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MEDICARE PART D: MEASURES NEEDED TO STRENGTHEN PROGRAM INTEGRITY

TUESDAY, JULY 14, 2015

House of Representatives,

Subcommittee on Oversight and Investigation

Committee on Energy and Commerce

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:00 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Tim Murphy [Chairman of the Subcommittee] presiding.

Members present: Representatives Murphy, McKinley, Barton, Burgess, Blackburn, Griffith, Bucshon, Flores, Brooks, Mullin, Hudson, Collins, DeGette, Schakowsky, Castor,

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Tonko, Yarmuth, Clarke, Kennedy, Green, Welch, and Pallone (ex officio).

Also present: Representative Bilirakis.

Staff present: Leighton Brown, Press Assistant; Noelle Clemente, Press Secretary; Jessica Donlon, Counsel, Oversight and Investigations; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Traci Vitek, Detailee, Health; Jessica Wilkerson, Oversight Associate, Oversight and Investigations; Ryan Gottschall, Democratic GAO Detailee; Ashley Jones, Democratic Director of Communications, Member Services and Outreach; Chris Knauer, Democratic Oversight Staff Director; Una Lee, Democratic Chief Oversight Counsel; and Elizabeth Letter, Democratic Professional Staff Member.

Mr. {Murphy.} Good morning. I convene this hearing of the Subcommittee on Oversight and Investigations.

We are here again today to discuss an ongoing problem with our entitlement programs--waste, fraud, and abuse--this time in the Medicare Part D program. However, the failures that we will hear about today go far beyond lost dollars and cents, rather, they are helping to feed the prescription drug abuse crisis that is gripping the country.

Medicare Part D is the fastest growing component of the Medicare program, providing approximately 39 million beneficiaries with supplemental prescription drug coverage. Given this rapid growth, Medicare Part D has been a prime target for fraud and abuse. In fact, this past June, the Department of Justice announced a nationwide Medicare fraud takedown, which led to charges against 243 individuals for approximately $712 million in false billings. More than 44 of the defendants were arrested on fraud related to Medicare Part D. This joint law enforcement effort, which involved the Department of Justice, the Department the Health and Human Services, the Office of Inspector General, and the FBI

should be commended. But more work needs to be done at the agency level to ensure that fraudsters are not able to take advantage of the program in the first place.

Thankfully, since the inception of the Part D program, the Office of Inspector General has been working diligently to reduce waste, fraud, and abuse in the program. The OIG has released numerous reports and issued several recommendations intended to strengthen the integrity of Medicare Part D, which would save taxpayers a tremendous amount of money and would ensure that prescription drugs are being used as intended and not overprescribed or diverted.

Unfortunately, CMS has not implemented these recommendations. In its portfolio, the OIG highlighted at least nine recommendations that CMS has not implemented. All of these recommendations were issued to CMS in at least one previous OIG report, and in some instances, up to five previous reports that date back to December 2006. And these are commonsense recommendations, for example, requiring plan sponsors to report all potential fraud abuse to CMS or the Medicare Drug Integrity Contractor. This recommendation was issued in five different OIG reports.

Another important recommendation: implement an edit to reject prescriptions written by providers who have been excluded from the Medicare program. That makes sense. Yet CMS hasn't taken action to implement these recommendations. And just 6 weeks ago, one of today's witnesses, Dr. Agrawal, testified before this Subcommittee and said, ``holding our feet to the fire is appropriate,'' and when asked about fraud occurring under CMS's watch, and as I said, that's precisely what we are going to be doing today.

CMS's failure to implement these recommendations has led to trends of questionable billing associated with pharmacies, prescribers, and beneficiaries. In fact, in its Data Brief, which analyzed prescription drug events, OIG found that a lot of questionable billing was tied to commonly abused opioids.

This Subcommittee has held a series of hearings examining the growing problem of prescription drugs and heroin addiction we know is ravaging our country. The opioid abuse epidemic resulted in a loss of 43,000 lives last year, and the problem continues to get worse.

As we examine the Medicare Part D program, it troubles me that between 2006 and 2014, the total number of

beneficiaries receiving commonly abused opioids grew by 92 percent, compared to 68 percent for all drugs. Similarly, the average number of prescriptions for commonly abused opioids per beneficiary grew by 20 percent, compared to 3 percent for all drugs. Since 2006, Medicare spending for commonly abused opioids has grown faster than spending for all Part D drugs. We need to take a closer look at those numbers and make sure that this program is not contributing to this devastating epidemic.

The OIG has outlined several commonsense recommendations that CMS can implement. Now it is incumbent upon CMS to take action and actually prevent fraud and abuse before it reaches a level that requires a nationwide takedown.

The Committee is concerned that it continues to hold hearings like this one today where we see steps not taken and tools not utilized to protect the integrity of these programs as well as taxpayers' dollars. Now, we acknowledge it is the people who are committing fraud, whether they are physicians or pharmacists or other people, they are the ones we are going after, but we are listening today to the ideas of Dr. Agrawal and Ms. Maxwell of how we can do that.

So I thank our witnesses for joining us. You have the ability to save the American taxpayer massive amounts of money, and of course, save lives in this process.

It is this Subcommittee's hope that we will hear concrete plans from you on how you will go about accomplishing this task. I might say, we need funds in other areas of care, and so we'd also like to hear when you make recommendations if there are some things that actually save us money that we know we need--for example, the mental health sphere--please tell us that as well.

[The prepared statement of Mr. Murphy follows:]

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Mr. {Murphy.} So thank you for being here today, and I now recognize the ranking member of the subcommittee, Ms. DeGette, of Colorado for 5 minutes.

Ms. {DeGette.} Thank you so much, Mr. Chairman.

Medicare Part D represents the fastest growing component of the Medicare program overall. From 2006 to 2014, spending for Part D drugs increased by 136 percent from $51.3 billion to $121 billion. In the last 5 years, the OIG has reported a 134 percent increase in complaints and cases involving the Part D program. The Office of Management and Budget has declared Medicare Part D a high-error program with an estimated improper payment rate of 3.3 percent, or $1.9 billion. That could make up the difference with the 21st Cures and the money we had to take out. P.S.

As with all federal healthcare programs, reducing improper payments and protecting taxpayer dollars must be a priority of the Department and a priority of this committee, but here's the part where I pile on to the Chairman's statement because it is not just about federal taxpayer dollars, it is about all of the other problems you have with

Medicare Part D.

As the Chairman said, we are in the midst of a prescription drug abuse crisis. In 2013, prescription painkillers were involved in over 16,000 overdose deaths, and heroin was involved in an additional 8,200 deaths. Over 2.1 million Americans live with a prescription opioid addiction while 467,000 Americans are addicted to heroin. These are absolutely devastating numbers, and the Chairman is right: this series of hearings that we have had this year has been, I think, one of the most eye-opening series of hearings that we have ever had in this committee illuminating this problem. And Part D is a part of it because drug diversion and overprescribing are serious challenges in the program.

Between 2006 and 2014, Part D spending for commonly abused opioids grew by 156 percent, which outpaced the growth of spending for all Part D drugs. Additionally, generic Vicodin was the number one prescribed drug in the Part D program in 2013.

The OIG is going to testify that investigations into Part D fraud, waste, and abuse have uncovered not only financial harm to the program but also serious medical harm

to individual patients from the inappropriate prescribing and diversion of opioids as well as other prescription drugs. Complex criminal networks involving healthcare professionals, pharmacies, and street traffickers are becoming a pervasive element of Part D fraud schemes. In fact, last month, the Department announced the largest takedown in the history of the Medicare Fraud Strike Force, resulting in charges against 243 individuals involving about $712 million in false billings. More than 44 of the defendants arrested were charged with fraud related to Part D.

So I want to take a minute to recognize both the OIG and CMS for the excellent work in achieving this important outcome and sending a message to the perpetrators that those who steal from federal healthcare programs will pay a high price for their crimes.

I look forward to hearing from Dr. Agrawal, our perennial witness to this committee now, about what the agency has done to strengthen program integrity in Part D, particularly as it pertains to the issue of drug diversion and overprescribing. I know that the agency's Overutilization Monitoring System has already resulted in a

substantial reduction in the number of opioid overutilizers in Part D, and I think this is an excellent step in the federal effort to address the prescription drug abuse epidemic.

However, as we are going to hear from OIG today, Part D remains vulnerable to fraud, and there are additional opportunities to identify fraud, waste, and abuse. As the OIG describes, ensuring the integrity of the Part D program requires constant and proactive efforts at every level from the plan sponsors to CMS Program Integrity Contractors to the oversight role. However, CMS does not require plan sponsors to report potential fraud and abuse. In 2012, only 35 percent of plans reported such data voluntarily. In the opinion of the OIG, the low level of fraud identified by some plan sponsors raises questions about the sufficient of their fraud and abuse detection programs.

I know, Dr. Agrawal, you will have more to tell us about this today. I think it is important, Mr. Chairman, that we follow up with the plan sponsors themselves to find out why they are not reporting this information about the fraud detection system. It would have been helpful to have them

here today but perhaps we can have another hearing, and with that, I yield back. Thanks.

[The prepared statement of Ms. DeGette follows:]

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Mr. {Murphy.} The gentlelady yields back.

I now recognize the Vice Chair of the full Committee, Mrs. Blackburn, for 5 minutes.

Mrs. {Blackburn.} Thank you, Mr. Chairman.

I want to say thank you to our witnesses. It is not your first appearance, and I am certain it is not going to be your last. We are so pleased to dig into this issue. The Chairman spoke very well to that.

And going back to what Ms. DeGette was saying, when you look at the opioids, you have got the abuse. The beneficiaries receiving these prescriptions grew by 92 percent in 8 years. Now, common sense is going to tell you something is wrong with that. I mean, that is just common sense. And then last month we had 243 individuals charged with $712 million in false billings. These people were also charged with money laundering, aggravated identify theft, and what these crimes highlight and what this growth highlights is basically what is happening at CMS, Dr. Agrawal, which is the pay-and-chase model, and it is just not working, and my office has just completed a study going back and looking at

the Inspector General reports, and I want you to know, HHS ranks as, I think it is number 4 over the past 10 years in collective abuse of--no, number 2. They are number 2 on the list, $10.3 billion wasted. OIG has pinpointed this. And you have good suggestions. You have got nine outstanding recommendations made for CMS right now that you can do something about this, and hasn't been implemented.

Now, you are going to say we need more money. Well, guess what? When you have got a budget that is closing in on a trillion dollars and you have got $10.3 billion worth of waste that you have done nothing about, we need to come dock you that $10.3 billion. And by that, that is just a 4-year window. You don't deserve more money. You don't deserve it because you're not taking good care of the taxpayer dollars that are coming your way.

What we want is to make certain that people that need a program and deserve a program and are rightfully in a program are going to receive the benefits of that program, but waste, fraud, and abuse is going to be targeted and it is going to be rooted out, and when you are given recommendations, we expect those recommendations to see an action. And don't

tell me you are overworked and don't tell me you don't have enough money because when you have got a job to do, you work until the job is done, and that is what we are wanting to see is that you are going to do your job.

So my question to you today is going to be very pointed. You have been given recommendations. Do you agree with the recommendations? What are you doing to enact those recommendations, and what is your timeline for having them completed?

And those are the questions I am going to have, Mr. Chairman. I will yield my time to whomever would like the balance of my time.

[The prepared statement of Mrs. Blackburn follows:]

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Mr. {Murphy.} Is anybody on this side who would like to speak on this?

If not, the gentlelady's time, she yields back, and now recognize the Ranking Member of the full committee, Mr. Pallone, for 5 minutes.

Mr. {Pallone.} Thank you, Mr. Chairman.

The Medicare Part D program has been a great success for our Nation's seniors and for people with disabilities, and I am glad we are here today to discuss ways to strengthen and improve it.

For decades before its enactment, seniors and disabled Americans, often living on fixed incomes, struggled to afford the rising costs of prescription drugs. Now, more than 40 million Americans have access to affordable medications through the Medicare Part D program, and the ACA strengthened Part D and took crucial steps to improve affordability and access by closing the gap in coverage where beneficiaries pay the full cost of their prescriptions, known as the donut hole. Before the ACA, many beneficiaries struggled with crippling out-of-pocket costs in the coverage gap. The ACA

gradually phases out the donut hole, and closes it completely by 2020. Since the law's enactment, 9.4 million seniors and people with disabilities have saved over $15 billion on prescription drugs, an average of $1,598 per beneficiary. In 2014 alone, nearly 5.1 million seniors and people with disabilities saved $4.8 billion, or an average of $941 per beneficiary. These are real dollars and real savings for Americans, allowing them to live healthier lives and have the peace of mind that they won't have to decide between putting food on the table or paying for lifesaving medications.

In addition, the ACA strengthened Medicare by improving the solvency of the program and strengthening program integrity. Notably, the law moved beyond the traditional pay-and-chase model to a preventative approach that seeks to keep fraudulent suppliers out of the program before fraud, waste, and abuse occur. For example, under the authorities in the ACA, CMS recently issued a final regulation that requires all Part D prescribers to enroll in Medicare. This will help ensure that Part D drugs are only prescribed by individuals who are qualified under State law and under the requirements of the Medicare program, and it implements a

longstanding recommendation by the Department's Office of Inspector General.

The same rule also gives CMS the authority to revoke a provider's Medicare Part D enrollment status under certain circumstances, including if CMS determines that the provider represents a threat to the health and safety of Medicare beneficiaries or has a pattern of prescribing Part D drugs that is abusive.

