

**“THE OPIOID CRISIS:
THE CURRENT LANDSCAPE AND
CMS ACTIONS TO PREVENT OPIOID MISUSE”**

HEARING
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT
OF THE
COMMITTEE ON WAYS AND MEANS
U.S. HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS
SECOND SESSION

JANUARY 17, 2018

Serial No. 115–OS10

Printed for the use of the Committee on Ways and Means



U.S. GOVERNMENT PUBLISHING OFFICE

33–659

WASHINGTON : 2019

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**“THE OPIOID CRISIS:
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CMS ACTIONS TO PREVENT OPIOID MISUSE”**

WEDNESDAY, JANUARY 17, 2018

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON OVERSIGHT,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:00 a.m., in Room 1100, Longworth House Office Building, Hon. Lynn Jenkins [Chairman of the Subcommittee] presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS SUBCOMMITTEE ON OVERSIGHT

FOR IMMEDIATE RELEASE
Wednesday, January 17, 2018
OS-10

CONTACT: (202) 225-1721

Chairman Brady Announces Oversight Subcommittee Hearing on “The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse”

House Ways and Means Committee Chairman Kevin Brady (R-TX), announced today that the Oversight Subcommittee will hold a hearing on “The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse.” The hearing will focus on efforts by the Centers for Medicare & Medicaid Services (CMS) to utilize data to identify individuals in the Medicare Part D program who are at risk to abuse opioids. The hearing also will examine the extent of the problem as well as the tools CMS has available to prevent individuals from receiving unnecessary opioids. **The hearing will take place on Wednesday, January 17, 2018, in room 1100 of the Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, <http://waysandmeans.house.gov>, select “Hearings.” Select the hearing for which you would like to make a submission, and click on the link entitled, “Click here to provide a submission for the record.” Once you have followed the on-line instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Wednesday, January 31, 2018.** For questions, or if you encounter technical problems, please call (202) 225-3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TDD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available at <http://www.waysandmeans.house.gov/>

Chairman JENKINS. The Subcommittee will come to order. Welcome to the Ways and Means Oversight Subcommittee Hearing on the Opioid Crisis, the Current Landscape and CMS Actions to Prevent Opioid Misuse.

Good morning. I want to thank the panel for coming and welcome you all to today's hearing, the Opioid Crisis, the Current Landscape and CMS Actions to Prevent Opioid Misuse. Opioid abuse has devastated communities across America. In 2016, more than 42,000 Americans died due to opioids, a level that is five times what it was in 1999.

My home State of Kansas is no exception. In 2000, 35 overdose deaths were attributed to opioids. In 2016, 159 people died from opioid abuse in Kansas. Overdose deaths in America are on the rise largely due to opioids, which account for three out of every five overdose deaths. These numbers are startling, and yet many experts believe they are too low. And, unfortunately, this epidemic continues to get worse, which is why finding ways to address the problem is a high priority for this Committee.

No community is immune to the effects of opioid abuse. Rural communities are hit particularly hard, as they often have limited access to critical services and resources to support those struggling with addiction. The immense cost opioids impose on society as a whole cannot be overstated.

According to the Centers for Disease Control, opioids imposed an economic burden of \$78.5 billion in 2013. Much of this is due to increased substance abuse treatment cost, lost productivity, incarceration, and other burdens put on the criminal justice system. Last year, the President's Council of Economic Advisors estimated the cost to be even higher.

In order to address the opioid crisis, we need to understand what the current state of the problem is. We also need to understand what tools are in place to address this problem and how they can be improved. Today we will examine how the Centers for Medicare & Medicaid Services, or CMS, is working to address opioid misuse in the Medicare Part D program.

More than 42 million beneficiaries rely on the program for prescription drugs, including opioids. It is critical that Medicare and private Part D plan sponsors have the tools they need to ensure that opioids are provided only when medically necessary. We have a panel of experts that can talk about what CMS and the plan sponsors are doing to identify those most at risk so that appropriate interventions can be taken.

Our witnesses today should provide the Committee with valuable insights into how things are currently working and what can be done to improve them. The Committee plans to do more oversight

on this issue as we continue to examine other ways to reduce opioid abuse.

Before closing, I want to recognize that a lot of what we will be discussing today will be sanitized to some degree, simply through the use of numbers and statistics. I would like the record to reflect that the Members of this Committee know that there are real people, real families, and real experiences behind every number. That is why we are here today and we are devoting time to such a critical issue.

With that, I want to thank our witnesses, and I look forward to their testimony. I now yield to the distinguished Member from Washington, Ms. DelBene, for the purposes of an opening statement.

Ms. DELBENE. Thank you, Madam Chair. And thank you for holding this important hearing. I would like to thank our witnesses also for taking the time to be with us here today.

And I would like to acknowledge our Ranking Member, Neal, and thank him for being here today and joining us. But I want to start by congratulating our new Chair of the Subcommittee on Oversight. Clapping is appropriate. No, no, I said that is good. I know you are a certified public accountant, and were the 37th Kansas State Treasurer, both of which will be valuable for this Subcommittee in particular, as we look at IRS reforms.

I look forward to working with you on this and other things that are under the Subcommittee's jurisdiction, and I hope we'll continue to work in a bipartisan fashion on issues that are important to all of us, just like today's topics. So, thank you very much, and welcome to your new role. And I yield back.

Chairman JENKINS. Thank you. I now yield to the distinguished Ranking Member of the Full Committee, Mr. Neal, for the purposes of a statement.

Mr. NEAL. Thank you, Madam Chairperson. Everyone in this room has a family member or knows someone directly impacted by the opioid epidemic, somebody down the street, a neighbor, or we have all witnessed wrenching consequences of what this has done to families across the country. In Massachusetts, there were 2,094 confirmed opioid-related overdose deaths in 2016. Although overdose rates are highest for people 25 to 54, this public health emergency also affects Medicare beneficiaries.

According to a study recently from Altarum in November of 2017, the economic burden from opioids was estimated to be \$95 billion in 2016, \$21 billion of which was attributed to healthcare services, direct and indirect cost, and \$55.6 billion lost to earnings and productivity.

In 2016, one-third of Medicare Part D beneficiaries filled a prescription for opiates. For one-third of these beneficiaries, we know part of the consequence. This number is too high and we need to explore better ways to manage chronic pain. I hope that we can work in a bipartisan manner to urge the Centers for Medicare & Medicaid Services to move quickly to implement recommendations.

Congress and the Administration need to do more to help Americans access necessary treatment for opioid use disorders. The Administration's emergency declaration expires next week, but nothing at the moment has progressed. Yet, another missed opportunity

for positive action. The most significant step that has been taken in recent years to stem the tide of the opioid crisis has been to expand Medicaid under the ACA to low-income working Americans who previously could not afford insurance.

The Medicaid expansion has provided millions of previously uninsured adults with access to health insurance, which includes coverage for substance abuse and mental health services. For Medicare, the specific topic of today's hearing, we need to look to beneficiary's ability to access treatment, as oftentimes providers aren't available to meet the need. We know there are significant groups and gaps in the coverage and access under Medicare that need to be acknowledged.

For example, Medicare does not cover outpatient treatment programs that provide comprehensive opiate addiction treatments, nor does Medicare cover methadone for addiction, which is often the treatment of choice for long term addicts. We clearly have our work to do this year, and we need to stop undermining the programs that provide coverage and treatment for those who need it, instead, strengthening and improving access to care and coverage.

And another reflection, just off the talking points. What this has done to labor participation rates across the country is an under-reported story. When the Department of Labor recently indicated that there are six million jobs in America every day that go unanswered, and when you consider that there are two million people with opiate addictions that are sitting on the sidelines who could be working, that is another consequence of what has happened.

A number of people across America, who have opiate addictions, who are sitting home in the afternoon playing video games rather than in the workforce, ought to alarm all of us, and there ought to be something that we can all agree to in terms of the treatment needs of those very people. But this has a personal consequence for all of us as well, as I indicated in the first sentence. We all have a neighbor, friend, or a relative who is battling this addiction. And this ought to be well beyond the consequence of partisanship in this institution. We ought to be trying to find some remedies. And I yield back my time.

Chairman JENKINS. Thank you, Mr. Neal.

Without objection, other Members' opening statements will be made part of the record.

Today's witness panel includes three experts: Gary L. Cantrell, Deputy Inspector General for Investigations at the Department of Health and Human Services Office of the Inspector General; Elizabeth H. Curda, Director of Health Care at the Government Accountability Office; and Kimberly Brandt, Principal Deputy Administrator for Operations at the Centers for Medicare & Medicaid Services.

The Subcommittee has received your written testimonies, and they will be made part of the formal hearing record. You each have 5 minutes to deliver your oral remarks. We will begin with you, Mr. Cantrell. You may begin when you are ready.

**STATEMENT OF GARY L. CANTRELL, DEPUTY INSPECTOR
GENERAL FOR INVESTIGATIONS, OFFICE OF THE IN-
SPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS)**

Mr. CANTRELL. Thank you. Good morning, Chairman Jenkins and Ranking Member Neal, and other distinguished Members of the Subcommittee. I am Gary Cantrell, Deputy Inspector General for Investigations at HHS OIG, and I am excited to be here today to discuss efforts by the HHS OIG to combat the opioid epidemic in Federal healthcare programs.

Given a long history of healthcare fraud enforcement, program knowledge, and data analytics capabilities, OIG is uniquely positioned to help lead this fight against illegal opioid prescribing in Medicare and Medicaid.

My testimony today will highlight our work to prevent opioid-related fraud and abuse, detect questionable prescribing and billing patterns, and enforce laws and regulations governing opioid prescribing.

Opioid-related fraud encompasses a broad range of criminal activity, from prescription drug diversion to addiction treatment fraud. Many of these schemes involve kickbacks, medical identity theft, and criminal enterprises. Developing these investigations is complex, requiring the use of confidential informants, undercover operations, and surveillance to gather evidence of crimes often committed by corrupt doctors, pharmacists, and criminal networks. In the worst cases, our special agents uncover evidence of illegal prescribing leading to patient deaths.

Given the complexity and high stakes of these investigations, OIG's partnerships with DOJ, FBI, DEA, and State Medicare fraud control units is critical to the success of these efforts. OIG and our Medicare Fraud Strike Force partners led the 2017 national healthcare fraud take-down. This take-down was the largest ever healthcare fraud take-down, resulting in over 400 individuals charged; 120 of these defendants were charged for their roles in illegally prescribing and distributing opioids.

The enforcement operation brought together more than 1,000 Federal and State law enforcement personnel, including 350 OIG special agents. OIG has also shifted resources to support the Attorney General's Opioid Fraud and Abuse Detection Unit, a multi-agency effort capitalizing on data, with dedicated prosecutors and agents focused solely on prosecuting opioid fraud in the healthcare system.

OIG uses advanced data analytics to put timely, actionable information about prescribing, billing, and utilization trends in the hands of investigators, auditors, evaluators, and our government partners. A recent report identifying Medicare beneficiaries receiving extremely high amounts of opioids and questionable prescribing patterns demonstrates the value of this approach.

Of note, the report uncovered that half a million Medicare beneficiaries received opioids in excess of CDC guidelines. Further, nearly 90,000 beneficiaries are at serious risk of opioid misuse or overdose. Some of these received extreme amounts of opioids, over 2½ times the CDC recommended amounts, when others appear to be doctor shopping.

To get to the source of this extreme use, OIG identified about 400 prescribers with questionable opioid prescribing patterns for these beneficiaries at serious risk. OIG is following up on these outlier prescribers, and we have also shared this data with our public and private sector partners. This is one example of how we leverage our relationships and empower our partners to help us tackle this problem.

Recognizing the growing severity of the opioid epidemic, OIG has initiated work beyond Medicare. The work identifies opportunities to strengthen program integrity and protect at-risk beneficiaries across multiple HHS programs. For example, OIG audits and evaluations currently underway address the broad range of opioid-related funding and activity at HHS, including opioid prescribing in Medicaid, transfer prescription drug monitoring programs, FDA's oversight of opioid risk management program and addiction treatment services.

OIG's work holds criminals accountable and results in impactful recommendations to improve program integrity, save tax dollars, and protect HHS beneficiaries from harm. Key recommendations to combat opioid-related fraud and abuse are outlined in my written testimony.

In summary, OIG will continue to focus our multidisciplinary efforts on the opioid epidemic. We will identify opportunities to improve HHS prescription drug and treatment programs, share data and educate the public, and identify and hold accountable perpetrators of opioid-related fraud.

I appreciate the opportunity to speak with you today, and I would be happy to answer any questions.

[The prepared statement of Mr. Cantrell follows:]



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

**Testimony Before the United States House of Representatives
Committee on Ways and Means
*Subcommittee on Oversight***

**The Opioid Crisis: The Current Landscape and
CMS Actions to Prevent Opioid Misuse**

Testimony of:

Gary Cantrell
Deputy Inspector General for Investigations
Office of Investigations
Office of Inspector General
Department of Health and Human Services

**January 17, 2018
10:00 a.m.**

Location: Longworth House Office Building, Room 1100

Testimony of: **Gary Cantrell**
 Deputy Inspector General for Investigations
Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Chairman Jenkins, Ranking Member Lewis, and distinguished members of the Subcommittee. I am Gary Cantrell, Deputy Inspector General for Investigations with the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG). I appreciate the opportunity to appear before you to discuss how OIG is combatting the opioid crisis in Federal health care programs.

OIG's mission is to protect the integrity of HHS programs and the health and welfare of the people they serve through prevention, detection, and enforcement. To accomplish our mission, OIG uses data analytics and real-time field intelligence to detect and investigate program fraud and to focus our resources for maximum impact. We are a multidisciplinary organization comprised of investigators, auditors, evaluators, analysts, clinicians, and attorneys. In addition, we depend on strong public and private partnerships to ensure coordinated enforcement success. OIG has identified curbing the opioid epidemic as one of the Department's Top Management and Performance Challenges in 2017. Key components of that challenge include addressing inappropriate prescribing of opioids, inadequate access to treatment, and misuse of grant funds as well as combatting fraud by treatment providers of opioid use disorders and diversion of prescription opioids and potentiator drugs.¹

OIG has a longstanding and extensive history of enforcement and oversight work focused on prescription drug fraud, drug diversion, pill mills, medical identity theft, and other schemes that put people at risk of harm. Several years ago, OIG detected—and began taking action to address—a rise in fraud schemes involving opioids, as well as associated potentiator drugs. In addition to increasing our investigative efforts to combat prescription drug abuse, we have responded to the growing severity of the opioid epidemic by focusing on work that identifies opportunities to strengthen program integrity and protect at-risk beneficiaries. OIG uses advanced data analytics tools to put timely, actionable data about prescribing, billing, and utilization trends and patterns in the hands of investigators, auditors, evaluators, and government partners. Our goal is to identify opportunities to improve HHS prescription drug programs to reduce opioid addiction, share data and educate the public, and identify and hold accountable perpetrators of opioid-related fraud.

In my testimony today, I will highlight law enforcement activities led by my Office of Investigations and discuss OIG's current efforts to combat opioid-related fraud, waste, and abuse. I also will highlight key OIG recommendations that would, if implemented, have a positive impact on the opioid problem.

OIG'S OFFICE OF INVESTIGATIONS TARGETS FRAUD, WASTE, AND ABUSE

OIG's Office of Investigations has investigators covering every State, the District of Columbia, Puerto Rico, and other U.S. territories. We collaborate with other Federal, State, and local law enforcement authorities to maximize our impact. Special Agents in our Office of Investigations

¹ Drugs that enhance the high or euphoria when combined with controlled substances.

have full law enforcement authority and use a broad range of investigative actions, including the execution of search and arrest warrants, to accomplish their mission. OIG and its law enforcement partners combine resources to detect and prevent health care fraud, waste, and abuse. During the last 3 fiscal years (FYs 2015 to 2017), OIG investigations have resulted in more than \$10.8 billion in investigative receivables (dollars ordered or agreed to be paid to Government programs as a result of criminal, civil, or administrative judgments or settlements); 2,650 criminal actions; 2,211 civil actions; and 10,991 program exclusions.²

Much of this work involves the Medicare and Medicaid programs and is funded by the Health Care Fraud and Abuse Control Program (HCFAC). The HCFAC provides funding resources to the Department of Justice (DOJ), HHS, and OIG, which are often used collaboratively to fight health care fraud, waste, and abuse. Since its inception in 1997, the HCFAC has returned more than \$31 billion to the Medicare trust fund. OIG is a lead participant in the Medicare Fraud Strike Force, which combines the resources of Federal, State, and local law enforcement entities to fight health care fraud across the country. Finally, OIG collaborates with State Medicaid Fraud Control Units (MFCUs) to detect and investigate fraud, waste, and abuse in State Medicaid programs.

THE OPIOID CRISIS

Opioid use is a rapidly growing national health care problem, and our Nation is in the midst of an unprecedented opioid epidemic.³ More than 50,000 Americans died from drug overdoses in 2015, of which 63 percent reportedly involved opioids.⁴ Deaths from prescription pain medication remain far too high, and in 2014, the most recent year on record, there was a sharp increase in heroin-involved deaths and an increase in deaths involving synthetic opioids such as fentanyl.⁵ According to the Centers for Disease Control and Prevention (CDC), approximately three out of four new heroin users report having abused prescription opioids prior to using heroin. Prescription drug diversion—the redirection of prescription drugs for an illegal purpose—is a serious component of this epidemic.

OIG'S OPIOID FRAUD ENFORCEMENT EFFORTS

Opioid fraud encompasses a broad range of criminal activity from prescription drug diversion to addiction treatment schemes. Many of these schemes can be complex, involving complicit patients or beneficiaries who are not ill, kickbacks, medical identity theft, money laundering, and criminal enterprises. The schemes also involve multiple co-conspirators and health care professionals such as physicians, nonphysician providers, and pharmacists. These investigations

² OIG has the authority to exclude individuals and entities from federally funded health care programs. The effect of an exclusion is that no payment will be made by any Federal health care program for any items or services furnished, ordered, or prescribed by an excluded individual or entity. No program payment will be made for anything that an excluded person furnishes, orders, or prescribes.

³ Centers for Disease Control and Prevention, *Prescription Painkiller Overdoses at Epidemic Levels* [press release], Nov. 1, 2011.

⁴ Executive Office of the President, The Council of Economic Advisors, *The Underestimated Cost of the Opioid Crisis*

⁵ Health and Human Services, *The Opioid Epidemic: By the Numbers* [Fact Sheet], June 2016.

can be complex and often involve the use of informants, undercover operations, and surveillance.

2017 National Health Care Fraud Takedown

OIG and our Medicare Strike Force partners led the 2017 National Health Care Fraud Takedown. The Takedown was the largest ever health care fraud enforcement action, resulting in 412 charged defendants across 41 Federal districts, including 115 doctors, nurses, and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately \$1.3 billion in false billings. Over 120 defendants, including doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.⁶ OIG also announced 295 opioid-related exclusions. The enforcement operation brought together more than 1,000 Federal and State law enforcement personnel, including 350 OIG Special Agents and 30 MFCUs.

Case Examples

The following are cases our agents have investigated. These case examples highlight opioid fraud schemes related to prescriber fraud, pharmacy fraud, and treatment/drug-testing fraud:

Prescriber Fraud

- Dr. Jaime Guerrero, an anesthesiologist in Kentucky, pled guilty to knowingly and intentionally distributing and dispensing Schedule II and III controlled substances to patients without a legitimate medical purpose. In one instance, Guerrero's distribution and dispensing of hydrocodone caused the death of one of his patients. Guerrero also pled guilty to three counts of health care fraud for fraudulently billing various health care benefit programs and for submitting fraudulent claims for patient health care counseling. Guerrero was sentenced to more than 8 years of imprisonment, agreed to pay \$827,000 in restitution to nine health care benefit programs, and forfeited his medical license and real property.
- In Pennsylvania, Dr. William J. O'Brien III worked with Pagan's Motorcycle Club, an outlaw gang known for violence and drug dealing, to operate a "pill mill" out of his medical offices. O'Brien wrote fraudulent prescriptions for oxycodone and other drugs, while the Pagans recruited "pseudo-patients" to buy the fraudulent prescriptions. After filling the prescriptions, the Pagans resold the pills on the street. O'Brien distributed more than 700,000 pills containing oxycodone and other Schedule II controlled substances in furtherance of the conspiracy. O'Brien was sentenced to 30 years of imprisonment and ordered to pay \$5.3 million in restitution.

Pharmacy Fraud

- Babubhai Patel was a licensed pharmacist who either owned or controlled 26 pharmacies in Michigan. Patel concealed his ownership and control over many of his pharmacies

⁶ Department of Justice, *National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for \$1.3 Billion in Fraud Losses*, July 2017.

through the use of straw owners. Patel offered and paid kickbacks, bribes, and other inducements to prescribers in exchange for their writing fraudulent opioid prescriptions for patients with Medicare, Medicaid, and private insurance and directing the patients to fill their prescriptions at one of Patel's pharmacies. Patel and his pharmacists billed Medicare and other insurers for dispensing the medications despite the fact that the medications were medically unnecessary and/or were never provided. Patel's pharmacies dispensed approximately 250,000 doses of OxyContin, 4.6 million doses of Vicodin, 1.5 million doses of Xanax, a potentiator drug, and 6,100 pint bottles of codeine cough syrup. Patel's pharmacies falsely billed Medicare and Medicaid approximately \$57.8 million for medications purportedly provided to beneficiaries over the course of the scheme. Patel was sentenced to 17 years of imprisonment and ordered to pay \$18.9 million in joint and several restitution.

- Michigan pharmacist Nadeem Iqbal owned and operated two pharmacies that he used to illegally distribute more than 200,000 doses of opioid medications such as OxyContin, oxycodone, and hydrocodone as part of a diversion scheme that billed the Medicare and Medicaid programs. Iqbal filled prescriptions for "runners" who presented as many as 25 prescriptions at a time for patients. The diverted opioids were later sold on the street for profit. Iqbal also tried to maintain a ratio of 70 percent noncontrolled prescriptions to 30 percent controlled prescriptions to avoid detection. Iqbal was sentenced to more than 4 years of imprisonment and ordered to pay over \$1.6 million in restitution.

Treatment/Drug Testing Fraud

- In a Massachusetts case worked with our MFCU partners, Dr. Punyamurtula Kishore and his company, Preventive Medicine Associates, Inc., pled guilty to charges of Medicaid kickbacks, Medicaid false claims, and larceny. Dr. Kishore owned and managed a network of 29 medical branches throughout Massachusetts under Preventive Medicine Associates and engaged in a complex scheme to pay bribes and kickbacks to induce sober homeowners to have their residents use his labs for drug screening of their urine samples. Drug screens are generally billed to the Massachusetts Medicaid program, MassHealth, for approximately \$100 to \$200. Dr. Kishore manipulated his business relationships with owners of sober homes to illegally obtain tens of thousands of drug screens paid for by MassHealth for sober house residents who were never treated by Preventive Medicine Associates providers. Kishore was sentenced to serve 11 months of imprisonment followed by 10 years of probation and ordered to pay \$9.3 million in restitution.
- In Virginia, OIG worked with our MFCU partners on a case involving the owners of a drug-screening lab for testing urine samples and an addiction practice who were engaged in a scheme to bill for unnecessary drug-screening tests of urine samples. Beth Palin and Joseph Webb owned Bristol Labs and Mtn. Empire Medical Care and used the businesses to bill expensive, medically unnecessary tests to insurance companies. At the facilities, uninsured or "self-pay" patients received a \$25 dip-stick or "quick cup" drug screen of a urine sample from Bristol Labs. However, if a patient was paying through insurance, Medicaid, or Medicare, Bristol Labs performed two separate, automated screens. These patients paid nothing out of pocket; however, Medicare, Medicaid, or their insurance

company would be billed between \$120 and \$1,800 for the tests each week. The tests were medically unnecessary, and the results of the tests were not used to direct patient care. The conspiracy fraudulently billed the Virginia Medicaid program, the Tennessee Medicaid program (TennCare), Medicare, and other insurers for medically unnecessary urine screens. Palin and Webb were both sentenced to 3 years of imprisonment and ordered to pay more than \$1.4 million in restitution.

OIG'S EFFORTS TO COMBAT THE OPIOID EPIDEMIC GO BEYOND ENFORCEMENT

Data Analytics

The OIG, including the Office of Investigations and OIG's Chief Data Office, use data analytics to detect and investigate health care fraud, waste, and abuse. Our Chief Data Office analyzes billions of data points and claims information to identify trends that may indicate fraud, geographical hot spots, emerging schemes, and individual providers of concern. At the macro level, OIG analyzes data patterns to assess fraud risks across Medicare services, provider types, and geographic locations to prioritize and deploy our resources. At the micro level, OIG uses data analytics, including near-real-time data, to identify potential fraud suspects for a more in-depth analysis and efficiently target investigations.

OIG Data Brief

In July 2017, OIG released a data brief entitled *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*⁷ in conjunction with the 2017 National Health Care Fraud Takedown. We found the following:

One in three Medicare Part D beneficiaries received opioids in 2016. In total, 14.4 million beneficiaries received an opioid prescription that year.

Approximately 500,000 beneficiaries received high amounts of opioids. To identify these beneficiaries, OIG looked at the morphine equivalent dose (MED) received by each beneficiary, which equates all of the various opioids and strengths into one standard value. Beneficiaries who received high amounts of opioids had an average daily MED greater than 120 mg for at least 3 months in 2016. A daily MED of 120 mg is equivalent to taking 12 tablets a day of Vicodin 10 mg or 16 tablets a day of Percocet 5 mg. These dosages far exceed the amounts that the manufacturers recommend. Beneficiaries with a cancer diagnosis and those enrolled in hospice were excluded from the analysis. Although beneficiaries may receive opioids for legitimate purposes, these high amounts raise concern due to the health risks associated with opioids.

OIG identified nearly 90,000 beneficiaries at serious risk of opioid misuse or overdose. OIG identified two groups of beneficiaries at serious risk of opioid misuse or overdose: (1) beneficiaries who received extreme amounts of opioids and (2) beneficiaries who appeared to be

⁷ OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, OEI-02-17-00250, July 2017.

“doctor shopping.”⁸ OIG identified 69,563 beneficiaries who received extreme amounts of opioids. They each had an average daily MED of more than 240 mg for the entire year.

OIG also identified 22,308 beneficiaries who appeared to be doctor shopping. They each received high amounts of opioids and had four or more prescribers and four or more pharmacies for opioids. While some of these beneficiaries may not have been doctor shopping, receiving opioids from multiple prescribers and multiple pharmacies may still pose dangers from lack of coordinated care. Typically, beneficiaries who receive opioids have just one prescriber and one pharmacy.

OIG identified about 400 prescribers with questionable opioid prescribing patterns for beneficiaries at serious risk. In the data brief, a total of 401 prescribers stood out as having questionable prescribing patterns; they ordered opioids for the highest numbers of beneficiaries at serious risk (i.e., those who received extreme amounts of opioids or appeared to be doctor shopping). In total, prescribers with questionable billing patterns wrote 265,260 opioid prescriptions for beneficiaries at serious risk, costing Part D a total of \$66.5 million.

Although some patients may legitimately need high amounts of opioids, questionable prescribing patterns can indicate that prescribers are not checking State databases that monitor prescription drugs, or that they are ordering medically unnecessary drugs that may be diverted for resale or recreational use. Another possibility is that the prescriber’s identification was sold or stolen and is being used for illegal purposes. Questionable patterns also raise significant concern that prescribers may be operating “pill mills.” A pill mill is a doctor’s office, clinic, or health care facility that routinely prescribes controlled substances—such as oxycodone—outside the scope of professional practice and without a legitimate medical purpose.

Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. Prescribers play a key role in combatting opioid misuse. They must be given the information and tools needed to appropriately prescribe opioids when medically necessary. States’ prescription-drug-monitoring programs can provide invaluable information to prescribers about a patient’s opioid prescription history. Prescribers must be vigilant about checking the State monitoring databases to ensure that their patients are receiving appropriate doses of opioids and to better coordinate patient care. At the same time, the Department must address prescribers with questionable prescribing patterns for opioids to ensure that Medicare Part D is not paying for unnecessary drugs that are being diverted for resale or recreational use.

Additional OIG Efforts Currently Underway

OIG is expanding our portfolio of audits and evaluations addressing opioid issues by focusing on work that identifies opportunities to strengthen program integrity and protect at-risk beneficiaries across multiple departmental programs. OIG currently has seven opioid-related audits or evaluations underway. They address the following issues:

⁸ Other beneficiaries may also be at serious risk of opioid misuse or overdose, but they were not the focus of this data brief.

- questionable prescribing patterns in Medicaid;
- Medicaid program integrity controls;
- CDC's oversight of grants to support programs to monitor prescription drugs;
- the Food and Drug Administration's oversight of opioid prescribing through its risk management programs;
- the Substance Abuse and Mental Health Services Administration's oversight of opioid treatment program grants;
- beneficiary access to buprenorphine medication-assisted treatment; and
- opioid prescribing practices in the Indian Health Service.

