse and abuse more than 60 years ago by creating programs to track the dispensing of prescription drugs. Currently, 49 states have enacted legislation authorizing Prescription Drug Monitoring Programs (PDMPs), and 46 states have operational PDMPs.[29] 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, including those dispensed to Part D beneficiaries. CMS, through the annual Medicare "Dear Doctor" letter, encouraged prescribers to use PDMPs. CMS also distributed an

[27] More information is available at http://www.justice.gov/opa/pr/2013/February/13-crm-233.html.

[28] Among the first to join this partnership are: America's Health Insurance Plans, HHS (including CMS and HHS OIG), DOJ (including FBI), Amerigroup Corporation, Blue Cross and Blue Shield Association, Blue Cross and Blue Shield of Louisiana, Coalition Against Insurance Fraud, Humana Inc., Independence Blue Cross, National Association of Insurance Commissioners, National Association of Medicaid Fraud Control Units, National Health Care Anti-Fraud Association, National Insurance Crime Bureau, New York Office of Medicaid Inspector General, Travelers, Tufts Health Plan, UnitedHealth Group, and WellPoint, Inc.

[29] *Status of Prescription Drug Monitoring Programs (PDMPs)*, PDMP Training & Technical Assistance Center, available at http://pdmpassist.org/pdf/pmpprogramstatus2013.pdf (last revised June 5, 2013).

article to encourage physicians to use their state PDMPs in the December 2012 issue of the Medicare Learning Network.

The President's Fiscal Year (FY) 2014 Budget includes proposals to build on these efforts. The first proposal would require states to monitor high-risk 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 $1.8 billion over ten years. The Administration is evaluating the utility of state PDMPs for reducing Medicare and Medicaid fraud as called for in President Obama's prescription drug abuse prevention action plan.[30] The second proposal would invest $640 million ($311 million base discretionary funding and $329 million proposed mandatory funding) in the Health Care Fraud and Abuse Control Program in FY 2014, to support efforts to reduce fraud through initiatives such as the HEAT task force and the Health Care Fraud Prevention Partnership.

Conclusion

CMS's role in the Part D program is not to just pay for drug coverage, but to ensure the best possible care for its beneficiaries. As evidenced by my testimony today, we are addressing the serious issues raised by the Committee, HHS OIG, and the GAO through a number of reforms, including enhanced Medicare provider screening, advanced data analysis, and improved stakeholder collaboration to change how we approach waste, fraud and abuse and improve the accuracy of our payments. CMS is broadening its focus from ensuring beneficiaries have access to prescribed drugs to ensuring that Part D sponsors implement effective safeguards and provide coverage for drug therapies that meet standards for safety and efficacy. CMS will continue to work with the Congress and this Committee in protecting taxpayer dollars, beneficiary health, and the integrity of the Medicare program.

[30] *Epidemic: Responding to America's Prescription Drug Abuse Crisis.* Executive Office of the President of the United States. 2011. http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf

Testimony of:
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and
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Office of Inspector General
U.S. Department of Health and Human Services

Hearing:
Curbing Prescription Drug Abuse in Medicare

Senate Committee on Homeland Security
and Governmental Affairs

June 24, 2013
Dirksen 342
3:00 PM

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Good afternoon Chairman Carper, Ranking Member Coburn, and other distinguished Members of the Committee. The Office of Inspector General's (OIG) testimony today discusses prescription drug fraud schemes; vulnerabilities in the Medicare Part D Prescription Drug program (Part D); and recommendations to protect the program against fraud, waste, and abuse and to protect program beneficiaries from harmful and unsafe prescribing.

With $66.9 billion in expenditures and 37.4 million beneficiaries enrolled,[1] it is essential that various players work together to protect the integrity of the Part D program and the health and welfare of the people it serves. Combating fraud, waste, and abuse involves a number of key partners, including the Centers for Medicare & Medicaid Services (CMS), CMS's contractor called the Medicare Drug Integrity Contractor (MEDIC), Part D plan sponsors, and the Drug Enforcement Administration (DEA), State Medicaid agencies, and State and local law enforcement. CMS is responsible for overseeing the program and paying plan sponsors; the plan sponsors are responsible for preventing and detecting fraud, waste, and abuse and appropriately paying for drugs under Part D; and the MEDIC is responsible for identifying and investigating potential fraud and abuse, as well as referring cases to law enforcement. OIG often partners with DEA, the agency responsible for enforcing the controlled substances laws and regulations, on cases where we have dual jurisdiction.

Since the inception of Part D, OIG has extensively examined the monitoring and oversight of the program and the effectiveness of controls to ensure appropriate payment and patient safety. Our work has found limitations in program safeguards that leave Part D vulnerable to fraud, waste, and abuse and Medicare patients vulnerable to potentially harmful prescribing. Notably, OIG has uncovered extreme prescribing patterns by hundreds of general-care physicians and questionable billing by thousands of retail pharmacies. Moreover, in a report we are releasing today, we found that Medicare paid millions of dollars for prescriptions from unauthorized prescribers, such as massage therapists and athletic trainers.

These vulnerabilities are even more concerning in light of our increasing investigations into drug diversion. Since 2008, OIG's investigations relating to Medicare Part D have nearly quadrupled.

[1]The Boards of Trustees, *Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2013 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, p. 10. [2] The Centers for Disease Control and Prevention (CDC) characterized prescription drug abuse as an epidemic. In 2010, for example, overdoses of prescription painkillers were among the leading causes of accidental death in the United States.

The serious and growing problem of prescription drug abuse lends a greater urgency to address drug diversion and to improve monitoring and oversight of the Part D program.[2]

Drug Diversion Is a Complex Crime Involving Many Co-Conspirators

Prescription drug diversion is a complex crime that can involve many co-conspirators—drug distributors and traffickers, health care professionals, drug-seeking patients, and pharmacies may all play a role, and criminal enterprises are becoming an increasing presence in prescription drug diversion.

Drug distributors, traffickers, and criminal enterprises

Prescription drug diversion often involves drug distributors and traffickers.[3] Criminal enterprises have also historically been engaged in the illegal drug trade. Of concern is that they are becoming an increasing presence in OIG's prescription drug diversion cases and represent a greater risk to our law enforcement officers, witnesses, and others engaged in investigating this crime. They frequently associate with and use other criminals, such as identity thieves and money launderers, to facilitate the fraud scheme.

Health care providers

Medical doctors, physician assistants, nurse practitioners, and other health care professionals can also be involved in drug diversion. Some health care providers become so entangled in the financial gain from prescription drug diversion that their entire practices are focused on writing illicit prescriptions. Clinics or health care practices that focus primarily on prescription drug diversion are known as "pill mills." While some providers bill for medical services that were never rendered and simply provide prescriptions to the patients, others may provide medically unnecessary and potentially harmful services to increase their financial profits. Some health care providers that engage in drug diversion schemes also struggle with prescription drug addiction.

Drug-seeking patients

Drug-seeking patients often visit multiple health care providers and pharmacies to obtain medically unnecessary prescriptions. Some use multiple false identities and may themselves be identity thieves. Drug-seeking patients often consume the drugs, sell them on the street for profit, or both.

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[2] The Centers for Disease Control and Prevention (CDC) characterized prescription drug abuse as an epidemic. In 2010, for example, overdoses of prescription painkillers were among the leading causes of accidental death in the United States.

[3] According to DEA, a prescription drug distributor is a person who is selling, furnishing, or delivering a controlled substance. The offense of drug trafficking refers primarily to the weight of the substances involved. Both distributors and traffickers may use multiple false identities in committing the crime. http://www.getsmartaboutdrugs.com/identify/what_is_distribution_whats_drug_trafficking.html

Some criminals, often known as "recruiters," target locations where drug-seeking patients are known to gather and offer them money for the use of their Medicare or Medicaid numbers. In some cases, recruiters offer several hundred dollars to drug-seeking patients to be transported to multiple medical appointments and then bill Medicare or Medicaid for those services.

Of particular concern are those cases when patient deaths occur as a result of the prescription drug diversion scheme. These are generally associated with "pill mills," which are sometimes advertised as pain management clinics. One particular pain management clinic was associated with the deaths of over 60 patients in a 5-year period. The patients were billed for minimal services or services that were not rendered and were required to return monthly to receive their prescriptions, without regard for medical necessity. The doctor and his wife were sentenced to over 30 years of imprisonment and ordered to pay $114,772, 524 in restitution to several government and private insurance plans and individuals.

Pharmacies

Pharmacies also play a role in drug diversion. Fraudulent pharmacies have been known to use patient Medicare numbers to bill for tens of thousands of dollars in unneeded prescriptions. In some fraud schemes, pharmacies stock or re-label expired and counterfeit medications and bill for them and sell them as legitimate prescriptions to unsuspecting patients. They may also bill for recurring refills that were never filled. Other pharmacies contribute to the fraud by filling prescriptions despite clear indicators they have been fraudulently obtained. Some pharmacies are even complicit in the scheme by paying patients with cash or narcotics to fill illegitimate and expensive prescriptions at their locations.

In one particular case, a licensed pharmacist who owned 26 pharmacies was the mastermind of a scheme that used an elaborate web of physicians, pharmacists, and patient recruiters to fraudulently bill Part D, Medicaid, and private health insurance carriers. This pharmacist paid kickbacks, bribes, and other inducements to physicians to write prescriptions for controlled drugs and expensive noncontrolled drugs. In addition, the physicians billed for services that were medically unnecessary or were never provided. The physicians directed their patients to fill their prescriptions at 1 of the 26 pharmacies, which then billed Medicare and Medicaid for expensive noncontrolled drugs but did not dispense them. The pharmacist then took his existing physical inventory of expensive noncontrolled drugs, repackaged them, and sold them to pharmaceutical suppliers. The pharmacist responsible for this egregious scheme was convicted along with 5 other connected individuals at trial, and an additional 14 conspirators have entered into plea agreements and await sentencing.

A unique set of fraud schemes involves what are termed as "phantom pharmacy" and "bust-out" schemes. Phantom pharmacies exist virtually or perhaps in an abandoned warehouse or office storefront. There is no legitimate pharmacy that provides services, but the pharmacy itself has an address or a P.O. box, a Medicare billing number, a bank account, and an electronic funds transfer number for transferring funds into the bank account. The identities of doctors, pharmacists, and patients are often stolen to perpetuate the fraud.

Another variation of this theme involves "bust-out" pharmacies, i.e., usually a small pharmacy that is about to go out of business. The pharmacy owner may advertise online or in the newspaper that the pharmacy is for sale with an active Medicare number. If the pharmacy is purchased by a criminal involved in the prescription drug diversion trade, it bills Medicare a large amount in a short period of time, collects the proceeds, and disappears.

It is important to note that prescription drug diversion cases investigated by OIG are not limited to controlled substances. OIG also has investigated matters that involve noncontrolled but high-cost prescriptions, such as respiratory, anti-psychotic, and HIV/AIDS medications. In one particular case, a pharmacy billed for very expensive medications that included anti-psychotics and respiratory and cardiac drugs but never dispensed the drugs. The perpetrators of this scheme were sentenced to 57 months of imprisonment and ordered to pay $4.9 million in restitution.

With the rise in prescription drug abuse, concerns about Medicare fraud, particularly pharmacy and prescriber fraud, have increased. These concerns are reinforced by OIG's recent evaluations, which focus on unauthorized prescribers, questionable prescribing patterns, and questionable billing by pharmacies for Part D drugs.

Medicare Paid for Drugs Ordered by Individuals Without the Authority To Prescribe

In the report that we are releasing today, OIG found that one of the most basic safeguards – that an item or a service was performed, provided, or prescribed by an appropriate medical professional – is not always operating effectively.

To be covered under Part D, drugs must be prescribed in accordance with State law, which specifies the types of health care providers that have the authority to prescribe drugs in the State. We found that, nationwide, Part D inappropriately paid $5.4 million in 2009 for 72,552 prescriptions ordered by individuals who clearly did not have the authority to prescribe. These individuals included massage therapists, athletic trainers, dental hygienists, and contractors responsible for home repairs. We even found that interpreters, lodging companies, and veterinarians ordered prescriptions. Medicare should never pay for drugs ordered by these individuals.

Additionally, in 10 States that we reviewed in depth, Part D inappropriately paid for drugs ordered by others who did not have the authority to prescribe. These included counselors, social workers, chiropractors, registered nurses, physical therapists, occupational therapists, and speech-language pathologists. In total, we identified almost 350,000 prescriptions ordered by these prescriber types in the 10 States. Part D paid $26.2 million for these drugs. It is important to note that our review focused on selected types of providers; they do not represent all provider types without the authority to prescribe.

Further, tens of thousands of drugs ordered by individuals without prescribing authority were controlled substances. These drugs are of particular concern because they have potential for abuse.

We found many examples in which Medicare paid for drug claims in which the prescribers were individuals without the authority to prescribe:

- One Florida massage therapist was listed as the prescriber on 3,756 prescriptions, amounting to $183,132.
- An Ohio social worker was listed as the prescriber on 1,639 prescriptions, which were all filled at 1 retail pharmacy.
- A registered nurse from California was listed as the prescriber on 1,111 prescriptions, which were filled at a single retail pharmacy in New York.

From the claims data, we could not determine whether the drugs were actually ordered by the unauthorized individuals listed on the claims or whether the providers' identification numbers were being misused. Either scenario is problematic and resulted in inappropriate payments and may have put patients' health and safety at risk.

These findings build on earlier OIG work that found that Part D paid for prescription drugs for which the claims had invalid prescriber identifiers. Specifically, in 2007, Part D sponsors and beneficiaries paid pharmacies $1.2 billion for claims that contained prescriber identifiers that had never been assigned or had been retired. For almost one-fifth of these claims, the prescriber identifiers did not meet the format specifications, yet sponsors' systems did not include edits to reject or flag claims with obviously inaccurate prescriber identifiers. For example, for some claims, the prescriber identification field contained the wrong number of characters.

CMS has reported taking several steps to address the problems we identified with invalid prescriber identifiers. CMS now requires that sponsors ensure that prescriber identifiers on Part D claims are active and valid. Today's report demonstrates the need for further action to ensure that each claim for a prescription contains not only a valid prescriber identifier but also one that corresponds to an authorized prescriber.

Hundreds of Physicians Had Extreme Prescribing Patterns

Vulnerabilities in the Part D program are not limited to unauthorized prescribers. In a report issued last week, OIG raised concerns about questionable prescribing patterns for 736 general-care physicians. These physicians were extreme outliers and prescribed very differently than their peers—they ordered an extremely high number of drugs per beneficiary; they had prescriptions filled at an extremely high number of pharmacies; they ordered extremely high percentages of brand-name drugs; or they ordered extremely high percentages of Schedule II or Schedule III drugs, which have the potential for abuse.[4] These drugs include oxycodone and morphine.

[4] Drugs and other substances that are considered controlled substances under the Controlled Substances Act are divided into five schedules. Drugs are placed on a certain schedule on the basis of having a medically accepted use in treatment in the United States, their potential for abuse, and the likelihood that dependence will result from that abuse.

Our analysis identified many examples of questionable prescribing patterns. A couple of them include:

- Medicare paid a total of $9.7 million—151 times more than the average—for 1 California physician's prescriptions. Most of this physician's prescriptions were filled by just two independent pharmacies, both of which OIG identified in a prior review as having questionable billing.