And finally, to reduce prescription drug abuse and diversion, CMS now requires plan sponsors to implement internal controls to prevent overutilization of both opioids and acetaminophen. These steps and many others are transforming Medicare Part D program integrity efforts, making them more data-driven and risk-based, and I look forward to hearing from both the Office of Inspector General and from CMS about the important steps the Agency has taken to improve program integrity in Part D.

I also wanted to highlight the important bipartisan work of this committee to address one of the OIG's recommendations to improve Part D program integrity. In 2014, the OIG once again recommended that CMS seek statutory authority to

implement a pharmacy lock-in program that would allow prescription drug plan sponsors in Medicare Part D to develop safe prescribing and dispensing programs for beneficiaries that are prescribed high volumes of controlled substances, and I introduced legislation on this issue immediately following the OIG's earlier work, the Medicare Prescription Drug Integrity Act of 2013. I am gratified that H.R. 6, the 21st Century Cures Act, passed overwhelmingly by the House last Friday, acts on this recommendation and gives Part D plan sponsors the authority to establish these lock-in programs. This provision strikes the right balance to protect the integrity of the Part D program and improve patient safety, while carefully protecting beneficiary access. It is a strong example of what this committee can achieve when working in a bipartisan manner to implement commonsense policy solutions.

So I look forward to hearing from Assistant Inspector General Maxwell about the OIG's outstanding recommendations and from Dr. Agrawal regarding CMS's ongoing efforts to strengthen Part D.

Thank you, Mr. Chairman, for convening this hearing

today. I was going to yield to--I don't know if anybody else wants the time. I guess not, so I will just yield back. Thank you.

[The prepared statement of Mr. Pallone follows:]

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Mr. {Murphy.} I thank the gentleman for yielding back.

I might comment on the opening statement. You can see that I think this committee does its best work when we are united, and it is clear that that is the case today.

I also want to make sure I ask unanimous consent if any other Members want to introduce any opening statements for the record, they can do so, and without objection, those documents will be accepted.

You are now aware that the committee is holding an investigative hearing, and when doing so has the practice of taking testimony under oath. Do either of our witnesses today have any objections to testifying under oath? Both of them say no. The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel. Do either of you desire to be advised by counsel during your testimony today? And both say no.

In that case, if you would please rise and raise your right hand, I will swear you in.

[Witnesses sworn.]

Mr. {Murphy.} Thank you. You may be seated. Both witnesses said yes.

You are now under oath and subject to the penalties set forth in Title XVIII, section 1001 of the United States Code. You may now give a 5-minute summary of your written statement, and we will start with you, Dr. Agrawal. You may begin.

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^TESTIMONY OF SHANTANU AGRAWAL, M.D., DEPUTY ADMINISTRATOR AND DIRECTOR, CENTER FOR PROGRAM INTEGRITY, CENTERS FOR MEDICARE AND MEDICAID SERVICES, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND ANN MAXWELL, ASSISTANT INSPECTOR GENERAL, EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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^TESTIMONY OF SHANTANU AGRAWAL

} Dr. {Agrawal.} Chairman Murphy, Ranking Member DeGette, and Members of the subcommittee. Thank you for the invitation to discuss CMS's recent work to improve the Medicare prescription drug program, also known as Medicare Part D. Our objective is to ensure that all Medicare beneficiaries receive the medicines they need while reducing and preventing prescription drug abuse.

We appreciate the subcommittee's continued focus on the problem of opioid abuse and efforts to combat the overutilization of prescription drugs. We also thank the OIG for its work to help us improve the Part D program.

The growth of prescription drug abuse has touched providers, pharmacies and beneficiaries in the Part D program. As this committee has heard, the problems with overutilization, drug diversion, and a variety of other issues are far reaching. The statutory construct of operating the Part D program requires CMS to work through hundreds of plan sponsors, which presents unique challenges to our program integrity efforts. It requires a coordinated, multifaceted approach to address the major players in Part D including prescribers, pharmacies PMSs, and plan sponsors.

CMS has taken concrete actions in recent years to strengthen the Part D program and address weaknesses identified by the OIG and others. One element of these changes has been enhancing the culture around Part D to focus--to include a focus on program integrity, one that emphasizes prevention over the pay-and-chase model, instituting and implementing new administrative authorities to ensure only legitimate providers are prescribing drugs to beneficiaries, and improving collaboration and data sharing with Part D plan sponsors, law enforcement, and other stakeholders.

In particular, CMS is focused on holding sponsors, prescribers, pharmacies and our contractors accountable for prescribing that is consistent with our goals and values of providing safe, high-quality, evidence-based care.

CMS has also taken steps to protect beneficiaries by ensuring that they are receiving prescription drugs from legitimate providers. CMS has announced plans to undertake a major programmatic change which will require prescribers of drugs paid for by Part D to enroll in Medicare, just as they would in Parts A or B of the program, and have begun outreach efforts to enroll over 400,000 prescribers by January 2016. We will then begin enforcement in June 2016 by requiring plans to deny Part D prescriptions that are written by prescribers who do not meet the necessary requirements.

During the enrollment process, prescribers will be subject to the same risk-based screening requirements, which have already contributed to the removal of nearly 575,000 provider and supplier enrollments from the Medicare program since the enactment of the Affordable Care Act. This enrollment standard will directly address issues OIG has noted including prescribers by excluded or invalid

prescribers through new point-of-sale edits Part D plan sponsors will be required to implement.

CMS also has new authorities to remove problematic prescribers from the Medicare program for abusive prescribing behaviors. Together, we believe these new policies will help prevent bad actors from taking advantage of the Part D program and potentially harming beneficiaries. We are also utilizing Part D data more effectively. CMS is doing more to analyze and share data with Part D plan sponsors to enhance the detection and prevention of fraud and overutilization in Medicare Part D. This includes the Overutilization Monitoring System, in which CMS identifies beneficiaries with potentially dangerous opioid utilization. We share a list of those beneficiaries with plan sponsors, which are then expected to use enhanced drug utilization review strategies such as case management and point-of-sale edits to prevent continued overutilization.

Further, plans are now allowed to share information about potentially dangerous beneficiary opioid use, actions that can help prevent beneficiaries from changing plans to avoid detection.

CMS has also developed high-risk pharmacy and prescriber assessments, which we produce for Part D plan sponsors. These assessments contain a list of pharmacies or prescribers identified by CMS as high risk based on a methodology which goes beyond simple outlier analysis. We provide plan sponsors with this information so they can initiate investigations and conduct audits, and ultimately terminate pharmacies or prescribers from their networks. Since 2013, plan sponsors have taken action against hundreds of pharmacies as a result of our Pharmacy Risk Assessments. Our newly implemented PLATO system allows plan sponsors to report back actions they have taken to address issues posed by pharmacies and prescribers.

We have also taken steps to improve data sharing with our colleagues in law enforcement. From January 2010 through the present, CMS made nearly 2,300 referrals to law enforcement. We are working closely with the OIG to prevent bad actors from fraudulently extracting trust fund dollars. Since 2013, CMS has been referring providers who qualify for permissive or mandatory exclusion from participation in federal healthcare programs to the OIG for exclusion. CMS

takes seriously the recommendations of the OIG and has taken strong steps to improve the integrity of the Part D program. We are committed to continue to work with the OIG, this committee, and others as we strengthen Medicare Part D.

I look forward to answering your questions. Thank you.

[The prepared statement of Dr. Agrawal follows:]

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Mr. {Murphy.} Ms. Maxwell.

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^TESTIMONY OF ANN MAXWELL

} Ms. {Maxwell.} Good morning, Chairman Murphy, Ranking Member DeGette, and other distinguished members of the subcommittee. I am pleased to join you today to discuss how we can protect Medicare's prescription drug program from fraud and abuse.

The OIG has made a strong commitment to help safeguard Medicare Part D. Just last month, OIG special agents and other law enforcement personnel fanned out across the country to conduct the largest criminal healthcare fraud takedown ever. A number of the arrests were for doctors and pharmacy owners involved in prescription drug fraud, and there are likely to be more arrests because we have found that Part D continues to be vulnerable to fraud.

Recently, we identified 1,400 retail pharmacies with questionable Medicaid payments. In one example, a Detroit-area pharmacy billed for commonly abused pain medications--opioids, to be exact--for 93 percent of its Part D patients. As this committee is well aware, abusing opioids can lead to

patient harm and event death. It is also tied to illegal drug trafficking, which is why the OIG is not stopping with the recent takedown.

As our special agents investigated and built these cases, OIG analysts were already proactively mining the data to identify new leads to help us--CMS--shut down and--target and shut down this problem.

As important as our law enforcement efforts have been, we cannot arrest our way out of this problem. We have to strengthen our defenses. OIG has several outstanding recommendations for fixing some of the systemic vulnerabilities that allow fraud and abuse to slip through undetected. To start, CMS can better leverage data as a tool to improve oversight and to keep up with the ever evolving fraud landscape. This should include collecting the data necessary to ensure that plan sponsors, the hundreds of private companies that administer the program, are effectively protecting the program. These plan sponsors are Part D's first line of defense.

Currently, as you already heard, CMS does not require these plan sponsors to report on the fraud and abuse that

they identify. While plan sponsors may report this information voluntarily, given the choice, we found that less than half chose to report. Information on identified fraud and abuse as well as how sponsors handle these cases would help CMS assess the effectiveness of sponsors' efforts to protect Part D. Better leveraging data should also involve expanding the analysis of the data CMS already collects. We recommend that CMS and plan sponsors monitor payment data for a wider range of drugs prone to abuse.

CMS does have several key initiatives underway focused on opioids, and while opioid abuse is certainly a major concern, OIG has identified questionable billing patterns related to other drugs. This includes non-controlled substance, which can present a substantial financial loss to Medicare and can be abused in combination with controlled substances.

In addition to better leveraging data, plan sponsors and CMS should buttress current defenses by adding the following three oversight tools to their current efforts.

First, plan sponsors and CMS need to implement stronger payment controls to stop paying for things they shouldn't be

paying for like payments for drugs prescribed by doctors excluded from the Medicare program, or paying for illegal refills of controlled substances. Second, another powerful preventative measure would be a lock-in program that restricts certain beneficiaries to a limited number of pharmacies and prescribers. This tool allows for better monitoring to prevent at-risk beneficiaries from overutilizing drugs that might harm them or diverting those drugs for illegitimate use. Finally, we recommend that CMS improve processes to recover inappropriate Part D payments.

Our recent law enforcement and data-mining efforts show that the current defenses are not strong enough. Plan sponsors need to reinforce that first line of defense but they cannot be the only line of defense. Ultimately, it is CMS that is responsible for ensuring the integrity of Part D.

For our part, we will continue to focus our full array of resources on protecting the program, and we stand ready to work with you, with CMS and others to improve program integrity.

At this time, I am happy to be of assistance and can answer any of your questions. Thank you so much.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The prepared statement of Ms. Maxwell follows:]

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Mr. {Murphy.} Thank you. I will now recognize myself for 5 minutes as we go through this.

First of all, we know that prescription drugs and medications can heal, they can reduce symptoms, they can keep people out of hospitals. Dr. Agrawal, does CMS have any kind of report that really takes an accounting as the prices have gone up in Medicare Part D? Has there been any corresponding decrease in hospitalizations or doctor visits? Is there any report of that type out there?

Dr. {Agrawal.} Chairman, that is a good question. I am not aware of a report along those lines. I may have just not seen it, so I am happy to take that question back.

Mr. {Murphy.} Thank you. I wish you would.

Ms. Maxwell, you pointed out in your testimony about nine unimplemented recommendations that the OIG identified. So as she stated that, Doctor--and some of those go all the way back to 2006. Does CMS agree with the recommendations made by OIG?

Dr. {Agrawal.} I think we do agree with the recommendations. I think we have expressed that in writing

to those reports. You know, what I would emphasize is, these are all recommendations that we are working to make progress on. I think it is very fair to say, you know, that we need to continue to work on it, need to get to completion. These are often multifaceted recommendations that require, you know, multiple levels of implementation.

Mr. {Murphy.} But you recognize some of these go back to 2006, so I am sure many members are going to key in on trying to get some commitments from you to get that done.

But let me focus on one of those. The OIG recommended that CMS exclude schedule II refills when calculating final payments to plan sponsors at the end of each year. So what action has CMS taken to implement that recommendation? Ms. Maxwell, can you answer that first? Do you know if they have taken action that?

Ms. {Maxwell.} Absolutely. It is my understanding--and this is one of the recommendations in which CMS did not concur with the recommendation of seven of the nine initially CMS did concur with. There are two they didn't. This is one of them. It is my understanding that CMS is concerned about the data that is available and the data does not make it

obvious what is a partial refill versus what is an illegal refill, and that they have instituted actions to make it more clear in the data. Our position is, once the data is clear, then you have the opportunity to put in an edit, and we would continue to recommend that they do put in an edit to stop those illegal refills.

Mr. {Murphy.} Dr. Agrawal, what is your plan of action here?

Dr. {Agrawal.} Yeah, I think Ms. Maxwell has characterized that correctly. So our concern is that the data is not completely accurate at this point. Early refills of schedule II drugs are illegal. We of course don't support early refills of those drugs. However, partial fills, particularly for beneficiaries that may be in long-term-care facilities, are totally legitimate and may actually help to address pain and other issues that they have. So what we are doing is working with plan sponsors to clarify coding requirements so that we can differentiate the legitimate payments from the illegitimate payments and then would be seeking to make the kind of change that is being described.

Mr. {Murphy.} And as part of that, hopefully you will

also going after people who have made the wrong claims and getting that money returned.

On page 3 of your testimony, Doctor, you had mentioned the President's budget proposes to provide the Secretary with new authorities to suspend coverage and payment for drugs prescribed by providers who have been engaged in misprescribing to suspend coverage and payment for Part D drugs when those prescriptions present an imminent risk to patients and require additional information on certain Part D prescriptions such as diagnosis instant codes and conditional coverage. Do you have any estimate that this will actually save money in terms of reducing some of the fraud and abuse to implement those recommendations?