Additionally, OIG is developing a toolkit that a variety of health care entities, such as insurers and enforcement organizations, can use to analyze opioid claims data to identify patients at risk of opioid misuse. We will also continue our efforts to educate communities, providers, patients, private plans, and others on how to detect fraud and abuse related to the opioid crisis.

OIG MAXIMIZES IMPACT THROUGH STRONG COLLABORATION WITH PUBLIC AND PRIVATE PARTNERS

In addition to Strike Force operations and other government collaborations, OIG engages with private sector stakeholders to enhance the relevance and impact of our work to combat health care fraud, as demonstrated by our leadership in the [Healthcare Fraud Prevention Partnership \(HFPP\)](#) and collaboration with the [National Health Care Anti-Fraud Association \(NHCAA\)](#). OIG strives to cultivate a culture of compliance in the health care industry through various educational efforts, such as Pharmacy Diversion Awareness Conferences, public outreach, and consumer education.

Medicare Fraud Strike Force

The Strike Force effort began in Miami in March 2007 and has expanded operations to eight additional cities. Strike Force teams effectively harness the efforts of OIG and DOJ, including Main Justice, U.S. Attorneys' Offices, and the Federal Bureau of Investigation (FBI), as well as State and local law enforcement, to fight health care fraud in geographic hot spots.

The Strike Force teams use near-real-time data to pinpoint potential fraud hot spots and identify aberrant billing. This coordinated and data-driven approach to identify, investigate, and prosecute fraud has produced significant results, highlighted by the July 2017 National Health Care Fraud Takedown. Since its inception in March 2007, the Strike Force has charged more than 3,000 defendants who collectively billed the Medicare program more than \$10.8 billion.

Collaboration with the Department

OIG collaborates with a number of HHS agencies, including the Centers for Medicare & Medicaid Services (CMS) and the Agency for Community Living (ACL), on fraud and opioid-related initiatives. OIG collaborates with CMS and ACL to educate providers, the industry, and beneficiaries on the role each one plays in the prevention of prescription drug and opioid-related fraud and abuse. We share our analytic methods and data analysis with CMS and work together

to identify mitigation strategies and develop follow-up approaches to deal with the prescribers and at-risk beneficiaries identified. OIG engages ACL's Senior Medicare Patrol and State Health Insurance Assistance Program through presentations on the prevention of fraud, waste, and abuse.

Opioid Fraud and Abuse Detection Unit

OIG provided critical support in the establishment of the new Opioid Fraud and Abuse Detection Unit established by the Attorney General in collaboration with OIG, FBI, and Drug Enforcement Administration (DEA). The unit focuses specifically on opioid-related health care fraud using data to identify and prosecute individuals who are contributing to the opioid epidemic. This collaboration led to the selection of 12 judicial districts around the country where OIG has assigned Special Agents to support 12 prosecutors identified by DOJ to focus solely on investigating and prosecuting opioid-related health care fraud cases. Each of the 12 districts is supported by OIG, FBI, and DEA.

The Healthcare Fraud Prevention Partnership and the National Healthcare Anti-Fraud Association

The HFPP and NHCAA are public-private partnerships that address health care fraud by sharing data and information for the purposes of detecting and combatting fraud and abuse in health care programs. OIG is an active partner in these organizations and frequently shares information about prescription-drug fraud schemes, trends, and other matters related to health care fraud.

Pharmacy Diversion Awareness Conferences

OIG has collaborated with the Drug Enforcement Administration to provide anti-fraud education at numerous Pharmacy Diversion Awareness Conferences held across the United States. The conferences were designed to assist pharmacy personnel with identifying and preventing diversion activity. Since 2013, OIG has presented at conferences in 50 States and Puerto Rico.

TOP OIG RECOMMENDATIONS FOR CMS RELATED TO THE OPIOID CRISIS

Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. It is necessary to address prescribers with questionable prescribing patterns for opioids to ensure that Medicare and Medicaid do not pay for unnecessary drugs that are harming beneficiaries or being diverted for resale or recreational use.

- 1) Restrict certain beneficiaries to a limited number of pharmacies or prescribers.

OIG recommends that CMS encourage implementation of the new Medicare Part D beneficiary lock-in authority under the Comprehensive Addiction and Recovery Act of 2016 (CARA). Lock-in would restrict certain beneficiaries to a limited number of pharmacies or prescribers when warranted and reduce inappropriate use of opioids among Medicare

beneficiaries and Part D fraud. This policy would provide coordination of care for beneficiaries being harmed by overprescribing and address beneficiaries who are doctor shopping or intentionally seeking unnecessary prescriptions.

2) Expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse.

Drug utilization reviews are intended to protect beneficiaries and reduce fraud, waste, and abuse. However, CMS's requirements for these reviews apply only to certain types of drugs. We recommend that CMS and plan sponsors monitor beneficiary utilization for a wider range of drugs susceptible to abuse than they currently do. In particular, we recommend expanding sponsors' and CMS's drug utilization reviews to cover certain noncontrolled substances such as HIV and antipsychotic medications that are used in combination with opioids as potentiators.

3) Require plan sponsors to report to CMS all potential fraud and abuse and any corrective actions they take in response.

CMS should collect comprehensive data from Part D plan sponsors to improve its oversight of their program integrity efforts, including the diversion of opioids for illegitimate use. Sponsors serve as the first line of defense against opioid fraud, waste, and abuse in Part D as they are responsible for paying claims and monitoring billing patterns. However, there is currently a lack of transparency on how Part D sponsors identify and investigate these matters.

4) Improve Medicaid data.

CMS does not have complete and accurate data needed to effectively oversee the Medicaid program, including opioids. Without accurate claims data, adequate oversight of the Medicaid program is compromised. OIG has a history of work that points to the incompleteness and inaccuracy of CMS's national Medicaid database, the Transformed Medicaid Statistical Information System (T-MSIS). Without a national dataset, CMS, States, and OIG are unable to identify nation-wide trends and vulnerabilities. This hampers program integrity efforts because fraud does not respect State boundaries. OIG recommends that CMS establish a deadline for when national T-MSIS data will be available for multistate program integrity efforts.

CONCLUSION

OIG has made combatting the opioid crisis a top enforcement and oversight priority. We will continue to leverage our analytic, investigative, and oversight tools, as well as our partnerships in the law enforcement and program integrity communities and with the Department to maximize our efforts. OIG will remain vigilant in following and investigating emerging opioid fraud trends, especially schemes involving patient harm and abuse.

Chairman JENKINS. Thank you, Mr. Cantrell. Ms. Curda, you are recognized for 5 minutes.

STATEMENT OF ELIZABETH H. CURDA, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE (GAO)

Ms. CURDA. Good morning, Chairman Jenkins, Ranking Member Neal, and Members of the Subcommittee. I am pleased to be here to discuss our report on the Centers for Medicare & Medicaid Services oversight of opioid prescribing in the Medicare program. Overprescribing and misuse of prescription opioids has led to significant increases in opioid use disorder, overdoses, and deaths in the United States.

Recognizing this, CMS developed an opioid misuse strategy with a goal to reduce harm from opioid misuse in its programs. Today I will discuss how CMS oversees opioid prescribing under Medicare Part D, both in terms of the beneficiaries who receive opioid prescriptions, as well as the providers who prescribe them.

To oversee beneficiaries, CMS relies on private insurers, known as plan sponsors, to monitor and take appropriate action to address potential opioid overuse. CMS employs an overutilization monitoring system to alert plan sponsors about very high-risk beneficiaries. These are beneficiaries receiving high doses of opioids from four or more providers and pharmacies or from six or more providers regardless of the number of pharmacies. Excluding cancer and hospice care, about 33,000 beneficiaries met these criteria in 2015. Plan sponsors are expected to review a quarterly list of identified beneficiaries, determine appropriate action, and then respond to CMS with information on their actions within 30 days.

The use of these criteria, along with plan sponsor actions, has helped to significantly reduce the number of these very high-risk cases.

However, CMS oversight does not address the over 700,000 beneficiaries potentially at risk of harm, based on CDC guidelines. These guidelines note that long-term use of opioid doses over 90 milligrams morphine equivalent per day are associated with significant risk of harm and should be avoided unless a provider determines that it is necessary.

This is particularly the case for patients aged 65 and older, because the drugs can more easily accumulate in the body to toxic levels. We recommended that CMS gather information on the total number of these beneficiaries over time to help assess progress in reaching the agency's goals related to reducing opioid harm and misuse. HHS concurred with our recommendation.

CMS oversees Medicare Part D providers through its contractor, NBI MEDIC, as well as through the plan sponsors. NBI MEDIC provides oversight by analyzing Medicare prescriber data for outliers and determining potential fraud. NBI MEDIC conducts its own investigations of potential fraud, waste, and abuse by providers, and also refers cases to law enforcement or the Office of the Inspector General.

CMS also requires plan sponsors to prevent, detect, and correct prescriber noncompliance, as well as fraud, waste, and abuse. However, NBI MEDICS analyses to identify outlier providers focused

broadly on all drugs at risk of abuse, rather than on opioids specifically.

We recommended that CMS require NBI MEDIC to gather separate data on providers who prescribe high amounts of opioids. This would allow CMS to better identify those providers who are inappropriately and potentially fraudulently prescribing high doses of opioids. HHS concurred with this recommendation as well.

CMS also lacks key information necessary for oversight of opioid prescribing because it does not require plan sponsors to report cases of fraud, waste, and abuse, cases of overprescribing, or any actions taken against providers. While CMS received some of this information from plan sponsors who voluntarily report their actions, it does not know the full extent to which plan sponsors have identified providers who prescribe high amounts of opioids or take an appropriate action.

We recommended that CMS require plan sponsors to report on investigations and other actions taken related to providers who prescribe high amounts of opioids. HHS did not concur, noting that plan sponsors are responsible for detecting and preventing fraud, waste, and abuse, and that CMS reviews cases when it conducts audits.

HHS also stated that it seeks to balance the requirements it places on plan sponsors. However, without complete reporting, CMS is missing key information that could help the agency achieve its goals. We continue to believe that CMS should require plan sponsors to report on the actions they take to reduce overprescribing.

In conclusion, having information on the total number of beneficiaries receiving potentially harmful levels of opioid medication, as well as complete information on providers who may be inappropriately prescribing opioids, could help CMS as it works to decrease the risk of opioid use disorder, overdoses, and deaths.

This concludes my prepared statement, and I am happy to answer the Committee's questions.

[The prepared statement of Ms. Curda follows:]



United States Government Accountability Office

Testimony

Before the Subcommittee on Oversight,
Committee on Ways and Means, House
of Representatives

For Release on Delivery
Expected at 10:00 a.m. ET
Wednesday, January 17, 2018

PRESCRIPTION OPIOIDS

Medicare Should Expand Oversight Efforts to Reduce the Risk of Harm

Statement of Elizabeth H. Curda, Director, Health Care

GAO Highlights

Highlights of GAO-18-336T, a testimony before the Subcommittee on Oversight, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

Misuse of prescription opioids can lead to overdose and death. In 2016, over 14 million Medicare Part D beneficiaries received opioid prescriptions, and spending for opioids was almost \$4.1 billion. GAO and others have reported on inappropriate activities and risks associated with these prescriptions.

This statement is based on GAO's October 2017 report (GAO-18-15) and discusses (1) CMS oversight of beneficiaries who receive opioid prescriptions under Part D, and (2) CMS oversight of providers who prescribe opioids to Medicare Part D beneficiaries. For the October 2017 report, GAO reviewed CMS opioid utilization and prescriber data, CMS guidance for plan sponsors, and CMS's strategy to prevent opioid misuse. GAO also interviewed CMS officials, the six largest Part D plan sponsors, and 12 national associations selected to represent insurance plans, pharmacy benefit managers, physicians, patients, and regulatory and law enforcement authorities.

What GAO Recommends

In the October 2017 report, GAO made three recommendations that CMS (1) gather information on the full number of at-risk beneficiaries receiving high doses of opioids, (2) identify providers who prescribe high amounts of opioids, and (3) require plan sponsors to report to CMS on actions related to providers who inappropriately prescribe opioids. HHS concurred with the first two recommendations, but not with the third. GAO continues to believe the recommendation is valid, as discussed in the report and in this statement.

View GAO-18-336T. For more information, contact Elizabeth H. Curda at (202) 512-7114 or curdae@gao.gov.

January 17, 2018

PRESCRIPTION OPIOIDS

Medicare Should Expand Oversight Efforts to Reduce the Risk of Harm

What GAO Found

The Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (HHS), provides guidance on the monitoring of Medicare beneficiaries who receive opioid prescriptions to plan sponsors—private organizations that implement the Medicare drug benefit, Part D—but lacks information on most beneficiaries at risk of harm from opioid use.

- CMS provides guidance to plan sponsors on how they should monitor opioid overutilization among Medicare Part D beneficiaries, and requires them to implement drug utilization review systems that use criteria similar to CMS's. CMS's criteria focused on beneficiaries who do all the following: (1) receive prescriptions of high doses of opioids, (2) receive prescriptions from four or more providers, and (3) fill prescriptions at four or more pharmacies. According to CMS, this approach focused actions on beneficiaries the agency determined to have the highest risk of harm.
- CMS's criteria, including recent revisions, do not provide sufficient information about the larger population of potentially at-risk beneficiaries. CMS estimates that while 33,223 beneficiaries would have met the revised criteria in 2015, 727,016 would have received high doses of opioids regardless of the number of providers or pharmacies. In 2016, CMS began to collect information on some of these beneficiaries using a higher dosage threshold for opioid use. This approach misses some who could be at risk of harm, based on Centers for Disease Control and Prevention guidelines. As a result, CMS is limited in its ability to assess progress toward meeting the broader goals of its Opioid Misuse Strategy for the Medicare and Medicaid programs, which includes activities to reduce the risk of harm to beneficiaries from opioid use.

CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria
Number of beneficiaries receiving high opioid doses (in tens of thousands) Estimated number of beneficiaries CMS would have tracked with revised criteria (in tens of thousands)



Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. | GAO-18-336T

CMS oversees the prescribing of drugs at high risk of abuse through a variety of projects, but does not analyze data specifically on opioids. According to CMS officials, CMS and plan sponsors identify providers who prescribe large amounts of drugs with a high risk of abuse, and those suspected of fraud or abuse may be referred to law enforcement. However, GAO found that CMS does not identify providers who may be inappropriately prescribing large amounts of opioids separately from other drugs, and does not require plan sponsors to report actions they take when they identify such providers. As a result, CMS is lacking information that it could use to assess how opioid prescribing patterns are changing over time, and whether its efforts to reduce harm are effective.

Chairman Jenkins, Ranking Member Lewis, and Members of the Subcommittee:

I am pleased to be here to discuss our recently released report on oversight of opioid prescribing in the Medicare program.¹ Misuse of prescription opioids, which are used to treat both acute and chronic pain, has become a serious public health problem for the U.S. population, including Medicare beneficiaries. The Centers for Disease Control and Prevention (CDC) reported that from 1999 to 2013 the rate of drug poisoning deaths from prescription opioids nearly quadrupled from 1.4 to 5.1 per 100,000 people.² In addition, the Department of Health and Human Services (HHS) Office of Inspector General (HHS-OIG) reported that 14.4 million people (about one-third) who participate in Medicare Part D received at least one prescription for opioids in 2016, and that Part D spending for opioids in 2016 was almost \$4.1 billion.³ GAO and the HHS-OIG have previously reported on inappropriate activities that can be associated with such prescriptions, including “doctor shopping” to receive multiple opioid prescriptions from different providers; the diversion of prescription drugs for uses other than what was intended; and questionable prescribing practices by providers, including those in Medicare.⁴

¹See GAO, *Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm*, GAO-18-15 (Washington, D.C.: Oct. 6, 2017).

²Department of Health and Human Services, Centers for Disease Control and Prevention, *Rates of Deaths from Drug Poisoning and Drug Poisoning Involving Opioid Analgesics—United States, 1999-2013*, Morbidity and Mortality Weekly Report, vol. 64, no. 1, (Atlanta, Ga.: Jan. 16, 2015).

³Department of Health and Human Services Office of Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, OE-02-17-00250 (July 2017). Medicare is a federal health insurance program for people age 65 and older, individuals under age 65 with certain disabilities, and individuals diagnosed with end-stage renal disease. Since 2006, Medicare Part D has offered voluntary prescription drug coverage through stand-alone prescription drug plans or through Medicare Advantage prescription drug plans, which combine medical and prescription drug benefits.

⁴See GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, D.C.: Sept. 6, 2011); and *Medicare Program Integrity: CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse*, GAO-15-66 (Washington, D.C.: Oct. 24, 2014). See also Department of Health and Human Services, Office of Inspector General, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, OEI-02-16-0029 (June 2016).

In March 2015, HHS announced plans to make addressing opioid abuse a high priority through two broad goals: (1) decreasing opioid overdoses and overall overdose deaths, and (2) decreasing the prevalence of opioid use disorder.⁵ In 2016, CDC issued guidelines with recommendations for prescribing opioids in outpatient settings for chronic pain.⁶ The guidelines recommended that providers use caution when prescribing opioids at any dose, carefully reassess evidence of individual benefits and risks when increasing opioid dosage to 50 mg morphine-equivalent dose (MED) per day or more, and either avoid or carefully justify dosage at 90 mg MED or more. CDC guidelines also noted that providers should use additional caution in prescribing opioids to patients aged 65 and older, because the drugs can accumulate in the body to toxic levels. Further, in January 2017, the Centers for Medicare & Medicaid Services (CMS), the HHS agency that administers Medicare, issued its Opioid Misuse Strategy for the Medicaid and Medicare programs, including Medicare Part D.⁷ The strategy includes the agency's plans to address concerns about beneficiary use of opioids and the prescribing of opioids by providers.

My remarks today discuss the findings and recommendations from our report on CMS efforts to oversee prescription opioids.⁸ Accordingly, this testimony focuses on (1) how CMS oversees beneficiaries who receive opioid prescriptions under Medicare Part D, and (2) how CMS oversees providers who prescribe opioids to Medicare Part D beneficiaries. For our report, we reviewed CMS opioid utilization and prescriber data, CMS guidance for plan sponsors, and CMS's strategy to prevent opioid misuse. We also interviewed officials from CMS, the six largest Part D plan sponsors—private organizations, such as health insurance companies,

⁵Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Death* (Mar. 26, 2015). Opioid use disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress as indicated by at least 2 of 11 criteria occurring within a 12 month period. The criteria include taking opioids in larger amounts or over a longer period of time than was intended, persistent desire or unsuccessful efforts to cut down or control opioid use, or a strong desire or urge to use opioids.

⁶Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity and Mortality Weekly Report, vol. 65, no. 1, (Atlanta, Ga.: Mar. 18, 2016).

⁷Centers for Medicare & Medicaid Services, *Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy 2016* (Jan. 5, 2017).

⁸See GAO-18-15.

contracted by CMS to provide outpatient drug benefit plans to Medicare beneficiaries—and 12 national associations selected to represent insurance plans, pharmacy benefit managers, physicians, patients, and regulatory and law enforcement agencies. More detailed information on our objectives, scope, and methodology for that work can be found in the issued report. We conducted the work on which this statement is based in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

CMS Delegates
Monitoring of
Beneficiaries who
Receive Opioid
Prescriptions to Plan
Sponsors, but Does
Not Have Sufficient
Information on Those
Most at Risk for Harm

**CMS Delegates
Monitoring of Individual
Beneficiaries' Opioid
Prescriptions to Plan
Sponsors**

Our October 2017 report found that CMS provides guidance to Medicare Part D plan sponsors on how the plan sponsors should monitor opioid overutilization problems among Part D beneficiaries. The agency includes this guidance in its annual letters to plan sponsors, known as call letters; it also provided a supplemental memo to plan sponsors in 2012.⁹ Among other things, these guidance documents instructed plan sponsors to implement a retrospective drug utilization review (DUR) system to monitor beneficiary utilization starting in 2013.¹⁰ As part of the DUR systems, CMS requires plan sponsors to have methods to identify beneficiaries who are potentially overusing specific drugs or groups of drugs, including opioids.

Also in 2013, CMS created the Overutilization Monitoring System (OMS), which outlines criteria to identify beneficiaries with high-risk use of opioids and to oversee sponsors' compliance with CMS's opioid overutilization policy. Plan sponsors may use the OMS criteria for their DUR systems, but they have some flexibility to develop their own targeting criteria within CMS guidance. At the time of our review, the OMS considered beneficiaries to be at a high risk of opioid overuse when they met all three of the following criteria:

1. received a total daily MED greater than 120 mg for 90 consecutive days,
2. received opioid prescriptions from four or more providers in the previous 12 months, and

⁹Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, accessed December 21, 2016, <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf>; and Centers for Medicare & Medicaid Services, *Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D*, accessed April 25, 2017, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf>.

¹⁰In addition to instructing plan sponsors to implement retrospective DUR systems, the guidance in the 2013 call letter includes information on other mechanisms to control overutilization. See <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf>.

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3. received opioids from four or more pharmacies in the previous 12 months.¹¹

The criteria excluded beneficiaries with a cancer diagnosis and those in hospice care, for whom higher doses of opioids may be appropriate.

Through the OMS, CMS generates quarterly reports that list beneficiaries who meet all of the criteria and who are identified as high-risk, and then distributes the reports to the plan sponsors. Plan sponsors are expected to review the list of identified beneficiaries, determine appropriate action, and then respond to CMS with information on their actions within 30 days. According to CMS officials, the agency also expects that plan sponsors will share any information with CMS on beneficiaries that they identify through their own DUR systems. We found that some actions plan sponsors may take include

- Case management. Case management may include an attempt to improve coordination issues, and often involves provider outreach, whereby the plan sponsor will contact the providers associated with the beneficiary to let them know that the beneficiary is receiving high levels of opioids and may be at risk of harm.
- Beneficiary-specific point-of-sale (POS) edits. Beneficiary-specific POS edits are restrictions that limit these beneficiaries to certain opioids and amounts. Pharmacists receive a message when a beneficiary attempts to fill a prescription that exceeds the limit in place for that beneficiary.
- Formulary-level POS edits. These edits alert providers who may not have been aware that their patients are receiving high levels of opioids from other doctors.
- Referrals for investigation. According to the six plan sponsors we interviewed, the referrals can be made to CMS's National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC), which is responsible for identifying and investigating potential Part D fraud, waste, and abuse, or to the plan sponsor's own internal investigative

¹¹These criteria are in effect through 2017. CMS announced in its April 3, 2017 call letter the revisions to the OMS criteria that will take effect in 2018. See *Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information*, accessed April 4, 2017, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>. Some of the beneficiaries that meet the OMS criteria may not be using the opioids themselves, but rather diverting them by either giving or selling them to others.

unit, if they have one. After investigating a particular case, they may refer the case to the HHS-OIG or a law enforcement agency, according to CMS, NBI MEDIC, and one plan sponsor.

Based on CMS's use of the OMS and the actions taken by plan sponsors, CMS reported a 61 percent decrease from calendar years 2011 through 2016 in the number of beneficiaries meeting the OMS criteria of high risk—from 29,404 to 11,594 beneficiaries—which agency officials consider an indication of success toward its goal of decreasing opioid use disorder.

In addition, we found that CMS relies on separate patient safety measures developed and maintained by the Pharmacy Quality Alliance to assess how well Part D plan sponsors are monitoring beneficiaries and taking appropriate actions.¹² In 2016, CMS started tracking plan sponsors' performance on three patient safety measures that are directly related to opioids. The three measures are similar to the OMS criteria in that they identify beneficiaries with high dosages of opioids (120 mg MED), beneficiaries that use opioids from multiple providers and pharmacies, and beneficiaries that do both. However, one difference between these approaches is that the patient safety measures separately identify beneficiaries who fulfill each criterion individually.

CMS Does Not Have Sufficient Information on Most Beneficiaries Potentially at Risk for Harm

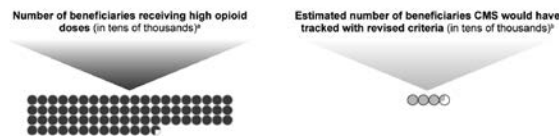
Our October 2017 report also found that while CMS tracks the total number of beneficiaries who meet all three OMS criteria as part of its opioid overutilization oversight across the Part D program, it does not have comparable information on most beneficiaries who receive high doses of opioids—regardless of the number of providers and pharmacies used—and who therefore may be at risk for harm, according to CDC guidelines. These guidelines note that long-term use of high doses of opioids—those above a MED of 90 mg per day—are associated with significant risk of harm and should be avoided if possible.

Based on the CDC guidelines, outreach to Part D plan sponsors, and CMS analyses of Part D data, CMS has revised its current OMS criteria to include more at-risk beneficiaries beginning in 2018. The new OMS

¹²The Pharmacy Quality Alliance is a consensus-based, multi-stakeholder membership organization that collaboratively promotes appropriate medication use and develops strategies for measuring and reporting performance information related to medications. The alliance developed all but one of CMS's Part D patient safety measures, and that one measure is not related to opioid safety.

criteria define a high user as having an average daily MED greater than 90 mg for any duration, and who receives opioids from four or more providers and four or more pharmacies, or from six or more providers regardless of the number of pharmacies, for the prior 6 months.¹³ Based on 2015 data, CMS found that 33,223 beneficiaries would have met these revised criteria. While the revised criteria will help identify beneficiaries who CMS determined are at the highest risk of opioid misuse and therefore may need case management by plan sponsors, OMS will not provide information on the total number of Part D beneficiaries who may also be at risk of harm. In developing the revised criteria, CMS conducted a one-time analysis that estimated there were 727,016 beneficiaries with an average MED of 90 mg or more, for any length of time during a 6 month measurement period in 2015, regardless of the number of providers or pharmacies used. These beneficiaries may be at risk of harm from opioids, according to CDC guidelines, and therefore tracking the total number of these beneficiaries over time could help CMS to determine whether it is making progress toward meeting the goals specified in its Opioid Misuse Strategy to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion. However, CMS officials told us that the agency does not keep track of the total number of these beneficiaries, and does not have plans to do so as part of OMS. (See fig. 1.)

Figure 1: CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria



Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. | GAO-18-336T

^aThis number includes beneficiaries with an average opioid morphine equivalent dose of 90 milligrams or more within a 6-month measurement period.

^bThis number is an estimate of how many beneficiaries would have met CMS's revised Overutilization Monitoring System (OMS) criteria. CMS calculated these totals by applying the revised OMS criteria to 2015 Part D data.

¹³According to CMS officials, the changes are partially in response to CDC's 2016 guidelines. The CDC guidelines noted that patients are at risk of harm above 50 mg MED and that providers should generally avoid increasing dosage to more than 90 mg MED of opioids, regardless the number of providers or pharmacies.

We also found that in 2016, CMS began to gather information from its patient safety measures on the number of beneficiaries who use more than 120 mg MED of opioids for 90 days or longer, regardless of the number of providers and pharmacies. The patient safety measures identified 285,119 such beneficiaries—counted as member-years—in 2016.¹⁴ However, this information does not include all at-risk beneficiaries, because the threshold is more lenient than indicated in CDC guidelines and CMS's new OMS criteria. Because neither the OMS criteria nor the patient safety measures include all beneficiaries potentially at risk of harm from high opioid doses, we recommended that CMS should gather information over time on the total number of beneficiaries who receive high opioid morphine equivalent doses regardless of the number of pharmacies or providers, as part of assessing progress over time in reaching the agency's goals related to reducing opioid use. HHS concurred with our recommendation.

CMS Oversees Providers through its Contractor and Plan Sponsors, but Efforts Do Not Specifically Monitor Opioid Prescriptions

Our October 2017 report found that CMS oversees providers who prescribe opioids to Medicare Part D beneficiaries through its contractor, NBI MEDIC, and the Part D plan sponsors.

- NBI MEDIC's data analyses to identify outlier providers. CMS requires NBI MEDIC to identify providers who prescribe high amounts of Schedule II drugs, which include but are not limited to opioids.¹⁵ Using prescription drug data, NBI MEDIC conducts a peer comparison of providers' prescribing practices to identify outlier providers—the highest prescribers of Schedule II drugs. NBI MEDIC reports the results to CMS.
- NBI MEDIC's other projects. NBI MEDIC gathers and analyzes data on Medicare Part C and Part D, including projects using the Predictive Learning Analytics Tracking Outcome (PLATO) system.¹⁶ According to NBI MEDIC officials, these PLATO projects seek to identify potential fraud by examining data on provider behaviors.

¹⁴Patient safety measures count member-years, which account for beneficiaries who are enrolled in a Part D plan for only part of a year.

¹⁵Under the Controlled Substances Act, which was enacted in 1970, drugs are classified as controlled substances and placed into one of five schedules based on their medicinal value, potential for abuse, and risk of dependence. Schedule II drugs have the highest potential for abuse of any drugs approved for medical use.

¹⁶Medicare Part C, also known as Medicare Advantage, is a private plan alternative to traditional Medicare, and covers all traditional Medicare services.