- Seventy-eight percent of the prescriptions ordered by one Florida physician were for Schedule II drugs. Schedule II drugs have the highest potential for abuse of any prescription drugs legally available in the United States. This physician prescribed massive amounts of Schedule II drugs for a single beneficiary, including a 20-month supply of morphine sulfate and a 17-month supply of oxycodone HCl.

In total, Medicare paid $352 million for Part D drugs ordered by the physicians with questionable prescribing patterns in 2009. Notably, 110 of these physicians were associated with 1 or more of the retail pharmacies we identified as having questionable billing as discussed below.[5] It is important to note that questionable billing does not necessarily mean fraudulent billing. However, these patterns raise flags that warrant further attention.

Thousands of Retail Pharmacies Billed Far Outside the Norm

Our prior analysis of Part D data also uncovered disturbing billing patterns by some pharmacies. When we examined the records for Part D drugs, we found that 2,637 retail pharmacies nationwide had billing patterns far outside the norm. These pharmacies billed extremely high numbers of drugs per beneficiary or per prescriber or billed extremely high percentages of Schedule II or Schedule III drugs, brand-name drugs, or refills relative to other pharmacies. While some pharmacies with questionable billing may be billing these amounts for legitimate reasons, this type of billing warrants further scrutiny. Medicare paid these pharmacies a total of $5.6 billion in 2009.

We uncovered many examples of pharmacies billing far outside the norm:

- One pharmacy had 85 percent of its total prescriptions for the year ordered by a single prescriber. Billing patterns like this may indicate that the pharmacy and prescriber were working together to defraud the Part D program.

- One pharmacy billed an average of $132,845 per prescriber, which is 73 times the national average. Virtually all of these prescriptions were for brand-named drugs. These included Dovonex (a drug that treats psoriasis), Zyprexa (an antipsychotic), and Flovent HFA (a drug that treats asthma).

[5] We considered a physician to be associated with a retail pharmacy if the retail pharmacy billed for at least 25 percent of the total cost of the Part D drugs that physician prescribed in 2009.

Medicare Paid for Schedule II Drugs Billed as Refills, Which Are Prohibited by Federal Law

In another review, we found that Medicare Part D inappropriately paid $25 million for Schedule II drugs billed as refills in 2009. Sponsors should not have paid for any of these drugs because Federal law prohibits the refilling of Schedule II controlled substances. A new prescription authorizing the pharmacy to provide the drug is required each time a Schedule II is dispensed. Paying for refills of highly addictive drugs raises public health concerns and may contribute to the diversion and resale of controlled substances. Some of these refills may have been inaccurately billed. However, three-quarters of Part D sponsors paid for these refills, indicating that many sponsors do not have adequate controls in place to prevent refills of Schedule II drugs.

Oversight and Monitoring by CMS, Plan Sponsors, and CMS's Contractor Are Limited

OIG's findings of claims for questionable, inappropriate, and potentially dangerous Part D drugs indicate that safeguards should be strengthened to better protect the program and beneficiaries. In addition to analyzing these claims, we have examined Part D oversight and the systems in place to protect program integrity. These reviews have focused on CMS's oversight functions; plan sponsors' identification of fraud and abuse; and the MEDIC's abilities to detect, investigate, and refer fraud in the Part D program.

All these reviews have identified vulnerabilities in efforts to combat Part D fraud and abuse. For example, we found that some plan sponsors did not identify any potential fraud and abuse incidents and that most potential fraud and abuse incidents were associated with only a small number of plan sponsors.

Further, the MEDIC has not fully utilized data analytics to identify potential fraud and abuse. CMS's plans had called for data analysis to serve as a cornerstone of its Part D integrity strategy. However, OIG's work revealed that only a small percentage of the MEDIC's investigations and case referrals originated through proactive methods, such as data analysis.

The MEDIC also faces challenges in effectively resolving instances of potential fraud, waste, or abuse. For example, there is no administrative mechanism to recover payments associated with inappropriate Part D claims. The MEDIC is also prohibited from sharing specific information with program integrity contractors that oversee Medicare Parts A and B and Medicaid. Further, the MEDIC lacks the authority to obtain information directly from pharmacies, physicians, and pharmacy benefit managers; it must obtain information through the plan sponsors. Finally, CMS does not require plan sponsors to refer instances of suspected fraud and abuse to the MEDIC, so it may be missing opportunities to develop and pursue fraud cases.

OIG Recommends Improvements in Part D Oversight and Monitoring

Taken together, OIG's findings consistently demonstrate the need for CMS to strengthen Part D monitoring and oversight. OIG has recommended numerous improvements to more effectively safeguard the Part D program from fraud, waste, and abuse. We have recommended that CMS:

- Require sponsors to verify that prescribers have the authority to prescribe drugs.

- Strengthen the MEDIC's monitoring of prescribers and pharmacies so that it systematically monitors them using measures such as the ones used by OIG and identifies the prescribers and pharmacies with questionable patterns.

- Strengthen sponsors' monitoring of prescribers and pharmacies by providing additional guidance on effective monitoring methods, emphasizing the importance of data analysis, and recommending that sponsors routinely generate and review reports on billing.

- Ensure that Part D does not pay for refills of Schedule II drugs, as such refills are prohibited by Federal law. CMS should exclude these drugs when calculating its final payments to sponsors at the end of each year.

- Require sponsors to refer potential fraud and abuse incidents that may warrant further investigation to CMS and other appropriate entities, instead of relying on sponsors to voluntarily report.

- Develop and implement an administrative mechanism to recover payments from plan sponsors for inappropriate Part D claims. CMS currently does not have such a mechanism to help safeguard Medicare funds.

- Clarify its policy and instruct the MEDIC regarding the circumstances under which it may share specific information with other entities, including State agencies. This would improve the MEDIC's ability to effectively identify and investigate potential fraud and abuse.

- Facilitate access to information necessary to ensure accurate coverage and reimbursement determinations. Requiring diagnosis codes on Part D claims could help plan sponsors and CMS determine whether a drug is covered under Medicare.

- Amend regulations to authorize the MEDIC to obtain information directly from entities such as pharmacies, physicians, and pharmacy benefit managers.

- Provide education and training for prescribers, including issuing reports similar to Comparable Billing Reports issued for other services, such as those provided under Part B. These reports would provide prescribers with important educational information and insight about their prescribing patterns.

CMS has agreed with many of our recommendations and it has taken some steps to strengthen Part D monitoring. While we appreciate CMS's agreement to implement certain recommendations, many of the vulnerabilities that OIG has identified stem from a lack of basic checks that should be occurring. It is important that CMS effectively follow through and implement these basic checks. OIG's next steps in oversight will be to review the effectiveness

of sponsors' drug utilization programs to ensure that Medicare payments meet program guidelines.

Conclusion: More Needs To Be Done To Safeguard the Program and Protect Patient Safety

The Part D program provides outpatient prescription drug coverage for 37 million Medicare beneficiaries at a cost of almost $67 billion. Numerous health care fraud investigations involving Part D and drug diversion have revealed complex crimes, some involving criminal enterprises. Ineffective or nonexistent program controls can cost beneficiaries and taxpayers millions of dollars. In addition, serious health consequences can result from inappropriate prescription drug use. Effective monitoring and oversight are essential to ensuring patient safety and preventing fraud, waste, and abuse.

To that end, all of the players discussed in OIG's testimony need to do more. CMS needs to improve its oversight and take the specific steps outlined above. The MEDIC needs to improve its monitoring of claims data and effectively develop and refer potential fraud cases to OIG. Sponsors need to strengthen their payments controls and reporting of fraud and abuse. The program needs effective controls that prevent problems from occurring and effective and aggressive responses in instances when problems occur.

For our part, OIG is committed to continuing our vigilant oversight of Part D integrity and investigating cases of suspected fraud to hold perpetrators accountable and protect beneficiaries. This mission is challenged by the declining resources that OIG has to bring to bear at a time when Part D fraud, waste, and abuse and prescription drug diversion cases are on the rise. While our Part D investigative caseload has almost quadrupled over the past 5 years, we are in the process of reducing our staff by about 20 percent as a result of expiring funding sources, compounded by the effects of sequestration. We are leveraging our analytic, investigative, and oversight tools as well as our Federal, State, and local partnerships to maximize the impact of our efforts.

Thank you for your interest in this important issue and for the opportunity to present the results of our most recent work related to Part D. OIG remains committed to carrying out our oversight and enforcement responsibilities in this area as comprehensively and effectively as possible with the tools and resources we have available.

TESTIMONY

Curbing Prescription Drug Abuse in Medicare

Ms. Alanna M. Lavelle
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3350 Peachtree Road, Atlanta, GA 30326

United States Senate
Committee on Homeland Security & Government Affairs

Monday, June 24, 2013:

Mr. Chairman and members of the Senate Committee on Homeland Security and Government Affairs, I am Alanna Lavelle, Director of Special Investigations for WellPoint, Inc. WellPoint is one of our nation's largest companies providing health and ancillary benefits to consumers and businesses, with nearly 36 million people in our affiliated health plans, and nearly 68 million people served through our subsidiaries. I also serve as the Chair of the National Health Care Anti-Fraud Association, the leading national association composed of both private and public sectors focused exclusively on fighting health care fraud and abuse. I joined WellPoint in 2004, after serving 25 years with the FBI. My experience in the FBI included managing a national health care fraud case during the critical Columbia/HCA investigation and initiating the first Health Care Fraud Task Force in Texas. I also served as the Supervisory Special Agent FBI liaison for the Centers for Disease Control (CDC), working closely with the CDC on Bioterrorism matters in the post 9/11 era. I am a registered Mediator and a Certified Professional Coder. I hold a M.S in Conflict Management and a B.A. in International Relations.

Thank you for the opportunity to provide testimony on behalf of WellPoint on a critically important issue that often yields tragic results: prescription drug abuse in the health care delivery system.

As one of the largest health benefits companies with nearly 36 million lives in our affiliated health plans, WellPoint believes that it is critical to address health care fraud and abuse. In a time of rising health care costs, it is essential to stop funding illegitimate uses of prescription drugs. The National Health Care Anti- Fraud Association estimates that financial losses due to health care fraud and abuse range from $70 to $234 billion a year — about $190 to $640 million per day. At WellPoint, we have a number of innovative strategies in place to do our part to eliminate wasteful spending.

However, the cost goes beyond the billions of dollars consumers, payers and the government spend unnecessarily. It also puts consumers' health at risk. For example, the steadily increasing incidence of physicians overprescribing narcotics that are not medically necessary contributes to inappropriate drug use by teenagers, patient overdoses and even death.

In order to truly make inroads into the problem of fraud and abuse associated with prescription drugs, a holistic view needs to be adopted, since the enormous costs of health care fraud are borne by all Americans, whether they have private health insurance coverage or government-provided health care. Moreover, it is clear that many of the same individuals and

entities that perpetrate fraud against government health care programs also engage in fraudulent activity in the private health insurance industry. Thus, the most effective way to address prescription drug fraud and abuse is to forge a close and active partnership between private health plans, government agencies, and the provider community. Fraud and abuse affects both publicly funded health care programs and privately funded health benefits — and it is only through cooperation and collaboration between the public and private sectors that the problem can be meaningfully addressed.

In addition, it is important to understand that stopping prescription-drug fraud and abuse will require a multifaceted approach, as there is more than one problem and more than one source. For example, drug fraud or abuse can be caused by overutilization (drug abuse) or fraudulent prescribing (for financial gain), and can be driven not only by the recipients of the drugs but also by prescribing providers. In addition, new schemes to defraud the system are constantly changing and evolving. For this reason, it is important to recognize that a one-size-fits-all solution does not exist. WellPoint stands ready to share with policymakers its range of experience in fighting prescription drug fraud and abuse and to work together with Congress, the Administration, and the agencies of jurisdiction to improve our partnership in this regard.

One of the significant strengths that WellPoint and other health plans provide is the data available from our integrated health care delivery system. This allows us the ability to see the entire health care spectrum and spot trends and outliers – such as the overprescribing physician or the patient receiving multiple prescriptions from multiple providers or pharmacies. For WellPoint's members that have both pharmacy and medical coverage under WellPoint, we have been able to identify:

- Members in crisis or at risk of harmful prescription drug use, including abusive or potentially addictive usage patterns;
- Members who may benefit from chemical dependency and/or pain management intervention to improve quality of life;
- Provider practice patterns regarding the overprescribing of medications; and
- Criminal enterprise and/or individuals defrauding the health care system, through the work of our fraud and abuse Special Investigations Unit (SIU).

Our goal at WellPoint is to prevent prescription drug fraud and abuse for the benefit of our members' health, as well as for the health care system as a whole. In order to meet this goal, WellPoint has developed numerous programs to identify prescription drug abuse and to intervene when appropriate.

WellPoint's Special Investigations Unit

To enhance our efforts to combat fraud and abuse, WellPoint has a dedicated fraud and abuse prevention team known as the Special Investigations Unit (SIU). I am one of the lead investigators, overseeing a team in the Southeast region. The SIU, led by a former Los Angeles Assistant United States Attorney, is staffed with employees having prior experience in the FBI, state law enforcement, and state insurance department fraud units. Medical professionals, including doctors and nurses who have clinical and coding expertise, also work within the SIU. Finally, the data analysis team is comprised of individuals with IT or other computer-related backgrounds. The investigators are responsible for investigating assigned cases in order to detect fraudulent, abusive or wasteful activities/practices and to recover funds paid on such claims. Our programs at WellPoint also include collaborative efforts between our SIU and our contracted pharmacy benefit manager, Express Scripts, to identify retail pharmacies cooperating with overprescribing or inappropriate prescription patterns and to exclude such pharmacies from our provider networks.

Current Trends in Prescription Drug Diversion

Today, some of the top fraud and abuse schemes we currently see in prescription drug coverage include:

- The practice frequently referred to as doctor shopping, whereby individuals obtain prescriptions for frequently abused drugs from multiple prescribers and then fill them at different pharmacies. Oftentimes providers as well as pharmacies are involved in the scheme.
- Bogus providers: these are providers that, although they may have National Provider Identifier numbers (which are usually stolen or purchased), do not actually perform services for real patients but bill insurers.
- Pain management doctors overprescribing pain medications.

WellPoint currently has 160 investigations open involving Part D, which include drug seekers (doctor shoppers), identity theft, over-prescribers and bogus pharmacy cases. WellPoint SIU refers every Part D case to the MEDIC, and WellPoint has the second highest number of referrals to the MEDIC nationwide. Our advanced analytics team at SIU target fraud and abuse including:

-Identification of member drug seeking and doctor shopping

-Geographic concerns - patients traveling long distances to prescribers and or pharmacies

-Regional/national prescription fraud and abuse trends

For example, in 2011, WellPoint had a Part D member who obtained 77 controlled substances from 59 physicians filled at 51 pharmacies. Physician specialties identified on the member's profile included emergency medicine, dentistry, dermatology, cardiology and internal medicine. This member drove to five outlying states to obtain and fill prescriptions and used eight different dentists for controlled pain medications. The member also visited 29 different emergency departments, averaging $800 per visit in her drug seeking efforts. While we referred the case to the MEDIC, we were unable to restrict the individual, as we currently do not have a restricted recipient program in place in Part D.