Dr. {Agrawal.} Yes, I think these kinds of recommendations really go at the heart of prevention, moving away from the pay-and-chase model that others have commented on. We did promulgate policy, as you know, last year requiring enrollment to prescribers and also with that implementing the ability to revoke providers for abusive prescribing. I think all of those things really do take a very strong step towards prevention, just as we have done in

other parts of the program and have been shown to be effective.

Mr. {Murphy.} I was hoping that was something you can give us some numbers on in terms of what you estimate that would be savings to Medicare Part D. That would be important to us if we implement those.

Let me mention something else here. This is on Medicaid but it is important, because a report just came out in March issued by the HHS Office of Inspector General and found that 92 percent of Medicaid enrolled children who are prescribed antipsychotic medications lacked ``medically accepted pediatric indications'' that would warrant such prescriptions. There were instances there of very young children being prescribed antipsychotics, 4-year-olds. It was a very disturbing and alarming report. That 92 percent number of not medically indicated was absolutely astounding. So given that, and I don't expect you to know this today, but if you do know, I would like to know what steps CMS is taking to root out the providers who are prescribing children powerful psychotropic medications when it isn't medically necessary. Would you make sure you get back to us on that?

Dr. {Agrawal.} Absolutely.

Mr. {Murphy.} And finally, the OIG has recommended that CMS implement an edit to reject prescriptions written by excluded providers. So Ms. Maxwell, what actions has CMS taken to implement that recommendation of those who aren't supposed to be prescribing at all?

Ms. {Maxwell.} It is my understanding that the sponsors are required to be monitoring excluded providers and making sure that the payments don't go to them. However, when we did look, we did find that CMS did accept PDE records from the sponsors that included excluded providers. There was about 15 million in gross payments over a 3-year period. So again, we continue to appreciate the steps that have been taken but there's obviously need for further steps and stronger payment controls be put into place.

Mr. {Murphy.} Okay. I would like to follow up but I am out of time so I will now turn to Ms. DeGette for 5 minutes.

Ms. {DeGette.} Let me sort of extend that previous line of questioning, which is, we are talking about the OIG report on Medicare Part D integrity and the report notes ``CMS relies on plan sponsors to be the first line of defense again

fraud, waste, and abuse in Part D.'' I am wondering if both of you can each comment on the role that plan sponsors play in this first line of defense against waste, fraud, and abuse. I am wondering what tools they use and what can be done. Dr. Agrawal?

Dr. {Agrawal.} Sure. Thank you. I do think, you know, the role of Part D plan sponsors is extremely important since they are paying claims or PDE records directly.

Let me just address maybe the prior point about providers first.

Ms. {DeGette.} Sure.

Dr. {Agrawal.} You know, I think it is absolutely indefensible for a Part D plan sponsor to pay the prescription of an excluded provider. Now, we have implemented edits behind those plan sponsors to indicate when they have done that so they can make the appropriate recoveries on their end. I also think prescriber enrollment and the screening requirements that I mentioned earlier will go a long way, because it will move those edits from after the PDE record to the point of sale when we have all 400,000 prescribers enrolled in the program.

So we can clearly buttress Part D plan sponsors but their role is absolutely vital. I think they need to be on top of the data. We share a lot of data with them so that they are aware of who the outlier prescribers and pharmacies and their networks are. They also have the ability to implement drug utilization reviews and other kinds of programs including case management to stem both abusive prescribing as well as abusive utilization.

Ms. {DeGette.} So let us talk about that data for a minute because they are not required to report the data on potential fraud and abuse, and in fact, the percentage of plan sponsors that voluntarily report this has declined over the last few years down from 40 percent in 2010 to 35 percent in 2012. Do you have any more recent data about the trends on this?

Dr. {Agrawal.} I don't think we have more recent data that I can share today. However, this is an area that we have been working to make progress as well. So as I mentioned, we give data to the plan sponsors on a quarterly basis, and just this year implemented a system for them to be able to report back to us what actions they took as a result.

I think that system, which allows the data to be reported, and then for it to be searchable and analyzable has been an important step moving us towards better reporting.

Ms. {DeGette.} What is your view on this, Ms. Maxwell?

Ms. {Maxwell.} It is absolutely true that, as I said in my oral, that the sponsors are the first line of defense. They administer the program and they are the ones that are paying the pharmacies but CMS, as I said, is the second line of defense, and if things do slip through the processes and edits they have in place, it is incumbent upon CMS to have the second line of defense to prevent that from happening. That prevents the Federal Government from actually reimbursing the mistakes the sponsors might be making.

Ms. {DeGette.} And do you think CMS is doing enough to encourage that?

Ms. {Maxwell.} I think CMS had made significant strides in response to many of our recommendations, and of course, we outline nine in the report that we believe are important to be included in their ongoing effort to improve program integrity.

Ms. {DeGette.} And what about the plan sponsors' fraud

detection programs themselves? Do you think that the plan sponsors are doing enough or can they be beefing up that over time?

Ms. {Maxwell.} If we had the data about the fraud and abuse incidents that they are detecting as well as the data about how they are responding, we would be able to answer that question with more authority. We really don't have the visibility that we think is necessary to hold them accountable.

Ms. {DeGette.} Is that something, Dr. Agrawal, you think you could provide?

Dr. {Agrawal.} Well, as I mentioned, we are getting some data from plan sponsors, and in particular, we are focused on where we give them a clear lead such as an outlier pharmacy or an outlier prescriber, what are they doing to investigate that lead downstream and then take the relevant actions. What we have found is certain plan sponsors are actually good at following up. So we have been able to see hundreds of pharmacies be excluded from networks because of the leads we give them. We also conduct compliance reviews of plan sponsors to make sure that program integrity

processes are a robust part of their operations. Again, some plan sponsors I think do quite well there and others have opportunities for improvement.

Ms. {DeGette.} Well, this is an area where it seems like there could be a lot of problems, and OIG has recommended making it mandatory that they report potential fraud and abuse. I am wondering, first, Ms. Maxwell, could you comment on that recommendation?

Ms. {Maxwell.} Absolutely. As you have pointed out, given the current state of affairs that it is not currently voluntary, we don't have full compliance.

Ms. {DeGette.} Right.

Ms. {Maxwell.} And so we believe we will not have full compliance unless it is mandated, and without the comprehensive reporting of that data, we can't look across the entire program and see--

Ms. {DeGette.} Dr. Agrawal, what is your agency's response to that?

Dr. {Agrawal.} Yeah, I think we can essentially agree with that, you know, the notion a lot. I think the question for us is, what kind of reporting is the most beneficial for

other plan sponsors and the agency, and so implementing something like the PLATO system, giving them leads, and then getting results from those leads is a step towards answering exactly that question of what kind of information return is useful to the agency and would be useful to other plan sponsors. I think as we get more information and get better understanding of the utility, we will be able to require more of plan sponsors.

Ms. {DeGette.} I am sure we have more questions around that line too. Thank you.

Mr. {Murphy.} Thank you. I now recognize the gentlelady from Tennessee, Mrs. Blackburn, for 5 minutes.

Mrs. {Blackburn.} Thank you, Mr. Chairman, and I am going to follow right along with what Ms. DeGette was saying.

It is troublesome when we hear--and Ms. Maxwell, of course, you all have so much work on this--with the voluntary nature of the reporting, and you have recommended that they make it mandatory, and so Dr. Agrawal, what are you doing to beef up the compliance? You can say well, we have PLATO, well, we have this, you know, but what are you doing to enforce this? How do the people that work at CMS understand,

this is an imperative. You have got to do this. I mean, how do you communicate that?

Dr. {Agrawal.} I think we take all of OIG's recommendations as important contributions, as imperatives. We do work to implement--

Mrs. {Blackburn.} Whoa, whoa, whoa. Wait a minute. They are not contributions. They have pointed out to you-- let us not even start down that road. It is not a contribution. It is, you are doing this wrong, you are wasting money, the fraud has been identified. Let us just say it like this. They have got nine recommendations on the table. Do you agree with those recommendations, yes or no?

Dr. {Agrawal.} I think we have indicated that we largely agree with those recommendations, yes.

Mrs. {Blackburn.} That is not the question that I asked. Yes or no?

Dr. {Agrawal.} Well, I think Ms. Maxwell has pointed out that the agency has agreed with seven of the nine recommendations.

Mrs. {Blackburn.} Okay. Well, the problem is, what are you doing then to take an action, and what is your timeline?

You know, you seem to come here and punt, and we have got another report that came out this morning. You are saying oh--and oh, by the way, it is only 2 months late. You are 2 months late with your report. People in the private sector that deliver a report 2 months late generally are, you know--they have other problems.

Okay. So let us look at this. You are saying you have recovered $454 million and that your Fraud Prevention System is returning a 10:1 ratio on this investment, and you are very proud of that, but you have got a lot of other waste that is out there, so I want to know from you specifically how are you enforcing the recommendations and what is your timeline for bringing your agency's work into compliance on a program that is really important to our Nation's seniors, and that is not that difficult a question. Now, getting the work done obviously that is a little bit harder for you, but we want to know specifics on your enforcement and specifics on your timeline of meeting this.

Dr. {Agrawal.} First, Congresswoman, let me just say on the Fraud Prevention System report that those numbers have been certified by the OIG itself, and this was a report that

we worked on in conjunction with them throughout the timeline--

Mrs. {Blackburn.} I am fully aware of that.

Dr. {Agrawal.} So I think the 10:1 ROI is positive, obviously, a good development for the system. As to your questions about the various recommendations, I am happy to take that back and we can give you responses for each recommendation, what we have done to implement them. I think on every recommendation we have worked to make progress to implement various systems and changes towards finally completing that recommendation, but these recommendations do take time to implement.

Mrs. {Blackburn.} Okay. You said you had the authority to do the job. We know that you have the money and the personnel. Why does the job not get done? Is it not a priority?

Dr. {Agrawal.} This is an absolute priority. We have many staff focused every day on the integrity of the Medicare program--

Ms. {Blackburn.} Do they understand that they are expected to meet a timeline? Do you all have a timeline?

You still haven't spoken to the timeline.

Dr. {Agrawal.} It think it depends on which recommendation you are referencing.

Mrs. {Blackburn.} No, no, all of them. You have got--you can't pick and choose on this. You have got a list of recommendations. You have had waste, fraud, and abuse identified. You know you have got problems with the opioids. You know that voluntary reporting gets you part of the way but it doesn't get you all the way, that this needs to be made mandatory. So as to the leader, what are you doing to make certain that there is a set timeline? When is the timeline? Is it the next report? Is it the next hearing? Is it the end of the year?

Dr. {Agrawal.} Yeah, so let me give you an example, Congresswoman. So we have been very specific when it comes to something like prescriber enrollment, which will actually go towards resolving at least two of the recommendations I believe that OIG has put forward around excluded providers or other kind of invalid prescribers. We have stated--you know, we promulgated the necessary rulemaking last year. We are now working with Part D plan sponsors to get these

prescribers enrolled so that we don't cause an interruption in legitimate access to services, and we have said that that enrollment requirement needs to be met by January 2016 between both the plan sponsors and CMS working collaborative together. We will then implement point-of-sale edits behind that enrollment in June of 2016, which I think will take a significant step towards really eliminating excluding prescribing or other invalid prescribing--

Mrs. {Blackburn.} So basically you are giving yourself a year to come into compliance with something that you know has been a problem.

Dr. {Agrawal.} Well, I think that that--

Mrs. {Blackburn.} I yield back my time.

Mr. {Murphy.} I now recognize Mr. Pallone for 5 minutes. We can let him answer? I will let him answer. Go ahead. You can answer. Let me do that first.

Dr. {Agrawal.} Thank you. I think it highlights some of the technical challenges in actually getting this work done. So we have to be very careful to actually enroll 400,000 prescribers so that we do not interfere in legitimate access to services that the Part D program provides

beneficiaries. We balance that against the need to do this quickly and effectively to stem the various weaknesses and issues that the OIG has correctly pointed out. This is a balance we work to achieve every day. So yes, it takes time. It takes time for prescribers to get up to speed on the requirements and get enrolled. It takes time for our Part D plan sponsors to initiate the necessary actions on their part and get the point-of-sale edits in place as well.

Mr. {Murphy.} Thank you.

Mr. Pallone.

Mr. {Pallone.} Thank you. I believe that both of our witnesses here today have studied a growing phenomenon that is deeply concerning, and that is the overprescribing and/or the overuse of opioids in Medicare Part D. This is an issue that we have all worked on for many years in response to OIG's earlier work on this topic.

I introduced the Medicare Prescription Drug Integrity Act of 2013. Since that time, OIG has repeatedly recommended that CMS seek statutory authority to restrict certain beneficiaries to a limited number of pharmacies or prescribers when warranted by excessive or questionable

billing patterns. This practice commonly referred to as lock-in I mentioned in my opening statement has been successful implemented in the private insurance market and some state Medicaid programs.

In the 21st Century Cures legislation that the House overwhelmingly passed on Friday, there is a provision that would allow Medicare Part D plan sponsors to use these types of drug management programs to curb potentially harmful use of opioids and other controlled substances, and that provision as agreed to in the legislation strikes the right balance between protecting beneficiary choice and access while also improving continuity of care by ensuring that those high-risk patients obtain and fulfill prescriptions for controlled substances only from designated providers, and I think that is a big step in the right direction.

So let me ask some questions. Ms. Maxwell, can you summarize OIG's findings that have led the agency to repeatedly recommend that Congress gives CMS authority to allow Part D plan sponsors to create these so-called lock-in programs?