-
- NBI MEDIC's investigations to identify fraud, waste, and abuse. NBI MEDIC officials conduct investigations to assist CMS in identifying cases of potential fraud, waste, and abuse among providers for Medicare Part C and Part D. The investigations are prompted by complaints from plan sponsors; suspected fraud, waste, or abuse reported to NBI MEDIC's call center; NBI MEDIC's analysis of outlier providers; or from one of its other data analysis projects.
 - NBI MEDIC's referrals. After identifying providers engaged in potential fraudulent overprescribing, NBI MEDIC officials said they may refer cases to law enforcement agencies or the HHS-OIG for further investigation and potential prosecution.
 - Plan sponsors' monitoring of providers. CMS requires all plan sponsors to adopt and implement an effective compliance program, which must include measures to prevent, detect, and correct Part C or Part D program noncompliance, as well as fraud, waste, and abuse. CMS's guidance focuses broadly on prescription drugs, and does not specifically address opioids.

Our report concluded that although these efforts provide valuable information, CMS lacks all the information necessary to adequately oversee opioid prescribing. CMS's oversight actions focus broadly on Schedule II drugs rather than specifically on opioids. For example, NBI MEDIC's analyses to identify outlier providers do not indicate the extent to which they may be overprescribing opioids specifically. According to CMS officials, they direct NBI MEDIC to focus on Schedule II drugs, because these drugs have a high potential for abuse, whether they are opioids or other drugs. However, without specifically identifying opioids in these analyses—or an alternate source of data—CMS lacks data on providers who prescribe high amounts of opioids, and therefore cannot assess progress toward meeting its goals related to reducing opioid use, which would be consistent with federal internal control standards. Federal internal control standards require agencies to conduct monitoring activities and to use quality information to achieve objectives and address risks.¹⁷ As a result, we recommended that CMS require NBI MEDIC to gather separate data on providers who prescribe high amounts of opioids. This would allow CMS to better identify those providers who are inappropriately and potentially fraudulently overprescribing opioids. HHS

¹⁷GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: Sept. 10, 2014). Internal controls is a process affected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

agreed, and noted that it intends to work with NBI MEDIC to identify trends in outlier prescribers of opioids.

Our report also found that CMS also lacks key information necessary for oversight of opioid prescribing, because it does not require plan sponsors to report to NBI MEDIC or CMS cases of fraud, waste, and abuse; cases of overprescribing; or any actions taken against providers.¹⁸ Plan sponsors collect information on cases of fraud, waste, and abuse, and can choose to report this information to NBI MEDIC or CMS. While CMS receives information from plan sponsors who voluntarily report their actions, it does not know the full extent to which plan sponsors have identified providers who prescribe high amounts of opioids, or the full extent to which sponsors have taken action to reduce overprescribing. We concluded that without this information, it is difficult for CMS to assess progress in this area, which would be consistent with federal internal control standards. In our report, we recommended that CMS require plan sponsors to report on investigations and other actions taken related to providers who prescribe high amounts of opioids. HHS did not concur with this recommendation. HHS noted that plan sponsors have the responsibility to detect and prevent fraud, waste, and abuse, and that CMS reviews cases when it conducts audits. HHS also stated that it seeks to balance requirements on plan sponsors when considering new regulatory requirements. However, without complete reporting—such as reporting from all plan sponsors on the actions they take to reduce overprescribing—we believe that CMS is missing key information that could help assess progress in this area. Due to the importance of this information for achieving the agency's goals, we continue to believe that CMS should require plan sponsors to report on the actions they take to reduce overprescribing.

In conclusion, a large number of Medicare Part D beneficiaries use potentially harmful levels of prescription opioids, and reducing the inappropriate prescribing of these drugs is a key part of CMS's strategy to decrease the risk of opioid use disorder, overdoses, and deaths. Despite working to identify and decrease egregious opioid use behavior—such as doctor shopping—among Medicare Part D beneficiaries, CMS lacks the

¹⁸According to CMS officials, the agency's regulations currently make reporting inappropriate prescribing and any actions against providers voluntary for plan sponsors. See 42 C.F.R. § 423.504(b)(4)(vi)(G)(3).

necessary information to effectively determine the full number of beneficiaries at risk of harm, as well as other information that could help CMS assess whether its efforts to reduce opioid overprescribing are effective. It is important that health care providers help patients to receive appropriate pain treatment, including opioids, based on the consideration of benefits and risks. Access to information on the risks that Medicare patients face from inappropriate or poorly monitored prescriptions, as well as information on providers who may be inappropriately prescribing opioids, could help CMS as it works to improve care.

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

GAO Contacts and Staff Acknowledgements

If you or your staff members have any questions concerning this testimony, please contact me at (202) 512-7114 or CurdaE@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this statement. Other individuals who made key contributions to this testimony include Will Simerl (Assistant Director), Carolyn Feis Korman (Analyst-in-Charge), Amy Andresen, Drew Long, Samantha Pawlak, Vikki Porter, and Emily Wilson.

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Chairman JENKINS. Thank you, Ms. Curda. Ms. Brandt, you are recognized for 5 minutes.

STATEMENT OF KIMBERLY BRANDT, PRINCIPAL DEPUTY ADMINISTRATOR FOR OPERATIONS, CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

Ms. BRANDT. Thank you. Chairman Jenkins, Ranking Member Neal, and Members of the Subcommittee, thank you for inviting me to discuss CMS's work to address the misuse of opioids in the Medicare Part D program.

CMS understands the magnitude and impact the opioid misuse epidemic has had on our communities and is committed to a comprehensive and multipronged strategy to combat this public health emergency.

As Principal Deputy for Operations at CMS, I am charged with directing cost-cutting issues that affect all of our programs, with the efforts to fight the opioid epidemic being one of our agency's biggest priorities. We cover over 58 million Medicare beneficiaries, and the opioid epidemic affects every one of them as a patient, family member, caregiver, or community member.

CMS recognizes that its primary role in the healthcare system is that of a payer. And as a payer, we are focused on the unique steps we can take to ensure that plans comply with requirements that protect beneficiaries.

For us, all of our efforts are ultimately focused on protecting the health and safety of our Medicare beneficiaries. Due to the structure of the Medicare Part D program, Medicare Advantage organizations and Medicare Part D sponsors are well-positioned to identify and address improper opioid utilization by working with prescribing physicians.

Our job at CMS is to oversee these efforts and to make sure that plan sponsors have the tools and information they need to be as effective as possible. We do this in a number of ways. First, as my colleague from GAO knows, we use the Overutilization Monitoring System, or OMS, to help ensure plan sponsors have established systems and programs to help prevent overutilization of prescription opioids.

Through this system, CMS identifies high-risk beneficiaries who have visited multiple pharmacies or prescribers. We then report these high-risk beneficiaries to plans who conduct case management or implement real time alerts at a pharmacy. This effort has been very successful, with a 61 percent decline in the number of beneficiaries meeting the OMS criteria from 2011 to 2016, even while Part D enrollment was increasing at the same time.

To improve on these outcomes and to better identify high-risk beneficiaries, we have improved the criteria used in OMS to reflect the Centers for Disease Control's prescribing guidelines. This action will allow us to better identify potential opioid overutilizers and is just one of the many ways we are collaborating with our colleagues in HHS to tackle this epidemic and further protect beneficiaries at high risk of opioid overutilization.

Thanks to recent action taken by Congress, CMS now has the authority to implement a new Medicare Part D lock-in policy. CMS has proposed to integrate this new authority with our OMS to ex-

pand upon our existing innovative approach to reduce opioid overutilization in the Part D program. We believe this approach will improve quality of care through enhanced coordination while maintaining access to necessary pain medications.

Second, all plan sponsors are using real-time alerts, referred to as safety edits, to flag potentially unsafe opioid prescriptions at the pharmacy. When these alerts are triggered, the pharmacist must take an action, depending on the type of safety edit, before the prescription can be dispensed.

Through this process, prescribers can receive important information about their patients, such as a better picture of a patient's total opioid dosage and prescription history. Ultimately, this helps prescribers make more informed decisions about the care that they are providing to their patients.

Third, CMS tracks and monitors the number of Part D beneficiaries who receive high doses of opioid prescriptions regardless of the number of prescribers and pharmacies being used by the beneficiary. Using this information, CMS sends monthly patient safety reports to plan sponsors so they can conduct case management. Ensuring that Medicare beneficiaries with substance use disorder have access to the most effective treatment is a critical component of addressing the epidemic.

We want to make sure that we cover the right treatment for the right beneficiaries in the right setting, and we are working to increase access to medication-assisted treatment by requiring that Part D formula include MAT drugs as well as Naloxone.

In addition to these efforts to identify and protect beneficiaries who are at high risk for opioid overutilization, CMS also uses data to identify prescribers and pharmacies with questionable opioid prescribing and billing patterns. Plans receive quarterly reports on outlier prescribers and pharmacies they can use to initiate new investigations, conduct audits, and take administration actions like terminating a pharmacy from their network.

Based on a recommendation by the GAO, these reports now separate outlier prescribers of opioids from other Schedule II prescribers.

As we move forward with our efforts to curb this public health crisis, CMS plans to enact comprehensive strategies from all Medicare Part D sponsors on their activities aimed at combatting the opioid crisis. This will help CMS better understand the approaches sponsors are taking from both their Medicare and commercial alliance. Once we receive this information, we will conduct an analysis and provide best practice guidance to all plans.

While CMS has taken numerous steps to improve our opioid overutilization and monitoring programs, we know there is much more we can do. We appreciate the work and recommendations from our colleagues at GAO and OIG, and we are continually assessing how we can best utilize our tools as a payer to build on their recommendations to tackle this crisis.

Thank you for your interest in our efforts to protect Medicare beneficiaries, and I look forward to answering your questions.

[The prepared statement of Ms. Brandt follows:]

STATEMENT OF

KIMBERLY BRANDT
PRINCIPAL DEPUTY ADMINISTRATOR FOR OPERATIONS
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

THE OPIOID CRISIS:
THE CURRENT LANDSCAPE AND CMS ACTIONS TO PREVENT OPIOID MISUSE

BEFORE THE
U.S. HOUSE COMMITTEE ON WAYS & MEANS
SUBCOMMITTEE ON OVERSIGHT

January 17, 2018

Statement of Kimberly Brandt
on
“The Opioid Crisis:
The Current Landscape and CMS Actions to Prevent Opioid Misuse”
U.S. House Committee on Ways & Means
Subcommittee on Oversight
January 17, 2018

Chairman Jenkins, Ranking Member Lewis, and members of the Subcommittee, thank you for inviting me to discuss the Centers for Medicare & Medicaid Services’s (CMS’s) work addressing the misuse of opioids by some providers and beneficiaries in the Medicare program. The Administration is aggressively fighting the opioid epidemic on all fronts. We understand the magnitude and impact the opioid misuse epidemic has had on our communities and are committed to a comprehensive and multi-pronged strategy to combat this public health emergency.

The number of Americans who are struggling with a substance use disorder, and specifically addiction to opioids, is staggering. In 2016 alone, nearly 64,000 Americans died from drug overdoses, the majority (over 42,000) of them from opioids. This amounts to nearly 116 Americans dying of an opioid-related overdose each day. Opioid addiction is deeply affecting communities, families, and individuals across the nation.

For this reason, combating the opioid epidemic is a top priority for the Department of Health and Human Services (HHS) and the Administration as a whole. In April 2017, HHS component agencies developed targeted initiatives to respond to this crisis with a multi-pronged approach identified to improve prevention, access to treatment and recovery services. HHS outlined its five-point Opioid Strategy, which provides the overarching framework to leverage the expertise and resources of HHS agencies in a strategic and coordinated manner. The comprehensive, evidence-based Opioid Strategy aims to:

- Improve access to prevention, treatment, and recovery support services to prevent the health, social, and economic consequences associated with opioid addiction and to enable individuals to achieve long-term recovery;

- Target the availability and distribution of overdose-reversing drugs to ensure the broad provision of these drugs to people likely to experience or respond to an overdose, with a particular focus on targeting high-risk populations;
- Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response as the epidemic evolves;
- Support cutting-edge research that advances our understanding of pain and addiction, leads to the development of new treatments, and identifies effective public health interventions to reduce opioid-related health harms; and
- Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

At the request of President Trump and consistent with the requirements of the Public Health Service Act, the HHS Secretary declared a nationwide public health emergency regarding the opioid crisis. The President also directed that executive agencies use all appropriate emergency authorities and other relevant authorities to respond to America's deadly opioid crisis.

CMS's actions under HHS's Opioid Strategy reflect its responsibility to protect the health of Medicare beneficiaries by putting in place appropriate safeguards to help prevent non-medical use of opioids, while ensuring that beneficiaries can access needed medications and appropriate treatments. CMS is focused on critical steps to help reverse the trends in the opioid epidemic. CMS's efforts to address this emergency have evolved to reflect the increasing severity of the crisis. CMS is committed to working closely with clinicians, health plans, pharmacy benefit managers and other providers to make sure that we are best using all the tools at our disposal to combat this public health crisis. For example, CMS has conducted listening summits with states, clinicians, pharmacy benefit managers, other providers and Medicare Part D plan sponsors that focused on best practices and statutory and regulatory reforms that would allow stakeholders to more aggressively monitor and take action against opioid misuse. CMS is working with the recommendations received from stakeholders to develop a comprehensive strategy on addiction

and opioid abuse within CMS programs. Additionally, through the Center for Medicare and Medicaid Innovation, CMS sought public input and suggestions on innovative payment system models that will help promote effective substance abuse treatment programs, including models focused on opioids and substance use disorder.¹

Preventing Overprescribing and Misuse of Opioids in Medicare Part D

Since its inception in 2006, the Medicare Part D prescription drug benefit program has made medicines more available and affordable for Medicare beneficiaries, leading to improvements in access to prescription drugs, health outcomes, and beneficiary satisfaction with their Medicare coverage.² Approximately 70 percent of Medicare beneficiaries have Medicare prescription drug coverage either from a Part D plan or a Medicare Advantage Plan offering Medicare prescription drug coverage. In 2015, Medicare Part D spending was \$137 billion; U.S. retail prescription spending was about \$325 billion. While most beneficiaries utilize, and clinicians prescribe, opioids in ways that are medically appropriate, opioid overutilization is nonetheless a significant challenge for the Medicare Part D program. CMS is utilizing the feedback and recommendations from the HHS Office of Inspector General (OIG)³, the Government Accountability Office (GAO)⁴, and stakeholders to combat prescription opioid misuse, overuse, and fraud.

Due to the structure of the Medicare Part D program, Medicare Advantage Organizations (MAOs) and Medicare Part D sponsors also have a primary role in detecting and preventing potential fraud, waste and abuse, including the misuse of opioids. CMS requires plan sponsors to have effective compliance measures that include measures to detect, correct, and prevent fraud, waste, and abuse. CMS also helps plans identify individuals potentially at risk for opioid abuse.

MAOs and Medicare Part D sponsors, working with prescribing clinicians, are well positioned to identify and employ best practices and the most appropriate care management interventions for

¹ <https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>

² In 2013, more than one million distinct health care providers collectively prescribed \$103 billion in prescription drugs under the Part D program. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>

³ For example: <https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf>, <https://oig.hhs.gov/oei/reports/oei-03-15-00180.asp>

⁴ For example: <https://www.gao.gov/products/GAO-18-15>

enrollees using high dosages of opioids. Medicare Part D plans are expected to use multiple tools including safety edits at the point of dispensing, better formulary management, and case management with beneficiaries' clinicians aimed at coordinated care. We also expect all Medicare Part D sponsors to focus on improving the coordination of care among beneficiaries that use high dosages of opioids, and Medicare Advantage (MA) plans with prescription drug coverage in particular can expand the care management they provide enrollees. CMS encourages Medicare Part D sponsors and members of their Pharmacy and Therapeutics (P&T) committees to keep abreast of current research, guidelines, and training materials related to the appropriate use of opioids and best practices for care management.

CMS has also significantly expanded its oversight of Medicare Part D plans to ensure that they are in compliance with requirements that protect beneficiaries and can help prevent and address opioid overutilization. CMS has a robust Medicare Part D opioid overutilization policy to provide specific guidance to plans on how to employ more effective drug utilization review programs to reduce overutilization of opioids and maintain access to needed medications among beneficiaries. CMS plans to require all Medicare Part D sponsors to submit a written strategy for addressing overutilization of prescription opioids, given the public health emergency, to CMS in Spring 2018.⁵ This information will help CMS better understand the approaches sponsors are taking, from both their Medicare and commercial lines, and CMS intends to disseminate best practices. CMS has implemented multiple initiatives that work together to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion in the Medicare program. These strategies include a medication safety approach to improve care coordination for high risk beneficiaries using opioids, quality metrics for plan sponsors, and data analysis of prescribing patterns to target potential fraud, waste, and abuse.

Overutilization Monitoring System (OMS)

In addition, CMS uses the Overutilization Monitoring System (OMS) to help CMS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications, including opioid pain

⁵ <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html>

medications. CMS provides quarterly reports of high risk beneficiaries to Medicare Part D plans through the OMS to assist plans in their efforts, and plans update CMS on their actions taken to reduce the risk of overutilization. If the plan sponsor of a particular beneficiary's plan has concluded that a beneficiary-level point-of-sale edit is appropriate to reduce prescription opioid overutilization, the sponsor may do so with the agreement of the beneficiary's prescribers or without such agreement if the prescribers did not respond to the sponsor's efforts to engage in case management with the prescribers. Also, if the beneficiary later changes plans, that sponsor is expected to use CMS's systems to share such a finding with the new sponsor. There has been a 61 percent decline in the number of beneficiaries meeting the OMS criteria from calendar years 2011-2016 even though enrollment in Part D is increasing.⁶ It is an encouraging sign that there has been a reduction in enrollees who are at the highest risk of harm for opioid overuse. CMS has continued to refine and improve the criteria used in OMS. Beginning this year, beneficiaries will be identified and reported to plans if in the most recent six months their use of opioids exceeds an average daily morphine equivalent dose (MED) of 90mg for any duration; and if they have received opioids from more than three prescribers and more than three pharmacies, or from more than five prescribers regardless of the number of opioid dispensing pharmacies.⁷ CMS appreciates the work and recommendations of the HHS OIG that have helped us to make this work more effectively.

More recently, CMS has focused on the concurrent use of opioids and benzodiazepines, and wants to raise public awareness of this important issue. The combination of opioids and benzodiazepines can exacerbate respiratory depression, which is the primary factor in fatal opioid overdose. The risk of opioid-related morbidity and mortality is increased in all patients receiving opioids, even those who do not show signs of aberrant drug behavior. In a 2015 study, investigators found that 49 percent of the study's population who died from a drug overdose while taking opioid analgesics were concurrently prescribed benzodiazepines.⁸ The Centers for Disease Control and Prevention advises clinicians to avoid prescribing opioids and benzodiazepines concurrently whenever possible to avoid putting patients at greater risk for

⁶ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>

⁷ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>

⁸ Park TW, Saitz R, Ganoczy D, et al. Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study. *BMJ* 2015;350:h2698

potentially fatal overdose.⁹ For these reasons, beginning in October 2016, CMS added a concurrent benzodiazepine use flag to OMS reports to alert sponsors that high risk beneficiaries have concurrent use of these medications.¹⁰

Although Medicare Part D sponsors' retrospective case management and CMS oversight through the OMS reduced very high risk overutilization of opioids in the Medicare Part D program, given the continuing national opioid epidemic, CMS believes that there may be opportunity for Medicare Part D sponsors to reduce such risk through safety alerts at the time of dispensing. Medicare Part D sponsors commonly implement safety edits to prevent the unsafe dosing of drugs at the time of dispensing as part of their concurrent drug utilization review requirements for all Medicare Part D drugs, such as drug-drug interactions, therapeutic duplication, or an incorrect drug dosage (e.g., doses above the FDA-approved maximum dosing). Plan sponsors can implement either soft or hard formulary-level safety edits. Soft edits are those that alert a pharmacist of possible overutilization at the point of sale and can be overridden by the pharmacist, while hard edits are alerts at the point of sale that require prescriber authorization and sponsor action to resolve the edit. For calendar year 2017, Medicare Part D sponsors were expected to implement additional soft or hard formulary-level safety edits for opioids based on a cumulative dose, using reasonable controls to limit false positives. As in 2017, we continue to expect sponsors to implement formulary-level soft and/or hard opioid safety edits for 2018, but hard edits are not required.

Medicare Part D "Lock In"

The Comprehensive Addiction and Recovery Act of 2016 (CARA) permits CMS to take important steps to help combat this epidemic. The law provides CMS with the authority to allow Medicare Part D plans to implement pharmacy and prescriber lock-in for their Medicare Part D beneficiaries that are determined to be "at-risk" of opioid misuse or abuse, subject to appropriate protections. Pharmacy and prescriber lock-in will provide plans with an additional tool to better coordinate care with their providers for the beneficiaries who meet the guidelines for lock-in. CMS held a listening session seeking input on key aspects of lock-in implementation, and

⁹ <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

¹⁰ <https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html>

received feedback from various stakeholders including beneficiary advocates, clinicians, pharmacists, pharmacy benefit managers and plan sponsors. They highlighted ways to successfully implement a lock-in provision, but also raised concerns with how to align lock-in with existing tools used in Medicare Part D to promote the safe use of opioids, as well as how to protect medically necessary access to opioids.

With stakeholder input in mind, CMS has proposed through rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries."¹¹ Specifically, CMS has proposed to focus its lock-in efforts to address opioid misuse in Medicare Part D. The proposal would integrate the Medicare Part D lock-in with the current Part D Opioid Drug Utilization Review (DUR) Policy and OMS. As described above, this current policy involves Part D prescription drug benefit plans engaging in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Thus, this proposal expands upon an existing, innovative, successful approach to reduce opioid overutilization in the Part D program by improving quality of care through coordination while maintaining access to necessary pain medications when clinically indicated. As with any proposed rule, CMS is seeking public input from all stakeholders and accepted public comment until January 16, 2018.

Preventing Inappropriate Prescribing of Opioids through Provider and Prescriber Data Initiatives

CMS has a number of authorities to help curtail prescribing practices that place patients at risk of harm. These authorities are employed judiciously to prevent bad actors who fail to meet Medicare requirements from harming beneficiaries. These efforts have helped CMS protect the most vulnerable beneficiaries from the harms associated with opioid overuse. CMS will continue to coordinate efforts to ensure that future prescribers identified as having questionable opioid prescribing patterns are referred for appropriate administrative action.

¹¹ <https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

Detecting and Preventing Potential Fraud, Waste, and Abuse through the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC)

CMS utilizes the NBI MEDIC to identify and investigate potential fraud, waste and abuse in Medicare Part C and Part D, and to refer cases to law enforcement agencies when necessary. In particular, the NBI MEDIC identifies prescribers of drug combinations known to increase the effects of opioids, those with prescribing behavior that indicates they may be operating a pill mill, and those who prescribe Transmucosal Immediate-Release Fentanyl products to non-cancer patients. CMS shares this information with plans to assist in their investigation of fraud, waste and abuse.

The NBI MEDIC also conducts data analysis and other work to support ongoing law enforcement activities. Examples include impact calculations, medical review of claims and medical records, and prescription drug invoice reconciliation reviews. As a result of its work, the NBI MEDIC makes recommendations for administrative action to both CMS and the OIG, including revocations of Medicare billing privileges and exclusions from Federally funded health care programs.

Additionally, plan sponsors report potential fraud to the NBI MEDIC. The NBI MEDIC uses the Predictive Learning Analytics Tracking Outcome (PLATO) system, which is a voluntary, web-based system that allows CMS, the NBI MEDIC, and plan sponsors to more easily share information and help combat potential fraud, waste and abuse in the Medicare Advantage and Medicare Part D programs. CMS's federal law enforcement partners can also access PLATO data.

CMS has directed the NBI MEDIC to increase its focus on proactive data analysis in Part D, including producing, at a minimum, quarterly reports to plan sponsors on specific data projects, such as high risk pharmacy assessments. These assessments contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and potentially terminate pharmacies from their network, if appropriate. In addition to the Quarterly Pharmacy Risk Assessment, the NBI MEDIC produces a Quarterly Outlier Prescriber Schedule II Controlled Substances Report, which provides a peer comparison of Schedule II controlled substances.

Using CMS Data to Understand Prescribing Patterns

To assist clinicians, nurses, and other health care providers to assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment, CMS released an interactive online mapping tool. The mapping tool allows the user to see both the number and percentage of opioid claims at the local level and offers spatial analyses to identify “hot spots” or clusters in order to better understand how this critical issue impacts communities nationwide.¹² The data reflect Medicare Part D prescription drug claims prescribed by health care providers. The data used in the mapping tool are de-identified to protect beneficiary privacy, contain information from over one million distinct providers, and characterize the individual prescribing patterns of those providers that participate in Medicare Part D. By openly sharing data in a secure, broad, and interactive way, CMS is supporting a better understanding of regional provider prescribing behavior variability and is adding insight to local health care delivery.

Using CMS Quality Measures to Assess Program Effectiveness

CMS also uses quality measures developed by the Pharmacy Quality Alliance to assess reductions in opioid overuse across the Medicare Part D program. CMS tracks overall statistics and progress, as well as plan performance, related to the proportion of Medicare Part D beneficiaries using high doses of opioids, those receiving opioids from multiple providers or pharmacies, and those who meet both measures' criteria. CMS communicates with plans about their performance on each of these measures, including sharing information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure are required to report actions they will take to improve performance.

Proposed Preclusion List

CMS has a responsibility to protect Medicare Part D beneficiaries and the integrity of the program, while minimizing disruption to beneficiaries' access to needed Medicare Part D

¹² <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html>

medications and the administrative burden on the provider community. To strike this balance, CMS has recently proposed¹³ that a Part D plan sponsor must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Medicare Part D drug if the individual who prescribed the drug is included on a “preclusion list.” The preclusion list would consist of certain prescribers that fall within either of two categories. The first category would be individuals and entities who are currently revoked from Medicare, are under an active reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. The second category would be individuals and entities whose billing privileges have engaged in behavior for which CMS could have revoked the prescriber’s billing privileges to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

The Healthcare Fraud Prevention System (HFPP)

The Healthcare Fraud Prevention Partnership (HFPP) is a voluntary, public-private partnership consisting of the Federal Government, state agencies, law enforcement, private health insurance plans, and healthcare anti-fraud associations. Established in July 2012 by the Secretary of HHS and the U.S. Attorney General, the HFPP provides visibility into the larger universe of healthcare claims and claimants beyond those encountered by any single partner. The ultimate goal of the HFPP is to exchange facts and information to identify trends and patterns that will uncover potential fraud, waste, and abuse that may not otherwise be identified.

The HFPP provides a unique opportunity for payers to combat the opioid crisis by identifying and sharing strategies to prevent prescription opioid misuse and opioid use disorder. By sharing information among payers, the HFPP aims to identify and intervene on behalf of patients at risk of opioid-related harm, as well as to target fraud, waste, and abuse in opioid prescribing. In January 2017, the HFPP released a White Paper that describes the best practices for serious consideration by all healthcare payers and other relevant stakeholders to effectively address and

¹³ <https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

minimize the harms of opioids while ensuring access to medically necessary therapies and reducing fraud, waste, and abuse.

Ensuring Access to Needed Treatments

A critical part of tackling this epidemic is making sure that Medicare beneficiaries grappling with Opioid Use Disorder (OUD) have access to the most effective treatment options. While there is no distinct Medicare benefit category for substance abuse treatment, such services are covered by Medicare when reasonable and necessary. Medicare covers a full range of services, including those provided for substance use disorders. Through its networks of health quality experts and clinicians, CMS advocates the sharing of best practices for OUD screening and treatment.

CMS is also working to encourage clinical screenings to identify individuals suffering from OUD and increasing access to behavioral and medication-assisted treatment (MAT), the most effective treatment for OUD. MAT is the use of medications, in combination with counseling and behavioral therapies, to treat substance use disorders, including opioid use disorders. MAT is a valuable intervention that has been proven to be the most effective treatment for opioid use disorder, particularly because it sustains long term recovery and has been shown to reduce opioid-related morbidity and mortality.¹⁴ CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. In addition, CMS is promoting improved access to the opioid overdose reversal drug naloxone by requiring that the antidote appear on all Medicare Part D formularies. We recognize that it is very important for Medicare beneficiaries and those who care for them to understand that these options are available to them under Medicare, so CMS is also working to educate clinicians, health plans, pharmacy benefit managers, and other providers and suppliers on services covered by Medicare to treat beneficiaries with OUD.¹⁵

¹⁴ <https://www.ncbi.nlm.nih.gov/pubmed/24500948>

¹⁵ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1604.pdf>

Conclusion

CMS is actively engaged in addressing the opioid epidemic and is committed to implementing effective tools in the Medicare program. CMS will continue to work with beneficiary and advocacy groups, health plans, our federal partners, and other interested stakeholders to address this devastating epidemic. CMS is committed to working with Medicare Part D sponsors to assure they are in compliance with requirements that protect beneficiaries and can prevent and address opioid overutilization. This epidemic is devastating families and communities, and CMS is committed to using all the tools at its disposal to take meaningful action to stem this tide. We look forward to working with this Committee and the Congress on these efforts.