WellPoint's Successful Fraud Prevention Programs

Our goal at WellPoint is to prevent health care fraud and abuse for the benefit of our members' health, as well as for the health care system as a whole. As such, WellPoint has developed a number of different types of programs to identify and prevent prescription drug fraud and abuse. Some of these include:

- Controlled substance utilization monitoring (CSUM) program
- Medicare and Medicaid restricted recipient program
- Pre-pay provider review program
- Bogus providers/pharmacies
- Predictive modeling program

Controlled Substance Utilization Monitoring (CSUM) Program

Our nation has a significant problem with prescription narcotic drug abuse and patients have, at times, gamed the system by a practice known as doctor shopping, whereby individuals obtain prescriptions for frequently abused drugs from multiple prescribers and then fill them at different pharmacies. Often times, they make multiple emergency room visits in order to obtain multiple prescriptions for narcotic drugs. This results in increased costs, not just for unnecessary medications, but also for related emergency room visits, in-patient hospitals stays, and visits to physician offices and clinics – all based on phantom illnesses and injuries used simply to get a prescription. WellPoint has found that its affiliated health plans have paid $41 in related medical claims for every $1 paid in narcotic prescriptions for suspected doctor shopping members.

Through a controlled substance utilization monitoring program, (CSUM), health insurers can aid in patient safety and identify those who are engaged in or contributing to prescription drug abuse. Our CSUM program in our commercial and Medicaid business identifies members who, within a three month period, visit three or more prescribing providers, visit three or more pharmacies, and have filled ten or more controlled substance prescriptions (narcotics, benzodiazepines and hypnotics) without a confirmed underlying medically necessary condition (such as cancer or multiple sclerosis) to justify numerous controlled substances. The goal is to prevent members who have exhibited a pattern of obtaining multiple prescriptions for controlled substances from different providers and multiple dispensations of these medications from continuing to obtain inappropriate amounts and dosages of drugs through their health care coverage. Members who are identified through this program are alerted to oversight of their Schedule II prescription drug activity and case managed. To date, the program has been very successful; for example it has helped saved millions of dollars in emergency department visits for drug-seeking behavior. There has not been significant abrasion, and in fact some members have found the program helpful in managing their treatment.

Medicaid Restricted Recipient Program

WellPoint has also implemented a restricted recipient program for our Medicaid plans in Indiana called "The Right Choices Program," and in Virginia called "RX Safe Choice," in which a member who has been identified at risk for abuse of controlled substances can be restricted to

the use of only one primary care physician, one retail pharmacy, and one hospital for any non-emergency care. Our case managers, who work specifically with both the Indiana and Virginia membership, work directly with providers and members regarding excessive controlled substance use. Once a member is placed in the program, the primary medical provider must approve all referral providers for the member. Efforts are made to connect members with behavioral health providers, case managers and community resources related to abuse and addictions.

WellPoint supports giving CMS the authority to establish a restricted recipient program in Medicare Part D for those beneficiaries displaying a pattern of misutilization. To ensure members' safety, WellPoint believes that plans should not implement policies of denying a prescription fill, even in cases of suspected overutilization. WellPoint asks that CMS be responsible for taking any enforcement action once members suspected of misuse or overutilization has been identified by the plan sponsor.

Provider Engagement in the Prescription Drug Trade

Provider involvement in the prescription drug trade of narcotics and other expensive drugs is a serious problem in our country, in particular in the state of California. As noted in a November 11, 2012 *Los Angeles Times* article, "federal researchers reported that emergency room visits resulting from the non-medical use of opioid prescription drugs - often used in pain relief - more than doubled from 2004 through 2008. There were as many visits for those prescription medications as for illegal drugs."[1] *Times* reporters analyzed 3,733 prescription drug-related deaths in four Southern California counties, revealing that just 71 doctors – one-tenth of one percent in those counties- had written prescriptions in 17 percent of such fatalities over six years. WellPoint SIU plays an instrumental part in identifying to California law enforcement agencies those providers who prescribe narcotics to individuals with no underlying medical conditions because it has access to pharmacy information and relevant medical records, enabling the identification of trends and outliers. We provide quarterly reports identifying the top prescribers in each California county and prepare individual reports where the recipients of the narcotics do not have underlying medical conditions.

[1] *Los Angeles Times*, November 11, 2012; "Legal Drugs, Legal Outcomes," by Scott Glover and Lisa Girion

Pain Management Doctors

Operation Pillbox is an example of a recent, ongoing initiative by WellPoint's SIU to identify providers who engage in unsafe practices that defraud insurers.

WellPoint's SIU launched Operation Pillbox in 2007, when our investigators noticed unusual prescribing patterns involving end-stage cancer drugs. Our investigators, working on behalf of our California health plan, determined that a number of physicians were prescribing an unusually large quantity of a very strong narcotic meant to treat cancer patients with severe pain. Their research found that just 10 physicians prescribed more than a quarter of that drug in the entire state, with some patients receiving more than $200,000 worth of the medication, despite the lack of clinical evidence that the patients had cancer.

The team then expanded their research to include other Schedule II narcotic drugs (such as oxycontin). They discovered that some physicians were prescribing these potentially addicting and life-threatening drugs with little or no medical justification. Believing that the suspect physicians may have been involved in the illegal sale and distribution of narcotics, WellPoint's investigators shared with local, state, and federal law enforcement authorities our information regarding the physician's background and prescribing patterns, the pharmacies involved, and the patients receiving the largest volume of the prescriptions. As a result, several of the physicians identified by Operation Pillbox have been arrested and criminally charged or stripped of their medical licenses. One of the physicians was linked to the overdose deaths of thirteen of his patients.

Pre-Pay Provider Review Program

Part of WellPoint's antifraud-program activities includes examining physician practice patterns, to determine whether outlier physicians whose practices are different from the norm are engaging in questionable behavior that are driving up costs and impacting patient safety. WellPoint investigators are able to identify aberrant provider practice patterns through data mining and analytics in which they look for outlier activities, such as significant dollar spikes in payments or cumulative dollar spikes in certain counties. WellPoint has implemented two such pre-pay provider review programs in which the most egregious billers who, after being educated and refusing to modify their billing behavior, are placed on "Flagged Pre-Payment Review." For

example, providers are identified as outliers if they show patterns of engaging in billing practices that are extremely aberrant compared to their specialty peers. "Upcoding" (coding a less intensive service as a more intensive procedure), billing an incorrect code to obtain coverage for a noncovered service, or billing at a particular facility to obtain extra reimbursement (e.g., billing a simple toenail clipping performed in an outpatient facility as debridement performed at an ambulatory surgery center) are examples of such outliers.

If a provider shows a pattern of engaging in such outlier behavior, WellPoint investigators and Medical Directors intervene to communicate with the provider to educate and attempt to correct his or her behavior if appropriate. About 60 percent of providers change their practices within 90 days after receiving such communications. However, the 40 percent of providers that continue to engage in incorrect coding may be placed on pre-pay review. In that case, providers must bill with paper claims accompanied by medical records so that we can determine whether the procedures billed for are reflected in the records.

Bogus Providers/Pharmacies and Identity Theft

Bogus providers are those providers that, although they may have National Provider Identifier numbers (which are usually stolen or purchased), do not actually perform services for real patients. Instead, bogus providers steal or purchase patient identification numbers, establish a fake storefront office furnished with limited inventory, obtain a post office box, and proceed to bill insurers for fraudulent services and devices. Bogus providers are a significant problem in both commercial health insurance as well as in the Medicare Advantage and Medicare Part D programs.[2]

WellPoint takes a multifaceted approach to identifying bogus providers and preventing their fraudulent billing. SIU's Provider Database team alerts investigators to the presence of new labs, pharmacies and durable medical equipment (DME) clinics, and performs a full background check as well as a drive-by of the provider's purported office space. WellPoint also matches U.S. Post Office box numbers against our current claims to determine whether multiple bogus providers are using the same P.O. Box to receive payments (or whether the new provider has simply switched names and continues to fraudulently bill). To date, in the state of California

[2] Of note is that Section 6401 of the Affordable Care Act provides for a ninety-day period of enhanced oversight for the initial claims of DME suppliers where HHS suspects there may be a high risk of fraudulent practices.

alone, WellPoint has stopped over 239 bogus DME providers before they were able to submit fraudulent claims to the company. Additionally, during the past six months, WellPoint has identified and targeted 63 bogus pharmacies through collaboration with our pharmacy benefit manager, Express Scripts. Through our combined efforts we have been able to terminate contracts and stop payments to these bogus pharmacies resulting in savings of $2.1 million.

A great example of the proactive work of the SIU in identifying bogus providers and also collaborating with our public partners at CMS and DOJ involves identifying and deterring health care fraud in the Medicare Advantage program. After a tip from one of our Medicare Advantage members who received an EOB for thousands of dollars of services he did not receive from an unknown provider, WellPoint commenced an investigation that led to the discovery of what appeared to be a large medical identity theft scheme perpetrated by an organized crime group. Further investigation of this organization resulted in discovery of bogus providers who were submitting fraudulent Medicare Advantage claims. In many cases, the perpetrators had stolen the provider identification numbers from local physicians, and utilized stolen Medicare Advantage identification members' numbers. Once this information was in hand, they began a deliberate and well-executed conspiracy to defraud our Medicare Advantage program. Our investigation revealed that claims paid from bogus providers were often for billings of a high volume of expensive infusion therapy (cancer and HIV-related) treatments for unknown conditions and from unknown providers. The claim profile of these providers exhibited the characteristics of having invalid contact information (but including identification information from legitimate doctors to make them appear genuine), as well as irregular banking methods to cash payment checks.

Our SIU worked closely with claims operations areas to develop a proactive program to assist in identifying any provider fitting the same claim and provider profile as the bogus providers. The proactive process involves identifying any previously unknown provider billing the suspicious high dollar infusion therapy. These providers and their claims are immediately pended in the system and submitted to the SIU for review. Additionally, with respect to providers already in the claims systems with the same billing and provider profile, an edit process was inserted in the claims system to pend and review claims similar to those used by the bogus providers.

As a result of the investigation, in 2011 SIU identified 36 bogus providers who engaged

in this scheme. Due to the proactive work of SIU, $33 million dollars of fraudulent claims were stopped during the claims adjudication process, or newly issued checks to the perpetrators were stopped before they were negotiated. The total amount in savings to the Medicare Advantage program was $33,748,292.94.

Predictive Modeling

WellPoint has recently contracted with a vendor to provide an automated solution to enable WellPoint to continuously monitor medical (professional claims on CMS Forms 1500) claims across the company in a post-payment or future pre-payment environment. The initial rollout focuses on deploying the solution in the post-payment environment. WellPoint initially rolled out the program in Georgia, with the intent to implement it enterprise-wide in 2013.

The program uses advanced neural network technology from FICO[3] to identify previously unknown and emerging fraud and abuse provider/member schemes. FICO-based analytics score suspect claims on a scale of 1-1000 and identify aberrant provider/member behaviors. Suspect providers and claims are reviewed by a triage unit and the SIU to identify potential fraud, waste or abuse, and depending on the type of findings are then assigned to the investigative unit to investigate, prevent and stop ongoing fraud and abuse.

Since we began using this tool, WellPoint's SIU has opened 200 investigations and has achieved $27 million in projected savings to date. For example, the program has revealed patients with consecutive days of anesthesia, which is not medically likely, as well as lab testing for cardiac risk or food sensitivities where labs were billing for hundreds of units of antigens. The program has also identified certain weaknesses in our systems and procedures, which we then work quickly to strengthen. In 2013, WellPoint will save over $13 million alone by placing a system edit for urine drug testing abuse by labs, one of the collateral abuses spawned by prescription drug abuse in the U.S.

[3] FICO is the acronym for Fair Isaac Corporation, which provides analytics and decision making services to assist financial services organizations in making complex, high volume decisions

Recommendations:

Based on our experience in combating prescription fraud and abuse, WellPoint offers the following recommendations to enhance future efforts throughout all sectors of health care:

- **Medicare Restricted Recipient Program**

WellPoint supports giving CMS the authority to establish a restricted recipient program in Medicare Part D for those beneficiaries displaying a pattern of misutilization. WellPoint systematically reports beneficiary-specific concerns— based on objective, standardized metrics—to CMS or to Medicare Drug Integrity Contractors (MEDIC) for appropriate action against the individual beneficiary. To ensure members' safety, WellPoint believes that plans should not implement policies of denying a prescription fill even in cases of suspected overutilization. From a health plan perspective, we would want to work with the prescribing physician and/or refer the case to CMS or its delegate. WellPoint asks that CMS be responsible for taking any enforcement action once members suspected of misuse or overutilization have been identified by the plan sponsor. Once sufficient due diligence has been conducted by CMS or its delegate to demonstrate abuse, or upon recommendation of the provider, the member can be placed in the restricted recipient program which the plan sponsors manage pursuant to clear regulatory protocols.

- **Dual Eligible Beneficiaries**

Through our experience in providing health care coverage through both our Medicaid state-sponsored programs and Federal programs, we have observed that a large portion of the opioid and controlled substance abuses in the Part D program occur among the dual eligible population – beneficiaries eligible for both Medicare and Medicaid and often under 65 years of age. In calendar year 2012 alone, WellPoint's SIU unit tracked 69 investigations of Medicare Part D beneficiaries under the age of 65. Under current law, dual-eligible beneficiaries are allowed to change plans on a month-to-month basis, which permits drug seekers to switch programs frequently in order to avoid detection and escape program edits or substance abuse programs.

WellPoint recommends that dual eligible beneficiaries with evidence of drug-seeking behavior should be locked into one managed care plan, rather than continue to be allowed to switch plans on a monthly basis to evade detection.

- **Improved Partnerships**

WellPoint supports better coordination and cooperation among CMS, DOJ, and all stakeholders. Right now, there is little collaboration between the agencies and the health plans that oftentimes have the information, experience and expertise necessary for preventing and fighting fraud and abuse. In order to be truly effective throughout the health care system, both public and private sectors should be working together to share successful anti-fraud practices, effective methodologies and information about ongoing fraud investigations. For example, while health plans currently share information with the MEDIC, we are rarely informed of the ultimate result, and information collected by the agency is rarely shared with the private payers. Another example is that CMS does not share information on revoked Medicare providers with private payers.

However, we are optimistic by the creation last year of the Healthcare Fraud Prevention Partnership, a voluntary partnership composed of both the public and private sector for the purposes of reducing the prevalence of health care fraud. WellPoint is an active participant, and I serve on the Data Analysis and Review Committee. It is our hope that the work of the partnership will lead to successful public/private collaboration in the prevention and detection of health care fraud.

- **Encourage Fraud Prevention by Private Health Insurers and in the Medicare Advantage Program**

Experience has proven in both private and public program fraud investigations that fraud prevention is much more effective and cost-effective than pursuing "pay and chase" type fraud investigations. "Pay and chase" investigations recoup only about 20 cents on the dollar, while fraud prevention investigations result in dollar-for-dollar savings by avoiding improper payments. Moreover, fraud prevention investigations often remove fraudulent and harmful providers from the healthcare system before they can do more damage to public and private healthcare programs and their members. In recent years the Department of Justice and HHS have

adopted successful fraud prevention tactics. The federal government should do everything it can to encourage fraud prevention for private health insurers, as well.

One way this can be done is to permit health insurers to lift the current restriction on health insurers' fraud programs in the Medical Loss Ratio (MLR) calculation, which appears in the MLR regulations for both commercial health insurers[4] as well as Medicare Advantage.[5]

For both public and private health care programs subject to the MLR, expenses for health insurer anti-fraud and abuse programs should be included as "activities that improve health care quality" in the MLR calculation, since they reduce waste in the health care system, reduce the cost of health care, and enhance patient safety by helping identify and remove providers and individuals engaging in unsafe and fraudulent practices from the health care system.