Ms. {Maxwell.} Absolutely. As our current data shows,

the rate of increase of use of opioids within Part D has far outpaced the general increase in drugs. In fact, it has grown 156 percent since the inception of the program. We also see, as I mentioned, the pharmacy fraud where we see pharmacies allowing for opioids to flow into the streets and be diverted. This poses not only a patient harm issue for the beneficiaries but also is a public health issue for some of those things that flow into the streets end up back on pharmacy shelves, which affects all of us. This is a significant issue, and we believe the lock-in would be a significant move forward in protecting the program beneficiaries from patient harm as well as the program from significant financial loss.

Mr. {Pallone.} Thank you.

Dr. Agrawal, do you believe that if a pharmacy lock-in provision in 21st Century Cures was signed into law, CMS would have a much-needed tool to address opioid abuse and overprescribing in Part D, and have these types of lock-in programs been successful in curbing opioid abuse and other programs?

Dr. {Agrawal.} Yeah, I would certainly agree with Ms.

Maxwell that we have seen beneficiaries that are really at safety risk from the levels of utilization of their opioid medications. We have been supportive of this kind of legislative change to provide a lock-in approach. It is part of the President's budget. I do believe that it would have impact as it has, as you have already pointed out, in both the private sector as well as in various Medicaid programs.

Mr. {Pallone.} Okay. I want to switch to that report that Mrs. Blackburn mentioned, the Fraud Prevention System report that the agency released this morning. The FPS uses predictive and analytics to detect troublesome billing problems and provide it to the Medicare program, and after 3 years of operation, CMS today reported that the system identified or prevented $820 million in inappropriate payments in the program's first 3 years.

So Dr. Agrawal, first of all, I want to commend you on your work on the FPS. In its third year, how has the program changed and matured? And let me throw in the second question too because of time. Does CMS plan to expand the program to Part C and Part D in the near future, and what additional plans does the agency have to expand the FPS to additional

fraud detection activities?

Dr. {Agrawal.} Sure. Thank you for the question. Currently, the FPS streams all Medicare A, B, and DME claims, so about 4-1/2 million claims per day. I think what we have seen over the last 3 years in terms of evolution of the program is more models being implemented, more sophisticated models being implemented that not only look at outlier behavior but are truly predictive models based on the input of our own investigative field staff as well as the input of law enforcement, both OIG and DOJ, based on prior kind of patterns of fraud and abuse that they have noted. So that is one really big change is on sort of the technology side and just improving the modeling.

The second is making sure that these leads are actually being followed. So this was almost a cultural change or just a contractor accountability change to make sure that our Program Integrity Contractors took these leads seriously, they formed a substantive, substantial part of their workload, and they were driving towards real administrative outcomes as quickly as possible.

I think what we will continue to do with this program is

continue to leverage the technology to implement new approaches like edits so that claims can be stopped from being paid, you know, before they are actually ever paid. We have been doing some of that already in the first 3 years, and we are looking to expand that capability substantially going forward. I think also the maturing of the modeling will facilitate this process.

To your question about other data sources, we have started to fold in Part D PDE records and we will be looking to do that more. I think in Part C, we still have the challenge of getting accurate encounter data from plan sponsors, so we are still working with the relevant parts of CMS and plan sponsors to help improve that encounter data.

Mr. {Pallone.} Thank you.

Thank you, Mr. Chairman.

Mr. {Murphy.} Thank you.

I now recognize Mr. Barton for 5 minutes.

Mr. {Barton.} Thank you, Mr. Chairman.

I guess the first thing we ought to do is thank HHS and the Inspector General for conducting the investigation and actually beginning to try to correct the problem and at least

identifying some of the bad guys. That is a good start.

My first question I guess would be to Dr. Agrawal. Is that correct?

Dr. {Agrawal.} You nailed it.

Mr. {Barton.} Well, how about that? Just a lucky guess.

How in the world can somebody be on Medicare Part D if they are not enrolled in Medicare? If I heard correctly, you said some people are actually getting the benefit but they are not in the program. I don't understand that.

Dr. {Agrawal.} No, sir, it is not on the beneficiary side of the equation. It is the prescriber, the physician or advanced-practice nurse, for example, who actually sends a prescription in, hands it to a patient. Currently or prior to last year, there was no specific enrollment requirement for the provider. There is now, so going forward, all prescribers are going to have to come into the program, be subject to the same screening standards as in the rest of Medicare.

Mr. {Barton.} Okay, but prior to this year, a provider could reject Medicare patients but prescribe Medicare Part D

prescriptions?

Dr. {Agrawal.} Correct. It is been a huge program integrity focus to bring this up to the rest of the level--to the level of the rest of the program.

Mr. {Barton.} But that is no longer a problem? That is one loophole that has been closed?

Dr. {Agrawal.} We are in the process of closing it as we--

Mr. {Barton.} In the process--

Dr. {Agrawal.} --get through enrollment. As I mentioned, we have to enroll 400,000 prescribers by January.

Mr. {Barton.} Okay. And if they have a doctor that is not in the program, you just send a letter to the patients that that is not a valid prescriber. Is that correct?

Dr. {Agrawal.} Yes. So the balance with beneficiary access to medications is important. What we have done is created essentially a transition period. So if a beneficiary takes a prescription to a pharmacy from a prescriber who is not enrolled, they will get that information but they will also get the medication so that there is no interruption in their therapy. They will not get it the second time. By

that time we would have expected the provider to either be enrolled or for the beneficiary to go to a different provider.

Mr. {Barton.} Okay. Now I am going to switch to Ms. Maxwell.

One of the recommendations that hasn't been acted on but apparently you all are beginning--the program is beginning to act upon is this idea of mandatory reporting from the play-ins. I am not a big fan of mandatory anything except people paying the taxes. I guess that ought to be mandatory. Why not go the other way? Why not create--I heard that--voluntary compliance but you go to jail if you don't voluntarily comply. All right. A minor point.

Why not go the other way and provide an incentive to the plan that you don't have to report, but if you do and it really is fraudulent and we recover some of the program funds, we will give you a percentage of the monies that are fraudulently--have been fraudulently paid and then recovered? Why not create an incentive program? That works for me, and I think most Republicans would prefer it. Now, I may be wrong but I would have an incentive to do it than a mandate

they have to do it.

Ms. {Maxwell.} You know, the heart of our recommendation is to have the visibility to oversight, so as long as we have the data and the visibility to what the plan sponsors were doing to protect the program, that is ultimately what we are after.

Mr. {Barton.} Congressman Gingrich when he was Speaker put in or at least requested that this committee put in a program where you could create a hotline that people could call in to, and if it turned out that--and this wasn't just for Medicare, this was before Medicare Part D obviously--but if there was fraud involved and somebody reported it and it was proven and stopped, the person who reported it got some sort of a bonus, and that would be another idea to think about.

I will go back to the doctor. This is my last question. You may have to get back to me on this. Just at the basic level, I would like to know where you think the primary cause of the fraud is. Is it from the patient's standpoint? You have got phantom patients perhaps. Is it from the pharmacy standpoint? Is it from a plan who is overbilling even though

they don't have patients? Or is it possible it could even be in the government itself where they work in conjunction with the plan to create fraud? Do you have any data on that?

Dr. {Agrawal.} I think what we see is that overutilization in Part D is multifaceted. It occurs at patient, prescriber, the pharmacy, which is why the response to it--and I think the OIG has pointed this out as well--the response to has to be multifaceted. The program has to try to address all of the different areas that fraud or abuse could be occurring.

Mr. {Barton.} If you identify the most prevailing area, then you put most of your assets there and you will have a better chance to get a greater return on your investigations.

With that, Mr. Chairman, I yield back.

Mr. {Murphy.} Thank you. The gentleman yields back.

I now recognize the gentleman from Massachusetts, Mr. Kennedy, for 5 minutes.

Mr. {Kennedy.} Mr. Chairman, thank you, and thank you for holding an important hearing. Thank you to our witnesses once again for coming back.

I am going to touch on some--try to flesh out a little

bit some of what my colleagues have already touched on for both of you. Obviously Medicare Part D is a large and important program, serving millions of seniors across the country and a good deal of them in my district. Given the scope and the number of transactions involved, proactive data analysis is an essential tool to focus on fraud detection and enforcement efforts.

The OIG Data Brief does just that, highlighting some notable outliers when it comes to pharmacy billing. In particular, the suspicious prescriptions for opioids are especially troubling, given the nationwide epidemic that we have heard about at previous hearings and some of my colleagues have already touched on.

So according to the Data Brief, ``spending for commonly abused opioids grew at a faster rate than spending for all drugs.'' That was on page 3, I believe.

So Dr. Agrawal, it is my understanding that the initial comparison with 2011 data shows that there has been a substantial reduction in the number of acetaminophen and opioid overutilizers. I was hoping you can try to flesh out a little bit more about CMS's measures to prevent the

overutilization of prescription medications within the Part D program.

Dr. {Agrawal.} Sure. So I think where there are--so again, multiple facets to the issue where there is beneficiary overutilization where, you know, we can identify beneficiaries that have exceeded what we would consider kind of standardly accepted safety thresholds. We share that information with Part D plan sponsors through our Overutilization Management System. That gives them the specific beneficiaries that they can then implement I think more proactive drug utilization reviews around including case management. What we have seen when we focus on things like schedule II drugs is a 30 percent decline in the prevalence of those beneficiaries, which shows that both the data sharing and the actions being taken on the part of the plan sponsors is having an impact, and we continue to provide that information on a quarterly basis so that plan sponsors can continue that work.

Mr. {Kennedy.} Thank you.

And Ms. Maxwell, you touched on in your opening statement one of the pieces that were highlighted in the

report of a Detroit-area pharmacy that billed for commonly used opioids for 93 percent of its beneficiaries. It amounted to 58 percent of all of its Part D prescriptions. Can you talk a little bit about OIG's plan for follow-up in the questionable pharmacy billing 3-year study and tell us a little bit more about the proactive analysis that you ensuring Medicare to take in a broader report?

Dr. {Agrawal.} Absolutely. As I mentioned in my opening remarks, when we were proceeding in the takedown, we were already mining the data for new leads. We already have 1,400 retail pharmacies targeted that had questionable Medicare billing. We are actively investigating some portion of those, and we have referred the rest to CMS for investigation. So the Data Brief allows us to see where there are areas for questionable billing and the next step is to investigate and weed out which one of those really represent legitimate business and which are fraud that we need to pursue either with OIG investigations or in conjunction with CMS.

Mr. {Kennedy.} And Dr. Agrawal, what's the--after those are referred over to CMS, what is CMS's next steps?

Dr. {Agrawal.} Yeah, so again, I would agree that these--that the analytical work is a good starting point for further refinement and then also investigative activity. Now, let me just say it is the construct of the program that CMS doesn't have a direct relationship with pharmacies. That relationship really occurs with Part D plans. Pharmacies don't enroll or anything like that in the program.

For that reason, we have to work through Part D plan sponsors by giving them better data and, you know, then they take the necessary investigative and other administrative actions. We certainly will utilize the information given to us by the IG so they gave us about a thousand of the roughly 1,400 pharmacies have been sent over to us, and we have been sharing that, or have shared that already with plan sponsors.

In addition, on a quarterly basis, we do similar work utilizing sort of a greater set of variables to identify high-risk pharmacies and again share that information on a quarterly basis, which has yielded literally hundreds of pharmacies being excluded from plan sponsor networks.

Mr. {Kennedy.} Thank you. And then the brief highlights some geographic hotspots as well, some metro areas

where average payments for certain drugs are much more than the average nationwide.

Ms. Maxwell, in conducting the analysis, did OIG evaluate patterns for all non-controlled drugs or did you just focus on specific ones?

Ms. {Maxwell.} We chose some examples to highlight the potential problems with non-controlled drugs, so there are other drugs that might be of concern that are not highlighted in that Data Brief but the ones we did highlight again like the questionable billing for the pharmacies are worthy of further scrutiny to understand what is happening and stay in front of the evolving healthcare fraud trends.

Mr. {Kennedy.} Thank you, and I yield back.

Mr. {Murphy.} Dr. Burgess is now recognized for 5 minutes.

Mr. {Burgess.} Thank you, Mr. Chairman, and I think you can tell, it is great that we are having the hearing on the integrity of the program as it relates to Part D drugs, particularly with respect to opioids, but you can tell there are a lot of general questions about inappropriate expenditures within the various programs at HHS, and Mr.

Chairman, I hope you will take this as perhaps a reason to consider having a general hearing, a general oversight hearing on inappropriate expenditures within the Medicare and Medicaid system.

Mr. Barton talked about previous efforts towards the concept of predictive modeling, and it does seem to me that this is an area where this would be perhaps a particularly useful type of activity. I mean, I got a call at 6 o'clock in the morning a couple of Sundays ago that there had been inappropriate expenditures on my MasterCard. It seems to me that with the amount of data that you all collect on a daily basis, you ought to be able to do a pretty good job of isolating--identifying and isolating and investigating unusual trends and expenditures. Is that not possible?

Dr. {Agrawal.} Dr. Burgess, I agree that it is. We have been--as I mentioned earlier, we are looking to include Part D data to a greater degree in the FPS system implementing new models just around this program as we demonstrated the impact of the FPS.

Mr. {Burgess.} It just calls up the question of, you know, the scale of the problem is likely to be much more

massive than any recovery that has been affected to date.

I do want to ask a couple of questions, and I realize it is a little bit off topic, but I know, Dr. Agrawal, we have talked about this before. Ms. Maxwell, I apologize, I don't remember whether our offices talked to you directly, but it does affect you also.