Chairman JENKINS. Thank you. And I appreciate all three of you being here today with your excellent testimony.

We will now proceed to the question and answer session. And I would like to direct my questions to Ms. Curda.

Ms. Curda, in your testimony, you discussed how the OMS tracks only a small portion of the potentially at-risk beneficiary population. Can you talk more about what GAO found?

Ms. CURDA. Sure. We found that the criteria that CMS is currently using in its OMS tracked the very high dose—beneficiaries who are getting very high doses, who are using multiple doctors, multiple pharmacies, but they aren't tracking the larger number of beneficiaries that are at risk of harm because they are receiving higher doses of opioids. These are those that are receiving more than 90 milligrams morphine equivalent dose per day, which is indicated in CDC guidelines.

According to a one-time analysis that CMS performed, this criterion covered about 700,000 beneficiaries in 2015. So, just relatively speaking, we are talking about 700,000 beneficiaries taking very, very high levels of opioids, versus the OMS criteria, which is in the sort of more tens of thousands range. And so, we recommended that they gather that data, not just for reporting back to the plan sponsors, but because it has this goal of reducing harm from opioid use, to track and monitor that information over time to see what is happening with that number of beneficiaries, to see is it going up, is it going down, and use it to inform its strategy.

Chairman JENKINS. Right. One of the recommendations that GAO made was for CMS to track beneficiaries receiving large amounts of opioids, irrespective of the number of pharmacies and providers that they used to obtain them. Can you talk about why you believe this to be important?

Ms. CURDA. Sure. CMS does track very useful information on—using its overutilization system, and also in its in-patient quality measures. But neither of those measures track the larger number of beneficiaries that are receiving harmful doses of—potentially harmful doses of opioid medication. And so we think that, in routinely collecting this information, they can better inform their strategy and track their goal achievements.

Chairman JENKINS. What specific data do you believe is important for CMS to track?

Ms. CURDA. This would be the patients receiving either 90 milligram morphine equivalent dose per day or greater through Medicare.

Chairman JENKINS. Okay. How much of that data is currently being utilized for CMS for these purposes, and why do you believe the current data CMS is monitoring to be insufficient?

Ms. CURDA. It is basically just a measurement issue. The CMS tracks data, but not at that level. And they don't use it for the purposes of monitoring this harmful use of opioids over time. So we believe that by collecting this information and monitoring it, over time they can better track whether they are achieving their goals.

Chairman JENKINS. Okay. Thank you. I would now like to recognize Ms. DelBene.

Ms. DELBENE. Thank you, Madam Chair. The Administration recently released guidance indicating that it would allow States to

implement work requirements to access Medicaid. Ms. Brandt, in your testimony to the Committee, you state one of the points of the comprehensive evidence-based opioid strategy is to “improve access to treatment and recovery services, and to enable individuals to achieve long-term recovery.”

In the guidance that was put out, the Administration requires exemptions for individuals with medical conditions, such as substance use disorders, and outlined that medical treatment for any—for their substance use may fulfill a work requirement.

My question is, how does a work requirement improve access to treatment? And, second, how can an individual who is suffering from addiction access treatment to fulfill their work requirement if they are not allowed to get Medicaid and can’t have that to cover such a treatment? So, we end up in this circular situation where someone doesn’t have coverage, so they can’t get treatment, but they can’t fulfill the work requirement because they need to be in treatment to do that. Can you explain how we would address that?

Ms. BRANDT. Thank you for your question. While the work requirements and the Medicaid requirements are not my day-to-day responsibility, I will do my best to sort of answer, to the best of my knowledge.

As part of our issuance last week, as you mentioned, States are required to take steps to ensure access to appropriate treatment or services. And one of the things that they are supposed to do is make reasonable modifications to ensure that people who are receiving treatment for substance abuse disorders or opioid treatments are able to have reasonable accommodations. And so we have worked to provide guidance to the States to help them to ensure that balance, and the goal is to ensure that the beneficiary who is receiving those treatments can hopefully be able to have the appropriate accommodations made so they can continue to receive it.

Ms. DELBENE. So, if a State doesn’t come up with a work—with the work-around, as you describe, how would someone access Medicaid so they can get treatment if they can’t fulfill their work requirement because they can’t fulfill—they aren’t allowed to access treatment?

Ms. BRANDT. Well, our goal is to work with the States to ensure that they would be able to provide those types of accommodations as part of what they are supposed to do under the mandate of the work requirement. And we would work with them to ensure that the beneficiary, hopefully, would be able to continue to receive those types of services.

Ms. DELBENE. Thank you. As CMS moves more providers to value-based payments in an effort to improve quality and lower healthcare costs, part of the challenge is to properly risk adjust for high-needs patients. And because substance use disorder is such a complicated condition that demands a tremendous amount of coordination of care, this may be one of the conditions that warrants a risk adjustment. And, in fact, this was done for a managed care demonstration in Massachusetts that focused on dual eligible enrollees under 65.

Ms. Brandt, have you considered how we can better align payment to promote coordination and quality care for people with sub-

stance use disorders in other value-based and managed care arrangements like ACOs and Medicare or Medicare Advantage Plans, and how is CMS promoting coordination of care between providers to mitigate the instances of high amounts of opioid prescribing?

Ms. BRANDT. Thank you for your question. As I mentioned in my oral and written testimony, ensuring good access to beneficiaries across our payment lines is one of the goals at CMS. And one of the things that we have been doing is looking across all of our payment types, especially as we begin the new payment rules for this year and as we have discussions with providers to determine where we can do more and how we can have better coordination with them on just these types of issues.

So it is something that we are currently engaged in as an agency, to try to figure out better ways to make sure that we are striking that balance and making sure, as I said in my testimony, that we have the right treatment, for the right people, in the right setting, at the right time.

Ms. DELBENE. I understand that the—things like the managed care demonstration in Massachusetts have been looking at these scenarios. Is there something that you have learned from these that will better inform us on how best to address more complicated situations like substance use disorders?

Ms. BRANDT. I can't speak specifically to the Massachusetts demonstration project because I am not familiar with the outcomes of that, but I can tell you that we have been looking at all of our demonstration projects, the models we run, and our Centers for Medicare and Medicaid innovation, as well as across the CMS programs to look at lessons learned and best practices, and we are trying to bring all that to bear as we try to figure out good solutions for this crisis.

Ms. DELBENE. Thank you very much. I yield back.

Chairman JENKINS. Mrs. Walorski is now recognized for 5 minutes.

Mrs. WALORSKI. Thank you, Madam Chair. Thank you to our witnesses for being here today. Like so many of the parts of the country, the opioid epidemic has affected my district in Indiana. It has destroyed lives, torn apart families, and put stress on first responders, hospitals, the foster care system, and other vital community institutions. Unfortunately, last year a dear friend of mine, a doctor in my district, was murdered for refusing to prescribe opioids.

Opioids come in many forms: pills, heroin, the emerging threat of fentanyl, and others. Unfortunately, this means that there are too many fronts in the fight.

Mr. Cantrell, I just want to ask you, identifying overprescribing by providers is incredibly important; however, examining at-risk beneficiaries can also help identify providers who are potentially overprescribing. The Inspector General identified in my State, Indiana, a prescriber who wrote an average of 24 opioid prescriptions each for 108 beneficiaries who received extreme amounts.

Can you talk about your approach to identifying potentially problematic prescribers, and then also, once these prescribers are identified, what happens?

Mr. CANTRELL. Yes, thank you. First of all, in our data brief, we used an analysis approach that we hadn't previously utilized. We wanted to first focus on the beneficiaries who are at greatest risk of harm because of the volume of opioids they were receiving. And, instead of just looking at the universe of claims, we look then at the individuals, the prescribers who were prescribing specifically to a high number of those at-risk beneficiaries.

So, that led us to, in our report, 400 different prescribers who were prescribing either to a large number of doctor-shopping Medicare beneficiaries, or to a large number of patients receiving high amounts of opioids.

So, when we have this analysis, we use this data—first, we report on these results, so that we can inform the public. We share this information with CMS, so they can begin engaging in administrative or other review to monitor these prescribers, and we refer many of these out to our field offices, to our partners at the Department of Justice for criminal investigation.

Now, with 400 different prescribers identified, it isn't necessarily the case that all are committing fraud, so we sift through the data to identify those that appear most likely to be committing fraud, send them out to the field, and then, ultimately, it takes boots on the ground to investigate these matters and bring individuals to justice who have committed this fraud.

And so it is very intensive work, and we work closely with DEA, FBI, State agencies, and local law enforcement, and this is a huge priority for us to bring individuals who are prescribing in the Medicare and Medicaid space these opioids illegally.

Mrs. WALORSKI. And just as a followup, I have heard from doctors in my district. They would like to have access to more data so they know, and they are a little bit less at risk on, you know, falling into some kind of a doctor-shopping kind of a network.

Can you talk about ways you believe we can improve data sharing to combat opioid abuse? And then, are there ways to improve data sharing really just while working within State privacy laws as well?

Mr. CANTRELL. Well, first of all, we certainly encourage the utilization of prescription drug monitoring programs in every State. We believe these are an important tool. For us, we see Medicare claims data, we have great visibility there. We have a little less, slightly less, but some visibility in the Medicaid, but we don't see cash-based transactions and other transactions like that, which the PDMPs would include.

And so, we think it is vitally important for prescribers and pharmacies to check these PDMPs to make sure that they are not dispensing to doctor-shopping patients. And we look for other ways to share this information across both the Federal Government and with the States and the private sector.

One of the things I think is most important that we have done is share their approach to this analysis, but also the underlying data with our private sector program integrity partners who we work with, through the Healthcare Fraud Prevention Partnership and the National Healthcare Antifraud Association. So they are empowered to conduct their own analysis, monitor these individuals, and hopefully have a broader impact.

Mrs. WALORSKI. I appreciate it. And, Ms. Brandt, just quickly, is—one of the things I have continued to work on here is access to non-opioid alternatives. Is CMS developing a plan to use more non-opioid alternatives for patients with chronic pain?

Ms. BRANDT. Yes. As I mentioned in my oral testimony, we are working to increase access to medication-assisted treatments and are looking and working with the CDC and other partners to determine—

Mrs. WALORSKI. On a scale of one to ten, where are we, in looking? What have we found? What are we doing?

Ms. BRANDT. We have done a number of stakeholder listening sessions over the past while, where we got a lot of valuable input, and we have been having meetings with NIH, CDC, and others. So I would say we are probably at about a six; we have more to do, but we are definitely moving in the right direction.

Mrs. WALORSKI. Thank you. Madam Chairman, I yield back.

Chairman JENKINS. Mr. Neal is recognized for 5 minutes.

Mr. NEAL. Thank you, Madam Chairperson.

Massachusetts, as I noted in my opening statement, is really—we are reeling from the addiction crisis, and your testimony was really well done this morning, the three of you. The number of opioid-related deaths in Massachusetts is now four times higher than it was 15 years ago, and it continues to get worse. We certainly owe it to our communities and to our families who have been hit by the epidemic to prevent addiction; that means earlier intervention and treating those afterward as well.

There is a compelling argument as to the most effective way to treat opiate addiction for all of us. Medication-assisted treatment, MAT, is the evidence-based standard for treating opioid addiction. Medical and substance use disorder experts in the President's own Commission point to MAT as a vital tool to attack the epidemic.

Medicare is usually the standard bearer when it comes to healthcare coverage, but Medicare does not cover a key MAT option, methadone for outpatient service. Ms. Brandt, Ms. Curda, you both testified about the importance of MAT in your opening statements.

What is the Administration doing, and what would you recommend that it continue to do or should do to expand access to medication-assisted treatment?

Ms. BRANDT. Well, as I mentioned, Congressman, we are continuing to look at the wide range of alternate treatments, such as Naloxone and others. We are well aware of methadone and the statutory impediments to that, but we are open to working—I know you have legislation on that—we are open to working with Congress to provide technical assistance on those issues. But we can continue committed at CMS to determine what all we can do to increase the access to medication-assisted treatments.

Ms. CURDA. We prepared a couple of reports on the issues surrounding access to medication-assisted treatment, not specifically in Medicare, but in general. The first report we did looked at the sort of regulatory and legal framework for access to these drugs, and also looked at some of the barriers to access. And there were things like not having enough doctors who have the appropriate waivers in order to prescribe this medication, and also in some

cases, simply attitudinal issues where this is viewed as perhaps a substitute for another kind of addiction.

So taking these issues into account, Congress passed legislation last year to enhance access to medication-assisted treatment, and we did a further report looking at HHS's roll-out of the grant programs intended to enhance access to medication-assisted treatment, and we found that they had a strategy for accomplishing this. They were getting the programs going. It was a little too early to assess their effectiveness, but we did note that they did not have any sort of measures in place for their goals for expanding access to MATs, so not knowing sort of what the ultimate goal is for that, and that they did not have sort of firm timeframes. They had planned an evaluation of their efforts, but they did not have any firm timeframes for when that would be done.

Mr. NEAL. Thank you. I hope the Administration and my colleagues on the other side, who I know are all sincere in their efforts on this, would also be supportive of another piece of legislation that I have offered, and that would be to hold harmless first responders who administer Naloxone. When they show up, oftentimes there is violent reaction as the high comes down, and they sometimes have to subdue the individual who has just been treated; save their lives, and then are attacked for saving their lives.

So I think holding those individuals harmless would make a good deal of sense, and I hope that the—in a bipartisan manner we might be able to address that part of this complicated issue as well.

Thank you for your testimony, and thank you Madam Chairperson; I yield back.

Chairman JENKINS. Mr. Schweikert is recognized for 5 minutes.

Mr. SCHWEIKERT. Thank you, Madam Chairman.

My assumption is that everyone in this room has been affected by addiction in a family member, a friend, or a neighbor. Growing up in a household where my mother was actually an addiction counselor, after years of fighting through her own demons, you actually just understand how complicated this is.

This is actually an interesting opportunity, as the Ranking Member was talking about some of the different pieces of legislation he has, and I agree, we should actually start to step up and do a package, because there is no golden bullet here, no magic bullet.

But I do want to also touch on—we have a piece of legislation, and it is bipartisan, we have Republicans, Democrats, and this Committee from E&C, and that is a mechanism to standardize the prior authorization process, so the electronic mechanism is underneath.

And Ms. Brandt, I am going to ask you to sort of walk us through right now for Part D, how prior authorization actually is working today, and then I want to sort of pitch everyone on the Committee, the concept of, let's actually put together a package of bills, hopefully our prior authorization standardization will be one of those. But how does it work today for Part D?

Ms. BRANDT. Well, let me caveat by saying, I am not a Part D expert, so I will give you the best of my understanding—

Mr. SCHWEIKERT. Okay.

Ms. BRANDT [continuing]. As to how it works. But currently the way it works is that the Part D sponsors have formularies which

have approved drugs on them, and as patients present, they see if the drugs that they are looking to receive, that are being prescribed to them, are off of that formulary. And then they determine whether or not, based on CDC prescribing guidelines, they meet the appropriate dosage amounts.

Some of what the GAO was saying, we have been working to incorporate into our Overutilization Monitoring System to determine that beneficiaries are not prescribed beyond what are acceptable levels in the program.

And so, using those types of criteria and screening, it is then determined what is appropriate to be able to authorize to be paid under the person's plan.

Mr. SCHWEIKERT. For our other witnesses—and thank you for that. Any other thoughts, that if I came to you—in reading the testimony, it looks like we are doing a much better job in our data collection and data modeling and finding bad actors.

Okay, now that we have the data, how do you move to a solution? Is it alternative pharmaceuticals? Is it a standardization of the red flashing light for the pharmacy or the doctor, saying, this doesn't need to be filled? You have the data; what is the next solution, what is the next layer?

Mr. CANTRELL. One of the things that we are recommending and continue to monitor is the beneficiary lock-in program that has now been authorized and CMS is working to implement. With the number of beneficiaries at risk because of the volumes of prescriptions they are receiving, I think this data analysis leads us to patients that maybe should be considered for this type of lock-in, at least gets us started as to where to focus these efforts, and that will help manage the care of these individuals who need services.

Mr. SCHWEIKERT. All right.

Ms. CURDA. We didn't acknowledge that issue specifically, but I think you can sort of take an all of the above approach, you can—all of these things working together can help. One thing we looked at, a couple of years ago, was more of a prevention focus. It gets very costly when it gets to the point where someone is addicted to opioids and requires therapy and treatment. It is much better to prevent the addiction in the first place; to the extent that we can have controls in place to flag these individuals who are getting very high doses, it is very helpful.

But we did a—the Comptroller General held a forum that talked about prevention and talked about educational healthcare and sort of a legal kind of strategy.

Mr. SCHWEIKERT. That is actually a very rational approach. In my last couple of moments, I will pitch our new Chairman, which I am elated to have you—I feel so tall next to you. There is an opportunity here for us to take a number of the pieces of legislation, because we know there are some alternative pharmaceuticals out there that actually have less addictive effects or more stabilizing effects.

There is my fixation on taking the data that has been collected, building that standardization on the preauthorization so we stop—it becomes almost a preventative because you don't write the prescription. And the uniqueness of this Oversight Committee, and its charter, we have the ability to do legislation. Maybe it is time we

all get together, figure out if we have solutions, bundle them together, and move forward.

And with that, I yield back.

Chairman JENKINS. Excellent. I yield to Ms. Chu for 5 minutes.

Ms. CHU. Thank you. Mr. Cantrell, in your testimony you mentioned an example of drug testing or treatment fraud in which sober living homeowners were bribed to direct their residents to a specific lab for their year-end sample screenings. As you noted, this resulted in fraudulent earnings at the expense of sober living homeowners and those residents who are in recovery.

I truly appreciate the OIG's attention to this issue, as I have heard directly from constituents about the fraud and abuse that can occur in sober living facilities. And, in fact, the bottom line is we need better oversight, because not only are these bad actors preying on vulnerable individuals who have just left treatment, but institutions like the OIG are playing catch-up to find these nefarious actors, and in the meantime, more individuals can be hurt.

So I believe we should be assisting those who have entered and completed treatment and who need support to make a full recovery. That is why I introduced the bipartisan H.R. 4684, the Ensuring Access to Quality Sober Living Act, and it would direct a Substance Abuse and Mental Health Services Administration, or SAMHSA, to develop a set of best practices for sober living facilities so that individuals and families with loved ones just leaving treatment can better identify the good actors from the bad.

So, Mr. Cantrell, can you expand upon the OIG's efforts to address fraud and abuse in the sober home industry?

Mr. CANTRELL. Yes. Thank you. Sober homes have become—we used to talk a lot about pill mills, now we have sober homes becoming fraud mills. These aren't services that are necessarily covered by Medicare or Medicaid, but they are ways to attract people at great risk because they are likely addicted—have a substance abuse disorder, need treatment, need services, but instead corrupt sober home owners are basically farming them out for either medically unnecessary services, treatment, or testing, or services and treatment that are just never provided.

Sometimes these homes are places where individuals can continue to get drugs. And so we have all read about the horror stories of individuals going to these homes trying to get treatment and ultimately overdosing. So this is a problem that is of great concern to us. Largely, it affects us on the ancillary services side as they farm them out, pay kickbacks to doctors and drug testing labs.

But it is also through the Healthcare Fraud Provisions Partnership, we know it has had an enormous impact on the private sector payers as well. So this is definitely a problem that we are noticing and we are tackling as it affects Medicare and Medicaid.

Ms. CHU. Well, I thank you for pursuing it.

And now I would like to address a question to Ms. Curda. We know that there is, of course, obviously, an unprecedented crisis, and we are going to have to find solutions that work for everyone, and that is why I believe we should be expanding our treatment options for a vulnerable population to include alternative medicines like acupuncture.

Acupuncture has been the subject of numerous studies by the National Center for Complementary and Integrated Health and the National Institutes of Health, and it has been found to be nonaddictive, noninvasive, and can be good for conditions like migraines, hypertension, chronic pain, or arthritis.

And, in fact, no less than 13 independent studies on the effectiveness of acupuncture are referenced in NCCIH's web page on acupuncture. At a time when there is an over prescription of opioids, I believe that we should be opening our doors to alternative treatments like acupuncture. And that is why I introduced H.R. 2839, the Acupuncture for Heroes and Seniors Act, which would ensure that qualified acupuncturist services are covered through Medicare.

It is currently available for individuals who receive their health insurance through the Affordable Care Act in States like California, as well as in some Medicaid plans, but seniors should not lose out.

So, Ms. Curda, has the GAO ever studied the impact of making acupuncture available through traditional Medicare plans?

Ms. CURDA. No, I don't believe that GAO has done that work.

Ms. CHU. Is it possible for GAO to evaluate the effectiveness of offering integrative health alternatives like acupuncture to opioid prescribing practices and government healthcare programs? Do you foresee any hurdles in such an examination?

Ms. CURDA. Yes. I think GAO could look at that question. The hurdle would be the sort of status of the literature and evidence in that area. We would probably want to first do a review of the literature to see, you know, what does the peer-reviewed literature say about the effectiveness of that treatment. And we could certainly describe, you know, what that evidence lays out.

Ms. CHU. Thank you.

Chairman JENKINS. Mr. LaHood is now recognized for 5 minutes.

Mr. LAHOOD. Thank you, Chairman Jenkins. And it is an honor to be part of this Subcommittee and Full Committee, and I appreciate the opportunity to have this subject matter before us today. And I want to thank the witnesses for your valuable testimony here today.

I represent a district in central and west central Illinois that is a rural district, 19 counties. And this is an epidemic that continues to rage in a district like mine. And it really transcends socioeconomic—all socioeconomic categories, rural, urban, and all sectors of society. And over the last 2 years, I have held a number of roundtables in my district with first responders, law enforcement, judges, treatment center providers, and physicians, to try to understand the issue better, but also look at how we, from a public policy standpoint, what we can do to fix this problem.

And as I look at the numbers in Illinois, data from 2016 shows that, in a 3-year period, deaths from overdose increased by 44 percent from 2013 to 2016, and over 80 percent of those deaths were attributed to opioids. Of those 80 percent of opioid-attributed deaths, there was a 70 percent increase from those attributed from opioids in that same 3-year period.

In Adams County, in my district, they have seen a 360 percent increase in emergency department visits related to opioid and her-

oin overdoses over that 5-year period from 2010 to 2015. Additionally, the county saw a 300 percent increase in overdose mortality rates due to opioids and heroin in the same period.

And looking at what is the solution, obviously, we have looked at—from a law enforcement perspective, what do we need to do on the criminal justice side? Also looking at how you hold doctors accountable, and what we do in that space. We have talked a lot about, you know, how we have more resources and money for treatment centers.

And in some ways, when we look at this epidemic and the direction we are going, I equate it in some ways to what drunk driving was in this country 25 years ago. It was raging out of control, so what did we do? We allocated resources, we raised awareness, we had a public campaign, and we also had something called Mothers Against Drunk Driving that was organic that started.

So I don't necessarily think this is a Federal solution, this is going to be solved in Washington, DC, and that we have to work with our local stakeholders in our different States and local areas that are doing a lot of good work on this. And so when I think about the testimony here today, Mr. Cantrell, I wanted to ask you, you talked a little bit about prescription drug monitoring systems.

In terms of States that have done a pretty good job on that, can you talk about examples of that, which have kind of been a model for how to do it, and what they have done to be successful?

Mr. CANTRELL. The OIG hasn't completed any work on evaluating PDMPs across the country. But in just talking to our staff across the country, our special agents, and hearing from individuals who work in different States, there are a couple of things that need to happen, I think, to make a PDMP successful.

One, it has to be—there needs to be some sort of requirement that data be entered in a timely fashion. I think that, for those that are successful, there is timely data entry, there is timely review of that data. Sometimes there needs to be interoperability. Some of these PDMP systems don't talk from State to State, and we see many fraud schemes, of course, that cross State lines.

So the States that have interoperability with their neighboring States, that is a plus. And then we have seen, in terms of data access, for us in law enforcement, some States restrict access for law enforcement, and other States allow that sort of access. From my perspective, of course, I believe in that law enforcement access to help identify those individuals who may be prescribing or doctor shopping in seeking to divert drugs. So those are some of the components of what I think can make up a successful PDMP.

Mr. LAHOOD. And is there an example or a model you can point to that has done a pretty good job around the country?

Mr. CANTRELL. I just heard anecdotally that, as Kentucky got started, they were doing a pretty good job; they are one of the earlier ones that I was hearing about. I have heard that the State of New York, from our agents, is doing a pretty good job, but I don't have any data or any statistics to point to their success or favor. That is just anecdotally what I have heard from some of our agents.

Mr. LAHOOD. Thank you.

Chairman JENKINS. Mr. Crowley is recognized for 5 minutes.

Mr. CROWLEY. I thank the Chair, I thank the Ranking Member for holding this hearing today on what has become a devastating epidemic for our Nation. My district, like many other districts across the country, has been ravaged by the opioid epidemic. More Bronx residents die of drug overdoses—more Bronx residents died of drug overdoses in 2016 than any other New York City borough.

Out of the 308 overdose-related deaths, 85 percent involved opioids generally, and 76 percent involved heroin or fentanyl. This devastation is unacceptable anywhere. But there is an aspect in my district that is notable, part of the opioid epidemic when compounded with other parts of the country.

The increase in prescription opioids across the country has led to a spike in heroin use, which people turn to for a more potent high as they run out of their prescription medications. Heroin has become even more accessible and cheaply available to communities across the country.

In a community like mine, which is still recovering from the aftermath of the failed tough on crime tactics of the 1980s and 1990s, residents have not properly dealt with their addictions and are more likely to use and abuse newly available heroin. That makes opioid-related overdoses a side effect of the race-based drug enforcement policies of the past.

As we work to address the opioid epidemic, I encourage this Administration and my colleagues in Congress to work toward a more holistic approach that focuses on treatment rather than punishment. And I challenge all of us to strive for a better understanding of the entirety of the epidemic, which impacts different communities on different levels.

Urban communities, particularly communities of color, must be a part of this conversation, and they must be a part of the solution to this terrible and growing problem.

Mr. Cantrell, in the OIG report, Opioids and Medicare Part D, there are concerns about extreme use and questionable prescribing, and it suggests that prescribers are not checking the State prescription drug monitoring databases, or these databases do not have current data.

Can you explain how prescribers are trained or are supposed to be trained on how to use their State prescription drug monitoring database?

Mr. CANTRELL. I am sorry, but I don't actually know the training requirements for the use of these prescription drug monitoring programs. And I would suspect it might vary from State to State.

Mr. CROWLEY. Do you have State-based data on where there are vulnerabilities of prescriber use of prescription drug monitoring databases?

Mr. CANTRELL. We do not at this time.

Mr. CROWLEY. Thank you. What are HHS-OIG's recommendations for improving prescriber use of these databases?

Mr. CANTRELL. Education is certainly one strong component. And we, along with the DEA, who goes around the country talking to pharmacists and prescribers, participated in these events to train and educate individuals in the community about the importance of this tool and the fraud schemes that they should be look-

ing out for when utilizing these tools. So I think education is critical.

And I, once again, this is not based on any analysis that we have done, but I have just heard there are some barriers to utilization because it can take a long time to access these PDMPs as they are providing patient care.

I have heard from individuals in the community that sometimes just the nature of the system can, maybe it is slow, and it can deter you. So I think that obviously any improvements that can be made to increase the timeliness of these sorts of data checks would be critical to ensuring adoption and use.

Mr. CROWLEY. I think there is one critical area in terms of government that can be involved in helping to get a handle on what is happening in each of the States. And I would hope that we would have a more robust addressing of the monitoring databases.

Mr. Cantrell and Ms. Curda, does the OIG or GAO look at race as a factor in collecting data regarding the opioid epidemic?

Mr. CANTRELL. We do not.

Ms. CURDA. We have not looked at that.

Mr. CROWLEY. Well, thank you. And I appreciate your time here today.

Thank you very much. I yield back.

Chairman JENKINS. Mr. Bishop, you are recognized for 5 minutes.

Mr. BISHOP. Thank you, Madam Chairman. Thank you to the panel for being here today and providing your valuable testimony. I appreciate the information that you shared and your expertise.

I am from the State of Michigan. I share all the same concerns that the rest of the Committee has on this subject. Each of us has our own stories to tell. Over and beyond the direct impact on families and individuals who are impacted by this scourge of opioid abuse, there is another statistic that I find alarming.

The American Enterprise Institute recently published a study looking at the cost of the opioid epidemic. And it did it by State. And I was astounded to see that in Michigan, where I am from, my home State, the cost of opioid addiction is over 4 percent of our State's GDP. And yet I look at other States on this table that we have been provided, and it shows other States that have also been impacted, but not to the extent that other States have.

There is a huge disparity in how much other States have been impacted. For example, the White House Council of Economic Advisors, it estimates the societal burden to fight the fatalities from opioid overdoses, and also estimated the nonfatal cost of the opioid epidemic in 2015 to be \$72.3 billion, and the fatal cost to be \$431.7 billion. And then you look at the State by State, and you see the huge disparity.