Currently the MLR final regulations for both commercial health insurance and Medicare Advantage merely give insurers a limited credit – up to the amount of fraud recoveries – for fraud prevention activities. In essence, this means that insurers will have to include as administrative expenses their largest portion of antifraud expenses -- those dedicated to fraud prevention. It is truly puzzling that at a time when the federal government is accelerating its efforts to prevent fraud in Medicare and Medicaid it has simultaneously issued regulations that will serve to discourage health insurers' fraud prevention efforts in the private and public sectors. Ironically, eliminating antifraud programs will tend to increase MLR percentages because claims will be higher, but an increased MLR will be at the expense of patient safety, quality of care, and controlling health care costs, which are the very goals of the Affordable Care Act.

If health insurers are discouraged from keeping their anti-fraud programs in place at the same time that anti-fraud efforts are increasing in the traditional Medicare program, federal law enforcement will lose a valuable source of information and tips about providers and recipients who may also be engaging in defrauding public programs. Additionally, restricting the expenses that Medicare Advantage plans can incur for fraud prevention activities may foster fraud and abuse in that program.

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[4] See 45 C.F.R. 158.140(b)(2)(iv).
[5] See 42 C.F.R. 422.2420(b)(2)(ix).

In conclusion, I would like to thank the Committee for the opportunity to testify today on behalf of WellPoint on this critical issue, and pledge our support in any efforts to make the health care system financially viable and safer for our members.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

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Statement of the National Community Pharmacists Association (NCPA)

United States Senate Committee on Homeland Security and Governmental Affairs

Hearing on Curbing Prescription Drug Abuse in Medicare

June 24, 2013

Chairman Carper, Ranking Member Coburn, and Members of the Committee:

The National Community Pharmacists Association (NCPA) welcomes and appreciates the opportunity to provide feedback and suggestions regarding efforts to combat fraud, waste, and abuse in the Medicare Part D program. NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. NCPA members are a primary access point for prescription medications for millions of Part C and D beneficiaries and NCPA members comprise a critical piece of the Part C and D prescription drug distribution system.

Community Pharmacy's Commitment to Fighting Fraud, Waste, and Abuse

NCPA strongly believes in the mission to eliminate fraud, waste and abuse in Medicare in order to bolster the integrity of the program and maximize the benefits provided to beneficiaries. Our members strive to do their part to help ensure these goals. NCPA and independent community pharmacists are committed to fighting fraud, waste and abuse within the Medicare prescription drug program, and offer the following recommendations:

Greater transparency and incentive realignment needed to combat waste and identify true fraud

Pharmacy benefit managers (PBMs) are corporate middlemen that contract with Part D plan sponsors to provide prescription drug coverage to tens of millions of seniors, individuals with disabilities, and low income individuals. While they play a large role in the delivery of health care to beneficiaries, they continue to operate in the shadows and their activities remain largely unregulated. As the largest payer of health care, the federal government must have a better understanding of their business practices, because the lack of transparency in PBM activities creates program vulnerability.

PBMs create potential for greater waste

The misalignment of payment incentives and profit motives of PBMs, who also own and operate their own mail order facilities, only serve to encourage greater utilization of mail order and the practice of automatic shipment of refills. An example is within the current structure of the Medicare star quality ratings for plans. One incentive for plans to improve their quality ratings is related to a medication adherence measure, which NCPA has contended is based solely on prescription claims data with no tie or correlation to outcomes. Prescription claims data is based on how many total days of therapy a patient

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actually has medication on hand, not whether it's been taken appropriately. We continue to reiterate our concerns that simply shipping the product every 30 or 90 days without proper clinical assessment of the patient for therapeutic appropriateness is not true adherence and in fact, can generate more waste. If ratings continue to be calculated on how many fills a patient receives without factoring true clinical improvement, plan sponsors will continue to be motivated to ensure that patients are always shipped refills, whether or not the medication was needed or wanted. A consequence of this is seniors can find themselves advancing through the Part D benefit phases prematurely if they truly did not need those extra refills but were billed anyway.

Furthermore, Medicare may be overbilled when medications are automatically filled without prior consent from the patient. NCPA supports the recent establishment by CMS of clear policies and parameters surrounding auto-ship refill programs in the Part D program. In the 2014 Call Letter issued by CMS to plan sponsors, the Agency stated that it has become aware that while pharmacies may obtain an initial beneficiary consent to provide automatic refills, the pharmacies may not have verified that the beneficiary needs the medication before each subsequent refill is delivered. In addition, CMS also has become aware that some mail order pharmacies are automatically delivering new prescriptions that a beneficiary's prescriber has phoned in or e-prescribed despite the fact that the patient may not want the prescription filled at that time or via mail order. CMS concluded that these automatic fill practices, "are potentially generating significant waste and unnecessary additional costs for beneficiaries and the Part D program overall." Therefore, CMS has advised that Part D sponsors should require their network retail and mail pharmacies to obtain patient consent to prior to the delivery of each prescription.

Abusive audit practices deterring from true patient care and fraud detection

Community pharmacists understand and support legitimate auditing practices, and while Part D pharmacy audits are necessary, drug plan intermediaries such as PBMs are abusing this process by singling out expensive drugs and using clerical, typographical and other trivial errors to recoup from pharmacies significant amounts that may not be returned to the Medicare program. NCPA appreciates the steps that Medicare officials took in the final Call Letter to address concerns about auditing issues that can negatively impact the program's cost and quality of care. Within the 2014 Call Letter, CMS admits that, "[t]he increasing incidence of these adjustments for 'routine clerical errors' rather than incorrect payment amounts (financial errors) may be related to the incentives in contingency reimbursement arrangements with claim audit vendors." The Call Letter goes further to state, "[w]e are concerned that the growing practice of post-audit total claim recoupments from pharmacies is distorting Part D payment, as well as compromising Part D data integrity and impairing our ability to oversee the program."

Not only does recoupment by PBMs for clerical errors take up valuable resources that should be targeted at identifying true fraud, waste, and abuse, it may also distract CMS from adequately providing oversight to the program which could compromise Part D data integrity. NCPA strongly encourages the Committee to work with the Agency and appropriate stakeholders to target true fraud, waste and abuse and to discourage practices that only serve to identify clerical errors and recoup large amounts from pharmacies. Furthermore, NCPA supports the bipartisan legislation introduced in the Senate which would achieve a more balanced business relationship between PBMs and community pharmacies, thereby allowing pharmacists to continue putting patients first in health care. *The Medicare Prescription Drug Program Integrity and Transparency Act* (S. 867) would focus pharmacy audits on uncovering actual fraud and abuse, bring transparency to generic drug reimbursement rates and give Medicare beneficiaries additional privacy and other protections.

Ensuring program integrity is a shared responsibility

NCPA applauds the Committee for taking a hard look at the vulnerabilities that exist within the Medicare prescription drug program that potentially lead to waste and fraud, and we strongly support efforts to eliminate such abuse within the program. However, we remain concerned that some of the efforts by the Agency and private payers to reduce fraud are overly broad, abusive, and inadvertently label legitimately operating pharmacies as bad actors. There needs to be a collective approach to controlling abuse and diversion that involves every stakeholder in the supply chain: manufacturer, wholesaler, prescriber, payer, pharmacist, and patient.

While we believe that all stakeholders should remain laser-focused on routing out fraud, waste and abuse, recent efforts to crack down on fraudulent behaviors have taken a broad approach and do not hone in on truly abusive practices. Strictly examining prescription drug event (PDE) records without placing some context around the claims data is like judging a book by its cover, which potentially places legitimately operating pharmacies in the spotlight for further scrutiny.

For example, independent pharmacies serve a disproportionately high number of long-term care and other patients who are prescribed more medications than the average Medicare beneficiary. In addition, independent pharmacies are often situated in underserved, rural areas with few physicians nearby and therefore may bill for a higher than average number of prescriptions per prescriber. Conversely, many independents are also located in urban areas near large teaching hospitals or cancer clinics where physicians prescribe a disproportionate share of controlled substances, including schedule II and III medications. Community pharmacists also serve diverse patient populations with specialized needs, which may necessitate the compounding of medications. Each of these examples are likely to result in a negative assessment by CMS or others of the pharmacies' risk and could inadvertently single out certain community pharmacies based on wholly unwarranted factors.

As one of the most accessible and trusted health care providers, community pharmacists recognize the importance of addressing the serious and growing problem of prescription drug diversion and abuse. NCPA is encouraged to see the that the Office of National Drug Control Policy (ONDCP) has made the issue of prescription drug abuse a top priority and believes that community pharmacists are well-positioned to respond to the action items laid out in the Administration's *Prescription Drug Abuse Prevention Plan*, particularly in the areas of education, tracking and monitoring, and proper disposal. We strongly believe in tactics that focus on prevention and proactive monitoring. Examples include: greater provider education, appropriate prescribing, and requiring all Part D prescribers to be validated as Medicare providers. In addition, with appropriate safeguards, we could support the concept of a "lock-in" program limiting certain patients to a specific pharmacy for controlled substances. However, such a system must be a level playing field for independent community pharmacies and not one that inadvertently incentivizes patients to use a national chain pharmacy, for example. Patients should not be locked against their will into a pharmacy they don't want to use or into mail order pharmacies, which typically ship 90-day supplies that are particularly inappropriate for controlled substances.

Given the climate of tightened resources, what's needed in terms of fraud protection efforts is for Medicare, payers, and providers to work smarter and more efficiently. We believe that all relevant stakeholders should work collectively, with timely feedback and information sharing in order to effectively address these issues. NCPA stands ready to work closely with the Committee, members of Congress, CMS, and other payer and provider groups on a set of sensible solutions that truly address fraudulent behavior, while preserving patient access to much needed health care products and services.

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

December 12, 2013

The Honorable Thomas R. Carper
Chairman
Committee on Homeland Security and Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

Enclosed please find responses to questions for the record arising from the appearance of Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, before the Committee on June 24, 2013, at a hearing entitled "Curbing Prescription Drug Abuse in Medicare." We hope that this information is of assistance to the Committee.

Please do not hesitate to contact this office if we may be of additional assistance regarding this or any other matter. The Office of Management and Budget has advised us that there is no objection to submission of this letter from the perspective of the Administration's program.

Sincerely,

Peter J. Kadzik
Principal Deputy Assistant Attorney General

Enclosure

cc: The Honorable Tom Coburn
Vice Chairman

Questions for the Record
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
U.S. Department of Justice

Committee on Homeland Security and Governmental Affairs
United States Senate
"Curbing Prescription Drug Abuse in Medicare"
June 24, 2013

Questions Posed by Senator Tom Coburn

In your testimony, you said there are more than 1.4 million registrants in the DEA database. You also said DEA maintains over 2 million registration records in a database that includes historical and current regulatory action(s) taken against a registrant.

1. **Does CMS, the MEDIC, or sponsors have access to this data?**

Response:

DEA currently provides access to the registrant database (excluding certain Personally Identifiable Information (PII) relating to individual registrants) to numerous regulatory and law enforcement agencies in furtherance of their respective missions in 43 states and trust territories and to the Office of Inspector General at the Department of Health and Human Services. While CMS, the MEDIC, or the sponsors do not have access to the registrant database, DEA makes the database, excluding PII, available to Federal and state regulatory or law enforcement agencies upon request. In addition, a version of the database is commercially available to the public for purchase on the U.S. Department of Commerce National Technical Information Service (NTIS) website.

In your testimony, you said DEA provides an electronic means by which registrants can check the validity of another registrant's DEA registration number free of charge. DEA also provides access to state agencies that have a responsibility to investigate health care fraud. DEA provides daily access to the registrant database to 41 states, Guam, and D.C., which have requested the data.

2. **Does CMS, the MEDIC, or sponsors have access to this data?**

Response:

Access to the data is available to CMS upon request; however, the online validation feature is not presently available to CMS, the MEDIC, or to the sponsors. You must be a DEA registrant to have access to this feature.

Questions Posed by Senator Mark L. Pryor

I understand that the Drug Enforcement Administration (DEA) released a proposed rule in December 2012 that would implement the Secure and Responsible Drug Disposal Act of 2010. I have heard concerns about the approach taken in that rule for the disposal of controlled substances in long term care facilities. The concerns focus on a lack of flexibility, diversion opportunities, a lack of harmonization with anti-kickback laws and other federal and state regulations, stockpiling risks and on the costs of pharmacy-operated disposal receptacles. Can you provide an update on the status of that proposed DEA rule on the 2010 drug disposal law?

3a. Is the DEA aware of those concerns?

3b. If so, how is the DEA planning to address those concerns?

Response:

On December 21, 2012, DEA published in the Federal Register a Notice of Proposed Rulemaking (NPRM) on the disposal of controlled substances. This NPRM proposes requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users. These regulations would implement the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111-273) by expanding the options available to collect controlled substances from ultimate users for purposes of disposal to include: take-back events, mail-back programs, and collection receptacles. The NPRM comment period closed on February 19, 2013. Since then, DEA has been carefully reviewing the almost 200 comments received to the NPRM from a wide range of interested persons. DEA is committed to addressing in the Final Rule all of the issues raised in the comments to the NPRM, including any concerns raised by the long term care industry and our Federal partners.

Post-Hearing Questions for the Record
Submitted to Jonathan Blum
"Curbing Prescription Drug Abuse in Medicare"

June 24, 2013

Senator Claire McCaskill

1. **The Inspector General said that a major barrier to the MEDIC's use of proactive methods is that it doesn't have access to patient and provider information. Why don't the MEDICs have access to the information they need to conduct proper oversight?**

2. **What are you doing to enhance the ability of the MEDICs to access the data they need?**

Answer to Q1 and Q2: CMS agrees with the OIG that in order to be effective the MEDIC must have access to relevant patient and provider information to carry out its work as a CMS Part D fraud contractor. Although the MEDIC has had access to Part D prescription drug event records for some time now, its access to other CMS data and systems was limited. As a result, recently, CMS expanded the MEDIC's access to more information and systems to assist its oversight functions. Since 2012, the MEDIC has been granted access to the Health Plan Management System modules, Provider Enrollment and Chain Ownership System (PECOS), and Statistical Analysis System Enterprise Business Intelligence, which allows for the manipulation of large amounts of data in a short amount of time. In addition, CMS has worked to increase communication and data sharing between the MEDIC and the Zone Program Integrity Contractors (ZPICs).

Pursuant to an OIG recommendation and concerns raised by the MEDIC, CMS is considering regulatory changes that would give the MEDIC greater access to pharmacy benefit managers (PBMs) and pharmacies and prescribers' records. Such access would give the MEDIC the ability to more quickly investigate its cases and remove the burden associated with going through the Part D plan to access relevant documentation that may be housed with a pharmacy or PBM.

3. **The MEDIC contractor is required to use proactive methods, including data mining and analysis, as well as external sources (e.g., leads from beneficiaries, law enforcement agencies, and Medicare Part C and D plan sponsors) to identify potential fraud and abuse. However, a 2009 report by the Department of Health and Human Services Office of the Inspector General found that only 4% of the MEDIC's investigations were initiated using proactive methods. That number has increased as of the HHS-OIG's January 2013 report, but only to 10%. Has the MEDIC been earning award fees despite its failure to conduct proactive**

reviews? Why have you failed to solve problems that the Inspector General first found four years ago?

Answer: Since the end of the OIG's review, CMS has refocused the goals of the current MEDIC's responsibilities. We are requiring the MEDIC to develop a new set of deliverables that include a monthly vulnerability report and data analysis plan report, which lists the project name, description, and status of each proactive data analysis study it conducts.