We had a hospital in Texas--Dr. Tariq Mahmood--who took $18 million for the development of an electronic record system and basically just put his medical records down to the basement and let the mice eat them, not computer mice, real furry mice. So what can you all do--I mean, yeah, one of the managers has gone to jail, the doctor will have a trial at some point, and likely will face jail time through the Department of Justice, but what can you all do to recover that $18 million that was inappropriately dispensed under the stimulus plan to this hospital chain?

Dr. {Agrawal.} So thank you for the question, and I am aware of the case. I have to tell you, I think it occurred a while back so we--you know, I think the general answer is, we do conduct audits of the EHR payments, incentive payments that we make, and where we find discrepancies, we are able to

recover those dollars. This was the case that I know we worked on conjoinedly with the OIG so I can't tell you if the audit came first or the OIG investigation did. If you are interested in that, perhaps I can take it back. But these audits are meant to address exactly the vulnerability that you are identifying, which is, you know, essentially false statements that you have implemented in EHR, a viable EHR system. We do look at that question.

Mr. {Burgess.} And to answer your question, I would be interested, but see, this is the problem and this is what just drives people crazy. We kind of get into this circuitous stuff between agencies, and I think--again, I think we have had this conversation before. I am told it is under investigation. But really, where are we at getting the 18 million bucks that the taxpayer is on the hook for for sending these dollars down to Dr. Mahmood? Does either office have that interest in recovering that money?

Dr. {Agrawal.} Of course we do, and I will happily take that question back, I mean, to specifically address whether the $18 million has ever been recovered. I don't want to leave you with a false impression about this particular case.

This was something that we did work in coordination with the OIG. It wasn't sort of a turf battle or anything like that, you know. My answer is just, I don't know if they identified the issue first and then came to us or vice versa. But we did coordinate across this case.

Mr. {Burgess.} I actually think it was my newspaper, the Dallas Morning News, that identified the problem and I brought it to your attention.

But, I mean, again, this is what just drives people crazy. You have a massive inappropriate expenditure of federal money, and then no one seems to be primarily responsible for going and recovering it, and quite honestly, reporting back to Congress about what the status of that recovery is. In your own statement this morning, Dr. Agrawal, you said well, this was some time ago. Yeah, it was some time ago, so we would like the dollars back, please, and I know this individual has--it has been reported that he has got plenty of assets so this is something that you would think with the full force of the Federal Government and Department of Justice we would be able to go and effect that recovery.

Thank you, Mr. Chairman. I will yield back the time, but I do want to follow up with both of you and understand where the status of this recovery is.

Mr. {Murphy.} Thank you.

I now recognize Mr. Yarmuth for 5 minutes.

Mr. {Yarmuth.} Thank you, Mr. Chairman. I appreciate your holding this hearing. I think as has been demonstrated, both sides are very much interested in rooting out all the waste, fraud, and abuse that exists in the Medicare system. Thanks to the witnesses for the work you are doing.

I tend to--I do have a question about that, but before I do that, I want to take this opportunity as I often do to talk about the experience in Kentucky with the Affordable Care Act and the great work that my Governor, Steve Beshear, and his team have done in implemented the expansion of Medicaid and what has meant for our State. We have more than a half-million people who are newly enrolled in Medicaid and in private insurance as a result of the ACA. That is in the range of 4.4 million. We have reduced the uninsured rate by almost 50 percent in Kentucky. In my district alone, the uninsured rate has dropped by 81 percent. Pretty astounding.

More importantly, for those who say that this is economically nonfeasible, the State employed the Deloitte firm to analyze the prospects for Kentucky's economy over the next 6 years under ACA, and they determined that under ACA, Kentucky would experience added economic activity of $30 billion, the creation of 40,000 new jobs, and I think most importantly, from the taxpayer's perspective, an impact, a positive impact on the State budget of $819 million. So I think those statistics demonstrate that the ACA can be very, very positive, not just in insuring people, giving them access to quality care but also from an economic perspective.

So we have talked a lot about Medicare Part D and the fraud provisions and your work in those areas. There is a related issue when we talk waste as well, and I wanted to talk about prescription drug costs. One of the things that-- when I was part of the Democratic Majority back in 2007, one of the first things we did was to pass a bill to allow Medicare to negotiate with drug providers on cost that was not implemented into law. But I was talking with a physician friend of mine the other day, who has done a lot of work in this area, and he was showing me some really incredible

statistics about the difference in cost of certain prescription medicines just in my district, and in some areas, the cost was 60 to 70 percent different from one outlet to another.

So my question is, if there is those--if there are those kinds of potential savings involve just in terms of going from one drugstore or one grocery store to another, why can't we have some kind of systemic approach to that from CMS? Doctor, do you want to respond to that?

Dr. {Agrawal.} Sure. Thank you for the question.

You know, I can tell from my own practice in the ER, drug costs are an important factor in this whole equation, and the ability of people to be able to pay for the drugs that they get.

I will tell you, as you pointed out, that this is an area where we do not have legislative authority to kind of engage in the negotiation that you are describing.

Mr. {Yarmuth.} Do you think that it could have a substantial impact on saving money for the taxpayers if you did have legislative authority to do that?

Dr. {Agrawal.} You know, I am not aware. I am sure

there is analyses that have been done. I am not aware at this moment what the expected impact would be. Perhaps we could get back to you about that.

Mr. {Yarmuth.} Well, again, this person has done a lot of work in the area, and he mentioned one drug--I know Ranking Member DeGette talked about saving a billion-plus something in one area--one drug that now is responsible for about $8 billion worth of sales in the United States every year that actually can be purchased for about 15 percent of that, so you are really talking there about a savings of almost $7 billion to the system per year if we just had that kind of power to deal with price. So I will just mention that for the record because I think that is something that--as we look at continuing to make Medicare and Medicaid sustainable over time, we are going to have to deal with the issue of the cost of prescription drugs as well as the fraud and abuse side.

So I thank you for your--

Ms. {DeGette.} Will the gentleman yield?

Mr. {Yarmuth.} I will yield.

Ms. {DeGette.} So the CBO estimates that allowing CMS

to negotiate Part D prescription drugs would save $155 billion over the next 10 years.

Mr. {Yarmuth.} That is real money.

I yield back, Mr. Chairman.

Mr. {Murphy.} And obviously there is more to it than that, and we will continue that discussion. Thank you.

I now recognized Dr. Bucshon for 5 minutes.

Mr. {Bucshon.} Thank you, Mr. Chairman.

I was a surgeon before, so I am intimately familiar with the situation, and the bottom line, it seems to me that, you know, nobody out there is defrauding the government over Lasix or Hyzaar to a large extent. I mean, in my view, we are talking about narcotics. We are talking about a funding stream from the Federal Government that is helping to facilitate the use of narcotics in our country. I mean, that is not the only issue but that is a huge part of it. Without the funding stream, the problem goes away.

And so there are multiple funding streams, and people that abuse narcotics, people that sell narcotics, when they find an avenue to get that paid for in some way, they will take it, and so my point is, there are a lot of other issues

other than just payment that this subcommittee has been trying to address, the inter connectability amongst EMRs including those at pharmacies, at the State level, at the federal level is critical so that we know who is prescribing these medications better than we know today. We know who is using these medications better than we know today. And it is going to take a multiagency approach at the federal level to address this problem. The payment is only piece of the pie, right? Payment is a big part of it.

We had a meeting of the Doctors Caucus this morning with the Surgeon General of the United States, a very impressive physician who we talked with him about trying to address this and using his national stage that he potentially has to address this problem. I have worked with--tried to work with the FDA, with the States, with physician organizations and many others. So this is a problem we are going to have to tackle, and I want to thank this subcommittee and the Chairman for bringing that--multiple hearings on that.

So the question I have, Dr. Agrawal, is, how much communication with the other agencies do you have, and is there the development of a plan that is coming together maybe

to address this problem knowing that really the big problem why you are being defrauded in Medicare Part D is because of the narcotics. I mean, that is the biggest problem. We all know it.

Dr. {Agrawal.} Thank you for the question. So I would highlight a few things. First, the Secretary of HHS has identified prescription drug abuse as a major priority for the Department, and there is a sort of three-part strategic approach to addressing this issue that the Department has taken on inclusive of all of its agencies. So one is exactly what you are describing, which is communication with the provider community to make sure that prescribing is appropriate, that utilization is appropriate. We are also looking at other facets, so medication-assisted therapy for substance abuse issues and the use of naloxone, for example, for emergent overdose issues.

CMS has a role to play in the broader kind of social landscape, and I think again, your point that this is not just a Part D issue but a kind of broader societal issue is exactly right. We are approaching it as a payer using every lever that we can from looking at prescribers to the

beneficiaries that might be abusing the program, identifies pharmacies that might be part of the problem and working very closely with plan sponsors. One even sort of broader partnership that I would point out is the Health Care Fraud Prevention Partnership where we are working with not just Part D or C plan sponsors but the private sector generally, a number of private payers, to look at these issues and others. So we have done, for example, an outlier pharmacy study with this public-private partnership, identified 8,000 pharmacies not just in the Part D world but also in the private just of pure private payer world that we are now looking at and working kind of individually. So I completely agree that partnership is at the center of this. We are trying various approaches to partnership to help ameliorate the issue.

Mr. {Bucshon.} Well, I mean, what does Anthem do, for example? I don't want to throw out any names but big insurance companies that pay for that are a payer, right? Because for the narcotics, if there is a funding stream, people are going to look to the funding stream to try to obtain these medications. I mean, that is just human nature.

Is there anything the private sector companies are doing

differently than maybe CMS is doing on that front?

Dr. {Agrawal.} Yeah, also an important question. So I think one of the advantages of the construct of the Part D program is that we do work through the private sector. So the common payers that you could identify are Part D plan sponsors, and so we are able to utilize the exact same tools and approaches that they have in their pure private side for the advantage of Medicare, whether it is--

Mr. {Bucshon.} So basically you are working through them. I know Medicare Part D works through plan sponsors. We have talked about that. So you are basically working through them and using their techniques to try to tackle this problem?

Dr. {Agrawal.} Correct, correct, in addition to the other things that we can do from an agency kind of federal leadership standpoint.

Mr. {Bucshon.} Okay. Thank you. I yield back.

Mr. {Murphy.} Mr. Green, you are recognized for 5 minutes.

Mr. {Green.} Thank you, and I want to thank both of you for being here today, and I want to take a few minutes to

talk about the recent successes in combating fraud and abuse in the Medicare program.

In June, HHS and the Department of Justice announced a sweep led by the Medicare Fraud Strike Force resulting in charges of 243 individuals for approximately $712 million in false billing. This was the largest takedown in the Strike Force history. More than 44 of the defendants arrested were charged with fraud related to the Medicare Part D program.

Ms. Maxwell, the Office of Inspector General was an integral part of this takedown. Can you tell me more about the OIG's role?

Ms. {Maxwell.} Absolutely. I would be happy to provide you more details about the national takedown.

As I mentioned, it is the largest criminal fraud takedown in the Medicare Strike Force history. About a third of the cases focused on Medicare Part D prescription drug fraud and also focused on Medicaid personal care services and Medicare home health. In particular, focused on the prescription drug, there were 44 defendants charged in related prescription drug fraud. We have--

Mr. {Green.} Go ahead. I was wondering, have those

gone to trial yet or is it too early?

Ms. {Maxwell.} Too early. So the takedown just happened last month, so we are still in the process of working through those.

Mr. {Green.} I understand the takedown involves a significant component of prescription drug fraud. Can you elaborate? Is this type of criminal fraud scheme increasing in prevalence in the Part D program?

Ms. {Maxwell.} Yes. We have seen an increase of 134 percent of our Part D cases. We have 540 pending cases in Part D alone.

Mr. {Green.} Okay. The Health Care Fraud and Abuse Control program, which funds the Medicare Fraud Strike Force, has recently seen record-breaking fraud and recovery efforts as well. In the fiscal year 2014 alone, the program recovered $3.3 billion from individuals and companies facing healthcare fraud allegations. Since its inception in 1996, the program has recovered $27.8 billion. The Affordable Care Act significantly increased funding for HCFAC, indexing the program's mandatory baseline and funding to inflation, providing over $3 million in additional funding.

Ms. Maxwell, how can we build on these successes in the future?

Ms. {Maxwell.} The HCFAC funding has been integral to the success of the OIG. It, as you mentioned, funds our Medicare and Medicaid operations both in investigations, audits and evaluations, and as we are looking at this Part D problem, that is the IG's approach. We have recognized this as a priority and we are taking an all-hands-on-deck approach. So we are using those funds to use all the tools available to the OIG to focus on this issue.

Mr. {Green.} The ACA provided new authorities to combat waste, fraud, and abuse such as enhanced penalties for fraudulent providers. Ms. Maxwell, how are these new ACA authorities assisting the Inspector General in successfully combating Medicare fraud?

Ms. {Maxwell.} The authorities have been incredibly helpful. We have been able to use our civil monetary penalty and exclusion authorities to help buttress and protect Medicare Part D.

Mr. {Green.} Okay. Dr. Agrawal, same question.

Dr. {Agrawal.} Yeah, the authorities in the ACA for CMS

have also been very significant. You know, what it did 5 years ago was, it embarked us on a pathway of enrolling every single provider and supplier that is in the program, subjecting them to common and consistent screening standards, which have led to over 500,000 enrollments now being deactivated or revoked. Bottom line is, they can no longer bill the program. So that kind of screening approach has been, I think, extremely effective. We have also obviously implemented other approaches along the way like the predictive analytic system that we described earlier to really augment these enrollment activities.

Mr. {Green.} Thank you, Mr. Chairman. I yield back.

Mr. {Murphy.} Thank you.

Mrs. Brooks is recognized next for 5 minutes.