And I am wondering, why does it cost West Virginia, which has the highest per capita burden at \$4,793 per resident? And then you look at Nebraska, which is \$465 dollars per resident. Why is that? Are there more resources there? Is there some kind of demographic there that is more susceptible to this? What causes this kind of data?

Can someone tell me that? Mr. Cantrell.

Mr. CANTRELL. Just in terms of what we see, what we focus on, fraud trends, you know, there is a variety of factors, but we definitely see that once a fraud scheme takes root, it becomes viral in communities. And that is no different, I think, than in the opioid epidemic. And our agents, unfortunately, in the Detroit area, see numerous fraud investigations related to illegal opioid distribution. And sometimes we are told that it is an export area. So that those drug schemes are meant to often export those drugs to other States where they can get higher reimbursement.

So this is the intelligence, you know, we hear from the ground. Once again, I don't have any analytics available to point to reasons why one State is different than the other, but, you know, we have continued throughout my career, my 20-year career, certainly to see South Florida as a hotspot or an epicenter of healthcare fraud in general. It has also been a point where we have seen lots of fraud related to opioids. Certain communities where this has taken root, it is hard to get rid of it once it has taken root.

Mr. BISHOP. But you can identify those areas, those demographics where this kind of abuse and fraud happens. You have indicated that you have an opioid abuse and fraud program that you administer. Can you tell us how that works and what the resources are? Who is in charge of it? What is your mission in that organization?

Mr. CANTRELL. So, that is a new unit, established by the Attorney General just last year. As it was initiated, they rolled out 12 prosecutors in 12 districts around the country to focus specifically on this epidemic. And as a partnership, FBI, OIG, DEA, we all dedicated agent resources to those prosecutors.

Now, that is just a small, at this point in time, kind of effort in comparison to the total effort nationwide in this area, but it is an important focus in areas that were not necessarily the bigger markets that had the greater resources. We focused on smaller markets in these first 12 districts to bring resources to various communities that hadn't necessarily seen the amount of resources in the past.

Mr. BISHOP. Thank you for that. You also mentioned there were private sector partners as well. I am interested to know what the private sector is doing to partner with you.

Mr. CANTRELL. So we talked, and CMS is an integral part of the healthcare fraud prevention partnership, but it provides a community of private sector payers, State agencies, as well as Federal payers and law enforcement to share, first of all, information about trends and schemes, but, also, it is a forum where they can safely share data from different resources, analyze that data, and come up with answers or identify issues across multiple data sources that were previously available to be searched across.

So I think, for me, it is certainly of great value in learning about these schemes, because some of these schemes, like the sober home scheme that was discussed earlier, I was hearing about it from our private sector partners before we were seeing it impacting Medicaid or Medicare. And so it is a great intelligence tool.

Mr. BISHOP. Okay. Thank you so much. And I yield back.

Chairman JENKINS. Mr. Meehan is recognized for 5 minutes.

Mr. MEEHAN. Thank you, Madam Chairman. I am grateful for you allowing us to sit in on this very, very important issue. And

I want to thank you for the work that you are doing, each of the panelists, engaged in what is a remarkable challenge for all of us, and particularly back in our communities.

I want to ask specific questions about the Medicare relationship to this, but in my own region of southeastern Pennsylvania, we have seen a staggering 83 percent increase in drug deaths. That is overwhelming. And when you look at what is driving that, the distinguishing issue appears to be fentanyl, but it is fentanyl which is tied to its use with, oftentimes, opioids. And I know we are dealing with a poly-drug environment, and there is no simple solution.

But if we are going to have an impact on this, we want to start by dealing with the opioid abuse in the first place. We have worked on some programs here in Congress with things that we have done already that have come from recommendations from people like you. One of those is the Medicare lock-in. And I have listened to each of the panelists describe in various ways how individuals have been able to utilize the system, either by going to multiple pharmacists, or multiple doctors, or multiple plans to get the drugs. And still staggering, that even with Medicare, we are talking about people who are later in life—often, not all the time—but later in life, and we are still talking about dependency in that group.

So the lock-in program, as I understand right now, Mr. Cantrell, would allow us to have a designated distributor and a much better control over that individual's relationship. Now, there have been recommendations and utilization by numbers of plans, but CMS itself, or at least the government, hasn't created it. Can you tell me where we are on that, where you think lock-in may be utilized?

Mr. CANTRELL. Well, first, I will say we are very supportive of lock-in, but I think I would like to defer to my colleague from CMS to talk about where it stands.

Mr. MEEHAN. Is this Ms. Brandt?

Ms. BRANDT. Yes.

Mr. MEEHAN. Because I was going to go to you next because you—

Ms. BRANDT. No problem.

Mr. MEEHAN [continuing]. Mentioned that in your testimony.

Ms. BRANDT. I am happy to. As I mentioned in my testimony, we really appreciate this, this additional tool from Congress. We agree with the OIG. We think this is going to be a very powerful tool. We are currently in the notice and comment period for this. We have to promulgate regulations to implement it. In fact, the comment period closed yesterday, so that's good timing with the hearing today.

But we are looking forward to reviewing those comments and then implementing those comments as we do the final rule. And then, beginning in 2019, we will be able to begin using this tool. And we are very excited at the potential that it is going to add to our suite of tools to help us address these types of issues.

Mr. MEEHAN. How do you think it is going to make a difference?

Ms. BRANDT. Well, it will make a difference because it will allow us, as you said, to limit. We will be able to limit a beneficiary to a pharmacy and be able to have them at one pharmacy. And that is the only place, or however it works out for implementa-

tion—we are still working all that out—but essentially, they could be limited to one pharmacy, which would allow us then to be able to see their billings just related to that pharmacy. Right now, they can go to multiple pharmacies, multiple prescribers. This limits the scope of that much more narrowly.

Mr. MEEHAN. Okay. If you know, because I am sure the comments have come from a variety of places, but I am assuming you have been monitoring this as we have been going through the comments. Have there been any observations which have influenced your thinking on this or any kind of a perspective that was shared in the comment period that either opens up a new place for us to consider the program or a concern that we may not have been thinking about?

Ms. BRANDT. Well, as the comment period did just close yesterday and because it is open rulemaking, I am afraid I can't speak to that, sir.

Mr. MEEHAN. Okay.

Ms. BRANDT. But as we move forward and have things that we can share, we will be happy to do so.

Mr. MEEHAN. Okay. Well, I appreciate that. May I just ask if anybody has a thought on one other problem that I am hearing quite a bit about, and it does relate to opioid abuse, but it is the abuse of treatment programs in certain States in particular, in which people appear to get treatment for a period of time, they go off, and there are almost finder's fees to get them in, and they walk out.

And people are targeting them to get them readdicted, getting them back into treatment so long as there is a payer, they are in, then they pull them out. And some of these things appear almost to be scams. Is anybody looking at this issue, or does anybody have any thoughts? The OIG.

Mr. CANTRELL. Unfortunately, we are seeing a great deal of fraud relating to the treatment side of this epidemic, where we need legitimate services the most.

We discussed the sober homes where addicted residents are sometimes farmed out for lab testing that is either never provided or isn't appropriate, and they are billing thousands of dollars for these residents, for these tests. They are offered counseling, which once again is never provided or isn't the quality of counseling that actually these individuals need.

And unfortunately, we are also seeing, in terms of some of the medication-assisted treatment, which, I think, many have discussed the importance of increasing access to that, we are seeing fraud schemes relating to this, the availability of these drugs that are intended to treat this crisis.

So the fraud has followed this epidemic from source all the way to treatment. And that is the unfortunate thing that we are seeing around the country right now.

Mr. MEEHAN. I would love to follow up more with you on that, but, Madam Chairman, I yield back.

Chairman JENKINS. Mr. Blumenauer is recognized.

Mr. BLUMENAUER. Thank you very much, Madam Chair. And I do appreciate our Subcommittee having this hearing. I think this is the first time Ways and Means has really dealt with this opioid

crisis and the impact it has on the things that we are responsible for.

I hope it is not the last. I hope that there is an opportunity—I think this is one thing that touches us all that we feel strongly about. It certainly impacts our community. It makes a difference in terms of employment. What is it, for one-quarter of the women who are ineligible of being in the workforce, there is an opioid problem, I am told.

I am concerned that, as we are looking at different therapies, different options, there is a way to focus on something that some of our States have done, the State of Washington, the State of Oregon, dealing with medical marijuana. And I have some material, Madam Chair, that I would like to place in the record that makes it clear that States that have worked with medical marijuana prescribe fewer pills.

[The submission for the Record of Hon. Earl Blumenauer follows:]

Physician Guide to Cannabis-Assisted Opioid Reduction

Prepared by Adrienne Wilson-Poe, Ph.D.
Distributed by Congressman Earl Blumenauer

Cannabis reduces opioid overdose mortality.

- In states with medicinal cannabis laws, opioid overdoses drop by an average of 25%. This effect gets bigger the longer the law has been in place. For instance, there is a 33% drop in mortality in California, where compassionate use has been in place since 1996 (1).
- This finding was replicated by Columbia's school of public health, using a completely different analysis strategy (2).

Cannabis reduces opioid consumption.

- Cannabis is opioid-sparing in chronic pain patients. When patients are given access to cannabis, they drop their opioid use by roughly 50%. This finding has been replicated several times from Ann Arbor to Jerusalem (3, 4).
- This opioid sparing effect is accompanied by an enhancement of cognitive function once patients begin cannabis therapy: this effect is most likely due to the fact that patients reduce their opioid use (5).
- Cannabis use is associated with a reduction in not only opioid consumption, but also many other drugs including benzodiazepines, which also have a high incidence of fatal overdose. In states with medicinal cannabis laws, the number of prescriptions for analgesic and anxiolytic drugs (among others) are substantially reduced (6). Medicare and Medicaid prescription costs are substantially lower in states with cannabis laws (7).

Cannabis can prevent dose escalation and the development of opioid tolerance.

- Cannabinoids and opioids have acute analgesic synergy. When opioids and cannabinoids are coadministered, they produce greater than additive analgesia (8). This suggests that analgesic dose of opioids is substantially lower for patients using cannabis therapy.
- In chronic pain patients on opioid therapy, cannabis does not affect pharmacokinetics of opioids, yet it still enhances analgesia. This finding further supports a synergistic mechanism of action (9).
- Pre-clinical models indicate that cannabinoids attenuate the development of opioid tolerance (10, 11).

Cannabis, alone or in combination with opioids, could be a viable first-line analgesic.

- The CDC has updated its recommendations in the spring of 2016, stating that most cases of chronic pain should be treated with non-opioids (12).
- The National Academies of Science and Medicine recently conducted an exhaustive review of 10,000+ human studies published since 1999, definitively concluding that cannabis itself (not a specific cannabinoid or cannabis-derived molecule) is safe and effective for the treatment of chronic pain (13).
- When 3,000 chronic pain patients were surveyed, they overwhelmingly preferred cannabis as an opioid alternative (14).
 - 97% "strongly agreed/agreed" that they could decrease their opioid use when using cannabis
 - 92% "strongly agreed/agreed" that they prefer cannabis to treat their medical condition
 - 81% "strongly agreed/ agreed that cannabis by itself was more effective than taking opioids

Cannabis may be a viable tool in medication-assisted relapse prevention

- CBD is non-intoxicating, and is the 2nd most abundant cannabinoid found in cannabis. CBD alleviates the anxiety that leads to drug craving. In human pilot studies, CBD administration is sufficient to prevent heroin craving for at least 7 days (15).
- Cannabis users are more likely to adhere to naltrexone maintenance for opioid dependence (16).

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Mr. BLUMENAUER. There is, on average, a 25 percent lower rate in terms of overdose deaths. The State that has had it the longest, medical marijuana, California, it is a third less. It is a cheaper alternative. It is not addictive, the way that we see with many of the opioids that have been handed out like Tic Tacs.

It is an area where the public has demanded change. Politicians haven't brought medical marijuana to 29 States. It has been the public that has voted for—at least—excuse me, I guess Vermont is in the process of being the first State that does it legislatively. But this has been driven by individual voters. It is supported by strong majorities of the American public. Florida approved, in 2016, a medical marijuana program with 71 percent of the population.

I would hope, Madam Chair, that we would have an opportunity to explore what the impacts are in terms of how Cannabis can prevent dose escalation and the development of opioid tolerance, which happens with people who are taking oxycodone or something like that.

We have the opportunity to be a viable first-line analgesic. We have an opportunity to make a big difference with our veteran populations, who, sadly, we have policies in the Federal Government now that prevent VA doctors from even talking to veterans about the implications of medical Cannabis, even in States where it is legal.

And I think we are missing a huge opportunity to help a troubled population, to cut down on the overdose deaths and save substantial amounts of money and, while we are at it, squeeze the black market, which is fueling a lot of other illegal activities.

I hope, Madam Chair, that my colleagues will have a chance to look at the materials. It just happens to be from a physician, a researcher from Oregon. I hope you won't hold that against it, but the whole second page is documented in terms of justifying the points that I am making.

This is something that we are no longer going to be able to avoid. The public is demanding it; 95 percent of the population has access to some form of legal marijuana. We have the so-called Charlotte's Web Law, where it is a low CBD dose that is available for children with severe seizure disorders. But when you put all that together, it is 95 percent of the population. The American Legion has come forward saying let's research this, let's look at it. We are hearing from veterans that it makes a difference.

Last month I was at our VA hospital, and we were dealing with this precise subject of opioid addiction. And I happened to raise, in the course of the meeting, I said we ought to be looking at medical marijuana and the impact it has. When I walked out of the room, I was followed by a veteran who was on the staff, who took my hands and said, "I am glad you raised that. I couldn't survive without medical marijuana."

I think we are missing the boat if we don't dive into this. And I would commend this to my colleagues for their attention. Thank you very much.

Chairman JENKINS. Mr. Reed is recognized for 5 minutes.

Mr. REED. Thank you, Madam Chair. And as I was listening to some of the exchanges, I wanted to take a moment before I got into my prepared questions. My colleague from Washington asked about

the work requirements for Medicaid, potential issues, and somehow that impacts substance abuse providers. And one of the things that it reminded me of is often Medicaid, and I know it is not the jurisdiction of this Committee, but Medicaid's—I seem to get the impression—goal of providing insurance coverage is the only metric that a lot of folks here in DC gauge its success by.

By that I mean getting people into Medicare programs, therefore, they have health insurance and, therefore, our job is done. But I think we can do better than that.

And, Ms. Brandt, I think your response to that question illustrated CMS' point of view that we can go beyond just insurance coverage and actually get to making people healthier. And so one of the questions I have for you when I want to understand the work requirements that are being proposed is: if someone is in treatment for drug addiction, I look at drug addiction as a disease. It is a medical-related situation. That individual, to me, is not an able-bodied individual as those work requirements I have advocated for over the years would envision.

If someone is seriously addicted and in in-patient-type treatment, is it CMS' position that that individual is able bodied as we are trying to define it under the proposed work requirements that are being discussed across the country today?

Ms. BRANDT. Thank you for your question. I am not sure I can specifically answer our definition of able bodied because, again, the work requirements are outside of the realm of what I deal with day-to-day, but I can tell you, as I mentioned before, that our goal is to make sure that States have steps that they are taking to ensure access to appropriate treatment services, particularly for those who have substance use disorders or opioid disorders.

So if there are people with addiction issues, our goal is to work with the States to ensure that they are providing access to those services and that they are giving appropriate—

Mr. REED. If that addiction is a disease and that prevents them from being able bodied, I would hope that our official policy position would be that that is not who we are addressing with our work requirement.

The other issue that I would raise on this that I am so passionate about, is one of the things that I hear from our employers across the country. One of the barriers to reemployment—which is empowering to individuals, employment, a job, an opportunity, does a lot for, not just earning their paychecks, but for their soul and their dignity and mental health and their physical health—is being addicted to drugs; not being able to pass a drug test.

So we have a program under Medicaid or Medicare that is trying to address opioid addiction; does that not help us to try to solve the overall issue, when it comes to the example for Medicaid, in regards to getting people empowered to be put back into the workforce by getting their addiction under control and having the goal of, not just insurance coverage for those individuals, but also the services and the treatments necessary to get them into a healthy position, which removes that barrier to reemployment that I am discussing here today.

Would you agree with that?

Ms. BRANDT. Well, as I mentioned, our number one goal is the beneficiary. Our goal is to make sure we are getting the right treatment for the right people at the right time, to help get them to be as able bodied and productive as possible.

Mr. REED. I appreciate that. And I share that commitment. And I hope our policies here at the Federal level achieve that, as we set them into a potential future course.

Now to my more prepared remarks. You know, one of the things that I have seen, as all of my colleagues have seen across this country, is that opioid addiction is something that knows no barriers. It impacts everyone. It doesn't delineate, you know, how much money you have, what kind of family you were raised in, what race you are, whether you are a man or a woman. Addiction is that demon that knows no boundaries, in my humble opinion.

And I am reminded of Vanessa, who we were able to assist through our office in the district, who was pretty much written off. Her parents pretty much adopted the tough love approach. And Vanessa came to us just recently after going through some very difficult times. And working with her parents, we were able to get her into a rehab situation. And her parents and her reunited, and at a town hall they were able to declare that she was opioid-free. That is a success story.

And so when I see the new programs that are coming out of CMS—I know I only have 24 seconds left—the Overutilization Monitoring System shows that we went from 29,000 in 2011 down to 11,000 in 2016, for at-risk beneficiaries. That is a significant improvement. How are we going to enhance and promote that type of program even further and get that into the system?

Ms. BRANDT. Well, we are continuing to constantly update that Overutilization Monitoring System. Most currently, we updated it to reflect the newest CDC guidelines. We have been very much focused on first-time opioid over-utilizers. And in fact, we have seen a 77 percent reduction in those since 2013, and we are continuing to use the work of our colleagues at GAO and the OIG and their recommendations to further refine our approach.

Mr. REED. I appreciate that. And to all the Vanessas out there, I just say we stand ready across both aisles to join hands to serve their needs and address their addiction to get them into that healthy life.

With that, I yield back.

Chairman JENKINS. Mr. Curbelo is recognized for 5 minutes.

Mr. CURBELO. Thank you, Madam Chairman, for this opportunity. And I thank all the witnesses. I am from South Florida, so regrettably, I have to raise the issue of healthcare fraud in this context, given that, unfortunately, we are known throughout the country for that issue.

Mr. Cantrell, can you describe some of the types of fraud schemes that you see out there related to opioids? And if you have any examples that are specific or relevant to South Florida, I would appreciate those as well.

Mr. CANTRELL. The fraud schemes, unfortunately, in many cases, we see them migrate from South Florida to other parts of the country. We found it to be a place where fraud schemes are born, in some instances. I know you know this, but that continues to be

an important area for our work in healthcare fraud. But in terms of opioid-related fraud, it runs the gamut.

We have seen situations where we have bad prescribers who are receiving kickbacks, who would write opioid prescriptions and also write prescriptions for other noncontrolled, high-expense drugs and get paid a kickback by a pharmacy. The pharmacy will dispense the opioid and never dispense the expensive drug, keeping all the profit that is paid by Medicare for that drug that was never even dispensed or medically necessary. That is one very egregious scheme.

We have seen examples of physicians who have gone into business with known criminal networks, outlaw motorcycle gangs, for the sole purpose of illegally distributing Oxy's and pairing up with known drug dealers. Sometimes we call them marketers or patient recruiters. In this case, in this area of fraud, they are simply pairing up someone who wants the drug with a pharmacy who is willing to get the drug for a kickback in most of these situations.

In some of these cases, this overprescribing leads to overdoses, and, unfortunately, sometimes an overdosed death for those who have been overprescribed. And so these schemes are not unique to South Florida. These are par for the course, and we are seeing these types of schemes around the country.

Some of the things that we have seen in places like South Florida and New York are schemes related to HIV medications, which are very expensive. And so we have individuals who have HIV, need the medication, but are willing to, in essence, sell it back to a pharmacy for a kickback or sell it on the black market for a profit.

So schemes like this, whether they are related to opioids or other expensive noncontrolled drugs, are certainly present in South Florida, but also in other areas of the country.

Mr. CURBELO. And do you think that government is doing enough to mitigate this, to address this? Do you think that law enforcement has the resources to pursue these types of cases?

Mr. CANTRELL. I will say that I don't think we have the law enforcement resources to address all the complaints that we have coming through our system. So there is more fraud out there than we are certainly able to address, given our resources. So what we do is utilize the data that we have available to us to maximize the use and the impact of the resources that we have.

So we focus our efforts in places like South Florida, whether it is South Florida or somewhere in Indiana, wherever the highest impact or the most impactful fraud schemes are, where there are potentially patients at risk or where there is certainly lots of money being stolen, we will focus those resources, utilizing data and also intel from the street, if you will, allowing traditional law enforcement methods to focus on the right areas.

There is, I think, more that we can certainly all do. And we have discussed some recommendations for CMS and identified many areas where they are going to improve their monitoring in this area, but it is a huge, enormous issue that requires resources and focus from a lot of different agencies.

Mr. CURBELO. Thank you very much for that response. And I would just encourage all of my colleagues—we focus on the victims

of opioid abuse, and we should because they are the ones suffering, but I think we also have to shine the light on the criminals and find a way to put a dent in all of these fraudulent schemes and operations that really open the door for so many vulnerable Americans to this type of addiction.

So I thank you, and I hope that we can begin in South Florida, just a place where a lot of these schemes begin, that perhaps we can begin solving the problem there.

I appreciate it.

Chairman JENKINS. Mr. Paulsen is recognized for 5 minutes.

Mr. PAULSEN. Thank you, Madam Chair, for putting this hearing together and for our witnesses today.

We have all heard the stories of tragedies of opioids that are impacting real people. These are real families and very heartbreaking stories of addiction and death. It is no different in Minnesota. I mean, in 2016, the most recent year of data that we have, we have seen a 12 percent rise in opioid deaths over 2015. So Minnesotans are suffering through this epidemic as well, like so many other States.

And one of the challenges that we have seen and had is that the theft of opioids from either pharmacies or even from people's trash has been occurring, where it is a problem due to outdated disposal techniques or information about how to properly dispose of opioids. So many people are now simply throwing them away and thinking nothing of it. Safe home disposal of unused and unwanted medications is one of the ways or tools to prevent theft and abuse from inappropriate access to these painkillers or prescription painkillers.

We know that many people, including younger people, in particular, start on this path to addiction and overdose by stealing medications that are prescribed to others. So we have a company in Minnesota that I toured not long ago, Vertitech, that makes a very low-cost, easy-to-use, safe disposal bag that properly and completely disposes of opioids, patches and pills. It is a little different than going to a senior fair that I have hosted where maybe the Hennepin County sheriff comes in and they have a proper disposal technique or facility that is filled immediately with seniors who come in and dispose of their medications.

So Ms. Brandt, let me just ask you, is CMS considering ways to help encourage Medicare and Medicaid beneficiaries to dispose of unused and unwanted medications as part of a more comprehensive strategy to confront this epidemic that we have? Or are you aware of the role that these drug deactivation bags can have in this space?

Ms. BRANDT. Well, one of the interesting aspects of my job is that I get to meet with and talk to a lot of people. And as I mentioned earlier, one of the things we did last fall was have a number of stakeholder meetings. And as part of one of those stakeholder meetings, this topic came up, and there was actually quite an active discussion about the disposal of drugs. And one of the things that we talked about was the types of bags that you are describing and how effective those can be in environments.

We also have heard from CVS, Walgreens, and several of the other pharmacies about ways that they have been doing things within their pharmacy networks to encourage that. So at CMS, one

of the things we have been looking at is how we can partner with our partners at CDC, the Drug Enforcement Agency, and others to really work to educate beneficiaries about the safe disposal of opioids and other types of drugs and the full range of tools available to them to dispose of them.

Mr. PAULSEN. That is great. I would encourage you to stay in touch with us or Members of Congress, obviously, to support this work that you are doing now around the safe medication disposal strategies that you are looking at, and certainly to partner with you. If there are any opportunities to do that, please let us know.

Ms. BRANDT. Absolutely. It is always helpful for us to hear about the strategies that you all are seeing in your communities and then have that dialogue. And we will definitely keep in touch.

Mr. PAULSEN. Thank you, Madam Chairman. I yield back.

Chairman JENKINS. I recognize Mr. Kelly for 5 minutes.

Mr. KELLY. Thank you, Madam Chair. And thank you all for being here.

I think Mr. Reed hit on a lot of different aspects about the personal involvement that we all have. And knowing too much about it because of going through things personally. And the quote that is out there or the saying that says "where we are all involved, we are either dependents or codependents." But what I wonder about is, I mean, this started, this war on drugs actually started back in 1970 with the opium wars, with President Nixon. And I think in the early 1970s, with President Reagan. Mrs. Reagan said to "just say no" and Mr. T said "just say no."

So I don't think it has been for a lack of concern, and it certainly hasn't been for lack of dollars that we have spent. I am in the automobile business. I don't want people to confuse what I am saying here. I am just saying that we do have the ability to track so many things.

I mean, if you were to come into the dealership today and ask me about a car, I can tell you the complete warranty history on that car, everything that has been done to it. The question then becomes, if we have this ability, why aren't we able to incorporate it with people who prescribe drugs? And maybe it is because of the HIPPA Act, I don't know, but we have so much technology out there today that allows us to really get an in-depth look at who it is that we are talking about, what they are prescribing, and who is getting the benefits of this.

So, Mr. Cantrell, I have heard from many healthcare providers who were frustrated with the HIPPA law that prevents their ability to coordinate care for substance disorder patients that are frequent fliers of their emergency departments.

If the law were amended to allow care coordination, does HHS have a sense of how much Medicare, Medicaid, and private plans, that cost would go down? There is a tremendous—the totality of this is just overwhelming. And I think sometimes we get confused. If we could just throw more money at it, we could get it fixed. We have thrown so much money away and seen nothing but an increase. Is there a better way to use this data and to coordinate it?

Mr. CANTRELL. We don't have any estimates of the impact of that sort of change, but I absolutely agree that there are more opportunities to utilize this data to more effectively manage this

issue, this crisis. And for Medicare, we have fairly good, strong data related to opioid prescribing.

In Medicaid, it is an area where we still lack visibility across the country, and it inhibits, we think, CMS' ability to oversee the Federal dollars that go out to Medicaid that relate to this opioid crisis, and it doesn't allow us to get a handle on the scope of the problem in Medicaid without going, in essence, State to State.

There is a system that CMS is working on to improve the access to that Medicaid data, and we think, as they continue to improve that data and get timely, full, complete data from all 50 States, we will have—I don't know what we will see, but it will be enlightening as we do the same kind of analytics that we are doing in Medicare against the Medicaid.

Mr. KELLY. I guess that is where I am coming from. Because I mean, and I really, I look at the private sector. I mean, if you wanted to—again, I am going to go back to what I do. If you wanted to find out if a car that you were looking to buy was ever involved in an accident, you go to the Carfax, and we have all seen this on TV. Why can't we go and find out exactly where the problem is? It just has to be there.

These are prescriptions. And I see the numbers, and we have all this tracking of everything we have done, yet we can't coordinate it. We can't put the two together to help the people that really need it the most. And look, I know it is about the money. There is no question. What a huge economic model this is. And again, because I am too personally attached to it, it is not spending more money. We keep thinking that the idea is to spend more money. I think if we are spending more money, it is probably going to have to do with personnel, people like you that handle these things, that never quit on this. This is not a nine-to-five job. This is 24 hours a day that we all worry about it.

I think the frustrating part, when we can separate ourselves from this, first of all, there is a huge loss for human beings. There is a huge loss in dollars that are being wasted because we can't connect the dots. We can't combine the information. I just don't know why we can do it so easily in the private sector with things that are just inanimate, but we can't do it where we are, when we are talking about human beings, being able to touch them, get them together and actually getting to know how we could serve them. And I don't know how much more it would cost because I think we don't have enough boots on the ground to see it.

The other thing is this waste, fraud, and abuse; it is incredible what is happening on our watch right now. I wouldn't care what the cost was if it was actually going to help a patient or a person. I just think it is so sad that we are in a situation right now. And the President has declared it a national emergency. Pennsylvania has declared it a national emergency. We started in the 1800s knowing what the problem was. We have gone through this whole process. We are no closer to the answer today than we were way back in the opium wars.

And I think that is the saddest part of it all. Where has it led? It is not because of the lack of investment or the lack of concern. How do we get to the point where we can actually connect this stuff so we don't have to worry about Vanessas or Jims or Bills or Marys

that are out there today? It is just a tremendous loss in human potential and taxpayer cost.

I thank you so much. Madam Chair, I thank you so much. And listen, what you are doing is incredible. I can tell you, I coached children's sports a lot in my life. I can't tell you the number of times I have been in a funeral home looking at some young person in a coffin, and around the room were pictures of them when they played for me at the Penn Street Cardinals or they played for me at our Little Marlins team. And I look at that, and I think, "what happened to that little boy, what happened to that little girl, that they reached this point in their life." I think it is just so tragic. And it is not about the money. It is about the results.