CMS agrees with the OIG that proactive investigations are important in the overall identification and prevention of fraudulent activity and we have taken additional steps to ensure the MEDIC is doing more proactive data analysis as part of its Statement of Work. Under the direction of CMS, the MEDIC has increased the number of proactive data analyses projects it completes since the end of the OIG's review. The structure of the MEDIC contract does not include award fees; as such, CMS has not paid the MEDIC for any additional services beyond what is included in their existing Statement of Work and Task Orders.

It is worthwhile to mention the MEDIC performs a variety of tasks for CMS in addition to proactive data analysis projects. The other work areas of the MEDIC include: (1) investigating and developing all complaints; (2) providing referrals; (3) conducting and assisting investigations; (4) completing other forms of data analysis; (5) offering CMS support; (6) providing the OIG and other law enforcement Subject Matter Experts for trial; (7) performing impact calculations; (8) conducting Regional Office education/presentations; (9) collaborating and educating Part D sponsors on identifying potentially-fraudulent schemes; and (10) maintaining a dedicated toll-free Part D fraud, waste, and abuse hotline. CMS evaluates the MEDIC on all the functions it is responsible for carrying out under the contract.

4. **The OIG also recently found that Medicare paid millions of dollars for prescriptions from unauthorized prescribers, including massage therapists, athletic trainers, dental hygienists, occupational therapists, and even home repair contractors. These should be among the easiest things to find and stop – prescriptions being written by people that have no business writing prescriptions. This seems like relatively low-hanging fruit as far as rooting out Medicare fraud goes. Was the MEDIC aware of these issues? Do they get the credit for bringing them to your attention, or did the OIG find them first?**

Answer: While the MEDIC was aware and had been investigating (or had referred to law enforcement) some instances of unauthorized prescribers, the OIG report did bring additional unauthorized prescribers to our attention. CMS shares your concern about any instance in which a prescription could have been written by a non-authorized prescriber, and unfortunately, given the nature of pharmacy claims processing, it is not always easy to identify at point-of-sale if an unauthorized prescriber wrote a prescription. We are exploring additional credentialing options that will help us more easily identify

unauthorized prescribers and, in the meantime, CMS has initiated a comprehensive investigation of the OIG findings. We will determine if they are attributable to an administrative error, such as the data accuracy of the taxonomy code (the type, classification, and/or specialization of health care providers) selected by the prescriber in the National Plan and Provider Enumeration System (NPPES) or are truly unauthorized Part D prescriptions. We are examining a sample of "unauthorized" prescriptions presented at the pharmacy to determine whether the prescription was actually written by an unauthorized prescriber, a claims data entry error that resulted in the appearance of an unauthorized prescriber (for instance due to the incorrect selection of the NPI number), or an incorrect taxonomy designation in the National Plan and Provider Enumeration System (NPPES) associated with the authorized prescriber. In the cases where we identify an incorrect taxonomy designation, we will reach out to the authorized prescriber and encourage him or her to correct the taxonomy information. Our initial findings from this investigation should be available by early 2014.

5. Part D sponsors are required to have a comprehensive plan to detect, correct and prevent waste, fraud and abuse. Do all the Part D sponsors even have a plan? Has anyone ever checked?

Answer: Yes, Medicare regulations require that all Part D sponsors have a comprehensive program in place to prevent, detect and correct fraud, waste, and abuse. Since 2010, CMS has conducted on-site audits of Part D sponsors' Compliance Programs to confirm that Part D sponsors have established and implemented effective Compliance Programs to prevent, detect and correct fraud, waste, and abuse. These audits include extensive review of documentation and systems, physical inspections of Part D sponsor facilities to observe non-compliance or potential fraud, waste, and abuse, and interviews with CEOs, Board Members, Compliance Officers, senior management, and front line staff. CMS holds the Part D sponsor's senior leadership (including the Board) accountable for ensuring the implementation of effective Compliance Programs.

In addition, on July 27, 2012, CMS issued revised Compliance Program Guidelines to all Part D sponsors, through manual guidance (Chapter 9 of the Medicare Prescription Drug Benefit Manual), to assist Part D sponsors in the establishment and implementation of effective Compliance Programs to prevent, detect and correct Medicare non-compliance and potential fraud, waste, and abuse.

6. Sponsors are not required to share information that they gather on fraud and abuse schemes with the MEDIC, nor, according to the IG, are they doing so. In fact, the IG states in their testimony that some plan sponsors did not identify a single potential fraud and abuse incident, and that only a small number of sponsors are reporting the majority of the incidents that ever get reported. Why aren't the Part D sponsors required to report these incidents?

Answer: As our regulations are currently drafted, the reporting of fraud, waste and abuse by Part D plans is voluntary. As we continue our education, outreach and oversight

efforts, CMS will monitor which plans are reporting fraud, waste, and abuse and will consider a requirement that Part D sponsors report instances of fraud, waste, and abuse. CMS is aware that certain Plan sponsors report more fraud and abuse than others, and through guidance and education, CMS will continue to encourage Part D sponsors to voluntarily refer potential fraud, waste, and abuse incidents that may warrant further investigation.

Senator Tom Coburn

1. **You said in your testimony that "prescription drug abuse is the Nation's fastest-growing drug problem," to the point where CDC calls it an "epidemic." As you know, prescription drug "lock in" program is common policy among private insurance plans and Medicaid, which effectively restricts Medicare beneficiaries to a single physician or pharmacy if they engage in doctor shopping to amass large quantities of prescription pain medications from multiple physicians and pharmacies.**

    a. **Please outline CMS's preferred parameters for a modification of the statute underpinning Part D to allow for plan sponsors to "lock-in" beneficiaries into *one pharmacy* if they are at risk of abusing drugs?**

Answer: Any statutory change should provide the Secretary with authority to ensure consistent implementation of such a program in a manner that does not impair beneficiaries' access to medically necessary drugs. The CMS Office of Legislation is available to provide your staff with more detailed technical assistance in developing any such legislation.

In addition, state Prescription Drug Monitoring Programs, which exist in 49 states, allow prescribers to check prescriptions, which helps to safeguard against patient doctor-shopping.

2. **On page 57 of the statement of work for the Medicare Drug Integrity Contractor (MEDIC), CMS says: "the MEDIC's ability to make use of available data and apply innovative analytical methodologies is critical to the success of a benefit integrity program." However, a January 2013 OIG report that found while the MEDIC has an annual budget of approximately $14 million, only 21 referrals to law enforcement were discovered through proactive means! CMS has a responsibility to taxpayers and patients to do better.**

    a. **What specific steps will you take to get better value from the MEDIC contract?**

Answer: Since the end of the OIG's review, CMS has refocused the goals of the current MEDIC's responsibilities to address the identified issues. We are requiring the MEDIC to develop a new set of deliverables that will help improve their performance and ensure they are meeting their responsibilities. The MEDIC deliverables include a monthly report which tracks total complaints, investigations, requests for information, outreach activities, proactive data analysis, and law enforcement referrals completed for Medicare Parts C and D programs. The monthly report also provides an overview of audits, data analysis, and investigative success stories. The MEDIC submits a monthly vulnerability report and data analysis plan report, which lists the project name, description, and status

of each proactive data analysis study it conducts. CMS is using these reports to ensure the MEDIC is being more proactive.

In addition, while the importance of referrals to law enforcement is clear, it should be noted that the MEDIC provides additional value beyond proactive analysis through overseeing efforts to detect, prevent and educate relevant parties on fraud, waste, and abuse, including by: (1) investigating and developing all complaints; (2) providing referrals; (3) conducting and assisting investigations; (4) completing other forms of data analysis; (5) offering CMS support; (6) providing the OIG and law enforcement with Subject Matter Experts for trial; (7) conducting impact calculations; (8) providing regional office education/presentations for the entire Medicare Part C and Part D programs; and (9) maintaining a dedicated toll-free Part D fraud, waste and abuse hotline.

b. What is your timeframe for doing so?

Answer: CMS has already refocused the MEDIC contract to address the OIG's recommendations; however, CMS will continue to review the goals, workload, deliverables and responsibilities of the MEDIC to evaluate the value the MEDIC brings to detecting, investigating and preventing fraud waste and abuse within Medicare Part C and Part D programs.

c. What assurances can you give this committee that CMS will do a better job of oversight?

Answer: As evidenced by my testimony, CMS is committed to addressing the serious issues raised by the Committee, HHS OIG and the GAO, through a number of reforms, including more rigorous oversight of the MEDIC contractor, proactive data analysis and data sharing with the Part D Plan sponsors, the implementation of a beneficiary opioid overutilization monitoring program, improved identification of prescribers, and the consideration of new regulations that would strengthen our ability to determine which physicians may prescribe drugs to Medicare beneficiaries. We are available to discuss our ongoing progress in this area.

3. In CMS's program manual, the agency recommends Part D sponsors use Drug Utilization Reviews to identify the number of prescriptions filled by an individual enrollee. Yet, we have seen the OIG's review and ProPublica's review of the data.

a. How regularly does CMS or its MEDIC contractor conduct Drug Utilization Reviews?

Answer: Each Part D sponsor is required to establish drug utilization management program and quality assurance measures and systems. CMS reviews and approves Part D sponsors' proposed utilization management edits (prior authorization, step therapy, and

quantity limits) prior to the start of each benefit year; other retrospective drug utilization reviews (DUR) protocols can be reviewed by CMS as part of our Part D sponsor audits.

CMS also has established a monitoring program to measure Part D sponsors' compliance to our opioid overutilization DUR policy. On a quarterly basis, Part D sponsors confirm that case management or action has been taken on any beneficiary enrolled in their plan that meet CMS' targeting criteria and report to us the status of case management investigations. CMS will take compliance actions against any Part D sponsor not meeting our opioid overutilization standards.

b. Why doesn't CMS or the MEDIC do more, when CMS is the one administering the program?

Answer: I agree that CMS must take additional steps to enable Part D sponsors to implement more effective controls. The MEDIC has new performance deliverables required under their contract. Specifically, the opioid overutilization DUR standard is one example of a step CMS has taken recently to target fraud, waste, and abuse using DUR protocols, and we are continuing to explore additional programs to implement. Because the Part D sponsors have the real-time pharmacy claims information necessary to implement controls at the point-of-sale, CMS developed a methodology to identify potential opioid overutilizers based on drug claims data through clinical thresholds (excessive cumulative dose over an extended period of time) and prescription patterns (multiple prescribers and pharmacies) that should trigger case management by Part D sponsors. The methodology excludes as early as possible those beneficiaries who have legitimate diagnoses that may warrant high opioid use (e.g., cancer patients or others who need palliative care), or who are borderline cases. Our methodology identified approximately 22,000 Medicare beneficiaries that met our targeting criteria.

Although we are early in the reporting by Part D sponsors, we have determined that our case management process has been able to distinguish between beneficiaries who warrant a reduction in opioid dosing and those who have no medical need for opioids. These beneficiaries are subject to opioid overutilization management by the Part D sponsor. CMS, through its Final Calendar Year 2013 Call Letter and subsequent guidance, outlined an approach to reduce potential opioid overutilization in the Part D program. Under this approach, Part D plans ensure safe dosages are dispensed through the improved use of concurrent claim edits and formulary utilization management design. CMS' guidance clarified that Part D sponsors should clinically analyze cases for unsafe cumulative dosing that DUR programing has identified through patterns that suggest potential overutilization of drugs.

Additionally, CMS has undertaken a communication and educational campaign about medication overutilization, particularly opioids, for physicians and pharmacies in the fall of 2012 to support Part D sponsors' strengthened efforts to address this issue in the Part D program. In November 2012, as part of the annual Medicare "Dear Doctor" letter,

CMS encouraged prescribers to work with Part D sponsors on overutilization case management.

In addition to these efforts, by leveraging our access to Part D claims data across all Part D sponsors, CMS is also conducting proactive data analysis to identify for Part D sponsors high-risk pharmacies and prescribers, allowing sponsors to better focus their anti-fraud efforts. An initial list of high-risk pharmacies was sent to plan sponsors in June 2013 and additional data-sharing is planned. These actions represent initial steps in what I anticipate will be a stronger partnership between CMS and Part D sponsors in combating Part D fraud and abuse.

4. **In your testimony, you said CMS is considering implementing strategies similar to the Fraud Prevention System and administrative actions into its management of the Part D program and its sponsors. However, the Inspector General's office has said most of the claimed "savings" from the system cannot be verified.**

    a. **Why is CMS considering this new direction, when the agency cannot successfully prevent egregious examples of fraud and waste at the moment?**

Answer: Based on CMS' analysis and the OIG's support, the Fraud Prevention System (FPS) shows significant promise and CMS expects results to improve as the system matures over time. CMS is committed to enhancing our ability to estimate savings with respect to both improper payments recovered and improper payments avoided for future reports, and we have been working very closely with the OIG to ensure they can verify the savings in future reports. We agree with the OIG, which acknowledged that reporting such amounts in accordance with requirements was inherently challenging because, primarily, it was a new venture and because of the decentralized nature of the Fraud Prevention System business practices.

In addition, CMS is broadening its strategy to stop Part D fraud and abuse, and is using all the tools we have at our disposal to address these serious concerns, including, but not limited to, the lessons learned from the implementation of the Fraud Prevention System. We continue to consider strategies similar to the FPS to address fraud in Part D because CMS anticipates being able to identify patterns and practices potentially indicative of fraud or abuse that would not be apparent using only Part D or only Part A and B data. Data analysis is only the first step, however; after identifying questionable prescribing, dispensing or beneficiary utilization, CMS, along with the MEDIC or ZPIC must work with Part D plan sponsors to confirm if there may be a legitimate reason for such outliers and then, when appropriate, take administrative actions to prevent further payments resulting from abusive prescribing. While data sharing with Part D sponsors will enable them to impose controls to prevent payments where there are indications of fraud or abuse, CMS is exploring its regulatory options to respond to such indications, providing a more comprehensive safeguard for the program.

5. **In your testimony, you said CMS recognizes that Part D plan sponsors face unique challenges in administering the drug benefit because they can manage the benefit only at the beneficiary level. They do not have access to Part D prescriber and pharmacy data beyond the transactions they manage for their own enrollees.**

    a. **What steps is CMS taking to share more complete, timely, and accurate data?**

Answer: CMS has access to all Part D data while plan sponsors only have access to their own Part D data. In order to provide more useful and timely data, CMS has begun sharing the results of its data analysis across the program with Part D plan sponsors. Specifically, we provided a list of pharmacies with a high risk assessment to plan sponsors to assist them in their fraud, waste and abuse detection efforts. CMS will provide this report to plan sponsors regularly and is also planning to release a prescriber risk assessment to plan sponsors. CMS will continue to explore ways to share additional data with plan sponsors to help them with their fraud, waste, and abuse efforts.