Mrs. {Brooks.} Thank you, Mr. Chairman.

I am a former United States Attorney, and so have been involved in--used to be involved when I was in Medicare fraud type of cases, and so I do want to commend you for this huge, massive sweep that just happened.

I am curious if you could share a little bit more about--during the time I was U.S. Attorney, mortgage fraud was kind

of overtaking the country and we had massive schemes involving mortgage fraud. Now it seems that we have massive schemes involving Medicare fraud, and I am curious whether or not in these investigations you have found are there connections between the different communities, and are there schemes that are more commonly being utilized than others, particularly with prescription drug issues? And I would like both of you to comment as to, you know, how prevalent were the identity theft issues in these prescription drug cases as well, whether it was identity theft of the beneficiaries or identity theft actually of prescribers? And I am just curious whether or not you were seeing any sort of certain types of enterprises and certain types of patterns bubbling up in these cases?

Ms. {Maxwell.} Absolutely. We are seeing a wide range of fraud schemes emerging in Part D, certainly in the national takedown that just happened last month, and it can range from small physician or pharmacy to a full-on criminal enterprise.

One of the new schemes we have been seeing in the emergence of patient recruiters that go out and they are in

the community, trusted individuals in the community that bring patients in to these schemes and bring them in as complicit beneficiaries. The fraud schemes in the takedown, we focused primarily on pharmacy fraud, and we see--for one example we saw in Miami, five pharmacy owners were charged with paying for beneficiaries' numbers so they could illegally bill and also paying a clinic provider to provide them adulterated prescriptions to bill for drugs they did not dispense.

Mrs. {Brooks.} And so in these different schemes, particularly going back to the patient recruiters, were they also charged and were they conspiracy charges that were brought against these individuals? Do we have appropriate laws on the books to deal with all of the different actors in the schemes?

Ms. {Maxwell.} I know that we are going after the entirety of the scheme and all the people involved. I am not a lawyer, so I would want to get back to you with specifics about our authorities to combat this.

Mrs. {Brooks.} Okay. I would be very interested in knowing whether or not if as the schemes--and we found this

in the mortgage fraud issues of the 2000s, that people would be recruiting potential home buyers as well who really weren't going to be buying homes. And so I think we could see these kinds of schemes obviously happening here.

I am curious what DEA's role is, Dr. Agrawal. It is my understanding that you don't have authority to revoke licenses, that it has to go from DEA to a medical licensing board or to a pharmacy board. What is the type of work that you are doing with DEA and are there any impediments that you and/or DEA have with respect to revocation of licensing, which is a huge penalty for any pharmacist or any physician or prescriber?

Dr. {Agrawal.} Yes, I would agree with you that licensure either medical licensure or the specific, you know, schedule II authority that the DEA license gives you is incredibly important and valuable to, you know, legitimate prescribers. Those authorities, as you pointed out, are levied somewhere else, either at the State level and the State medical board or through DEE directly. But where we have really tried to get involved is making sure that our licensure information is up to date and that we are taking

the relevant downstream actions from any licensure changes, whether it is a suspension or revocation or whatever.

The rulemaking that we engaged in last year that I mentioned earlier actually specifically links our revocation authority to the DEA license, and needing to have a valid DEA license in place actually prescribed in the program. So that is a place--you know, I think these are examples of where we can key off the work of other agencies as they engage in their oversight and enforcement responsibilities.

Mrs. {Brooks.} Do you report anything to the licensing agencies of the States yourself?

Dr. {Agrawal.} We do. So we are able to make referrals informally to them about concerning prescribing habits, and we have done that. I think we see a wide degree of discrepancy between licensing boards that actually do something as a result versus not.

Mrs. {Brooks.} Okay. Thank you. I have nothing further. I yield back.

Mr. {Murphy.} Mr. Tonko, you are recognized for 5 minutes.

Mr. {Tonko.} Thank you, Mr. Chair.

This subcommittee held a number of hearings earlier this year to examine the current opioids abuse epidemic. Dr. Agrawal, you mentioned in your testimony that the epidemic has touched all parts of the Part D program. The spending for opioids has increased substantially over the past decade, and the number of prescription drugs overdose deaths is staggering, to say the least. We need to use all of the tools at our disposal to combat this problem.

Over the past several years, CMS has taken a number of steps to strengthen Medicare program integrity including measures to prevent overutilization of prescribed medications. In January 2013, CMS implemented the Medicare Part D Overutilization Monitoring System that requires plan sponsors to have a drug utilization management program in place.

So Dr. Agrawal, how does that system work so as to reduce potential opioid overutilization in the Part D program, and would authority from plan sponsors to put so-called pharmacy lock-in programs in place complement that system?

Dr. {Agrawal.} Sure. The way the system works is, the

agency identifies for plan sponsors those beneficiaries that have very high utilization of things like opioids using commonly accepted standards of, you know, sort of safety threshold. We provide those specific beneficiaries to the plan sponsors on a quarterly basis and then require them to take downstream utilization control steps including case management. What we have seen from the time that we have been doing this and working with plan sponsors in this way is a 30 percent reduction in the prevalence of those beneficiaries. So clearly, you know, impact is possible and we are looking to--and we continue to do this to ensure that we get as much impact as we can.

I think to the second question, you know, lock-in has been discussed, I think, quite a bit. We, you know, do view it as favorable and it does have, you know, good impact in the private sector as well as in various State Medicaid programs. It is part of the President's budget, and we look forward to working with this committee on getting that passed.

Mr. {Tonko.} And what is the role of the plan sponsors in identifying potential opioid overutilization?

Dr. {Agrawal.} Yeah, the plan sponsors have a critical role, you know, throughout Part D whether it is with opioids or other schedule II drugs, other medications generally. You know, I think that is why we have highlighted making sure that they have robust compliance programs in place, robust utilization programs in place so they can address a wide array of issues. We also engage in a lot of data sharing with them, both about abusive prescribers, abusive pharmacies, outlier beneficiaries. You know, this is a partnership really to ensure the integrity of the Part D program. The agency and Part D plan sponsors really have to work very closely together.

Mr. {Tonko.} And the system has been in place about 2 years. Is that correct?

Dr. {Agrawal.} The OMS system?

Mr. {Tonko.} Right

Dr. {Agrawal.} I think that is right, yes.

Mr. {Tonko.} Okay. And the data that are returning are showing great promise, I understand. Have you seen a reduction in the number of overutilizers in Part D?

Dr. {Agrawal.} Yeah, we have, so again, of the

beneficiaries that we have identified exceeding or meeting a certain safety threshold and that we have shared with plan sponsors. We have seen a 30 percent reduction or roughly 30 percent reduction in the prevalence of those beneficiaries.

We have also exchanged information about acetaminophen because it often is kind of coingested with opioids and is liver-toxic in and of itself, and there we have seen a 91 percent reduction in the prevalence of those at-risk beneficiaries.

Mr. {Tonko.} And you noted in your testimony that there are a number of additional tools in the President's 2016 budget. Those tools would prevent the inappropriate use of opioids. Can you elaborate on those offerings that he is presenting to us?

Dr. {Agrawal.} Sure. I think the main one that I can highlight we have discussed to some degree is the lock-in approach that would essentially restrict certain beneficiaries to, you know, based on kind of abusive utilization to select pharmacies and select prescribers, and that is an approach that has been utilized in the industry before. It is a way of trying to balance access to

appropriate care and medications against that potentially abusive behavior. So that is something that we view as potentially having significant positive impact, and we hope this committee and others help to work with us on that.

Mr. {Tonko.} Thank you.

And Ms. Maxwell, the OIG Data Brief noted that there has been substantial growth in spending in Part D drugs, especially for commonly abused opioids. How can the OIG's recommendations to combat fraud and abuse help combat this situation, this problem?

Ms. {Maxwell.} Similar to the conversation that you have just been having, we do recommend that a lock-in program be instituted to help address this problem.

Mr. {Tonko.} Thank you very much, Mr. Chair. I yield back.

Mr. {Murphy.} The gentleman yields back.

I now recognize the gentleman from Oklahoma, Mr. Mullin, for 5 minutes.

Mr. {Mullin.} Thank you, Mr. Chairman, and I thank both of you all for being here.

Doctor, I was just going over some of our notes on this,

and I was disturbed because we have talked before, and we have talked about the abuse of opioids--it is not going to come out. Anyways, we know what we are talking about.

Mr. {Murphy.} Opioids.

Dr. {Agrawal.} With narcotics.

Mr. {Mullin.} Thank you, narcotics. And not enough coffee today.

Anyways, as we were discussing, some statistics came up, and we noticed that Part D spends on average the beneficiaries around $105 per individual. In Oklahoma, we see that at $165 per individual enrolled in Part D. And 43 percent of those enrolled in that receive this drug that is commonly abused. Doesn't that seem a little high to you?

Dr. {Agrawal.} I think Part D is like any other sector of healthcare. We have seen the increasing use of opioid medications throughout healthcare, whether that is in the public sector or in the private, you know, and again, I think we have to be careful. I sort of take this as a physician to heart. There are people who have legitimate pain issues that need to be addressed with these powerful medications.

Mr. {Mullin.} But 43 percent enrolled in it in the

State of Oklahoma alone? I mean, that seems awfully high to me.

Dr. {Agrawal.} Yeah, I agree, you know, that number does seem high. You know, I think the question that is very difficult for anyone to answer is what portion of that is the totally legitimate utilization that you would expect to see.

Mr. {Mullin.} Well, in our previous hearing about Medicaid fraud and the addiction of these drugs, I asked you about the number of beneficiaries being prescribed methadone as a first line of defense, right? And then these numbers come out from last year, and by CMS's own recommendation, it says it shouldn't be used as a frontline defense. But yet, like I said, in Oklahoma, 43 percent of those enrolled in Part D beneficiaries are still receiving it. Abuse seems like it speaks for itself through numbers. As a business owner, I look at financial sheets all the time, especially when we would go in, we would go to purchase a company, I could look at the financial sheets and I could immediately tell you where the balances were messed up at, and what would do when we would see something like that is, we would cut that part out to make the company profitable again. If we

are seeing numbers like this, isn't it easy to say that until we get a hold of it, we should just cut it out? There are other drugs on the market. We don't have to be prescribing this stuff at the rate that we are. Until we understand it more or can oversee it in a better capacity, we should pull it. We do that all the time with drugs, don't we?

Dr. {Agrawal.} So, you know, I am not an addiction expert, and you know, I think--

Mr. {Mullin.} You don't have to be.

Dr. {Agrawal.} --there clearly is a role--

Mr. {Mullin.} The numbers speak for themselves. I don't know how many hearings we have had of this. We have even brought in a detective from Oklahoma that talked about it.

Dr. {Agrawal.} I think there is clearly a role for medication-assisted therapy in the substance abuse space. What we focus on rather than just eliminating a benefit for an entire group of people, some of whom might really actually need that benefit, is to try to cut away the waste, abuse, and fraud that may be occurring. So that is the role of things like the Overutilization Monitoring System that look

sat bennies--

Mr. {Mullin.} I get that, but just last year we still had 43 percent in Oklahoma prescribed to it. I can't get that out of my head. You can't convince me that nearly half of those on the Part D is needing these type of prescribed drugs when it is not supposed to be the first line of defense. It sounds like to me it is an easy way for them to just prescribe it and move on.

There is not enough research being done to make sure that it is not being abused. We are putting people on this and they are blindly taking it because their physician prescribes it to them and then they are becoming addicted to it. Is this not throwing up red flags? Is there not something that we can do at a more aggressive rate than just simply looking into it?

Dr. {Agrawal.} Well, Congressman, I think you are pointing out what I think the agency has been saying is that this is a multifaceted issue. So whether you are talking about the patient or--

Mr. {Mullin.} I know, but saying--

Dr. {Agrawal.} --prescriber--

Mr. {Mullin.} --is two different things.

Dr. {Agrawal.} Correct, and that is why we are focused on doing with all of these different programs that we have that look at prescribers, that look at beneficiaries getting the drugs. We have programs around data transparency to send information to prescribers about their own prescribing habits so they can see how it compares to others.

I think this is a complex problem. I am not sure that a single number is something that the agency can respond to because it really, you know, matters what is underneath that number, what is the appropriate utilization that you would like to see.

Mr. {Mullin.} And sir, I get that and I am out of time.

Thank you, Chairman, for indulging me there.

Mr. {Murphy.} The gentleman yields back.

I recognize Ms. Castor for 5 minutes.

Ms. {Castor.} Well, thank you, Mr. Chairman, for calling this hearing. I think it is an important time for us to take a hard look at Medicare Part D. We are about 10 years into the existence of the program. We have 42 million Americans who rely on the benefit. A lot of the

consternation goes with how it was constructed where you would get coverage and then you would reach a certain level of coverage and then fall off a cliff into a donut hole, and that made it very difficult for many of our neighbors to get the care that they need.

But thankfully, the Affordable Care Act has brought some significant reforms to Part D. Most important is closing the donut hole. As a result of the ACA, 9.4 million seniors and people with disabilities have saved over $15 billion on their prescription drugs, an average of about $1,600 per beneficiary.

And I wanted to pull up the statistics for the State of Florida and make sure they are on the record. Since 2010, overall savings for Florida's seniors under the Affordable Care Act now has been almost a billion dollars, $979 million, and in 2014, Florida's seniors saw savings of about $306 million. On average, that is about $884 back into their pocket of our older neighbors, so that has been very beneficial.

And just as important as the savings to our neighbors is the overall savings to the program. OMB has deemed Medicare

Part D a high error program, meaning it has an improper payment rate above a certain threshold, 3.3 percent, which amounts to $1.9 billion in improper payments, and we have got to save these dollars. So I really appreciate the work that the IG and CMS has been doing.