Please let's find a way to put this together so we can track it the right way. Thank you so much. I know I am way over my time, but I will tell you what, this is overtime. This goes back to the 1870s. And if we are no closer to a cure today than we were then, what was the whole purpose and the exercise? Thank you for staying on this and not giving up.

Chairman JENKINS. Mr. Rice is recognized for 5 minutes.

Mr. RICE. Thank you, Madam Chairman.

I got a call from a friend of mine a couple of weeks ago about his daughter who had been arrested, and she had drugs on her person and is probably going to jail. I knew this young lady growing up. She grew up with my children. She played with my children. She is a fantastic, bright young lady who has just, her life is spiraling downward.

And I read these statistics on South Carolina. Do you know the number of deaths from opioid abuse have doubled in the last 3 years? They surpassed traffic deaths a couple of years ago. The national statistics say opioid deaths killed 60,000 people last year, which is significantly more than if you combine homicides and traffic deaths nationally.

So, and if you look at the graph, I mean, it goes from flat to straight up. It is not leveling off. We haven't peaked. It is just accelerating. So whatever we are doing, clearly it is failing. We are not doing enough.

I look at how you, you know, what you guys do is try to track where there are problem users and attack that, or problem prescribers and attack that, but that is not working. I look at your definitions just from this hearing summary today that you consider a beneficiary at risk if they receive a daily dose of greater than 120 milligrams, get prescriptions from four or more providers, and fill prescriptions from four or more providers. Good grief. Good grief.

I mean, clearly, if you have those three conditions combined, that is obviously a huge problem. In 2016, despite your efforts, despite these programs that you have put in place, you tell us a beneficiary in New Hampshire received 134 prescriptions for opioids from one prescriber, including 13 months of OxyContin, that is 80 milligrams; 13 months of OxyContin, 60 milligrams; 13 months of OxyContin, 40 milligrams; 14 months of oxycodone, 30 milligrams; and 13 months of fentanyl patches. You guys didn't catch that? Good grief. Whatever you are doing is not working.

A beneficiary in Washington, DC received prescriptions for opioids from 42 different prescribers and filled them at 37 different

pharmacies in a year. In a single month, this beneficiary received 2,330 pills from prescriptions written by just one prescriber. And we didn't catch that? You know, it is just overwhelming and depressing that we are so bad at this.

One problem I see is what Mr. Kelly was referring to a minute ago, is the inability of the Federal Government to bring itself into the modern age of technology. I know, talking with folks on the IRS in this Subcommittee, talking with folks in Social Security, that they are still using Cobol and Fortran in a lot of their stuff, and they are using computers that have magnetic tape and all that, where everybody else left that behind, you know, decades ago.

The IRS has 52 points of failure where only one person knows how to program these old computers. And if this person dies or retires, they don't know what they are going to do. Is CMS in that condition? Is CMS in such a bad shape, such a bad shape that it is impossible for them to accumulate and interpret the data that we are talking about?

Ms. BRANDT. Well, we made numerous strides at CMS over the past several years, and particularly in the past 2 years, to really try to become more modern with our data.

As Mr. Cantrell mentioned, one of the big developments that we have, which is going to go a long way toward helping us with having more of a full picture, is that we were seeing comprehensive Medicaid data from all of our States.

One of the challenges we have——

Mr. RICE. What does that mean when you say——

Ms. BRANDT. That means——

Mr. RICE. You said you will soon have comprehensive Medicaid data from all of our States. That is a fascinating statement right there. What does that mean?

Ms. BRANDT. Let me demystify it for you. That means at the current point in time we have over 46 States and our goal is to have all 50 States——

Mr. RICE. We have 50 States.

Ms. BRANDT. Yes. We have 46 out of the 50 States that are currently reporting in their Medicaid data. We are working with the other four States to get all of that data in. And once we are able to have all of the States reporting in data in a consistent format, then we will be able to use that data to do more of the data analysis——

Mr. RICE. Okay. Can you do that by regulatory requirement, or would that require some legal, some legislation?

Ms. BRANDT. This is all within our authority. We are using our regulatory authority to do that.

Mr. RICE. And basically, you are going to say “if you don't meet these benchmarks by this date, we are not going to pay for the prescriptions anymore,” I hope?

Ms. BRANDT. Well, that's true with part of this on the Medicaid side. And then on the Part D side of the house, Medicare Part D side, we work with the plan sponsors, who are the ones who actually receive the data.

Mr. RICE. So have you given them benchmarks and set forth the timelines by which they have to meet those benchmarks?

Ms. BRANDT. On the Medicaid side, we have. We have been working with them. They have deadlines they have to meet. And we are working with them to ensure that they are meeting those reporting deadlines.

And on the Medicare Part D side, we consistently work with the plans to issue updated guidelines to make sure that they are reporting to us with as accurate information as possible.

Mr. RICE. So what does that mean? That you haven't given them the guidelines?

Ms. BRANDT. No, we have, but we update the guidelines on an ongoing basis. So, for instance, we just issued——

Mr. RICE. Are you getting the Medicare Part D information from all 50 States now?

Ms. BRANDT. Well, that comes from the plan sponsors, not from the States. So the States provide us with Medicaid data, which is for drugs that are covered under Medicaid——

Mr. RICE. Okay. So from the plan sponsors, are you getting information——

Ms. BRANDT. Yeah.

Mr. RICE [continuing]. From all 50 States?

Ms. BRANDT. Well, the plan sponsors operate in all 50 States, but they, themselves, are the frontline. They are the ones who provide the point-of-sale data.

Chairman JENKINS. The gentleman's time has expired.

Mr. RICE. All right. I just want to ask one quick question. I know I am over time. Just one quick question.

Mr. Cantrell, is there any legal impediment to you gathering this information from all 50 States? Because if there is, we need to fix that. What is that legal impediment, if there is one, and how do we fix it?

Mr. CANTRELL. There is no legal impediment. Given the progress that has been made at CMS for doing this, it might not make sense for us to independently do it separately.

So we are hoping to leverage CMS' effort to collect this data in all 50 States, but in order to do our work and do it independently, we have and continue to get data directly from the States——

Chairman JENKINS. Thank you, Mr. Cantrell. Thank you, Mr. Rice. The gentleman's time is expired.

I would like to recognize the distinguished Member from Washington, Ms. DelBene, for a request.

Ms. DELBENE. Thank you, Madam Chair. Congressman Lewis, the Ranking Member of this Subcommittee, was unable to join us today. And I would just like to ask unanimous consent to enter his opening statement into the record.

Chairman JENKINS. Without objection, so ordered.

[The submission for the Record of Hon. Suzan DelBene follows:]

Ranking Member John Lewis' (GA) Opening Statement
Ways and Means Oversight Subcommittee Hearing on
The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid
Misuse
January 17, 2018

Good Morning, and thank you for holding today's hearing, Madam Chair. I join you in welcoming all our witnesses and thanking them for being with us today.

I also would like to welcome two additional Democratic members to the hearing: Ranking Member Neal, and Congresswoman Chu. I know how important this topic is to them and the districts they serve. I thank them for joining us.

Before I begin, I would like to welcome and congratulate the new Chair of the Oversight Subcommittee. I know that you are a certified public accountant and served as Kansas State Treasurer. I look forward to working with you and continuing the bipartisan tradition of our good friend, Mr. Buchanan.

As you know too well, Madam Chair, the opioid crisis is tearing our country apart. No state is immune, and no community is beyond its reach. Every day, nearly 100 people die in this country from this deadly epidemic.

Unfortunately, we have seen this before, and I hope that we will learn from mistakes of the past. We know that addiction is not a crime; it is a difficult and painful disease to treat. Similar to the crack, cocaine, and heroine crisis, this is a true public health emergency. It will impact every American in every part of our country, and people of all ages and backgrounds.

Each and every person here knows all too well that we are losing this battle, and something must be done. Today, our health system is struggling under the crippling weight of the newest wave of painkillers that are stronger and more deadly.

My home state of Georgia has more clinics targeting opioid addiction than anywhere in the south. Yet, people of all ages and all backgrounds are dying. Just last month, best friends -- two teenagers from Georgia -- died on the exact, same day from an overdose.

Press reports contain story after story about how this crisis is wreaking havoc in Atlanta suburbs, and destroying families across the country. Madam Chair, it is simply heart-breaking. We must come together and do all we can to get a handle on this crisis. We must be brave, informed, and, we must act quickly.

Today, I would like to hear what Congress can do to help all frontline agencies combat this crisis. In particular, I look forward learning more about the resources and tools available to the Centers for Medicare and Medicaid Services (CMS) to fight opioid misuse.

Again, I thank the Chair for holding this hearing, and I look forward to the testimony. Thank you.

Chairman JENKINS. I would like to thank our witnesses for appearing before us today. Please be advised that Members have 2 weeks to submit written questions to be answered later in writing. Those questions and answers will be part of the formal hearing record.

With that, the Subcommittee stands adjourned.

[Whereupon, at 11:46 a.m., the Subcommittee was adjourned.]

[Questions for the Record follow:]

Questions for the Record
Kimberly Brandt, Principal Deputy Administrator for Operations
Centers for Medicare & Medicaid Services
"The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid
Misuse"
Ways & Means Oversight & Investigations Subcommittee
January 17, 2018

Questions from Chairman Lynn Jenkins

- 1. You testified that plan sponsors are on the front lines in efforts to combat opioid abuse- what are some things that CMS is doing to facilitate greater information sharing among plan sponsors, and between plan sponsors and CMS?**

Answer: This Administration is aggressively fighting the opioid epidemic on all fronts. We are utilizing many tools across our programs to effectively target our work, and we are continuously exploring new options. One of our most important roles in the fight against the opioid epidemic is to share valuable data and facilitate its use among our Federal and State law enforcement partners, States, providers, and plans. For example, through our web-based PLATO system, we allow Medicare Part C and Part D plan sponsors, along with CMS and law enforcement, to share information regarding potential fraud, waste, and abuse, including information on opioid prescriptions. In addition, we have mechanisms in place for plan sponsors to pass along information to one another when beneficiaries switch plans. In particular, plans conduct case work and may determine that a point-of-sale edit at the pharmacy is needed to control the amount of opioids a beneficiary may receive. If the beneficiary switches plans, the new plan will receive an alert through our enrollment system that the beneficiary had a point-of-sale edit in place through their prior plan. Such information sharing will facilitate a faster review by the new plan, who may also choose to provide for such an edit.

In addition, CMS has directed the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to increase its focus on proactive data analysis in Part D, including producing, at a minimum, quarterly reports to plan sponsors on specific data projects, such as high risk pharmacy assessments. These assessments contain a list of pharmacies identified by CMS as high risk and provide plan sponsors with information to initiate new investigations, conduct audits, and potentially terminate pharmacies from their network, if appropriate. In addition to the Quarterly Pharmacy Risk Assessment, the NBI MEDIC produces a Quarterly Outlier Prescriber Schedule II Controlled Substances Report, which provides a peer comparison of Schedule II controlled substances.

Sharing valuable data and facilitating the use of best practices among plan sponsors will continue to be a high-priority tool as we move forward with efforts to fight the opioid crisis. For example, CMS plans to require all Medicare Part D sponsors to submit a written strategy for addressing overutilization of prescription opioids, given the public

health emergency, to CMS in Spring 2018.¹ This information will help CMS better understand the approaches sponsors are taking, from both their Medicare and commercial lines, and CMS intends to disseminate best practices.

- 2. The Department of Health and Human Services Office of the Inspector General (HHS OIG) identified more than 90,000 beneficiaries they believe to be at serious risk of opioid misuse or overdose. This is significantly higher than the number identified by CMS's Overutilization Monitoring System (OMS), which according to the Government Accountability Office totaled 11,594 in 2016. What is CMS doing to evaluate its criteria to ensure that the OMS is identifying all at-risk beneficiaries?**

Answer: CMS is always working to improve its programs. We updated the OMS opioid overutilization criteria for implementation in 2018 based on the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain and feedback gathered from plans, including the methods they were already using, to better identify at-risk beneficiaries who may need case management.² Under the new criteria, OMS will flag beneficiaries who, during the most recent six months: received opioids from more than three prescribers and more than three dispensing pharmacies or more than five prescribers regardless of the number of dispensing pharmacies; and were prescribed opioids with an average daily morphine equivalent dose (MED) greater than or equal to 90mg for any duration. Beneficiaries with cancer or in hospice are excluded.

CMS also provides plan sponsors with Patient Safety Opioid Measures Reports, which identify Part D beneficiaries who receive high doses of opioid prescriptions, regardless of the number of prescribers and pharmacies being used by beneficiary. CMS identified a large proportion (88%) of the at-risk beneficiaries identified by the Department of Health and Human Services Office of the Inspector General (OIG), using the current and updated OMS criteria and the Patient Safety reports.

In addition, all plan sponsors use soft and/or hard edits for opioid prescriptions, which give pharmacists real-time alerts regarding possible overutilization at the time of dispensing. Soft edits can be overridden by the pharmacist, but hard edits require the beneficiary to receive a separate approval from the plan sponsor, and the prescriber must attest that a prescription is medically necessary before it can be filled.

Questions from Rep. Jackie Walorski (IN-2)

- 1. How does CMS utilize abuse deterrent (AD) opioids in the context of the Part D Opioid Overutilization Policy and Overutilization Monitoring System for treating high-risk Medicare beneficiaries?**

¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-262.html>

² <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>

Answer: Abuse deterrent opioids are a potential tool in tackling the opioid epidemic. To advance the goal of identifying patients who are at risk of adverse events due to overutilization of opioids and could benefit from further case management, we include abuse-deterrent opioids in the OMS. However, it is the responsibility of the plans to negotiate with drug manufacturers and determine which FDA-approved pain medications to make available to their beneficiaries and to make decisions weighing the trade-offs on the cost and effectiveness of abuse deterrence.

2. **To implement the Comprehensive Addiction and Recovery Act (CARA) lock-in requirement, CMS proposed that a Part D plan sponsor "may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) and/or pharmacy until at least six months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary. " If an at-risk beneficiary is identified but the Part D plan sponsor must wait six months before it can lock the beneficiary into a pharmacy, this individual could continue to obtain high amounts of opioids from multiple prescribers and/or pharmacies, divert the drugs, or even worse, overdose and potentially die. Given this, why would CMS propose a six-month waiting period, particularly during the midst of an opioid public health crisis?"**

Answer: The Comprehensive Addiction Recovery Act (CARA) provides CMS with the authority to allow Medicare Part D plans to implement prescriber and/or pharmacy lock-in for their Medicare Part D beneficiaries, subject to appropriate protections. This means CMS can allow plans to limit at-risk beneficiaries' coverage of frequently abused drugs to a selected prescriber, a selected pharmacy, or both a selected prescriber and selected pharmacy, with some exceptions.

Under our Proposed Rule,³ as soon as beneficiary is identified and verified as being at-risk, plans would be allowed to implement a pharmacy lock-in. However, because a prescriber lock-in impacts the beneficiary's relationship with his or her health care providers and may impose burden upon prescribers in terms of prescribing frequently abused drugs, we proposed that plans must include a six-month waiting period before implementing a prescriber lock-in. We expect that this six-month waiting period will provide the sponsor additional time to use and assess the results of other tools designed to resolve the beneficiary's overutilization, such as a pharmacy lock-in, a beneficiary-specific point-of-sale edit, or case management, which plans have told us can take three to six months. We specifically solicited comment on this proposal and are reviewing the comments submitted in response to our proposal.

3. **At the hearing, we spoke about technologies that offer alternatives to opioid-based pain medications across all care settings. What is CMS doing to evaluate these alternatives? What steps is CMS taking to ensure**

³ <https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

coverage and payment policies support these technological alternatives?

Answer: Evidence-based policy and program development is an integral part of all of CMS's priority areas. Both medicinal and non-medicinal therapeutic alternatives to opioid-based pain medications exist; although Medicare coverage and payment varies. In general, Medicare covers items and services that are "reasonable and necessary." This includes several non-pharmacologic therapies and other non-opioid pharmaceuticals. CMS uses the national and local coverage determination process to evaluate new or promising items and services with respect to Medicare Parts A and B, through well-delineated processes set forth in statute. Those items and services for which evidence demonstrates improvement in health outcomes in the Medicare population are more likely to be coverable, while those items and services for which such evidence is insufficient or lacking warrant further research. Therefore, CMS is playing an important role in expanding access to evidence-supported treatments and services while also specifying the subpopulations of patients who can benefit meaningfully from their use. CMS collaborates with research-focused HHS agencies, such as the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ), who can concentrate research resources on these need areas.

4. In situations where coding of pain-reducing alternatives is grouped with other services, does CMS separately track and or reimburse for these technologies?

Answer: Given the wide range of treatments that may be alternatives to opioid based medications, coding and reimbursement can differ based on various factors, including the site in which care is provided or the type of treatment provided. For example, the coding of a physical therapy visit will be handled differently than that of a device, even if both are alternatives to prescribing opioids. There is no one Medicare code that signifies that a treatment or a device is an alternative to opioids. If you have concerns or questions about the coding of a particular opioid alternative technology, CMS is happy to examine the situation and provide more information.

5. What is CMS currently doing and what can be done to educate providers on technology alternatives to opioids?

Answer: CMS's primary role with respect to Medicare is to serve as a payor, and we do not establish prescription guidelines or recommend specific treatments. However, we have published several educational materials for providers and prescribers that we also make available online to raise awareness on the non-medical use or abuse of opioids by patients. Information in these materials includes signs of opioid diversion and symptoms of abuse and clinical practices to minimize the non-medical use of medication.

In addition, CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's (TCPI's) Practice

Transformation Networks.⁴ TCPI is designed to use peer-based learning networks for information sharing, outreach, and dissemination of evidence-based practices to educate prescribers on safe and appropriate methods of pain treatment. For example, the TCPI Medication Management and Opioid Initiative is mobilizing the existing network of more than 100,000 clinicians into action to address the opioid crisis, generating collaborations with other CMS quality improvement projects, showcasing successful strategies in engaging providers and patients on proper opioid utilization and spreading the successful strategies throughout all CMS communities.

6. Has CMS considered using demonstrations by the Center for Medicare and Medicaid Innovation (CMMI) to test and collect evidence on the effectiveness of non-opioid alternatives for pain management?

Answer: The CMS Center for Medicare and Medicaid Innovation (CMMI) maintains an expanding portfolio supporting the development and testing of innovative health care payment and service delivery models. Last fall, we announced that we are setting a new direction for CMMI and will carefully evaluate how models developed consistent with the new directions can complement what we are learning from the existing initiatives. As part of this initiative, CMS sought public input and suggestions on innovative payment system models that will help promote effective substance abuse treatment programs, including models focused on opioids and substance use disorder.⁵

7. HHS has included improving pain management as one of the pillars of its opioid strategy. What is CMS doing to advance the practice of pain management?

8. The FDA has approved more than 200 pain management medical devices. What is CMS doing to ensure that providers are aware of and patients have access to non-opioid treatments covered by Medicare and Medicaid?

Answer to 7 and 8: Evidence-based practice is an integral part of all of CMS's priority areas, but expanding the evidence base of effective and alternative treatments for acute and chronic pain is especially vital. The opioid crisis cannot be tackled by CMS alone, and that is why we are collaborating with research-focused HHS agencies, such as the NIH, to identify services that need more evidence to support coverage by Medicare and other health plans.

CMS has partnered with the CDC to develop the Opioid Safety Commitment poster campaign,⁶ which promotes the most effective pain management treatments and strategies. This campaign emphasizes patient engagement, clinician counseling regarding opioid alternative pain management strategies, and discussion with patients of the risks and benefits of opioids when opioids are prescribed.

⁴ <https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/>

⁵ <https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>

⁶ <https://www.cdc.gov/drugoverdose/prescribing/posters.html>

CMS has a number of initiatives underway to increase the use of recommended evidence-based practices for pain management. CMS provides outreach regarding best practices and technical assistance through the Transforming Clinical Practice Initiative's (TCPI's) Practice Transformation Networks.⁷ TCPI is designed to use peer-based learning networks for information sharing, outreach, and dissemination of evidence-based practices to educate prescribers on safe and appropriate methods of pain treatment. For example, the TCPI Medication Management and Opioid Initiative is mobilizing the existing network of more than 100,000 clinicians into action to address the opioid crisis, generating collaborations with other CMS quality improvement projects, showcasing successful strategies in engaging providers and patients on proper opioid utilization and spreading the successful strategies throughout all CMS communities.

CMS also promotes free educational materials for health care professionals on CMS programs, policies, and initiatives through the Medicare Learning Network (MLN).⁸ The *CDC Guidelines for Prescribing Opioids for Chronic Pain* is featured in the January 12, 2017⁹ MLN Connects newsletter.

9. The National Pain Strategy outlined by the HHS, focuses on key areas of pain management, including education and training, service delivery, and reimbursement. What is CMS doing to improve pain management consistent with the policies outlined in the National Pain Strategy?

Answer: Effective treatments for pain can take many forms, and Medicare covers items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury. While many of the CMS efforts are focused on reducing the overuse or misuse of prescription opioids, we simultaneously recognize that prescription opioids can be an effective and appropriate treatment for pain. We rely on and collaborate with our counterpart agencies such as the NIH and FDA to evaluate coverage for effective pain treatments (including non-opioid alternatives), strengthen the collection of public health data, support research on pain and addiction, advance better practices for pain management, and identify services that need more evidence to support coverage by Medicare and other health plans.

We also partner with the private sector to improve patient safety and advance high-quality treatments, including pain management. In September 2016, we awarded \$347 million to 16 national, regional, or state hospital associations, and health system organizations to serve as Hospital Improvement Innovation Networks (HIINs). HIINs work at the regional, State, national, or hospital system level to sustain and expand reductions in patient harm and 30 day hospital readmissions in the Medicare program,

⁷ <https://innovation.cms.gov/initiatives/Transforming-Clinical-Practices/>

⁸ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/Index.html>

⁹ https://www.cms.gov/Outreach-and-Education/Outreach/FFSPovPartProg/Provider-Partnership-Email-Archive-Items/2017-01-12-eNews.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc471878721

and to disseminate valuable information about potential solutions to other hospitals and providers. The period of performance for the HIINs began in September 2016 and consists of one 24-month base period and one 12-month option year, during which they will support 4,000 hospitals.

While specific efforts differ by HIIN, several have taken steps to address pain management, particularly as it relates to opioid use. For example, one HIIN partnered with the American Society of Anesthesiologists to launch the Safer Post-operative Pain Management: Reducing Opioid-related Harm pilot program. The pilot, which was launched in September 2017 and will run through March 2018, includes 30 hospitals and is focused on improving post-operative opioid pain management by providers and clinicians, as well as patients and their family members.¹⁰ Other HIINs offer opportunities, such as webinars, for health care professionals to hold discussion around and share implementation examples of guidelines and standards for pain management, opioid prescribing practices in a variety of settings, and patient education on pain management and opioids.^{11, 12, 13}

10. Collection of pain data is vital to identifying trends in terms of morbidity and mortality and disability rates amongst pain populations. Better data is necessary for clinicians to more effectively help manage their patient's chronic pain and reduce opioid reliance. Despite this critical need, the CDC does not currently collect pain statistics. What data sets does CMS rely on regarding opioid prescriptions and chronic pain? Would CMS benefit from collection of CDC data?

Answer: Data plays a vital role across CMS programs and Agency efforts to strengthen the health care services and information available to our beneficiaries and the health care providers who serve them. We rely on and collaborate with our federal partners, including the NIH and FDA, to evaluate coverage for effective pain treatments (including non-opioid alternatives), strengthen the collection of public health data, support research on pain and addiction, advance better practices for pain management, and identify services that need more evidence to support coverage by Medicare and other health plans.

To help collect useful data on pain control and treatment, last August, CMS finalized¹⁴ an update to the survey¹⁵ we use to measure and publicly report patients'

¹⁰ <https://www.premierinc.com/premier-inc-launches-national-hospital-initiative-improve-opioid-safety-partners-american-society-anesthesiologists/>

¹¹ <https://www.vizientinc.com/Events/2017-10-18-HIIN-Community-Knowledge-Network>

¹² https://www.alliance4ptsafety.org/THAMAPS/media/media/Final-ADE-Opioid-Safety-Webinar-Slides_508.pdf

¹³ https://www.haponline.org/Portals/0/docs/Downloads/HEN/Educ_Temp_HAP_16_Ltrhead.pdf?ver=2017-05-18-115304-600

¹⁴ <https://www.federalregister.gov/documents/2017/08/14/2017-16434/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>

¹⁵ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS.html>

perceptions of their hospital care. Our changes were in part due to stakeholder recommendations to replace existing pain management questions, which ask patients to indicate how well and how often their pain was controlled during their stay, with new questions that would ask patients to indicate how well his or her providers communicated with them about their pain management options. Modified survey questions will be used for the payment determination for Fiscal Year 2020 and subsequent years.

In addition, every time a beneficiary fills a prescription under Medicare Part D, a prescription drug plan sponsor must submit a summary record called the prescription drug event (PDE) data to CMS. While CMS utilizes PDE data to make payments to plans and administer the Part D program, it also provides information about prescribing, including the prescribing of opioids to Medicare beneficiaries.

To assist clinicians, nurses, and other health care providers to assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment, CMS released an interactive online mapping tool. The mapping tool allows the user to see both the number and percentage of opioid claims at the local level and offers spatial analyses to identify “hot spots” or clusters in order to better understand how this critical issue impacts communities nationwide.¹⁶ The data reflect Medicare Part D prescription drug claims prescribed by health care providers. The data used in the mapping tool are de-identified to protect beneficiary privacy, contain information from over one million distinct providers, and characterize the individual prescribing patterns of those providers that participate in Medicare Part D. By openly sharing data in a secure, broad, and interactive way, CMS is supporting a better understanding of regional provider prescribing behavior variability and is adding insight to local health care delivery.

Questions from Rep. Patrick Meehan (PA-7)

1. In a 2017 report, the HHS OIG described the diversion risk for "potentiator drugs" which, when combined with an opioid, increases the opioid's effects and the potential for a drug overdose. In the report, OIG suggested that CMS monitor literature, clinical guidelines, and other data to identify opioid "potentiators" that may increase the risk of overdose when used in combination with opioids. The OIG also recommended that CMS expand OMS to include "potentiator drugs." Has CMS implemented these recommendations? If so, what is the status? If not, why has CMS not implemented these recommendations?

Answer: Yes, CMS monitors available literature, clinical guidelines, information from other stakeholders, and internal data to proactively identify opioid potentiators that may increase the risk of overdose when used together with opioids. CMS has also added

¹⁶ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html>

benzodiazepines, a class of potentiator drugs, to the OMS. In the 2017 final Call Letter¹⁷, CMS encouraged Part D sponsors to evaluate their claims data and use drug utilization management tools that are available to them as necessary to help address the concurrent use of opioids and benzodiazepines. CMS has added a concurrent benzodiazepine use flag to OMS reports starting with the October 2016 cycle. A field in the beneficiary current opioid overutilization issue report indicates if the beneficiary concurrently received a benzodiazepine. In addition, CMS includes the total number of beneficiaries with a potential opioid overutilization issue concurrently receiving a benzodiazepine in the contract summary report. CMS' expectation is that Part D sponsors will consider benzodiazepine use within their opioid overutilization review process and include this information within their discussions with prescribers. Further, we have made a commitment to the OIG to continue reviewing the clinical research for additional potentiator drugs, and to include those in our strategies as appropriate.

Questions from Rep. Joseph Crowley (NY-15)

- 1. In the OIG Report, "Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing," the methodology states, "In total, 60,742 prescribers ordered opioids for beneficiaries who received extreme amounts and 79,175 prescribers ordered opioids for beneficiaries who appeared to be doctor shopping." However, earlier in the report, OIG states that nearly 200 prescribers each ordered opioids for dozens of beneficiaries who received extreme amounts of opioids. Can you clarify this discrepancy?**

Answer: CMS defers to the OIG on the methodology used in their report.

- 2. In the OIG Report, "Ensuring the Integrity of Medicare Part D," OIG found, "... that plan sponsors frequently lack adequate controls to prevent Schedule II drug refills, which are prohibited by Federal law to control access to these drugs." In that same report, OIG recommends that CMS, "Exclude Schedule II refills when calculating final payments to plan sponsors at the end of each year." What would be the appropriate method or control for preventing plan sponsors from preventing Schedule II refills in the first place?**

Answer: CMS concurred with this OIG recommendation that edits should be in place to prevent the billing of Schedule II drugs as refills and committed to exploring modifications to PDE edits to alert Part D sponsors to inappropriate refills of Schedule II drugs. CMS has determined that fully addressing this recommendation will require a regulatory change to fix the transaction standard to identify the difference between a partial fill and an illegal refill which will need to be promulgated outside of CMS.

¹⁷ See: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf> (P. 214-215)



U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

February 23, 2018

The Honorable Lynn Jenkins
Chairman
Subcommittee on Oversight
Committee on Ways and Means
House of Representatives

Subject: Actions to Prevent Opioid Misuse – GAO Responses to Questions for the Record

This letter notifies you of our enclosed responses to questions for the record following the January 17, 2018 hearing entitled "The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse." If you or your staff have any questions about our responses, please contact me at (202) 512-7114 or curdae@gao.gov.