6. **The Inspector General's office found that improvements are needed to ensure the provider enumeration and Medicare enrollment data are accurate, complete, and consistent. In both data bases, roughly half of the information on providers was inaccurate and CMS did not verify most provider information in either database. CMS cannot keep fraud out the Medicare program if they cannot even ensure that the providers enrolled in the program have basic information that is complete, accurate, and verified. CMS concurred with the OIG's recommendations.**

    a. **What specific steps has CMS taken to resolve the issues in OIG's report?**

Answer: CMS agrees with the OIG and strongly believes that one of our most important roles in preventing and detecting Part D fraud, waste, and abuse is to responsibly manage and leverage our provider enrollment data. Over the past few years, CMS has made some important changes to our policies and operations. Specifically, CMS has changed our rules so that beginning in 2013 all prescribers' Part D drug claims are required to have a valid national provider number. Already, in the first quarter of 2013, 99.6 percent of all Part D claims were compliant with this requirement. CMS has begun working on developing mechanisms to further verify provider enumerator data and implement processes to deactivate NPIs when appropriate for potentially fraudulent providers. CMS is also proposing regulatory changes that would require all Part D prescribers to be validated as Medicare providers.

    b. **Can you give the committee a timeframe or work plan for when the vulnerabilities will be finally addressed in total?**

Answer: CMS continues to work on developing mechanisms to further verify NPPES and PECOS data. CMS is taking several actions to resolve this issue, including working on a process to rapidly deactivate NPIs for practice locations that are determined to be invalid. In conjunction with other data obtained, CMS will take action to deactivate NPI records with invalid practice locations or other circumstances justifying deactivation. CMS has already implemented a method to immediately identify providers and suppliers who are deceased by obtaining the deceased provider data on a more frequent basis.

In addition, CMS plans to use the Automated Provider Screening (APS) system to screen and validate provider and supplier information such as licensure and exclusion data in an effort to improve and standardize the enrollment data verification by the MACs. CMS plans to screen all initial enrollments, changes, and revalidation through APS for providers and suppliers of all risk levels. CMS also plans to analyze information from APS and other investigative methods to conduct ad hoc site visits using the National Site Visit Contractor to further validate information provided during the enrollment process. Because of the evolving nature of vulnerabilities, CMS is unable to identify a timeframe in which our oversight of provider enumerator data will be complete, but would be happy to provide the Committee with updates on our progress.

7. **CMS does not currently share information on providers who have had their billing privileges suspended as an "early alert" warning on potentially problematic prescribers with plans or state medical boards which license and discipline doctors.**

    a. **Are there good reasons why this does not occur?**

Answer: CMS agrees we need to share information regarding high risk prescribers with plan sponsors and states; we have recently begun work to help address this need. CMS is planning to release a prescriber risk assessment to plan sponsors, helping to identify for plans which providers may be prescribing inappropriately. CMS is also developing a process in which the MEDIC will share prescriber information with the Federation of State Medical Boards (FSMB). The information shared with the FSMB would be a compilation of the results of an investigation, proactive data analysis and /or complaints.

    b. **When will CMS do that?**

Answer: CMS anticipates having the process in place by early 2014.

8. **The IG's office said they appreciate CMS's agreement to implement certain recommendations, but "many of the vulnerabilities that OIG has identified stem from a lack of basic checks that should be occurring."**

    a. **Will you give us a complete workplan and timeframe for when CMS will implement all of the recommendations?**

Answer: Yes, per the request of the Committee, CMS plans to report on a periodic basis regarding our ongoing efforts to combat prescription drug abuse in the Part D program.

9. Who checks to be sure a provider has a VALID DEA number before a claim is paid—a sponsor? Who checks to be sure a provider has a VALID DEA number after a claim is paid—a sponsor, the MEDIC?

Answer: Under the Controlled Substances Act and regulations, it is the responsibility of the dispensing pharmacy to ensure the legitimacy of the prescription for a federally controlled substance that may only be prescribed by providers with valid DEA numbers. To assist pharmacies with this responsibility, a "public" version of the database of individual DEA numbers is commercially available for purchase through the U.S. Department of Commerce National Technical Information Service (NTIS). However, with respect to institutional DEA number (*e.g.*, a hospital's number), the institution is required to keep a list of internal codes and the corresponding individual practitioners and to make the list available at all times to other DEA registrants and law-enforcement agencies upon request for the purpose of verifying the prescribing practitioner's authority. The DEA does not maintain a list of internal codes for each institution's DEA number. Thus, the internal codes cannot be verified electronically by a pharmacy, and there is no requirement for a publicly-available database that can be used to verify that a particular prescriber is authorized under an institutional DEA number. Under DEA guidance, pharmacists should contact the hospital or other institution for verification if they have any doubts in filling such a prescription.

CMS' policy with respect to DEA numbers does not supersede or alter pharmacy obligations relative to the Controlled Substances Act and regulations. However, under Part D program law and regulations, in order to be a valid prescription all Part D drugs must be dispensed pursuant to all applicable state and federal laws, and invalid prescriptions may affect Part D sponsors' payments from CMS. Thus, sponsors do conduct certain, targeted point-of-sale (POS) checks before issuing payment for a prescription. Since sponsors are expected to take reasonable steps to ensure their network pharmacies are complying with all applicable laws without unreasonably delaying a beneficiary's access to medications, we have clarified this guidance to state that when a prescriber has an individual DEA number that can be cross referenced to the NPI, we expect Part D sponsors to confirm that the controlled substance prescribed is consistent with that prescriber's DEA Schedule registration. If the sponsor cannot match the NPI to an individual DEA number, we do not require the sponsor to validate the DEA number. Thus, our guidance to sponsors is consistent with what sponsors are able to do with the publicly available databases described above.

10. The TULSA WORLD recently ran a story about a senior who tragically lost her life under apparent neglect or malpractice from a physician with multiple serious infractions with the State's medical board. http://www.tulsaworld.com/article.aspx/Plea_for_help/20130623_11_A1_CUTLIN213814

In such a case, I think most would agree Medicare should know about these multiple serious infractions, especially when a patient might be harmed.

a. Under Medicare Part D, are sponsors required to get enforcement or infraction information on individual providers from the state medical boards? If they do so, how timely is that information, and how frequently is it updated? Do sponsors receive information from the Federation of State Medical Boards? If they do so, how timely is that information, and how frequently is it updated?

Answer: CMS is proposing regulatory changes under section 6405 of the Affordable Care Act to require the Medicare enrollment of the prescribing provider in order for the Part D program to cover prescription costs.

Currently, medical licenses are typically granted to physicians and other medical practitioners by the board of medicine in each state. A physician or other medical practitioner who does not have an active medical license in a state is not permitted to practice medicine in that state. CMS does not require that Part D sponsors access enforcement or infraction information from state medical boards because it is not a final action resulting in termination or suspension of medical licenses. For the purposes of fee-for-service Medicare, CMS will revoke a provider's enrollment if the provider does not have an active medical license or if a state licensing board's enforcement or infraction action is based on a felony conviction or other law enforcement action. The regulatory change we are considering under section 6405 would also include a proposal to allow CMS to revoke prescribers for similar infractions when determined appropriate.

Additionally, certain felony convictions will result in exclusion by the OIG from all Federal health care programs, and Part D sponsors are responsible for checking the OIG exclusion list every month for their contracted prescribers. Part D sponsors may purchase access to the Federation of State Medical Boards to determine if a prescriber has had his/her license suspended or revoked in their particular state.

b. Under Medicare Part C, are plans required to get enforcement or infraction information on individual providers from the state medical boards? If they do so, how timely is that information, and how frequently is it updated? Do plans receive information from the Federation of State Medical Boards? If they do so, how timely is that information, and how frequently is it updated?

Answer: Medical licenses are typically granted to physicians and other medical practitioners by the board of medicine in each state. If a physician or other medical practitioner does not have an active medical license in the state, they are not permitted to practice medicine, including participating in the Medicare program.

Additionally, certain felony convictions will result in an exclusion by the OIG from all Federal health care programs, and Medicare Advantage Organizations (MAOs) are responsible for checking the OIG exclusion list every month for their contracted prescribers. Additionally, MAOs may purchase access to the Federation of State Medical Boards to determine if a prescriber has had his/her license suspended or revoked in their particular state. CMS does not require that MAOs access infraction information from state medical boards because an infraction is not a final action resulting in termination or suspension of a medical license.

c. Under Medicare Parts A and B, does CMS or its contractors receive enforcement or infraction information on individual providers from the state medical boards? If they do so, how timely is that information, and how frequently is it updated? Does CMS or its contractors plans receive information from the Federation of State Medical Boards? If they do so, how timely is that information, and how frequently is it updated?

Answer: Medical licenses are typically granted to physicians and other medical practitioners by the board of medicine in each state. If a physician or other medical practitioner does not have an active medical license in the state, they are not permitted to practice medicine. CMS checks physicians' licensure status during the enrollment and revalidation process. CMS will revoke a provider's enrollment in fee-for-service Medicare if the provider does not have an active medical license. If a state licensing board's enforcement or infraction action is based on a felony conviction or other law enforcement action, CMS may revoke the provider's Medicare FFS enrollment based on those grounds.

11. Why has the Medicare Appeals Council upheld the ability of Medicare to pay for DNA testing in recent months when these tests are not clinically needed or determinative?

Answer: CMS is only aware of one Medicare Appeals Council decision on DNA Specimen Provenance Assignment (DSPA) testing, in February 2013; and, in that decision, the Council found that the DSPA tests at issue were not covered by Medicare. In this case, the Administrative Law Judge had previously found that the DSPA testing fit the definition of diagnostic testing and was covered as medically necessary for each of the beneficiaries whose claim was at issue. However, the February 2013 Medicare Appeals Council decision reversed the Administrative Law Judge's decision and found that the DSPA tests at issue were not diagnostic laboratory tests, were not otherwise within a Medicare benefit category, and were not covered by Medicare.

Senator Jeff Chiesa

1. **One way for prescription drug abusers to obtain controlled substances is to "doctor shop" which allows them to get prescriptions from multiple physicians, filled in several different pharmacies to avoid detection. What number of Medicare enrollees participate in "doctor shopping"? Of that number, how many of those are dual eligibiles?**

Answer: While it is difficult to identify a number or percentage of the full Medicare population, based on an algorithm used to identify opioid overutilization, CMS identified 22,222 beneficiaries in 2011 that met our targeting criteria for potential opioid overutilizers, which includes doctor shopping. Of those beneficiaries, approximately 16,000 were dually-eligible. The methodology excludes those beneficiaries who have legitimate diagnoses that may warrant high opioid use (*e.g.*, cancer patients or others who need palliative care), or who are borderline cases.

Post-Hearing Questions For the Record
Submitted to Gary L. Cantrell and Stuart E. Wright
From Senator Tom Coburn
"Curbing Prescription Drug Abuse in Medicare"
June 24, 2013

Questions from Senator Coburn:

1. **Is it accurate that it currently takes up to 12 months to exclude a provider from Medicare? If so, shouldn't CMS alert Part D sponsors about questionable providers before that time?**

OIG processes exclusions within a range of time periods. The exclusion process begins when another entity outside of OIG finalizes certain actions, such as a conviction or State professional board licensing action. Such an action triggers a potential exclusion determination by OIG. The timeframe in which OIG receives referrals of potential exclusions varies – currently, OIG is receiving referrals 130 days, on average, from the triggering action. Once OIG has received all relevant information from a referring entity, it takes six months, on average, to complete the exclusion process.

OIG has recommended that CMS alert sponsors routinely about questionable providers. Specifically, in our report titled *Retail Pharmacies with Questionable Part D Billing* (OEI-02-09-00600), OIG recommended that CMS analyze billing data to detect pharmacies with characteristics that indicate a high risk for fraud and provide this information to sponsors routinely to assist them in targeting pharmacies for auditing and further review.

2. **OIG recommends ensuring that Part D does not pay for refills of Schedule II drugs, since such refills are prohibited by Federal law. Yet, OIG suggests this is happening.**
    - **Are you saying that CMS is not adequately enforcing current Federal law? Who at CMS is failing to do so?**
    - **How would CMS fix this?**

In 2009, Medicare Part D inappropriately paid $25 million for Schedule II drugs billed as refills.[1] Sponsors should not have paid for any of these claims because Federal law prohibits the refilling of Schedule II controlled substances. Paying for such drugs raises public health concerns and may contribute to the diverting of controlled substances. Three-quarters of Part D sponsors paid for Schedule II drugs billed as refills, indicating that many sponsors do not have adequate controls to prevent these refills.

Some of these drugs may have been inaccurately billed. It is possible that some long-term-care pharmacies incorrectly billed these drugs as refills when the drugs were dispensed as partial fills. Partial fills, which are allowable for Schedule II drugs under certain conditions, occur when a pharmacist does not dispense all doses of the prescribed medication at one time. Several concerns exist, however, if partial fills are inaccurately billed as refills. For example, if some of

[1] OIG, *Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills*, OEI-02-09-00605, September 2012.

these refills were actually partial fills and were not accurately billed as such, beneficiaries and the Government may have overpaid for copayments. Incorrect billing affects the accuracy of Prescription Drug Event (PDE) data, which can hinder efforts to ensure payment accuracy and to detect and prevent fraud, waste, and abuse.

To address these findings, OIG recommends that CMS issue guidance to sponsors to prevent billing of Schedule II refills and to ensure accurate billing of partial fills. OIG also recommends that CMS exclude Schedule II refills when calculating payments to sponsors.

3. OIG recommends strengthening the MEDIC's monitoring of prescribers and pharmacies on a more data-driven, proactive basis.

- **In your opinion, could CMS do this under its current contract with the MEDIC? Would it need a contract modification?**

According to the MEDIC's current statement of work, the MEDIC is required to detect and deter fraud, waste, and abuse in Parts C and D and to perform proactive data analysis. We believe that the MEDIC could improve its monitoring of prescribers and pharmacies by strengthening its proactive data analysis to identify those with questionable patterns. CMS concurred with the recommendations in our reports to strengthen the MEDIC's monitoring of pharmacies and to expand its analysis of prescribers.[2] Furthermore, CMS stated that it will continue to work with the MEDIC to accomplish this analysis.

We believe the MEDIC could do this under its current contract without a contract modification. However, OIG defers to CMS to respond to questions about its contract details.

- **What rules currently hold the MEDIC back from sharing data with States or other entities?**

As described in an OIG report from January 2013,[3] the MEDIC reported in June 2012 that it was prohibited by CMS from sharing specific information related to its investigations and cases, such as a beneficiary's or provider's billing history, with other program integrity contractors, such as Zone Program Integrity Contractors (ZPIC). The MEDIC explained that it can share general schemes and summary data but not specific information.

In comments to our draft report, CMS explained that this was true early in the MEDIC program because of a regulatory restriction (42 CFR 423.322). However, according to CMS, Section 6402(b) of the Patient Protection and Affordable Care Act (ACA) authorized the MEDIC to share specific information related to its investigations and cases with other HHS contractors. However, CMS added that because of a conflict of interest with one ZPIC, the MEDIC had been instructed not to share specific claim information until the conflict of interest was mitigated.

Because it was unclear with whom the MEDIC could share information, OIG recommended that CMS instruct the MEDIC when it can share specific information with other entities, including

[2] OIG, *Retail Pharmacies With Questionable Part D Billing*, OEI-02-09-00600, May 2012 and *Prescribers With Questionable Patterns in Medicare Part D*, OEI-02-09-00603, June 2013.
[3] *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310, January 2013.

ZPICs and State agencies. CMS concurred with this recommendation and provided guidance to the MEDIC in January 2013. This guidance stated that Section 6402 of ACA authorized the MEDIC to share Part C and Part D data with any Medicare contractor for the purpose of oversight, evaluation, and enforcement of the Medicare program. However, it is not clear to OIG whether this guidance permits the MEDIC to share Part C and Part D data with State agencies.

- **Why do CMS regulations prohibit the MEDIC from obtaining information directly from entities such as pharmacies, physicians, and pharmacy benefit managers?**

Current regulations at 42 CFR 423.505(i)(3)(iv) require sponsors' contracts to specify whether these entities should produce information either to the plan sponsor to provide to CMS, or directly to CMS or its designees (e.g., the MEDIC). Therefore, the choice of whether the information can be directly obtained by the MEDIC is determined by the sponsor.