Clearly, we have to do more, and I want to compliment the Medicare Strike Force, especially for the June takedown. In Florida, they arrested about 73 people. South Florida has been a problem area, and I am going to get into a little bit more.

Ms. Maxwell, what is the explanation for the--I know you have said it multifaceted but break it down a little bit more. What is the explanation for the increasing cases of fraud nationwide?

Ms. {Maxwell.} I think as we have been talking, there is a lot of money at stake that is enticing, and we are continuing to build the tools to protect the program. Our role in that is multifaceted. As you had mentioned, we have investigations where we actually go out to try and catch criminals who are defrauding the program, but we also have a role to audit and evaluate and make sure that there are

systemic fixes. As I had mentioned in my oral, enforcement is never going to be enough. We need to look at the program as a whole and make sure that the plan sponsors have compliance programs in place to protect the program and that CMS also has strong resources to back that.

Ms. {Castor.} So your OIG report emphasizes two areas of opportunity to improve Part D program integrity, first, in the use of data to identify vulnerabilities, and second, an increased oversight by all parties responsible for protecting Part D, and I know this has to include the new emerging criminal networks, because what we saw in Florida, especially Miami, of people that have been convicted of drug trafficking had served their time, came out of prison and are now looking at Medicare Part D fraud. What can--what else do we need to be doing to combat these criminal networks, and explain to us what some of their schemes are under Part D?

Ms. {Maxwell.} Absolutely. I think one of the things that we are doing very successfully now and have continued to focus on are the Medicare strike forces in which we partner with CMS and other local and State law enforcement to stay on top of this fraud and address these emerging issues as they

hit the ground.

As you know, fraud is ever evolving, and so--

Ms. {Castor.} So one of the--I wish Mrs. Brooks was still here. She is a former U.S. Attorney. One of the weaknesses has been the penalties, the criminal penalties. Do you agree?

Ms. {Maxwell.} We could always--yes, we could strengthen our penalties.

Ms. {Castor.} Okay. And Dr. Agrawal, does CMS need specific direction to require all plan sponsors to report all fraud information rather than keeping it strictly voluntary?

Dr. {Agrawal.} Sure. So as I mentioned earlier, we are working to evolve the reporting that is both given to plan sponsors as well as what they give back to us. We have started by focusing on leads, investigative leads, for plan sponsors to develop and then take any necessary administrative actions on. We implemented an IT system called PLATO earlier this year for them to be able to--

Ms. {Castor.} My time has run out. Could you just say yes, that would be helpful if it was mandatory rather than voluntary?

Dr. {Agrawal.} I think it could be helpful to help--you know, to continue to evolve the program and evolve the relationship between the agency and plan sponsors.

Ms. {Castor.} Thank you.

Mr. {Murphy.} The gentlelady yields back.

Now Mr. Collins of New York.

Mr. {Collins.} Thank you, Mr. Chairman, and I want to thank my fellow committee members for the line of questioning we have had today.

So we had an interesting discussion, Dr. Agrawal, last time, if you remember, on Six Sigma Lean Six Sigma.

Dr. {Agrawal.} Yeah, I don't totally remember it as a discussion but we had that conversation, I guess.

Mr. {Collins.} So let me pick up. After that meeting, what did you think, do or say when you went back to your office? What did you think, do or say when you went home that night? And did you take anything positive out of that discussion or whatever you want to call it?

Dr. {Agrawal.} I think where there are ideas that benefit the program that we can implement differently to improve the integrity of Medicaid, of Part D and Medicare,

whatever the case may be, we take that input seriously, whether it comes from the committee, the OIG, the GAO, or others. So again, we take good ideas seriously and we work to implement them. It may not be instantaneous or overnight but the work is constant.

Mr. {Collins.} So afterwards, did you give any more thought to your 6.7 percent five-star error rate that you were at the FAA would allow 10 airplanes a week to crash and give yourself five gold stars or did you understand the tone of any of that and did you take any of that back to say oh, my God, a 6.7 fraud rate is not only not acceptable, it is certainly not a bell ringer to say you did a good job.

Dr. {Agrawal.} Yeah. You know, again, as I think we had communicated in that last discussion is, you know, we are not tone deaf and we understand that there is work to be done. I look at that error rate and, you know, recognize that it needs to come down. You know, nothing about that line of questioning sort of augmented or changed the recognition.

Mr. {Collins.} Did you change your 6.7 to something lower or is your error rate this year still 6.7?

Dr. {Agrawal.} Sir, that is measured on an annual basis. It is not going to change day to day.

Mr. {Collins.} See, being a private-sector guy, well, if I was your boss, how long do you think you would work for me?

Dr. {Agrawal.} Sir, I am certain misgivings about thinking about working for you.

Mr. {Collins.} As you should. As you should.

Dr. {Agrawal.} Let me be clear about something perhaps. So I came to this job just over--

Mr. {Collins.} That was funny, by the way.

Dr. {Agrawal.} Thank you. I appreciate it.

Look, I appreciate the message that you are trying to send and I appreciate the tone of the sort of last line of questioning last time. I think what I should have said then in response and what I say to you now is, I came to this job from the private sector. I have been a clinician. I have taken care of thousands of Medicare and Medicaid beneficiaries. My purpose is coming here was to help ameliorate, make progress on exactly these kinds of issues. I think what would be helpful is a collaborative approach.

If we can do that, if we can work together on devising solutions and getting them implemented, nothing would make me happier. I think merely pointing out that there is an error rate and kind of harping on it over and over doesn't help necessarily make that progress.

Mr. {Collins.} So, I mean, if you looked into Six Sigma Lean Six Sigma, as the county executive of the largest update county in New York that was effectively bankrupt when I took over, we took that county from number 62 to number one in 3 years. Three years after, I had 500 certified yellow belts, green belts, black belts, master black belts. My deputy county executive was a master black belt. We had so much money in our county 3 years in, we were paying cash for capital projects. We paid down $150 million of our county debt. We had $100 million county surplus in 3 years. Lean Six Sigma works but it starts with somebody at the top, in my case, the CEO of a county, but also it could be the head of quality control, the head of manufacturing, who comes in and says I don't want to accept 67,000 errors per million opportunities; I want zero, and I am going to measure that every day and I am going to chart that every day, and you

know what? I am going to send myself and I am going to send others to schools, to training to find out how to process map an error.

What Dr. Burgess pointed out, and I got one of these phone calls the other day too, I got one from American Express. There was a $25 innocuous charge. They said this looks like it could be fraud, and it turns out it was. That was 15 minutes after somebody put through that transaction. That is an organization that gets it. That is an organization that says we won't accept any errors, let alone 67,000.

So I guess as my time runs out, I would simply challenge you to dig into Lean Six Sigma more. It does work. It can be implemented in government but it starts with the person in charge, someone like yourself saying I just categorically reject the level of fraud or other errors and I am going to be proactive in finding out how to do it better, and I would just perhaps challenge you to look into this a little further.

And with that, I yield back.

Mr. {Murphy.} The gentleman yields back.

I now recognize Ms. Clarke for 5 minutes.

Ms. {Clarke.} Thank you, Mr. Chairman, and I thank our Ranking Member. I thank our witnesses. This is a very complex issue. There is no doubt about that. But the stakes are very high with respect to what is happening to the American people and the illicit prescription drug proliferation that is taking place in many parts of our Nation.

Ms. Maxwell, I think we all agree on the importance of ensuring drugs are prescribed and dispensed appropriately and legitimately. The Office of Inspector General's report suggests several ways to strengthen Part D program integrity efforts. The report recommends that CMS determine the effectiveness of programs and take action to ensure that sponsors' compliance plans meet CMS requirements.

So Ms. Maxwell, what more could be done to ensure that sponsors' fraud detection efforts are effective?

Ms. {Maxwell.} Our recommendations point to mandating the reporting of fraud and abuse that sponsors identify as well as mandating the reporting of what sponsors do with that. We believe that comprehensive reporting from all plans

would allow CMS the visibility and the tools to be able to assess the effectiveness of what is happening at the sponsor level.

Ms. {Clarke.} So that sounds like a logistical challenge, right? You have several sponsors. Right now they voluntarily make that information available. Can you drill down a little bit deeper in terms of systems that could be established that either trigger some sort of an action on the part of CMS or what would you suggest? Because if it is voluntary, you know, they are operating businesses, they are sponsors. How do you sort of hold them accountable in the course of the time that they are spending doing all the other activities that they need to do to run their companies?

Ms. {Maxwell.} Sure, and because they are required right now to report voluntarily, I would assume--and I would defer to Dr. Agrawal for the specifics--I would assume that there are processes for that reporting to happen. So the systems are in place. The question is, why isn't everyone using them. So when we look for the voluntary reporting, we only see 35 percent. So the other plans have capacity; they have just opted not to do the reporting.

Ms. {Clarke.} So Dr. Agrawal, is it an issue of at this stage voluntary just does not work and that it has to be a mandate?

Dr. {Agrawal.} Well, to answer your question, we have been working to enhance systems that allow plans to report data back to us. We implemented a major enhancement earlier this year that allows that data to not only be reported but also be kind of searchable so it can be utilized. What we have been doing is focusing on getting these plan sponsors better data about leads that they should be investigating and potentially taking action on. I think as we further that relationship, as we give them more data, we will be very interested in hearing back from them and perhaps in a mandate exactly what work that they have done. But we find that just by improving the system and improving the collaboration, we get better reporting.

Ms. {Clarke.} So baked into what you are saying is that there was an assumption that there was some misgivings or misunderstanding of what exactly the sponsors were to do to report voluntarily? Is that sort of where the thinking is?

Dr. {Agrawal.} Well, I think that sponsors like many

private companies have concerns about reporting data back, especially when it would be visible to other--you know, potentially visible to other plan sponsors. So one way that we have worked with them not just on the system enhancement side and making the process easier is, we actually allow them to report certain information deidentified of source. So they tell us a problematic pharmacy or problematic prescriber what they have done to take action against that entity or individual. But we are not--it is not necessarily clear to us which sponsor--or it can be sort of deidentified which sponsor put that in.

From a private-sector kind of competitive standpoint, that input made sense to us, and so we have taken as a step allowing them to input that kind of data so that we get better reporting about the actual problem, which is the fraud and abuse in the program.

Ms. {Clarke.} So that can be a double-edged sword, right? They don't want the information attributed to them on the basis of some sort of a proprietary disadvantage. Is that what you are saying?

Dr. {Agrawal.} Well, I think, you know, there is a

narrative that, you know, fraud and abuse just doesn't occur in the private sector. We have heard numerous committees kind of, you know, suggest that that is the case. I think, you know, you have programs like Part D which is conducted through the private sector and yet we see these problems. So, you know, I think what we have to do is get to a place where we are really doing the best we can to get all the right information from plans. As we develop that expertise, we can, you know, implement more stringent guidance, perhaps getting to the kind of mandate that OIG is requesting of us. But, you know, we are taking steps along that kind of evolutionary pathway.

Ms. {Clarke.} Let me ask, Dr. Agrawal, there is some troubling findings that the GAO report was reported in 2014. CMS conducted audits of Part D plan sponsors in 2013. Of the plans the agency audited, there were fraud, waste, and abuse findings in nearly all of the audits, 94 percent. Specifically, CMS found inadequacies in plan sponsors' compliance training, resolution of fraud, waste, and abuse inquiries in a timely manner, and corrective actions taken in response to potential fraud, waste, and abuse. These are

troubling findings, and I think it goes to my previous question. How does CMS evaluate the effectiveness of sponsors' compliance programs? Have these efforts changed recently? And what is CMS doing to follow up with the audited plans to ensure that these deficiencies are being remedied?

Dr. {Agrawal.} Thank you for the question. So we do conduct audits of--compliance audits of plan sponsors to make sure that they are compliant with our regulations, not only on the fraud, waste, and abuse but also, you know, obviously inclusive of their program integrity work.

Recently, we have stepped up the amount of both the volume of audits that we do as well as the focus in making sure that program integrity is part of those audits. Where is a deficiency identified, we work with them like we would any other contractor, which is we can send letters of concern, we can place them on corrective action plans. There is an array of tools to get contractors into compliance with our expectations.

Ms. {Clarke.} Thank you. I didn't realize I was so far over time. If you could send us something in writing--

Dr. {Agrawal.} Sure.

Ms. {Clarke.} --that outlines that, that would be helpful.

Thank you. I yield back.

Mr. {Murphy.} Thank you.

Mr. McKinley is recognized for 2 minutes.

Mr. {McKinley.} Thank you, Mr. Chairman. Again, I apologize. I had to step out. We have a pipeline safety issue downstairs in another committee, and we just had a fire in a pipeline last week, and I needed to be there for that.

But back on this panel, a few months ago we had a discussion here about one of the big problems here with opioids was overprescription, and I don't know that we came up with a solution how we are going to address that because I don't think we want Congress to be practicing medicine. But then we got into a discussion, I think it was with, Doc, and that was over getting the prescription database in real time across the country to be able to have that so that we might be able to track the abuse that is happening that way. Are we making any progress on that from either one of you? Can you address that issue?

Ms. {Maxwell.} The Inspector General has not done any work--you are talking about the prescription drug monitoring bases in the States, I take it?

Mr. {McKinley.} In States they have--it is not in real time, it is within a week they will file the information. But the problem of abuse is because it is in real time. Someone goes across the river into Ohio or West Virginia or Kentucky and they are abusing the system. We have been talking about that, my goodness, for at least years. I am just curious what progress we are making on that. We heard from the attorneys general who were all suggesting that is one of the best way we could make progress in abuse within our Part D. I haven't heard what progress we are making.