Sincerely yours,

A handwritten signature in cursive script, reading "Elizabeth H. Curda".

Elizabeth H. Curda
Director, Health Care

Enclosure

The Honorable Lynn Jenkins

1. **Your testimony specifically referenced recommendations by the Department of Health and Human Services Office of the Inspector General (HHS OIG) that CMS require plan sponsors to report on specific actions addressing fraud and abuse. Why do you believe this is important?**
 - a. **What kind of information from plan sponsors do you believe will be particularly helpful?**
 - b. **How could this information be further utilized, beyond what's being done today?**

The June 2015 HHS OIG report included recommendations that CMS require plan sponsors to report all potential fraud and abuse, as well as data on the inquiries and corrective actions they take in response to incidents of fraud and abuse. Similarly, in our October 2017 report, we recommended that CMS require plan sponsors to report to CMS on investigations and other actions taken related to providers who prescribe high amounts of opioids. As noted in our report, CMS has developed a voluntary reporting system that plan sponsors can use, but CMS officials told us that they do not have information on all actions taken by plan sponsors. Therefore, CMS does not know how often or what proportion of actions plan sponsors voluntarily report. Without this information, CMS cannot determine the extent to which plan sponsors are taking action to reduce overprescribing. Therefore, CMS is unable to adequately determine the effectiveness of its efforts to achieve the agency's goals of reducing the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion.

In particular, in our October 2017 report, we noted that CMS is missing information on cases of fraud, waste, and abuse; cases of overprescribing; or any actions taken against providers. Similarly, the HHS OIG report noted that CMS is missing consistent information on the number of specific instances of potential fraud, waste, and abuse that plan sponsors identified and actions they took to address these issues. For example, the HHS OIG found that not all plan sponsors conducted inquiries, initiated corrective actions, or made referrals for further investigation after identifying potential fraud and abuse.

As noted in our report, CMS needs information on the investigations and actions taken by plan sponsors to be able to determine the effectiveness of its efforts to reduce harm from opioids. Similarly, the HHS OIG report also noted that this type of information could allow CMS to more actively monitor plan sponsors' efforts to protect Part D from fraud, waste, and abuse. The HHS OIG report further indicated that this information could show whether differences across plan sponsors reflect differences in actual fraud, or if they reflect disparities in the actions that plan sponsors take.

The Honorable Joseph Crowley

1. In the OIG Report, "Opioids in Medicare Part D: Concerns About Extreme use and Questionable Prescribing," the methodology states, "In total, 60,742 prescribers ordered opioids for beneficiaries who received extreme amounts and 79,175 prescribers ordered opioids for beneficiaries who appeared to be doctor shopping." However, earlier in the report, OIG states that nearly 200 prescribers each ordered opioids for dozens of beneficiaries who received extreme amounts of opioids. Can you clarify this discrepancy?

According to the report, the HHS OIG first determined that in total, 60,742 prescribers ordered opioids for beneficiaries who received extreme amounts and 79,175 prescribers ordered opioids for beneficiaries who appeared to be doctor shopping. Then, for each of these prescribers, they calculated the number of beneficiaries in each group for whom the prescriber ordered opioids. Finally, they identified the prescribers who ordered opioids for the highest number of beneficiaries in each group. The nearly 200 prescribers they identified are those who ordered opioids for at least 44 beneficiaries who received extreme amounts. Additional details about the methodology used in this report are best addressed by the HHS OIG.

In the OIG Report, "Ensuring the Integrity of Medicare part D," OIG found , "...that plan sponsors frequently lack adequate controls to prevent Schedule II drug refills, which are prohibited by Federal law to control access to these drugs." In that same report, OIG recommends that CMS, "Exclude Schedule II refills when calculating final payments to plan sponsors at the end of each year." What would be the appropriate method or control for preventing plan sponsors from preventing Schedule II refills in the first place?

The issue of schedule II refills was outside the scope of GAO's work for our October 2017 report. Therefore, we are not in a position to recommend how to prevent Schedule II refills.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



FEB 27 2018

The Honorable Lynn Jenkins, CPA
Chairman
Committee on Ways and Means
Subcommittee on Oversight
United States House of Representatives
Washington, DC 20515

Dear Madam Chairman:

I am writing in response to questions for the record from you and other Members following my testimony before the Committee on Ways and Means, Subcommittee on Oversight, on January 17, 2018, entitled "The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse."

If you have any questions, please contact me or your staff may contact Jason Wittemen, Director of Congressional Affairs, at (202) 708-9755 or Jason.Wittemen@oig.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Cantrell".

Gary L. Cantrell
Deputy Inspector General for Investigations

Enclosure

Gary L. Cantrell, Deputy Inspector General for Investigations
 Office of Inspector General, U.S. Department of Health and Human Services
 Responses to questions for the record following a hearing entitled "The Opioid Crisis: The
 Current Landscape and CMS Actions to Prevent Opioid Misuse" on January 17, 2018
 Submitted on February 27, 2018

1. The Inspector General has recommended CMS incorporate "potentiator drugs" into its utilization reviews, why do you believe this to be important? How would greater visibility into possible potentiator combinations better support the goal of identifying beneficiaries at risk of abuse?

Potentiator drugs are medications that, when mixed together with other drugs, cause a synergistic effect or exponential high. Drug potentiation can be an appropriate tool in mainstream medicine to enhance treatment outcomes. For example, potentiators can enhance effectiveness of cancer chemotherapy and hepatitis C treatments.¹ Opioid potentiators also have some legitimate uses, such as enabling adequate pain control with lower doses of opioids and lower risk of adverse events.

However, some misuse and abuse potentiator drug combinations for recreational endeavors. The National Vital Statistics Report showed that in 2014 almost one-half of drug overdose deaths involved more than one specific drug.² Blending certain dangerous combinations of drugs in supra-potent doses in non-medically approved manners creates a greater euphoria. This provides a greater high, but also causes greater respiratory depression that may lead to overdose death. Thus, potentiator drug combinations cause more deaths than would opioids by themselves.

Individuals that misuse and abuse drug and potentiator combinations may utilize recreational "recipes" available on the Internet in drug blogs and other open-source avenues of information. The combinations may involve a potentiator that is a controlled substance, a non-controlled substance, or even an over-the-counter medication.

OIG monitors potentiator drugs by reviewing multiple sources of data for new recipe combinations, and then matches the new combinations to existing billing databases to identify potential fraud schemes. States also recognize the value of monitoring potentiator drugs. For example, at least four states require the inclusion of gabapentin, a known potentiator drug, into their Prescription Drug Monitoring Databases.

OIG believes that CMS can greatly assist in monitoring for potentially deadly combinations of opioids and potentiators by incorporating this information into its utilization reviews and identifying prescribers and at risk beneficiaries engaging in misuse of potentiators with opioids.

¹ <https://www.nature.com/articles/s41598-017-04406-0>

² https://www.cdc.gov/nchs/data/nvsr/nvsr65/nvsr65_10.pdf

2. OIG has recommended increased reporting by plan sponsors on specific actions addressing fraud and abuse. Why do you believe this is important?

- a. What kind of information from plan sponsors do you believe will be particularly helpful?**
b. How can that information be further utilized, beyond what is being done today?

Plan sponsors are the first line of defense against fraud, waste, and abuse, as they are responsible for paying claims, monitoring billing patterns, and preventing and identifying fraud, waste, and abuse. The reporting of all potential fraud and abuse by plan sponsors to CMS and/or the Medicare Drug Integrity Contractor (MEDIC) is voluntary and OIG work has revealed most plan sponsors choose not to report all potential fraud. If plan sponsors were required to consistently report all potential fraud, CMS and the MEDIC could more effectively monitor plan sponsors' efforts to protect Part D from fraud, waste, and abuse. Additionally, when plan sponsors identify potential fraud and abuse, they are required to initiate inquiries and take corrective actions, as necessary. However, CMS does not require plan sponsors to report data concerning those actions.³

If CMS were to require plan sponsors to consistently report information related to their fraud and abuse detection programs, CMS could use that information to help evaluate the effectiveness of those programs. CMS could also use the information to determine whether variation in plan sponsor reporting is a natural variation or whether it indicates problems such as weaknesses in plan sponsors' fraud and abuse detection programs or a lack of common understanding of fraud and abuse terms in reporting.

Collecting comprehensive data from plan sponsors provides insight into utilization and prescribing patterns to help identify providers with questionable prescribing patterns and beneficiaries at risk of opioid and prescription drug misuse. Information on plan sponsors' program integrity efforts to identify and investigate suspected fraud and abuse can also be utilized to identify emerging schemes and geographical hotspots to help focus audits, evaluations, and investigations related to opioids, prescription drug fraud, and drug diversion.

The Honorable Patrick Meehan

- 1. Why is HHS OIG keeping open its recommendation that Medicare implement a lock-in program? Given that Medicaid and commercial plans already use lock-in, do you expect the majority of plan sponsors to implement a Medicare lock-in program in 2019?**

OIG's recommendation that CMS restrict certain beneficiaries to a limited number of pharmacies or prescribers remains open. CMS has issued draft regulations that, if enacted, will implement section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA). Once CMS has finalized and implemented the regulatory requirements in section 704 of CARA that allow for the establishment of drug management programs, we will consider this recommendation fully

³ <https://oig.hhs.gov/oei/reports/oei-03-15-00180.pdf>

implemented. At this time, we do not have data on the number of plan sponsors that will implement Medicare lock-in programs in 2019.

2. **The Medicare lock-in provision in the Comprehensive Addiction Recovery Act (CARA) of 2016 included a Sense of Congress that Medicare Advantage (MA) organizations and Part D plan sponsors should consider using e-prescribing and other health information technology tools to support combating fraud. What is the utility of e-prescribing and other information technology tools in combatting the opioid epidemic? Are you aware of whether and how these tools are being used to prevent opioid abuse?**

While OIG does not have any specific work on e-prescribing or health information technology systems as they relate to addressing opioid abuse, we recognize the utility of these tools in combatting the opioid epidemic.

E-prescribing involves the submission of a controlled substance prescription to a target pharmacy electronically versus providing the patient with a paper prescription to bring to the pharmacy or phoning the pharmacy to orally provide the prescription information.

Advantages of e-prescribing could include quicker aggregation of information into a patient's electronic health record (EHR), more efficient aggregation and recording into State Prescription Drug Monitoring Program databases, and greater security for signatures (EHR authentication and password protection). E-prescribing could also cut down on the value of prescription pad thefts and decrease the ability to alter prescriptions. E-prescribing could reduce these prescription vulnerabilities, but would not likely eliminate controlled substance fraud.

The Honorable Joseph Crowley

1. **In the OIG Report, "Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing," the methodology states, "In total, 60,742 prescribers ordered opioids for beneficiaries who received extreme amounts and 79,175 prescribers ordered opioids for beneficiaries who appeared to be doctor shopping." However, earlier in the report, OIG states that nearly 200 prescribers each ordered opioids for dozens of beneficiaries who received extreme amounts of opioids. Can you clarify the discrepancy?**

The OIG report *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing* identified almost 90,000 Part D beneficiaries that were at serious risk of opioid misuse or overdose. These included 69,563 beneficiaries who received an extreme amount of opioids and 22,308 beneficiaries who appeared to be doctor shopping. A total of 2,028 beneficiaries were in both groups.

The report further found that about 401 prescribers had questionable opioid prescribing patterns for these beneficiaries. These prescribers ordered opioids for the highest number of beneficiaries at serious risk. Specifically, 198 prescribers ordered opioids for at least 44 beneficiaries who received extreme amounts, while 264 prescribers ordered opioids for at least 21 beneficiaries who appeared to be doctor shopping.

The number of prescribers mentioned in the methodology is the total number who ordered at least one opioid for at least one beneficiary at serious risk. A total of 60,742 prescribers ordered opioids for at least one beneficiary who received extreme amounts, while 79,175 ordered opioids for at least one beneficiary who appeared to be doctor shopping.

2. In the OIG Report, “Ensuring the Integrity of Medicare Part D,” OIG found, “...that plan sponsors frequently lack adequate controls to prevent Schedule II drug refills, which are prohibited by Federal law to control access to these drugs.” In that same report, OIG recommends that CMS, “Exclude Schedule II refills when calculating final payments to plan sponsors at the end of the year.” What would be the appropriate method or control for preventing plan sponsors from preventing Schedule II refills in the first place?

To implement OIG’s recommendation to exclude Schedule II drugs billed as refills when calculating final payments to plan sponsors at the end of the year, CMS should put edits in place to identify refills of Schedule II drugs submitted by sponsors on prescription drug event (PDE) records. CMS should also exclude these PDE records when calculating its final payments to sponsors during payment reconciliation at the end of each year.

To ensure that partial fills, which are allowed, are not inappropriately flagged as illegal refills, CMS could issue regulations related to the Health Insurance Portability and Accountability Act (HIPAA) pharmacy transaction standards to make reporting of partial fills more distinct from refills.

[Submissions for the Record follow:]

**Statement for the Record
to the
House Committee on Ways and Means, Oversight
Subcommittee**

**The Opioid Crisis: The Current Landscape and CMS
Actions to Prevent Opioid Misuse**

17 January 2018

Introduction

Chairwoman Jenkins and Members of the Committee, thank you for the opportunity to offer this statement for the record. The American Association of Nurse Anesthetists (AANA) is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists, with membership that includes more than 52,000 CRNAs and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 43 million anesthetics to patients each year in the United States. CRNAs provide acute, chronic, and interventional pain management services. In some states, CRNAs are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

The House Ways and Means Subcommittee on Oversight's hearing, entitled "The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse" comes at an important time. Opioid abuse and misuse is a significant national problem that has grown substantially over the past couple of years and the AANA is committed to collaboratively working toward a solution to this dangerous drug epidemic. CRNAs are exceptionally qualified to help eradicate the opioid epidemic that is tearing at the fabric of our nation. According to the National Academy of Medicine's report "*Relieving Pain in America*," approximately 100 million Americans suffer from unrelenting chronic pain and many rely on CRNAs as their primary pain care specialist.¹

CRNAs are an Underutilized Resource in Combating the Opioid Epidemic

Suffering from chronic and acute pain is a personal experience that, if left undertreated or mismanaged, can radically change an individual's quality of life and impact important relationships. The AANA believes that one method to help treat chronic and acute pain, while providing the maximum benefit to the patient that will help prevent reliance on opioids, is to utilize a patient-centered, multidisciplinary, multimodal treatment approach to pain management as a primary pain management modality. Acute and chronic pain is best treated and managed by an interdisciplinary team that actively engages with the patient to diagnose and manage their pain for improved well-being, functionality, and quality of life. As members of the interdisciplinary team, CRNAs are well positioned to provide holistic, patient-centered, multimodal pain treatment and management across the continuum of pain and in all clinical settings (e.g., hospitals, ambulatory surgical centers, offices, and pain management clinics).²

As a main provider of pain management services, CRNAs are uniquely skilled to provide both acute and chronic pain management in a patient centered, compassionate and holistic manner. As anesthesia experts, CRNAs are qualified pain practitioners who work in many practice settings to treat patients suffering from a wide range of acute and chronic pain conditions. CRNA chronic

¹ Institute of Medicine (IOM). *Relieving Pain in America: A Blueprint for Transforming Prevention Care, Education, and Research*. Washington, DC: The National Academies Press. 2011.

² AANA Chronic Pain Management Guidelines, September 2014, available at: <http://www.aana.com/resources2/professionalpractice/Pages/Chronic-Pain-Management-Guidelines.aspx>.

pain management practitioners are able to minimize the use of opioids to address chronic pain through the use of a multimodal approach that includes pharmacologic and non-pharmacologic pain mitigation strategies. Furthermore, the holistic approach that CRNA pain management practitioners employ when treating their chronic pain patients may reduce the reliance on opioids as a primary pain management modality, thus aiding in the reduction of potential adverse drug events related to opioids. This is shown in a recent study which calls for an increased number of nursing pain specialists “to not only implement aggressive acute pain care to prevent chronic pain but also to effectively treat chronic pain with evidence-based integrative therapies that include multimodal analgesia, interventional techniques, and complementary and alternative approaches to pain management.”³

In developing the plan of care for the patient, CRNAs obtain patient history, evaluate the patient, order and review necessary diagnostic testing, and assess the patient’s psychological and emotional state. Non-pharmacologic pain mitigation techniques are often employed in the treatment of chronic pain and considered as part of the care plan. These techniques may include patient education regarding behavioral changes that can decrease pain, such as weight loss, smoking cessation, daily exercise, stretching, and physical or chiropractic therapy. Such therapies may not be sufficient when used alone, but they have significant benefit when they are used in a complementary manner with other therapies.

As anesthesia professionals, our goal is to decrease or eliminate the need for opioids by collaborating with the patient and the interdisciplinary team on a comprehensive plan for pain relief known as enhanced recovery after surgery, or ERAS⁴. For surgical pain, using specific protocol-driven ERAS pathways improves patient outcomes by reducing the patient’s stress response to surgery, shortening the overall hospital length of stay, and accelerating the return to normal daily function. The patient’s pain management plan of care begins pre-procedure and continues through post-discharge using opioid-sparing techniques such as regional anesthesia including placement of epidural catheters, targeted peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures. The evidence is quite clear that careful assessment, evaluation, and treatment of acute pain, with appropriate prescribing of an opioid, may prevent access to unused opioids and development of opioid dependency and abuse. CRNAs play a critical role by ensuring proper anesthesia services management which can make a tremendous difference in terms of improving patient flow, patient safety, and cost savings.

By virtue of education and individual clinical experience and competency, a CRNA may practice chronic pain management utilizing a variety of therapeutic, physiological, pharmacological, interventional, and psychological modalities in the management and treatment of pain. The Council on Accreditation of Nurse Anesthesia Programs (COA) already requires acute and chronic pain management content in the curriculum of the 115 accredited nurse anesthesia programs, and the AANA provides advanced workshops to CRNAs specifically on pain management, including acute and chronic pain, to enhance their skills and increase their awareness of the complications associated with opioid use and misuse.

³ Schoneboom B et al. Answering the call to address chronic pain in military service members and veterans: Progress in improving pain care and restoring health. *Nursing Outlook* June 2016.

⁴ AANA. Enhanced Recovery. www.aana.com/enhancedrecovery.

CRNAs provide holistic anesthesia and pain related care for patients of all ages in all communities across the US. From entry into practice education and certification through ongoing education and skills acquisition throughout their career, CRNAs provide robust, patient centered acute and chronic pain management services. Prescriber education is also essential to curbing the opioid epidemic, and CRNAs are also well-positioned to educate clinicians and patients alike on the minimization or elimination of prescribed opioids for both acute and chronic pain management. The National Board of Certification and Recertification for Nurse Anesthetists (NBCRNA) offers a voluntary nonsurgical pain management (NSPM) subspecialty certification for CRNAs.⁵ The Council on Accreditation of Nurse Anesthesia Educational Programs (COA) requires acute and chronic pain management content in the curriculum of the 120-accredited nurse anesthesia educational programs, and for continued learning, the AANA offers CRNAs a continuum of educational resources for pain management practice. These resources include advanced acute and chronic pain management workshops for CRNAs to enhance their skills to improve quality of life and to mitigate complications associated with opioid use and misuse. The AANA, State Nurse Anesthetist Associations, universities and other stakeholders play an active role in CRNA education and professional development, reinforcing how to safely integrate and, when appropriate, eliminate opioids in acute and chronic pain management. Professional development opportunities include educational webinars, online continuing education, conferences, and peer reviewed publications. Additionally, Texas Christian University, the University of South Florida, and Middle Tennessee School of Anesthesia offer fellowships to CRNAs seeking to further specialize in this growing field.

In addition to the education efforts by the AANA, the AANA along with the American Association of Colleges of Nursing and other APRN organizations are developing a joint online educational series that will serve as a resource for practicing nurses, faculty, and students on opioid topics. As part of this initiative, these organizations presented four webinars in the Fall of 2016 to provide an overview of the current need to address opioid use disorder and overdose; integration of timely content into education program curricula; and the Centers for Disease Control and Prevention's (CDC) new prescribing guideline.

In addition to the education efforts by the AANA, the AANA along with the American Association of Colleges of Nursing and other APRN organizations are developing a joint online educational series that will serve as a resource for practicing nurses, faculty, and students on opioid topics. As part of this initiative, these organizations presented four webinars in the Fall of 2016 to provide an overview of the current need to address opioid use disorder and overdose; integration of timely content into education program curricula; and the Centers for Disease Control and Prevention's (CDC) new prescribing guideline.

Invite the AANA to Collaborate in the Development of Educational Recommendations for Pain Management and Safe Use of Opioid Analgesics

CRNAs have for many decades and continue to provide access to acute and chronic pain management services in their community. The AANA supports healthcare provider and patient

⁵ See: <http://www.nbcrna.com/NSPM/Pages/Non-Surgical-Pain-Management.aspx>.

education regarding alternative non-pharmacologic and pharmacologic modalities for pain management that minimize the use of opioids. Many clinicians across numerous specialties, such as primary care, anesthesia, addiction, pain, emergency, and palliative care are involved in the management of acute and chronic pain. Promotion of collaborative, multidisciplinary clinician and patient education, research, and practice will have a positive impact on patients who seek and increasingly rely on acute and chronic pain management services.

Any national education framework should be in the form of recommendations that are adaptable to profession- and practice-specific requirements. Interprofessional education should also cover topics such as identification of individuals at risk of opioid abuse, signs of drug seeking behavior, acute and chronic pain management options for patients with substance use disorder or in recovery, criteria for referral to medication assisted treatment and for transfer of the patient to a specialty pain care provider. Patient education recommendation regarding multimodal pain management alternatives and related therapy should be developed to increase patient awareness for make best decisions for their plan of care for safe or no opioid use.

Education should be evidence-based and align with national guidelines, such as the Centers for Disease Control and Prevention (CDC) *Guideline for Prescribing Opioids for Chronic Pain*. The AANA has many resources related to acute and chronic pain management and substance use disorder which can be applied to patient care settings, such as *Addressing Substance Use Disorder for Anesthesia Professionals*, *Chronic Pain Management Guidelines* and *Regional Anesthesia for Surgical Procedures and Acute Pain Management*.

Many nursing and medical organizations, patient advocacy groups, and governmental agencies share the common concern of increased opioid use, abuse, and deaths in the US. The AANA encourages the use of federal and non-federal partnerships, including nursing and medical professional organizations, including the AANA, FDA, CDC, American Nurses Association, Substance Abuse and Mental Health Services Administration, and SmartTots, to support a collaborative, multidisciplinary effort in the refinement of healthcare provider education models surrounding pain management and safe opioid use. The AANA welcomes the opportunity to serve as member of the multidisciplinary collaborative.

Conclusion

In conclusion, CRNAs are vital to helping resolve the widespread opioid drug crisis, a huge challenge facing our nation's healthcare system, with services that eliminate or decrease the use of opioids to address pain through multimodal pain management techniques. Using a patient-centered, multidisciplinary, multimodal treatment approach including interventional pain management can help reduce the reliance on opioids as a primary pain management modality, thus helping curb the prescribed opioid epidemic.

In many rural and frontier areas, CRNAs often are the only health care professionals trained in pain management in these communities. Without CRNAs to provide chronic pain management services, patients in vast rural and frontier areas would lose access to vital treatment, which could result in poor healthcare outcomes, lower quality of life, and unnecessary costs to patients

and the healthcare system. According to a 2012 analysis by the Lewin Group of four case studies based on the real life situations of four individuals living in rural communities representing different geographic locations throughout the U.S., the direct medical costs of alternatives such as surgery or nursing home care range between 2.3 times to more than 150 times the cost of a CRNA providing these services in the community.⁶ The AANA and its members look forward to collaborating with our healthcare colleagues to develop and implement multimodal pain management initiatives that reduce our nation's dependence on opioids.

⁶ The Lewin Group, Cases: Costs of Alternative Pain Management Paths, August 14, 2012, available at: <http://www.lewin.com/publications/publication/201208140454.html>.





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January 12, 2018

Seema Verma
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Verma,

The undersigned members of the Abuse Deterrent Coalition (ADC) offer the following comments for consideration on Docket No. CMS-2017-0157, "Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program."

The ADC is a forum of abuse-deterrent formulation technology innovators, patient and issue associations and pharmaceutical manufacturers created to educate the public, policy makers and related regulatory agencies on the importance of abuse-deterrent (AD) opioids technologies utilized in the fight against prescription drug abuse. The Coalition serves as a unified voice for legislative and regulatory initiatives that support the required use of AD technologies for prescription drugs that have a high potential for abuse.

Addressing and curtailing the abuse of prescription opioids is a multi-model process requiring action from multiple stakeholders to successfully reduce the abuse of prescription opioids. For example, the Opioid Action Plan developed by the U.S. Food and Drug Administration (FDA) in February 2016 appropriately focuses on both patients and the community at large to ensure balanced access to effective pain medications, while reducing the societal burden of opioid abuse, misuse and diversion.

The President's Commission on Combating Drug Addiction and the Opioid Crisis also recognizes the value AD opioids can provide as an alternative to non-AD opioid medications.¹ In addition to effective treatment of the negative consequences of opioid abuse (i.e., Naloxone for overdose and medication assisted therapy [MAT] for addiction), supporting the development and increasing the availability of AD opioids represents a critical component of drug abuse prevention efforts.

In administering Part D, CMS has a tremendous opportunity to add to the effort to reduce and deter the abuse of prescription opioids. The agency's own statistics show that opioid use by Medicare beneficiaries is ubiquitous: one in every three Medicare Part D beneficiaries received at least one prescription opioid in 2016,² and 500,000 beneficiaries received high amounts of opioids through Medicare Part D for extended periods of time.³ In the proposed rule, CMS has estimated that more than 319,000 beneficiaries could be potentially at-risk for opioid overutilization under varying scenarios.⁴ The Department of Health & Human Services Office of the Inspector General (HHS OIG) also has acknowledged that although beneficiaries may receive opioids for legitimate purposes, the high number of at-risk beneficiaries appropriately raises concern.⁵

AD opioids are a currently available tool specifically designed to help reduce the risks associated with abuse, misuse and diversion of prescription opioids. Moreover, AD opioids not only deter abuse, misuse and diversion of the drug by patients for whom they are prescribed -- in this case, Medicare beneficiaries -- but also by others who may have access to the products in the home (family members, hired workers, etc.). AD opioids offer the promise of a significant public health benefit by deterring the illegal diversion of opioids.⁶ Deterrence (prevention) of prescription opioid abuse is a more cost-effective approach to

¹ Available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

² Department of Health and Human Services Office of Inspector General, Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing, OEI-02-17-00250, available at <https://www.oig.hhs.gov/oei/reports/oei-02-17-00250.pdf>

³ Cite Part D rule

⁴ HHS Office of Inspector General, Semiannual Report to Congress, November 2017 (pg. 6) available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-fall-2017.pdf>

⁵ Ibid.

⁶ NAVIPPRO Internet Survey Report. Prepared for KemPharm; March 2016Source

reducing prescription opioid abuse than focusing alone on a post-addiction treatment regimen as the result of abuse⁷.

While the FDA has encouraged the development and licensure of AD opioids—ten AD opioids have received a label of abuse deterrence by the FDA and 6 are currently available on the market—utilization remains very low.⁸ As FDA Commissioner Scott Gottlieb, M.D., has noted, “[AD opioid] uptake has been slow among doctors who are treating patients in pain. The reason for their more limited use is likely multifold. We know there can be a learning curve that comes with new technologies. Some prescribers may not be aware of the existence of these drugs, or may be uncertain of when to prescribe the abuse-deterrent versions. But we also know a significant barrier to use can be price.”⁹

To more effectively combat the prescription opioid abuse crisis, CMS has an opportunity to provide valuable assistance to Part D plans to ensure both improved education among providers, particularly those treating at-risk beneficiaries, as well as adequate access to AD opioids on plan formularies.

CMS should instruct Medicare plans on the need to educate providers on prescription opioid abuse prevention and mitigation efforts, including the use of AD opioids. In the 2017 plan year, many Part D plan sponsors did not include AD opioids on their allowable prescription drug formularies; and even in instances when the AD opioid was technically a covered service, many plans employed a variety of coverage restrictions, preauthorization, “fail-first” and other formulary tools to limit provider choice and deter greater patient access to AD opioids.

While these drug management techniques are not unique, due to the gravity of the prescription opioid abuse crisis several states have enacted policies in commercial markets to:

⁷ Medical cost savings associated with an extended-release opioid with abuse-deterrent technology in the US. *US Journal of Medicinal Economics*. March 2016.