In comments to our draft report on November 5, 2012, CMS did not concur with our recommendation to amend regulations to authorize the MEDIC to directly obtain information from these entities. CMS stated that it chose not to be prescriptive with respect to the choice of method for providing the information. OIG will continue to monitor this issue.

4. **OIG recommends CMS recover payments from plan sponsors for inappropriate Part D claims.**
   - **Would this best be accomplished by the Part D RAC or the MEDIC?**

Unlike the Parts A and B fee-for-service program where CMS pays the providers directly and has the claims processors collect overpayments, the Part D program works under a capitated payment methodology where CMS pays plan sponsors advance monthly payments and the plan sponsors pay providers for prescription drugs and other services. Part D sponsors also receive low income subsidy, reinsurance, and, in some cases, risk corridor payments that are linked to claims data submitted to CMS and reconciled after the end of the plan year. Although the identification of the inappropriate payments could be accomplished by the MEDIC or the Part D RAC, the recovery of any payments from sponsors would likely take place during the reconciliation process by CMS. In other words, CMS would ultimately determine who would recover funds associated with inappropriate Part D claims.

5. **OIG had recommended that CMS require sponsors to verify that prescribers have the authority to prescribe drugs.**
   - **Is that something that you think CMS could do quickly?**
   - **Could you comment on the workability or degree of ease for plans in operationalizing that?**

OIG did not assess how quickly or easily CMS could implement this recommendation. That said, CMS did concur with OIG's recommendation and provided comments on the draft report. Specifically, CMS stated that it would "issue guidance requesting our sponsors to include a retrospective review in their required programs to combat fraud, waste, and abuse where data anomalies, such as those identified by OIG in this report, suggest possible inappropriate

prescribing and to report any potential fraud to the MEDIC for further investigation." CMS also stated that current PDE guidance provides Part D sponsors with a process to delete PDEs that are fraudulent. PDEs from prescribers confirmed by the MEDIC as not having prescribing authority would be communicated back to sponsors, who would then delete the PDEs and implement point-of-sale edits to reject claims from these unauthorized prescribers in the future. CMS did not comment on when these changes would be implemented.

6. **OIG said "it is important that CMS effectively follow through and implement these basic checks."**
    - **Has CMS given you a timeframe or workplan for ANY of the recommendations you have made in either of your two recent reports?**

CMS has not given OIG a timeframe in which they would implement these recommendations. However, CMS is required to provide OIG with a corrective action plan (i.e., final management decision) addressing recommendations made in each report within six months of issuing the final report. For OIG's recent reports discussed in the hearing, we anticipate receiving CMS's corrective action plans by December 21, 2013. In these documents, CMS should describe actions that it plans to take to address our recommendations as well as timeframes for completing such activities.

- **Once OIG makes a recommendation, how often does OIG follow-up with the agency to ensure progress has been made in accomplishing it?**

Within six months of issuing a final report, the agency provides OIG with a final management decision detailing its plan to address report recommendations. For those recommendations with which the agency concurs or plans to take action to address, OIG requests that the agency send a status update on its progress each year until the OIG considers the recommendation implemented.

7. **OIG suggested requiring diagnosis codes on Part D claims to help determine whether a drug is covered under Medicare.**
    - **Would this be costly to implement?**
    - **Commercial plans merely look for drug utilization to inform certain diagnosis (like cancer) and then examine the outliers. Couldn't the MEDIC use that approach?**

In the report *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), OIG recommended that CMS "facilitate access to information necessary to ensure accurate coverage and reimbursement determinations." Specifically, OIG stated that diagnosis codes could help drug plan sponsors and CMS ensure that a drug meets the definition of a Part D-covered drug (i.e., is used for an indication approved by the Food and Drug Administration or a medically accepted indication supported by specified compendia).

OIG made this recommendation to ensure that claims are paid only for drugs covered by Part D. OIG did not analyze the costs of requiring diagnosis codes on Part D claims. The MEDIC could look for outliers of utilization of certain drugs as one approach to look for questionable

prescribers or beneficiaries. However, OIG remains concerned that CMS is paying for drugs that are not covered by Part D. We believe that it is important for sponsors and the MEDIC to have access to information, such as the diagnosis codes, to determine whether a drug is covered.

8. Who checks to be sure a provider has a VALID DEA number before a claim is paid? What information do you currently receive from the DEA? Would more be helpful?

After clarification from Josh Trent, staff for the Committee, OIG understands that the first part of this question was intended to address checks on providers with valid National Provider Identifier (NPI) numbers rather than DEA numbers (because CMS now requires only NPI numbers). Mr. Trent explained that the question was also intended to inquire whether the Fraud Prevention System (FPS) checks for valid NPI and DEA numbers.

OIG defers to CMS on questions related to the FPS. We note that CMS issued a final rule with comment period that would effectively require plan sponsors to check a provider's NPI number. Currently, Part D plan sponsors submit PDE records to CMS after they reimburse pharmacies for Part D enrollees' prescription claims. On April 12, 2012, CMS issued a final rule with comment period that requires plan sponsors to submit to CMS only PDE records that contain an active and valid individual prescriber NPI. The rule also requires sponsors to ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary's access to a covered Part D drug. The new rules are effective for PDEs submitted on or after January 1, 2013. [77 Federal Register 22143-22148]

As outlined in Chapter 5 of the Prescription Drug Benefit Manual, Part D sponsors are also required to confirm the validity of DEA numbers on claims for Schedule II-IV drugs (or map the prescriber NPI to a valid individual DEA number) and confirm that the controlled substance is consistent with the DEA Schedule registration.[4] However, CMS clarified in a May 21, 2013 memorandum to Part D sponsors that when a prescriber is prescribing under the DEA registration of a hospital or institution and does not have an individual DEA registration, CMS does not require plan sponsors to reject these claims for controlled substances. In the memorandum, CMS stated its belief that information is not available to sponsors to allow them to map an individual prescriber's NPI onto an institution's DEA registration; CMS also expressed concern that rejecting claims in these circumstances could impede beneficiary access to necessary medications.[5]

Regarding DEA information, OIG receives active and retired registrant information. We also obtain other supporting information about Controlled Substance schedules from another source. OIG communicates openly with DEA and other partners on a number of activities, including enforcement and fraud detection efforts. OIG will continue to coordinate with DEA on specific data sets and information sharing in the future.

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[4] CMS, *Medicare Prescription Drug Benefit Manual – Chapter 5*, Section 90.2.4, September 20, 2011. *Available at:* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

[5] CMS, *Clarification of Chapter 5 of the Prescription Drug Manual, Sec. 90.2.4 – Controlled Substances*, May 21, 2013. *Available at:* http://www.ama-assn.org/resources/doc/washington/cms-controlled-substances-prescribing-memo-21may2013.pdf.

Post-Hearing Question for the record
Submitted to Gary L. Cantrell and Stuart E. Wright
From Senator Jeff Chiesa
"Curbing Prescription Drug Abuse in Medicare"
June 24, 2013

Question from Senator Chiesa:

1. **One way for prescription drug abuse to obtain controlled substances is to "doctor shop" which allows them to get prescriptions from multiple physicians, filled in several different pharmacies to avoid detection. What numbers of Medicare enrollees participate in "doctor shopping"? Of that number, how many of these are dual eligible?**

OIG has not conducted analysis on this topic. However, in 2011, the General Accountability Office (GAO) issued a report on this topic entitled, *Instances of Questionable Access to Prescription Drugs*. According to this report, GAO found indications of doctor shopping in the Medicare Part D program. Specifically, about 170,000 beneficiaries received the same class of frequently abused drugs, such as hydrocodone and oxycodone, from five or more prescribers in 2008.[6] About 72 percent of these beneficiaries received the Medicare Low-Income Subsidy.

OIG plans to conduct a future review to determine how selected Part D sponsors are detecting and deterring overutilization of Part D drugs by beneficiaries.

[6] GAO, *Instances of Questionable Access to Prescription Drugs* (GAO-11-699). *Available at*: http://www.gao.gov/assets/590/585424.pdf.

Post-Hearing Questions for the Record for the
Senate Homeland Security and Governmental Affairs Committee Hearing:
"Curbing Prescription Drug Abuse in Medicare"
Submitted to Alanna Lavelle
From Senator Tom Coburn

1. You have experience in law enforcement and industry. WellPoint uses a controlled substance utilization monitoring program in their commercial and Medicaid business and has also implemented a restricted recipient program for Medicaid plans. WellPoint supports giving CMS the authority to establish a restricted recipient program in Medicare Part D for those beneficiaries displaying a pattern of misutilization.
    - **What kinds of successes have you seen with this program? (Restricted Recipient Program)**
    - **How many beneficiaries on average may be affected?**
    - **Can you talk a little bit about misperceptions you have heard about the merits of this well-designed tool? (Restricted Recipient Program)**

Response:

Attached is an exhibit outlining details of our experience with various state restricted recipient programs in the Medicaid arena.

Some say that the Part D multi-payer design (where some plans are solely stand alone pharmacy) creates challenges for implementing a restricted recipient program. However, only when the problem is discussed in detail can any challenges be addressed and overcome. Some also contend that a restricted recipient program can create a barrier between beneficiaries and needed care. State Medicaid programs have not found this to be the case and in fact such programs have been found to often help beneficiaries get the appropriate care management necessary. In addition, any issues can be addressed through beneficiary appeals to more narrowly tailor the beneficiary restrictions. While CMS has been unsure that a restricted recipient program would be more effective in preventing prescription drug abuse than enhanced DUR procedures,[1] it should be noted that in its April 2012 call letter CMS now permits sponsors to implement beneficiary-specific point-of-service restrictions under certain conditions.[2] Thus, it appears that CMS may be open to the concept of a restricted recipient program, and it bears further discussion and exploration.

[1] Testimony of Jonathan Blum, Director, Center for Medicare Management, October, 2011, found at: http://www.hhs.gov/asl/testify/2011/10/t20111004a.html

[2] CMS Memo, "Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 2, 2012, found at: http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2013.pdf

2. WellPoint's Special Investigation Unit refers every Part D case to the MEDIC, and WellPoint has the second highest number of referrals to the MEDIC nationwide.
    - **Could you describe the kind of relationship you have with the MEDIC? Do you think the current contract is very effective?**
    - **How would you like to see the MEDIC contract modified?**

Response:

We have, and continue to have, a good, working relationship with the MEDIC. However, we have some recommendations on how the MEDIC and Part D fraud investigations could be made much more effective than they are currently. These recommendations include:

- **Hire the MEDIC investigators as employees with full investigatory powers**. A central problem in the use of a contractor, the MEDIC, rather than federal government employees is that MEDIC investigators lack legal investigatory authority and as such are hampered in their investigations. We recommend that MEDIC investigators be hired as federal government employees in OIG, perhaps as GS-1810s, so that they have full investigatory powers. While we realize that the OIG has been laying off employees due to budget cuts and sequestration cuts, hiring OIG fraud investigators would result in significant savings to the Medicare trust fund.
- **End the subcontractor relationship with MEDIC.** A second problem results from the retention of a subcontractor, Rainmaker Solutions, in January 2011. This subcontracting relationship interferes with communications between sponsors and the MEDIC and has consequently made sponsors' fraud investigations less effective. We recommend that the subcontractor relationship not be retained and that funds used to hire the subcontractor be used for better purposes to fight fraud and abuse.
- **Improved communication from DOJ and law enforcement to plan sponsors.** A third problem is that sponsors experience lack of feedback from federal prosecutors and law enforcement on cases they have referred once a decision to prosecute a case has been made. Even public facts of record such as indictments, pleas, convictions, and sentencing are not communicated to sponsors. Sponsors are forced to query public databases to discover the statuses of cases they referred to the MEDIC, which adds inefficiency to the process. We recommend that once an indictment is filed, federal law enforcement or the Department of Justice communicates that fact to the sponsor that originally referred the case, and that the sponsor is also informed of guilty pleas, convictions, sentencing and restitution.

3. In your testimony, you said plan sponsors are rarely informed of the ultimate result, and information collected by the agency is rarely shared with the private payers and said CMS does not share information on revoked Medicare providers with private payers.
    - **Can you talk about the negative impact this has on the sponsors who are trying to fight waste and fraud in their plans?**
    - **What other information would you like to have from CMS?**

Response:

At a minimum, we would like CMS to share with sponsors in a timely fashion the lists of excluded providers, as well as the lists of providers who have been disciplined.

While CMS currently does share provider revocations with sponsors, it takes about a year before the exclusion lists are up to date on the CMS website. In order to be most fully effective in their anti-fraud programs, sponsors need to know within a short period of weeks whether a provider was revoked. Too great a period of time between revocation and communication to sponsors gives those providers carte blanche in the interim to defraud the Medicare Part D program.

There is a list of disciplinary proceedings against providers available but only to law enforcement, not sponsors. This lack of communication also unnecessarily hamstrings sponsors' anti-fraud investigations.

As an example of the lack of federal information sharing resulting in increased plan losses, in 2010 we identified a Florida provider who was billing for infusion therapy of a drug that was not infused. By the time we identified this provider, we had paid out over $9.5 million in fraudulent claims in the past year. Once we put a stop pay on those claims, we were able to prevent $2.5 million more fraudulent claims from this provider from being paid. When we referred this provider to the HHS OIG, we were informed that the provider had been a person of interest to OIG for several years. Two and one-half years after contacting the OIG, the federal investigation is ongoing due to switches in personnel, the provider is still in practice, and federal agencies are unable to identify where the fraudulently billed funds are. Presumably the fraud is ongoing.

4. In your testimony, you said WellPoint recommends that dual eligible beneficiaries with evidence of drug-seeking behavior should be locked into one managed care plan, rather than continue to be allowed to switch plans on a monthly basis to evade detection.
    - **Would you be willing to review draft legislation from my office on this topic?**

Response: Yes, we are willing to review draft legislation on this issue.

5. In your testimony, you warned that the Medical Loss Ratio in the Affordable Care Act effectively "means that insurers will have to include as administrative expenses their largest portion of antifraud expenses -- those dedicated to fraud prevention." You said "It is truly puzzling that at a time when the federal government is accelerating its efforts to prevent fraud in Medicare and Medicaid it has simultaneously issued regulations that will serve to discourage health insurers' fraud prevention efforts in the private and public sectors."
    - **How would you recommend Congress modify existing MLR regulations to address this problem?**

Response: Currently the Medicare Advantage MLR (which is also applicable to Part D) permits sponsors to include in their incurred claims fraud prevention expenses up to the amount of fraud recoveries (i.e., amounts collected from fraud perpetrators).[3] The Medicare Advantage MLR regulation can be amended as follows to permit sponsors to include fraud prevention expenses as

[3] 42 C.F.R. § 422.2420(b)(2)(ix).

related to "activities that improve health care quality."[4] This recommendation recognizes the fact that Part D anti-fraud investigations lead to improved patient safety by avoidance of overprescription.

We realize that concerns have been raised that if the MLR credit were expanded to include fraud prevention expenses greater than fraud recoveries, there might be no effective control on the anti-fraud program expense included in the MLR calculation. To address that concern, we suggest that a cap be placed on the anti-fraud program expenses similar to that imposed on expenses for ICD-10 compliance and implementation.