Dr. {Agrawal.} Yeah, so the implementation of PDMP, prescription drug monitoring programs, like the systems that you are describing are, you know, as you know, State-level initiatives. HHS has been involved in--

Mr. {McKinley.} They can only do it statewide. I am talking about interstate, and that is where the catch comes into it because so many of us are in border states that we can cross easily over to where population is generally on a

border. So help me out a little bit about where we are going from the federal. Is there a role for us to play? Because you mentioned earlier, Doc, you said we need a collaborative effort. I am looking to see what do you need from us to help out, to make this collaborative effort.

Dr. {Agrawal.} Yeah, that is a good question. So I think I would have to take that back in terms of, you know, the kind of interoperability issue that you are identifying or getting more States on board because as I mentioned, that is being done at the HHS level. There is less of a direct kind of CMS role in that set of activities. I am happy to take that back.

I will you from just sort of my experience as a clinician, you know, one way that States, you know, try to remedy this issue, and you see this sort of in the D.C., Maryland, Virginia area, is by encouraging providers to get access to numerous different databases. Now, it is not a perfect approach but I will tell you, I have utilized that approach in my own practice just to make sure that, you know, a patient or a beneficiary is not crossing States line to kind of game the system and get these medications.

Mr. {McKinley.} I have less than 2 minutes. Let me go back to another statement you made to the Congressman from New York.

You said we need to have more collaborative effort. What did you mean by that? Is there something we are not doing? Because our whole role here is to try to be supportive. So are we not being collaborative?

Dr. {Agrawal.} No, and, you know, I appreciate the question. The comment wasn't really about the committee as a whole or anything like that. I think it is, from my perspective, a certain tone of kind of questioning that I find to be less constructive, but it was not about the committee in general. In fact, I think there have been ideas exchanged in recent hearings and certainly even today that I think do demonstrate that kind of collaboration.

Mr. {McKinley.} In the last minute that I have, I remember the issue was over the 6.7 percent, but where do we think--I am just curious, where should it be? If not 6.7, should it be 3, 2? Where do you--and is that the goal? Are we making progress or is it--have we plateaued at 6.7 or has it risen to 6.7? I don't know the trends. I am just

curious. What can you share with us about the level of abuse?

Dr. {Agrawal.} Sure. So there is yearend variability in the number, and I think what the--there is two things that I think really have greatest impact on the number. One is, what are the requirements that we are implementing that either might be new requirements or that we are working to enforce more closely. What we find from a program integrity standpoint is that when there are new requirements or enforcement steps up, inherently the error rate tends to rise because even legitimate providers are not able to keep up with those changes. So it takes a period of education to actually get everybody into compliance. It then allows the trend to come back down.

Mr. {McKinley.} Is the trend rising or is the trend going down?

Dr. {Agrawal.} I don't have the figures in me. I mean, there is yearend change but we can get that to you.

Mr. {McKinley.} Let us say over the 15 years, has the trend, is it increasing or decreasing?

Dr. {Agrawal.} We can go back as far as the error rate

has been measured but we will share that with you.

Mr. {McKinley.} Thank very much.

Dr. {Agrawal.} Absolutely.

Mr. {McKinley.} I yield back my time.

Mr. {Murphy.} I think we all as Members have spoken here. There is a few things I want to just wrap up--oh, I am sorry. Mr. Griffith is here.

Ms. {DeGette.} And Mr. Bilirakis came in.

Mr. {Murphy.} Mr. Bilirakis is here too. Then we will go with Mr. Griffith for 5 minutes. I am sorry.

Mr. {Griffith.} That is all right. Thank you, Mr. Chairman.

Mr. {Murphy.} You snuck in on me.

Mr. {Griffith.} Mr. Chairman, first I would ask unanimous consent to insert into the record a statement from the National Community Pharmacists Association.

Mr. {Murphy.} Without objection.

[The information follows:]

********** COMMITTEE INSERT **********

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Mr. {Griffith.} Let me go to Mr. McKinley's question real quick, and I understand that, you know, maybe Maryland, D.C. and Virginia, you can check that, but there are some real difficulties from my district. If you count the Commonwealth of Virginia, you can actually, if you work it out really well, you could hit five States in a single day. So I do think we need to be looking at some way that doctors can check because you get town there in that little corner of Virginia and you are touching West Virginia, Kentucky, Tennessee and North Carolina all within a matter of, you know, 45 minutes to an hour. So you could--you would have to work it. You would have to be at the doorstep of somebody first thing in the morning but you could hit five States in a single day. So I would ask you to take a look at what Mr. McKinley raised.

Now, my question also is about the methodology used in the OIG report on questionable billing practices. We all want to stop these things. We want to stop folks from abusing the opioids, et cetera. As the five factors you used seemed cut and dried without much room for additional

consideration, my concern is that these results could present a broad generalization about pharmacies which may not paint the whole picture. For example, as I just described to you, I represent a fairly rural area, and that area has a higher percentage of senior citizens than the Nation as a whole. So a pharmacy might dispense a higher percentage of pain relievers when compared to other pharmacies in a different geographic or demographic area simply because there are not as many pharmacies around and perhaps the other pharmacies have a younger population that they serve.

It also would not be unreasonable to expect higher-- expect them to have a higher dispensation of controlled substance from a pharmacy located near a hospital or a surgery center or an oncology center. There are also pharmacies who are contracted providers for long-term care facilities and hospices. So how does CMS plan to address the results from the study that truly target the bad actors that we all want to get to without hitting the good guys who are just trying to serve their customers? And this came up earlier as a part of a complaint because one of my rural pharmacies has one supplier for their medicines, and at one

point they got cut off and so they were having to tell their customers yeah, I can't fill it today, come back at the end of the week when we change months. Well, that is hard if you are a senior citizen and you need that pain medication, and in fact, a friend of mine's wife was told that who had just gone through some surgery. She had to wait 3 days. They managed, but that is really not the way it ought to work, whether you would be in the urban areas in the northern part of Virginia, Maryland and D.C. or you are in southwest Virginia in the rural areas. How do we fix it?

Dr. {Agrawal.} Yeah, I think you make a good point. You know, this kind of data analysis is a starting point and, you know, I think as to the specific methodology, I will defer a bit to the OIG. But you know, data analysis is always the beginning point of our investigations. Now, I had shared earlier that on a month--on a quarterly basis, we send lists of concerning or high-risk pharmacies to Part D plan sponsors. Our methodology takes 16 variables into account, and in order for a pharmacy to make it onto the list, they have to be a statistical outlier in at least four of the variables. So the purpose there is to do exactly what you

are describing, which is try to bring a little more specificity to the methodology. But again, after that follows the investigation. I think it is really challenging unless the data is extremely cut and dry, which occurs in rare situations, to take administrative action without the ensuing investigation in between. That is where we really try to get to the bottom of, is something really bad happening here or is this just an outlier, but it is explained by certain geographic factors that you have identified.

Mr. {Griffith.} I appreciate it very much. I appreciate you all being here today. I apologize. I too have been--we have got pipeline issues as well, as you might imagine, and I was in the other hearing.

Mr. Chairman, I appreciate your time, and I yield back.

Mr. {Murphy.} The gentleman yields back.

I now recognize Mr. Bilirakis from the full committee for 5 minutes.

Mr. {Bilirakis.} Thank you, Mr. Chairman. I appreciate it. Thanks for holding the hearing. Thanks for allowing me to participate today.

Medicare Part D has been an important addition to the Medicare program, one of the most successful programs, I think, in the history of the Congress. It is a program that my constituents love and something that Congress should be proud of.

However, I have been concerned about the growing prescription drug problem in the United States and within the Medicare program. That is why in 2013 myself and our colleague, Ben Ray Lujan, first introduced the Medicare Part D Patient Safety and Drug Abuse Prevention Act, which would create a drug management program to prevent physician shopping and pharmacy shopping within the Medicare program. I am proud that we were able to include it in the 21st Century Cures bill that we passed last week.

It is important to the Medicare program to bring a commonsense provision that has been used in Medicaid, Tricare and commercial insurance. It also makes reforms to the MEDIC program in keeping with some of the OIG recommendations. That is the 21st Century Cures bill that makes those reforms.

The first question is for Ms. Maxwell. In your testimony, you talk about the need for a lock-in program in

Medicare Part D to deal with prescription drug abuse and the problem of drug diversion. Do you have any estimate on the size of the problem? How many people and how much money are being lost to prescription drug abuse?

Ms. {Maxwell.} I don't have those specific figures but I do have the figures in our Data Brief that the growth in prescribing opioids has been significant. It has been a 156 percent increase since the beginning of the program, which outpaces the growth in the general program. And so it is a continuing concern. We also have seen a tremendous increase in complaints against Part D so we have significant concerns about this. We do as a result recommend the lock-in. As you mentioned and as I think we have been talking about different ways to deal with doctor shopping, which can result either in patient harm or the diversion of opioids into the street. One way would be the PDMP to provide access to data around this issue and across State lines by the way is this lock-in, I mean specifically directed at that issue.

Mr. {Bilirakis.} Very good. Thank you.

Dr. Agrawal, I am sorry if I mispronounced. I just got here. In 2014, CMS issued rules for Part D and stated that

they had the authority to remove abusive prescribers from the Medicare program. Can you give me an update on this? How many abusive prescribers have been identified in the Medicare program and how many prescribers have been removed from the Medicare program?

Dr. {Agrawal.} Sure. So yes, you know, this is part of our overall approach to extending our enrollment requirements into Part D, so what we have been working on is getting prescribers enrolled. I think I mentioned earlier that there are 400,000 prescribers that have written prescriptions in Part D that we are working to enroll. We are also working to develop exactly the kind of cases that you are identifying, so through proactive data analysis, kind of starting to tee up these cases for the first time. I am not sure that we have conducted a specific revocation action using only that authority yet. Usually we try to do them in combination, and we may have added that authority to kind of another revocation action but I can look into whether there is a case that we uniquely utilized that authority.

Mr. {Bilirakis.} Thank you. One more question, Mr. Chairman.

Ms. Maxwell and Dr. Agrawal, when the MEDICs investigate a case and finish their investigation, I am assuming it is automatically referred to DOJ. Is that the case?

Ms. {Maxwell.} I believe they do make referrals as part of their requirements.

Mr. {Bilirakis.} Okay. If DOJ chooses not to pursue the case, maybe because of the view of the fraud is too small to be worth their time, does the information get automatically referred to State and local agencies or State licensing authorities? Can you answer that question?

Ms. {Maxwell.} I am not aware of that specific mechanism. I do know that we are concerned when law enforcement action doesn't take place, that there are no mechanisms and processes to refer it for recovery of the inappropriate payments.

Mr. {Bilirakis.} How about, are Part D plan sponsors provided updates by the MEDICs? How does the MEDIC work with local authorities and State licensing agencies?

Ms. {Maxwell.} Again, I am not familiar with the specifics. Perhaps Dr. Agrawal is--

Dr. {Agrawal.} Sure. So the MEDIC--I think this was in

the testimony--MEDIC provided 2,300 referrals to law enforcement over the last, I think it is 5 years. Obviously we try to refer as much over to law enforcement as we can that we think kind of meets the threshold for law enforcement activity and investigation.

Where law enforcement doesn't accept a case, we have a few options. We have shared information with State medical boards to try to get action on their part. We regularly share information with Part D plan sponsors. We do that on a routine basis as well as an ad hoc basis if new issues come up or there are new entities or individuals that become concerning.

I think the threshold of our authority currently, you know, there is the, you know, OIG recommendation around recovery of dollars that Ms. Maxwell discussed. I think there are certain limits in our authority that prevent us from going directly to, say, a pharmacy and requesting recovery of those dollars. We do have to work through Part D plans, but there are a variety of avenues to do just that.

Mr. {Bilirakis.} Very good. Thank you. Thank you, Doctor. Thank you, Ms. Maxwell. I appreciate it, Mr.

Chairman, and I yield back.

Mr. {Murphy.} Thank you. The gentleman yields back.

I do want to follow up. The committee sent a letter to CMS seeking information about the improper-payment rate and that response is due tomorrow. Will the committee receive that response tomorrow?

Dr. {Agrawal.} We have been working diligently on it. I think you will get the response tomorrow.

Mr. {Murphy.} Thank you. By the way, you seemed to suggest something earlier that the ACA is causing an improper-payment rate to rise. Is that--did we misunderstand that?

Dr. {Agrawal.} No. I don't know if this was perhaps your line of questioning. No. What I had said is that, you know, in the program integrity world, what we see often is that the improper-payment rate rises when there are new, stringent requirements that providers must meet, whether that is documentation requirements, enrollment requirements or other. So for example, the 6.7 rate that we discussed last time in Medicaid is largely driven by providers needing to enroll in Medicaid programs and States have adequate

resources and systems to conduct that enrollment activity. I don't think anybody doubts the importance of enrollment. We talked about that as one of the major levers that we are now implementing in Part D that I think will be quite useful. We have already seen its impact in the rest of Medicare. But like any other requirement or standard, it can be hard for providers to keep up and that can sometimes result in the improper-payment rate going up.

Mr. {Murphy.} All right. Well, we want you to continue to stay on that.

Ms. Maxwell, thank you so much. We do appreciate all that your offices do. It means a lot to this committee.

The next time we see you, Dr. Agrawal, I hope you will me a report that all those have been put into place. As you know, some have been sitting around for nearly 10 years, and that is just not acceptable. So we thank you.

I thank all the witnesses and Members who participated in today's hearing. I remind Members they have 10 business days to submit questions for the record. We will have a number of those and ask the witnesses to respond promptly to the questions.

And with that, this committee is adjourned.

[Whereupon, at 12:15 p.m., the subcommittee was adjourned.]