⁸ AD opioids constituent less than 4 percent of the total opioid marketplace in Medicare Part D. need cite

⁹ Statement from FDA Commissioner Scott Gottlieb, M.D., on steps to promote development of generic versions of opioids formulated to deter abuse. Nov. 21, 2017. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm586117.htm>

- Cover AD opioids on formularies on a basis that is not less favorable than non-AD opioid products;
- Prohibit plans from requiring patients to “step through” a non-AD opioid before receiving an AD opioid;
- Require coverage of AD opioids at the same cost-sharing tier as non-AD opioids; and
- Require prior authorization for AD opioid only if prior authorization for non-AD opioids is also required.^[1]

As Dr. Gottlieb has stated, “Transitioning from the current market, dominated by conventional opioids, to one in which most opioids have abuse-deterrent properties, holds significant promise for a meaningful public health benefit,” we urge the CMS to review plan formularies to ensure adequate access to AD opioids and consider formulary management restrictions where appropriate.

In the Proposed Rule, CMS identified more than 300,000 beneficiaries potentially at risk for opioid abuse because of very high prescribing patterns – and has suggested that these individuals are responsible for potentially hundreds of millions of abuseable opioid tablets that could be diverted to improper use every year.¹⁰ The CMS is one agency playing a critical part in our national opioid response. By adding its support for the appropriate substitution of AD opioids for those identified as “at-risk” Part D beneficiaries, it could potentially serve a very important role in deterring the illegal diversion of prescription opioids.

^[1] See: Massachusetts: Mass. Gen. Laws ch. 258, §9 (2015) available at <https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter258>; Florida: Fla Stat. §422 (2016) available at <https://www.flsenate.gov/Session/Bill/2016/0422/ByVersion>; Maryland: Md. Ins Code § 15-849 (2015) available at <http://law.justia.com/codes/maryland/2015/article-gin/title-15/subtitle-8/section-15-849>; West Virginia: W. Va Code §4146 (2016) available at: http://www.legis.state.wv.us/Bill_Status/bills_text.cfm?billdoc=HB4146%20SUB%20ENR.htm&yr=2016&sesstype=RS&i=4146; Maine: 24-A MRSA §4320(2016) available at https://legislature.maine.gov/legis/bills/bills_127th/billtexts/HP063801.asp.

¹⁰ 300,000 beneficiaries' x 60 opioid pills month x 12 months = 216,000,000.

Recommendation:

As AD opioids are designed, and appropriately prescribed, for patients with acute or chronic pain, the undersigned Members of the ADC urge the CMS to consider and encourage substitutable utilization of AD opioids over existing and more abusable versions of the same non-abuse deterrent moiety formulations in the context of the Part D Opioid Overutilization Policy and Overutilization Monitoring System.

The CMS has the authority to make the recommended policy change:

Prior to implementation of the Medicare Part D benefit, the CMS created the six protected classes, designed to ensure access to treatments for certain highly sensitive diseases. The CMS used its authority under the “anti-discrimination” clause in the statute to provide these protections. It was not until 2008 when Congress enacted the Medicare Improvements for Patients and Providers Act (MIPPA) that the six protected classes were established in statute and required Medicare Part D drug plans to include access to all or substantially all drugs in the six identified categories. In 2010, Congress made further modifications to the protected classes, including the authority to “identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.”¹¹

Similarly, CMS could use its general authority under the “anti-discrimination” clause in 1860D-(4), that it used to establish protections for certain drugs or the more explicit authority under the “classes of clinical concern” to ensure proper Medicare beneficiary access to AD opioids.

CMS also proposes at § 423.100 to designate all (emphasis added) opioids as “frequently abused drugs,” excepting buprenorphine for medication-assisted treatment (MAT) and injectables. The AD Coalition urges the CMS to exclude AD opioids from this definition of “frequently abused drug” as there is no evidentiary data to support the thesis that AD opioids are frequently abused and existing observation data supports their exclusion from this broad standard.¹²

¹¹ Pub. L. 111-148, 124 Stat. 119 (March 23, 2010).

¹² “Effect of Abuse-Deterrent Formulations and IR Opioids on Abuse, Overdose and Death from Rx Opioids” presentation to NASACA, Richard C. Dart, MD, PhD, Executive Director Denver Health and Hospitals Authority (RADARS) Slides 12-16 (October 17, 2017).

President Trump has declared the opioid abuse crisis a nationwide public health emergency. The FDA's Opioid Action Plan incorporates AD opioids as a critical tool in the effort to reduce abuse, misuse and diversion of prescription opioids. The CMS can add to the effort to promote the deterrence of the deliberate misuse, abuse and deterrence of prescription opioids by ensuring appropriately broad and favorable Medicare beneficiary access to AD opioids by allowing complete and equitable formulary access to these innovative products.

Sincerely,



Dan Cohen
Abuse Deterrent Coalition
Chairman



Dr. Klaus-Dieter Langner
Grünenthal GmbH
Member of the Corporate
Executive Board (CSO)




Travis Mickel
KemPharm
President, CEO & Co-Founder



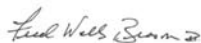
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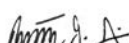
Tim Hermes
Depomed, Inc.
VP Government Affairs



Brian Kennedy
Alliance for Patient Access
Alliance for Balanced Pain
Management
Executive Director



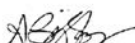
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Peter Pitts
Center for Medicine in the
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President



Damon Smith
Alnus Formulations
CEO



Gregory Sturmer
Elysium Therapeutics, Inc.
President & CEO



Mike Heffernan
Collegium Pharmaceutical, Inc.
CEO



Bob Twillman, Ph.D., FAPM
Academy of Integrative Pain
Management
Executive Director



Robert B. Jones
Acura Pharmaceuticals
President and CEO

To the ladies and gentlemen of the Committee on Ways and Means I submit this letter.

I am a concerned American citizen. I have raised two adult children. One is a drug abuser and the other is not. I am luckier than most families. Neither I nor their father have ever abused alcohol or drugs. I have been prescribed Hydrocodone and Oxycodone on numerous occasions for pain management and by the grace of God never became addicted.

I am concerned about the opioid crisis in this country. The most recent statistic I have heard is that 1 in 6 households are affected. I have done some research online. I have listed those sites below. The running theme seems to be that pharmaceutical companies and dispensers of the medications are the root of this problem. They are the high level drug dealers of this country.

Shockingly, there does not seem to be any Federal, State or Local oversight that is truly effective in monitoring or enforcing laws around the dispensing of these medications in a proper fashion. There does appear to be some movement toward holding producers and dispensers responsible but it is few and far between. I hope you will establish laws and funding to enforce them and mandate very strict measures to hold these providers responsible for their behaviors.

In this day and age of not assigning blame or punishing those at fault it is time to assign punishment to the point where it hurts. Pharmaceutical companies, pharmacies, and doctors should be losing their licenses, livelihood and be incarcerated. Any monies collected should go to funding enforcement and rehabilitation for the addicted. These stiff penalties will make it clear that this behavior will **not be tolerated at all**. They are **committing mass murder** and getting away with it. Low level street dealers go to prison for doing much less.

I sincerely pray that you will have the courage to put this country back on a clean path of health. I hope you will also include treatment measures for those people who are addicted that does not include incarceration.

I found this small bit of information shocking and very telling:

What is a prescription drug monitoring program (PDMP)?

According to the **National Alliance for Model State Drug Laws (NAMSDL)**, a PDMP is a **statewide** electronic database which collects designated data on substances dispensed in the state. The PDMP is housed by a specified statewide regulatory, administrative or law enforcement agency. The housing agency distributes data from the database to individuals who are authorized under state law to receive the information for purposes of their profession.

The DEA is not involved with the administration of any state PDMP.

Thank you for taking the time to read my letter. I hope and pray every day that our country can be saved from this plague.

Sincerely,

Nola

Online research I have read:

<http://www.foxnews.com/us/2017/11/10/federal-prosecutors-take-on-pharmaceutical-companies-for-their-alleged-role-in-opioid-crisis.html>

<https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/>

<https://www.drugwatch.com/featured/opioid-crisis-big-pharma/>

https://www.huffingtonpost.com/entry/pharma-corruption-started-the-opioid-epidemic_us_59d4f8c7e4b0da85e7f5ed58

<https://www.usatoday.com/story/news/politics/2017/10/23/fda-chief-supports-opioid-prescription-limits-regrets-agencys-prior-inaction/774007001/>

<http://www.nejm.org/doi/full/10.1056/NEJMp1308222#t=article>

<http://www.newsweek.com/has-big-pharma-made-america-country-opioid-drug-addicts-648480>

<https://www.publicintegrity.org/2016/09/18/20200/politics-pain-drugmakers-fought-state-opioid-limits-amid-crisis>





Statement for the Record

**House Committee on Ways and Means, Oversight
Subcommittee**

**The Opioid Crisis: The Current Landscape and CMS
Actions to Prevent Opioid Misuse
17 January 2018**



Dear Chairwoman Jenkins and Ranking Member Lewis:

We thank you for holding this hearing on such a critical topic impacting our nation. We appreciate the opportunity to submit a statement for the record. Headquartered in Alpharetta, Georgia, Halyard Health is a leading medical device company with more than 700 employees in Georgia, more than 1,500 nationwide, and more than 12,000 worldwide and operates 14 manufacturing facilities around the world. Halyard Health is focused on advancing health and healthcare by preventing infection, eliminating pain and speeding recovery. Our innovative products, which are described in more detail below, are proven effective treatments for pain without the use of opioids.

Halyard Health applauds your attention to this public health crisis. Likewise, we are encouraged by the U.S. Food and Drug Administration and The President's Commission on Combating Drug Addiction and the Opioid Crisis for highlighting the use of medical devices as preventive alternatives to opioids¹. As a leader in the pain management space, Halyard Health is committed to working with Congress and the Administration to raise both patient and health care provider awareness, as well as create access for the appropriate prescribing and use of medical devices as alternatives to effectively treat and manage pain before narcotics, like opioids, are prescribed.

While it is critical that your subcommittee examine ways to identify individuals at risk of abusing opioids and how to eliminate the apparent excessive on-going prescribing patterns, we believe it is equally important that we, as a nation, encourage non-opioid treatments that can effectively address people's legitimate pain, including the use of innovative medical device treatments. The President's Commission on Combating Drug Addiction and the Opioid Crisis recommended that CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain.²

As a company committed to advancing health by eliminating pain and speeding recovery, Halyard Health joins with the President's Commission and urges CMS to implement these recommendations by working with stakeholders, like us, to identify barriers to non-opioid treatments for pain, and to then reduce or eliminate those barriers.

According to the CMS Opioid Misuse Strategy Report in 2016, it's estimated that roughly one out of five patients with non-cancer related pain is prescribed opioids. While there are times that opioids are a clinically justified option for the treatment of pain, evidence suggests that alternative methods of treating pain are being overlooked.³

¹ <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm>

https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

² https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf (Page 14)

³ <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf> (Page 20)



Halyard Health's advanced minimally invasive cooled radiofrequency device, known as the Coolief® Cooled RF Pain Management System, safely ablates the sensory nerves causing individuals pain in the spine, hip and knee joints. Published peer-reviewed studies show that this technology can provide chronic back pain patients up to two years of pain relief, improved physical function and reduction in pain medications.

Our non-narcotic pain pump, the ON-Q® Pain Relief System, delivers local anesthetics to surgical wound sites over a three-day period. Patients begin using the ON-Q pain pump immediately in the hospital post-surgery and wear it home for continuous use. The ON-Q® pump is indicated to significantly decrease pain and narcotic use when used to deliver local anaesthetics to or around surgical wound sites, or in close proximity to nerves, when compared to narcotic only pain management.

These medical devices provide patients with non-opioid pain treatment options and thereby avoid the need for opioid prescriptions.

It's estimated that every year nearly 70 million patients are prescribed opioids for post-surgical pain. Of those patients, one in 15 will go on to experience long-term use or abuse.⁴ According to the CDC, to reverse this epidemic we need to improve the way we treat pain. We must prevent abuse, addiction, and overdose before they start.⁵ There are also studies that show, if given the choice, nearly 3 out of 4 patients would choose non-narcotic pain medications for postsurgical pain management.⁶

Halyard urges CMS to identify current coverage and payment obstacles that discourage the deployment of these alternative medical device treatments. We have begun a promising collaboration with the agency and Principal Deputy Administrator Kim Brandt to further such cross-program review.

We also urge CMS to incentivize the use of non-opioid treatments in existing and new payment models and to work with industry stakeholders like Halyard Health to identify innovative tools and treatments that can minimize our nation's reliance on opioids. For example, in the existing bundled payment for care improvement models (BPCI), CMS could inform participating providers that costs associated with non-opioid treatments, like medical devices, would not count against them in the total cost of care calculation and we could see behavior shift. Similarly, adding quality measures focused on opioid alternatives to the list of quality measures in the same demonstration would likely also be effective. The same holds true for the total knee replacement demonstration. At present, CMS does not dis-incentivize providers from prescribing opioids. While innovative payment models need to be developed to stem and then turn the tide on our nation's opioid crisis, implementing our recommendations would be relatively quick, and simple to track, providing

⁴ Becker's Spine Review: Mary Rechtors Nov 3, 2015: Reducing Opioid Dependence: Available From: <http://www.beckersspine.com/spine/item/27948-reducing-opioid-dependence-the-multimodal-approach-to-pain-management.html> Accessed January 2018.

⁵ <https://www.cdc.gov/drugoverdose/opioids/prescribed.html>

⁶ Apfelbaum JL, Chen C, Mehta SS, Gan TJ. Postoperative pain experience: results from a national survey suggest postoperative pain continues to be undermanaged. *Anesth Analg*. 2003 Aug;97(2):534-540.



CMS some “quick win” opportunities and momentum towards developing more comprehensive innovative payment models.

The FDA recently released its 2018 Strategic Policy Roadmap⁷ that puts reducing the burden of the opioid crisis at the top of its agenda. The agency plans to work on advancing the development of medical devices that can treat pain and are less likely to lead to addiction. FDA Commissioner Scott Gottlieb also recently testified that more than 200 pain treating medical devices have been approved by the agency⁸.

Halyard further urges CMS to work with the FDA to assist medical device innovators with approved or soon-to-be approved products to obtain fair and reasonable reimbursement in appropriate care delivery settings in an expedited fashion.

Halyard Health stands ready to work with you, your colleagues and the Administration, particularly CMS, FDA and the CDC, to advance awareness and access to medical device-based pain management therapies as we collectively seek to stem this nation’s opioid epidemic. Please consider us, and in particular our health economics team, a resource to you and the subcommittee.

⁷ <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm>

⁸ Testimony of FDA Commissioner Scott Gottlieb before the U.S. Senate Committee on Health, Education, Labor & Pensions. Full Committee Hearing: The Federal Response to the Opioid Crisis (October 5, 2017) <https://www.help.senate.gov/hearings/the-federal-response-to-the-opioid-crisis> (between 2:43:00 - 2:45:00)

Statement for the Record**Submitted by****The Premier healthcare alliance*****The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse*****House Ways and Means Oversight Subcommittee****January 17, 2018**

The Premier healthcare alliance appreciates the opportunity to provide a statement for the record on the House Ways and Means Oversight Subcommittee hearing, titled “The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse.” Premier is a leading healthcare improvement company, uniting an alliance of approximately 3,900 U.S. hospitals and health systems and approximately 150,000 other providers and organizations. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Premier, a Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide.

We applaud the leadership of Chairman Jenkins, Ranking Member Lewis and members of the Subcommittee for holding this important hearing today to address this devastating epidemic that is hitting so many of our communities and the patients that our Premier alliance members serve.

Premier and its members are continuing to take significant steps to improve pain management efforts, and reduce addiction, overuse and misuse of opioids by spreading and scaling resources, tools and practices focused on improving healthcare quality and patient safety.

Among the problems exacerbating the opioids epidemic and getting in the way of these and other healthcare providers’ efforts is one that has received little attention, yet addressing it is absolutely critical to stemming the tide of addiction. Incredible as it seems, a 40-year old law, 42 CFR Part 2 (Part 2), currently bars healthcare providers from accessing their patients’ medical history on substance use without complex and multiple patient consents. This forces providers to play Russian roulette with every prescription, often learning of problems only after an adverse event or an overdose.

In answer to this problem, the *President’s Commission on Combating Drug Addiction and the Opioid Crisis* urges rapid adoption of legislation that will greatly improve caregivers’ ability to provide whole-person, coordinated care, prevent adverse events and enhance treatment for patients struggling with substance use and addiction. Premier has joined with a coalition of patient, provider, clinician and addiction treatment organizations committed to helping end the

opioids crisis to call on Congress to pass the Overdose Prevention and Patient Safety Act ([H.R. 3545](#)) and the Protecting Jessica Grubb's Legacy Act ([S. 1850](#)).

Part 2 is outdated and does not reflect the robust HIPAA protections now in place or the way care is delivered today

Part 2 was implemented during the Nixon Administration before electronic records and during the early days of the “war on drugs.” It was designed to ensure a safe path for seeking treatment and to protect patients from being discriminated against by law enforcement, housing authorities and employers. This was long before the robust patient privacy protections required by the Health Insurance Portability and Accountability Act (HIPAA) were put in place and before new models of accountable care when providers were put at risk for outcomes, making access to information even more important.

Most patients assume caregivers have an awareness of any addictions or prior substance use that may need to be factored into treatment and prescribing. And why wouldn't they?

Even if substance use contributes to co-morbid or complicating factors, providers have no ability to learn this history and tailor care plans, leading to gaps and missed opportunities for addiction treatment. This outdated law even forces the Centers for Medicare & Medicaid Services to remove claims where substance use disorder is a primary or secondary diagnosis before sending data to providers who are part of ACOs, bundled payment and other alternative payment models. Removing this data translates to providers missing roughly 4.5 percent of inpatient Medicare claims and 8 percent of Medicaid claims¹.

This poses a serious safety threat to patients with substance use disorders considering the potential for drug contraindications and co-existing medical problems. Without full and complete information on patients' substance use, we have effectively set up a two-tiered system – one where those struggling with addiction receive uncoordinated, incomplete care that can exacerbate their condition, lead to unnecessary emergency department visits and even result in overdose.

Congress can remove this information barrier that is costing lives and preventing informed, coordinated care for patients struggling with substance use and addiction

A simple change would amend Part 2 to align with HIPAA's treatment, payment and operation protections, which will allow sharing of medical records among providers for those with addictions, just like we have done for every other disease and condition since 1996.

The legislation in no way compromises the existing privacy protections in Part 2 that protect an individual from having their information disclosed to the courts in civil proceedings, or to life and disability insurance companies, employers and landlords/housing agencies. In fact, the legislation includes a new provision that actually strengthens the existing prohibitions on the use or disclosure of substance use treatment information in criminal proceedings.

If enacted, the legislation would have an immediate impact in the fight against opioid misuse, at virtually no cost to the taxpayer.

Premier strongly encourages Congress to pass this legislation swiftly in order to improve outcomes and remove this information barrier to responsible care. This is a commonsense, bipartisan-backed solution that will have a real impact on patient lives.

We thank the Subcommittee again for holding this critical hearing today. If you have any questions or comments, please contact Duanne Pearson, Director of Federal and Affairs, at duanne_pearson@premierinc.com or 202.879.8008.

ⁱ Austin B. Frakt, Ph.D., and Nicholas Bagley, J.D. N Engl J Med 2015; 372:1879-1881 May 14, 2015.
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House Ways and Means Subcommittee on Oversight Hearing on

**The Opioid Crisis: The Current Landscape and CMS Actions to Prevent
Opioid Misuse”**

**Statement for the Record
Quest Diagnostics Incorporated**

January 17, 2018

**Mike Prevostnik
Senior Vice President and General Counsel
Quest Diagnostics Incorporated**

Chairman Jenkins, Ranking Member Lewis, and Members of the Subcommittee:

Quest Diagnostics appreciates the opportunity to discuss additional strategies that could help facilitate identifying Medicare beneficiaries at risk for opioid misuse. Quest Diagnostics is the nation's leading provider of diagnostic information and we manage the largest database of de-identified clinical laboratory data - 40 billion test results, with annual increases of 3 billion tests results. We partner with the Centers for Disease Control and Prevention (CDC) on a variety of projects to help shape public health policy for the good of all citizens. We partner with the government to use our information database to shape future healthcare policies and population messaging, and for detecting changing trends at local, state and national levels. Our Health Trends™ research derives clinically significant public health insights that enable policy makers and health care practitioners to take information-based actions that improve the health care of Americans. Quest Health Trends studies have been published in peer-reviewed medical journals as well as by the company as a public service. These expansive reports cover wide ranges of medical conditions including diabetes, kidney and heart disease, lead poisoning and drug use. The Quest Drug Testing Index has been utilized by government employers and policy makers for more than 29 years.¹ For the past six years, Quest Diagnostics has published the annual Prescription Drug Monitoring Report as an industry update of more than 3,000,000 drug test results that are focused on the clinicians who prescribe controlled medications and monitor patients for compliance.²

In its October 2017 report, the Government Accountability Office found that the Centers for Medicare and Medicaid Services (CMS) provides guidance to Medicare Part D plan sponsors on how the plan sponsors should monitor opioid overutilization among Medicare beneficiaries, but that CMS does not have sufficient information on most beneficiaries potentially at risk for harm. The most recent policy initiatives by CMS and others have focused on limiting the number of pills provided by a prescription and decreasing the number of prescriptions actually written. States have also focused on developing or enhancing prescription drug monitoring programs. Efforts to decrease opioid prescriptions have shown successes, but it is not enough – 2016 drug overdose deaths are spiraled upward to an all-time high. It is clear that while these efforts are worthwhile and provide additional tools to combat opioid abuse, they have focused on prescribing patterns, and that alone is not enough. It is critically important that healthcare providers have accurate, comprehensive information to manage the millions of patients who are appropriately prescribed opioids.

Prescription drug monitoring testing is a trusted source of objective information for actual drug use or non-use. For a health surveillance program to be effective, it is important to understand not only prescribing patterns, but how patterns relate to actual patient drug use.

Drug use and non-use information provides a unique insight into the breadth and depth of the ongoing opioid epidemic. Our 2017 Prescription Drug Monitoring Health Trends report reveals continued drug use trends that are troubling including:

- >50% of drug tests are inconsistent with drugs prescribed
- 36% of inconsistent results are drugs not prescribed
- dangerous drug combinations occur, both prescribed and non-prescribed; and
- all age groups, genders and health plan payer types are at risk for misuse.

Healthcare providers need to be aware of potentially dangerous drug interactions that occur beyond the prescription level. To understand the relationship between drugs prescribed and combinations of drugs actually used, we performed a study for the two drug classes that contribute to the rising overdose death rates – opioids and benzodiazepines. Both classes can depress breathing and combined use of these drugs can be dangerous and potentially fatal.

We believe our study to be the first national examination of concurrent use of opioids and benzodiazepines compared to prescribing information. Prior analysis of concurrent use of these drugs focused on prescribed data and did not identify situations where patients may not have used their prescribed drugs or patients may have used non-prescribed drugs. The Journal of Addiction Medicine (JAM) published our study November of 2017.³ The JAM is the official peer-reviewed publication of the American Society of Addiction Medicine. *Our study results far exceeded previous estimates of combining opioids and benzodiazepines based on prescription drug monitoring databases alone, suggesting that prescription drug monitoring databases and monitoring programs do not fully reflect the extent to which individuals combine these drug classes in the United States.*

The key findings of our 48 state study of 231,000 prescription drug monitoring drug tests from 144,000 patients (prescribed at least one drug and co-tested for opioids and benzodiazepines) include:

- prescribing information submitted with test requests indicated 11.2% of patients were concurrently prescribed both opioids and benzodiazepines. This compares favorably with 9.6 percent concurrent opioid and benzodiazepines prescribing patterns reported in a previous analysis of millions of patients filling prescriptions for both drug classes.⁴
- prescription drug monitoring test results demonstrated 25.8% of test results were positive for concurrent use of opioids and benzodiazepines.
- compared to 11.2% expected concurrent use, the 25.8% actual concurrent use prescribed suggests that PDMP prescribing data alone will underestimate the extent to which patients combine prescribed and non-prescribed drugs.

While some patients may be appropriately prescribed both opioids and benzodiazepines, the Quest Diagnostics study results of concurrent use of opioids and benzodiazepines are significant public health warning related to the August 2016 FDA issuance of "boxed warning" of prescription opioids and benzodiazepines that alerted prescribers to the dangers of concurrent drug use. Additionally, more than 30 percent of opioid-related deaths also involved benzodiazepines, according to the CDC.

Drug testing enhances patient safety by:

- alerting providers that a patient may not be taking prescribed medication(s) and may be a possible diversion risk;
- augmenting existing subjective tools (e.g. patient medical history, risk assessment, etc.) that providers use to determine patient risk for drug use;
- supporting the observation that patient self-reporting of drug use has limited validity. Monitoring only behavior can fail to detect drug use problems that are revealed by drug testing;
- assisting healthcare providers with making evidence-based decisions prior to and throughout treatment, including whether to choose non-opioid therapy or opioid therapy and referral for Substance Use Disorder treatment; and
- helping to maintain the healthcare provider-patient relationship. Mandatory testing guidelines for all opioid-prescribed patients de-stigmatizes “drug testing” and helps the maintain provider trust with his/her patients.

For these reasons, we are working to encourage all states to adopt drug testing guidelines similar to the CDC opioid prescribing recommendations for baseline and appropriate periodic testing. PDMP prescribing data is an important tool but cannot detect actual drug use.

Recommendation 10 of the ‘CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016’ requires drug testing as a component for Assessing Risk and Addressing Harms of Opioid Use.⁵ Incorporating drug tests into patient management can lead to earlier clinical interventions when clinicians are able to detect initial/early prescription misuse, potential drug diversion, dangerous drug combinations, and patients progressing to using illicit drugs. The specific guidance issued by the CDC states:

“[W]hen prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”

CMS should work with Medicare Part D plan sponsors – all health plans in the Medicare Advantage program as well - to encourage the adoption the CDC guidelines as they relate to base line drug testing and appropriate follow up testing as part of their practice. The population likely to use opioids and the seriousness of the risk for misuse are well documented. The potential adverse events can range from drug diversion to death. Together, these factors make it logical for CMS to encourage the adoption of CDC guidelines throughout the health care system. Use of baseline and periodic drug testing as assists providers to have precise information about the patient’s current use of opioids or combinations of drugs. Over time, providers would have information documenting the patients’ compliance with treatment regimens that prescribing data bases alone cannot provide.

Other federal programs have recognized the value of baseline drug testing and appropriate follow up testing. Both the U.S. Department of Defense and the U.S. Department of Veterans Affairs have adopted similar guidelines as a key step in combatting the opioid epidemic.

In addition, it is ironic that Medicare cuts to clinical laboratory reimbursement that just began in 2018 as a result of CMS' flawed implementation of section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA") will threaten access to critical laboratory services for the most vulnerable Medicare beneficiaries as implementation plays out over the next several years. These cuts come at a time when the role that laboratory testing plays in the fight against the opioid epidemic is needed most.

Although Congress directed CMS to conduct a market-based refresh of the Medicare Clinical Laboratory Fee Schedule under PAMA, the sample of data CMS collected to inform the refresh was grossly flawed and was from less than 1% of the laboratories paid under the CLFS. CMS excluded almost all hospital outreach laboratories and most physician office laboratories in the survey. This flawed approach resulted in grossly inaccurate and lower rates in the new CLFS which are not market-based. Although CBO scored Medicare program spending reductions to clinical laboratories under PAMA at \$1.0B over the first 3 years of implementation, the rates that CMS published in late 2017 will reduce reimbursement to clinical laboratories by a staggering \$3.6B.

CMS ignored the intent of Congress to refresh the CLFS in a truly market-based manner. The CLFS rates that CMS published under PAMA over-emphasize high-volume independent laboratories that primarily serve metropolitan areas in a highly cost-effective manner. Smaller laboratories that serve rural and more expensive settings, such as nursing homes, whose rates were largely not included in the survey, will be forced to reduce service or exit the laboratory market altogether as a result of PAMA. These laboratories simply will not be able to sustain these drastic reimbursement reductions, which are on track to be 30% by 2020 for many common laboratory tests. As high-volume independent laboratories traditionally have not serviced these more expensive healthcare delivery settings, they will be even less likely to replace fill the laboratory testing access needs when these smaller laboratories exit the market. Because laboratory testing is critical to enabling healthcare providers to monitor patient adherence to prescribed drug therapies and to detect the various forms of opioid misuse, this reduction in access to laboratory testing at this critical time in our fight against opioid abuse should be of paramount concern.

Countering the problem of over-testing, all drug testing should be performed in a manner that is risk relevant and tests ordered according to what is medically necessary to manage the individual patient. Quest Diagnostics provides clinically and fiscally responsible options for what is medically necessary.

In conclusion, baseline testing and appropriate follow up drug testing produces objective information that added to other risk assessment tools like access to prescription drug monitoring programs can assist providers in determining the patient's risk for misuse of opioids. It is important for Medicare to provide appropriate reimbursement for laboratory testing. It also is important that all federal programs, including Medicare, encourage the adoption of CDC guidelines as an important step in combatting the opioid crises.

We appreciate this opportunity to discuss this crucial public health issue.

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