Additionally, some have contended that the MLR formula should not be altered because the return on investment (ROI) for anti-fraud programs is very favorable. It's important to understand that the ROI for anti-fraud programs takes into account fraudulent claims prevented. However, in the Part D context, the savings (the returns) recognized by anti-fraud programs inure not to the benefit of the plan sponsor, but to CMS and ultimately beneficiaries in the form of lower Part D premiums. Thus, under the current MA/Part D MLR rules a Part D plan sponsor must fund its anti-fraud program out of its capital and surplus and is only given credit in the MLR for fraud recoveries, which are a very small part of total fraud savings. We believe that a portion of the savings should be returned to the plan sponsor to support effective anti-fraud programs in Part D.

Sample regulatory language is as follows (changes appear in bold underline or strikeout):

42 C.F.R. § 422.2420 Calculation of the medical loss ratio.

(2) The MLR for an MA contract—
(ii) That includes MA–PD plans (defined at § 422.2) must also reflect costs and revenues for benefits described at § 423.104(d) through (f) of this chapter.

(b) Determining the MLR numerator.
(1) For a contract year, the numerator of the MLR for an MA contract (other than an MSA contract) must equal the sum of paragraphs (b)(1)(i) through (iii) of this section, and the numerator of the MLR for an MSA contract must equal the sum of paragraphs (b)(1)(i), (iii), and (iv) of this section. The numerator must be determined in accordance with paragraphs (b)(5) and (6) of this section.

(2) Incurred claims for clinical services and prescription drug costs.

~~(ix) Claims payments recoveries as a result of fraud reduction efforts, not to exceed the amount of fraud reduction expenses.~~

[4]The regulation requiring Part D sponsors to implement measures addressing drug overutilization categorizes drug overuse as a "quality assurance" activity, and supports this recommendation. *See* 42 C.F.R. § 423.153 Drug utilization management, **quality assurance**, and medication therapy management programs (MTMPs).

42 C.F.R. § 422.2430 Activities that improve health care quality.

(a) Activity requirements. Activities conducted by an MA organization to improve quality must fall into one of the categories in paragraph (a)(1) of this section and meet all of the requirements in paragraph (a)(2) of this section.

(1) Categories of quality improving activities. The activity must be designed to achieve one or more of the following:

(i) To improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives **(including restricted recipient and lock-in programs)**, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage.

(iii) To improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage.

(b) Exclusions. Expenditures and activities that must not be included in quality improving activities include, but are not limited to, the following:

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims, including ICD–10 implementation costs in excess of 0.3 percent of total revenue under this part, and maintenance of ICD–10 code sets adopted in accordance with to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.

(8) **Expenses attributable to f**raud prevention activities **in excess of 0.5 percent of total revenue under this part**.

6. In your testimony, you talked about the importance of risk scores for claims before they are paid. You said WellPoint's Special Investigations Unit has opened 200 investigations and has achieved $27 million in projected savings to date.
   - **In your experience, is the MEDIC for Part D doing anything like this?**
   - **Do you have any experience with CMS's Fraud Prevention System?**

Response:

- We are not aware of the MEDIC using risk scores for claims in Part D.

- Any experience we have with CMS' Fraud Prevention System would be through our subsidiary, National Government Services (NGS).

7. Who checks to be sure a provider has a VALID DEA number before a claim is paid?

Response:

Our pharmacy benefit manager checks for valid DEA numbers of prescribers. However, the issue is not whether a provider has a valid DEA number. Rather, the problem is that entities are fraudulently obtaining NPIs (National Provider Identifiers), and if an entity has an NPI, it can then fraudulently get a DEA number. When checked, NPPES (National Plan and Provider Enumeration System), the subagency that administers the NPI system, will affirm that an NPI number fraudulently obtained is indeed valid. But the underlying data and assertions upon which an NPI was granted could be false, as they are never verified. For example, last week our SIU discovered a false NPI and called NPPES to check. The NPPES staff person affirmed that she simply assigns NPIs over the Internet with no verification. For example, the NPI application allows use of a P.O. Box as a mailing address, which makes it very easy for fraudsters to defraud the government – they don't even have to set up a false storefront.

We understand that when CMS first issued the requirement for NPIs there was a need for providers to get NPIs in an administratively simple and easy manner so that providers could meet compliance deadlines. However, at this juncture there is a need to identify and prevent provider fraud by tightening the procedures and verification around entities applying for new NPIs.

The items of information that a person or entity is required to input in applying for an NPI are as follows:

Information Required for Individual Providers

- Provider Name SSN (or ITIN if not eligible for SSN)
- Provider Date of Birth
- Country of Birth
- State of Birth (if Country of Birth is U.S.)
- Provider Gender
- Mailing Address
- Practice Location Address and Phone Number
- Taxonomy (Provider Type)
- State License Information
- Contact Person Name
- Contact Person Phone Number and E-mail

Information Required for Organizations

- Organization Name
- Employer Identification Number (EIN)
- Name of Authorized Official for the Organization

- Phone Number of Authorized Official for the Organization
- Organization Mailing Address
- Practice Location Address and Phone Number
- Taxonomy (Provider Type)
- Contact Person Name
- Contact Person Phone Number and E-mail

We recommend that at a minimum, the NPPES should obtain the following information before issuing an NPI to verify that a person or entity is who he/she/they say they are.

1. Copy of government issued document (passport, state driver's license, etc.) for the person or entity making the application.
2. For corporations – a copy of the Secretary of State - Division of Corporations document showing they are a state licensed entity.
3. Copy of state issued license (pharmacy, medical license, etc.).

Additionally, the NPPES should require the individual or organization to supply a street address rather than a P.O. Box as a mailing address.

WELLPOINT

State Medicaid Provider Assignment Or Lock-In Programs And Requirements

To ensure the appropriate utilization of pharmacy services within the Medicaid program, states have instituted lock-in programs to serve as both educational and monitoring tools for members receiving pharmacy benefits with the potential for improper and/or overutilization of Medicaid services. This comparison includes a brief overview of WellPoint Medicaid Market lock-in program requirements and parameters.

State	Summary of State Lock-in Program
Florida	The State mandates capitated health plans may have a pharmacy lock-in program that conforms to state requirements. Members are locked-in for a 12-month period and can only obtain Medicaid prescribed drug services from a designated pharmacy provider and from no other provider. The State designates the pharmacy to which the recipient will be locked-in. Members released after the 12-month period are notified via a letter 30 days prior from disenrollment. Newly enrolled members are permitted to respond 21 days from the receipt of the lock-in letter and request for a different prescription and/or appeal of the decision. All newly enrolled members are assigned a case manager and are given an initial assessment. ▸ Member Lock-in Criteria: Currently, the State has **487 members** in its lock-in program. To meet the requirements for lock-in, a member must have sought three or more opiates from three or more different prescribers at more than three pharmacies in a 90-day period.
Georgia	Health plans participating in Georgia's Program Integrity Program, which locks-in members to pharmacies and a Primary Care Physician (PCP), must allow members to change pharmacies for good cause, such as recipient relocation or the pharmacy does not provide the prescribed drug; provide case management and education reinforcement of appropriate medication use; annually assess the need for lock-in for each member; and provide monthly reporting on the program to the Department of Community Health. Members enrolled in the program are locked-in for a 12-month period. Members have a 10-day window to file a grievance to appeal the decision. ▸ Member Lock-in Criteria: There are currently **2,324 members** enrolled in the program. To meet the requirements for lock-in, the member must have sought and/or used two or more prescribers and two or more pharmacies and five or more controls with three or more opioids in last 45 days.
Indiana	Indiana works directly with health plans to implement the three-tiered Controlled Substance Utilization Monitoring (CSUM) Process, which locks-in member to pharmacies and a PCP. The CSUM process includes: (1) member and provider awareness of need is identified; (2) prior authorization for all controlled substances; and, (3) members identified to have abusive patterns are locked-in to a specific pharmacy for a 24-month period and are given a 30-day window to respond to the lock-in request. ▸ Member Lock-in Criteria: There are currently **700 members** locked-in. To meet the requirements for a lock-in, a member must be receiving medication from three or more physicians or from three or more pharmacies and ten or more narcotic medication prescriptions. The member's profile must not meet criteria for medical necessity or a physician has not supplied diagnosis of need for regimen. A member also qualifies if they were referred to CSUM due to suspected fraud, such as reports of stolen prescriptions, repeated loss of prescriptions, consistent prescription refill too soon and frequent emergency department visits.
Kansas	Currently, the State mandates the pharmacy, PCP and hospitals lock-in requirements for health plan participation to include monitoring and educational tools for persistent member non-compliance with Managed Care Organization (MCO) requirements; engaging in abusive or threatening conduct; committing fraud or abuse of medical benefits; and, overutilization of Medicaid services. Members identified as potential enrollees receive a warning letter and if their behavior does not improve within 60 days of receipt, they are locked-in. Locked-in members are initially enrolled for a 24-month period; however, if enrollment continues beyond this timeframe, there is no definite date of termination. Members have 30 days from the date of the certified letter to respond with a grievance. ▸ Member Lock-in Criteria: There are currently **163 members** locked-in. Members qualify for lock-in for concurrently obtaining services from two or more providers of the same specialty, not in the same group practice, with no referrals; using two or more emergency facilities for nonpemergent diagnoses; consistently seeking/obtaining medical services which are not supported by diagnosis or medical records/documentation; excessive inpatient hospital services; or, excessive and/or duplicative medications, supplies, appliances, durable medical equipment or outpatient services. Members may also meet the requirements by visiting two or more pharmacies, two or more prescribers and five or more controlled substance claims, of which three must be opioids in a 45-day period. A member also qualifies if they are suspected of fraud, such as reports of stolen prescriptions, repeated loss of prescriptions, consistent prescription refill too soon and frequent emergency department visits.
Louisiana	Health plans participating in Louisiana's pharmacy and providers lock-in program must allow members to change pharmacies for good cause, such as recipient relocation or the pharmacy does not provide the prescribed drug; provide case management and education reinforcement of appropriate medication use; and biannually assess the need for lock-in for each member. The health plan must also provide the member access to a 72-hour emergency supply of medication at pharmacies other than the designated lock-in pharmacy. Eligible members are locked-in for a 24-month period. Members have a 10-day window to respond and file a grievance regarding the lock-in. ▸ Member Lock-in Criteria: There are **no members** currently enrolled in the program. To meet the requirements for a lock-in, the member must have sought two or more prescribers and two or more pharmacies and five or more controls with three or more opioids in the past 45 days.

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Maryland	Currently, the State mandates health plan requirements for participation in the Corrective Managed Care (CMC) Program. The program monitors and promotes appropriate use of controlled substances. The program identifies members who appear to be receiving duplicate controlled drug therapy, visiting multiple prescribers and/or patronizing multiple pharmacies to obtain controlled substances. Member information is shared with prescribers, pharmacy providers and PCPs in order to prevent any abusive behavior. If, despite the best efforts of the prescriber and pharmacist, there still continues to be overutilization or perceived misuse of a controlled substance by a member, the member can be locked-in. Under a lock-in pharmacy agreement, the recipient will be required to fill prescriptions for all medications paid fee-for-service at one predetermined pharmacy. Members found eligible are initially enrolled for six- , 12-, 18- or 24-month periods and the health plan is responsible for tracking this process. ▸ Member Lock-in Criteria: There are currently **121 members** locked-in. Members qualify for lock-in for seeking six or more opiate prescriptions and three or more different providers in a one-month period, two or more opiate prescriptions each for at least 360 doses in a three-month period or discharged by a provider because of suspected opiate prescription fraud.
Nevada	Nevada requires participating health plans to monitor and direct members to see a certain pharmacy provider for whom compliance or drug seeking behavior is suspected. Prior to placing the member on pharmacy lock-in, the health plan must inform the member and/or their representative of the intent to lock-in. The health plans grievance procedure shall be made available to the member being designated for pharmacy lock-in. Eligible members are locked-in for a 12-month period. Members have a 10-day window to respond to the lock-in. The lock-in request shall be reviewed and documented by the health plan and reported every quarter. The member may be removed from lock-in when the health plan has determined that the compliance or drug seeking behavior has been solved and the recurrence of the problem is judged to be improbable. The State shall be notified of all lock-in removals. ▸ Member Lock-in Criteria: There are currently **655 members** enrolled in the program. To meet the requirements for a lock-in, the member must have sought two or more prescribers and two or more pharmacies and five or more controls with three or more opioids in the past 45 days.
New Jersey	There are currently **659 members** enrolled in the program. Note: Contract and member lock-in program criteria follow process similar to Louisiana. See the State of Louisiana for more information.
New Mexico	There are currently **369 members** enrolled in the program. Note: Contract and member lock-in program criteria follow process similar to Nevada. See the State of Nevada for more information.
New York	Currently, the State requires all members residing in Medicaid Managed Care mandatory counties and for Family Health Plus are subject to a 12-month pharmacy and provider lock-in period. Members have an initial 90-day grace period during which they may disenroll without cause. The local district of social services is responsible for notifying members of their right to change health plans in their enrollment confirmation notice. The State Department of Health is responsible for providing notice of the end of the lock-in and the right to change health plans at least 60 days prior to the first enrollment anniversary date. ▸ Member Lock-in Criteria: There are currently **432 members** locked-in. To meet the requirements for a lock-in, the member must have sought two or more prescribers and two or more pharmacies and five or more controls with three or more opioids in the past 45 days.
South Carolina	Currently, the State partners with health plans to identify members previously locked into a single pharmacy while in fee-for-service or other MCOs on a monthly basis. The State and health plans will utilize data available that may indicate the need for pharmacy restriction including, but not limited to lab data, medical claims, authorizations and referrals from health plans or providers. Identified members are initially enrolled for a 12-month period. ▸ Member Lock-in Criteria: The number of total enrolled members is currently not available.
Tennessee	Currently, the State of Tennessee handles its own lock-in program. Participating health plans are required to provide the State with the necessary data to identify potential pharmacy lock-in candidates. ▸ Member Lock-in Criteria: Not Available.
Texas	Texas provides the state Medicaid agency with the authority to restrict a Medicaid recipient to a designated provider if the agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State. Current requirements outlining the length of the lock-in period are being determined. Enrolled members are given 10 days to respond to the lock-in request. ▸ Member Lock-in Criteria: There are currently **96 members** enrolled in the program. To meet the requirements for a lock-in, a member must have sought and/or used two or more non-emergent emergency department visits, four or more pharmacies, ten or more controlled substance prescriptions from two or more providers, four or more prescribers or three or more psychotropic prescribers in a 90-day period. If a member has been treated with opioids for more than six weeks by two or more providers or diagnosed for alcohol/drug abuse (including recreational), they also qualify.
Virginia	There are currently **68 members** locked-in. Note: Contract and member lock-in program criteria follow CSUM process. See program criteria for Indiana for more information.
Washington	Currently, the State mandates the provider and pharmacy lock-in requirements for health plan participation. Members who consistently utilize multiple pharmacies and/or physicians to obtain multiple medications or medical services will be evaluated for enrollment in the Washington Lock-In Program. Members found eligible are locked-in for a 24-, 36- or 72-month period and have 10 days to respond to the lock-in request. ▸ Member Lock-in Criteria: The State currently has **191 members** locked-in. To meet the requirements for a lock-in, a member must have sought and/or received services from four or more different providers; had prescriptions filled by four or more different pharmacies; received ten or more prescriptions; had prescriptions written by four or more different prescribers; received similar services from two or more providers in the same day; had ten or more office visits; or made two or more emergency department visits in a 90-day period during the past 12 months.