

# Testimony Before the United States Senate Committee on Finance Health Care Subcommittee Field Hearing

Examining Efforts to Prevent Opioid Overutilization and Misuse in Medicare and Medicaid

Testimony of:

Maureen Dixon
Special Agent in Charge, Philadelphia Regional Office
Office of Investigations
Office of Inspector General
Department of Health and Human Services

May 29, 2018 1:00 p.m. Bensalem Township Municipal Building, Bensalem, Pennsylvania Good afternoon, Chairman Toomey. I am Maureen Dixon, Special Agent in Charge of the Philadelphia Regional Office, Office of 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 for several years, identified curbing the opioid epidemic as one of the Department's Top Management and Performance Challenges. Key components of that challenge include addressing inappropriate prescribing of opioids, inadequate access to treatment, and misuse of grant funds. In addition, combatting fraud issues, such as drug diversion and fraud committed by providers, presents a significant challenge for the Department.

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 the Office of Investigations and discuss OIG projects currently underway 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

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> Drugs that enhance the high or euphoria when combined with controlled substances.

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 have full law enforcement authority and use a broad range of investigative actions, including the execution of search and arrest warrants, to accomplish our 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.<sup>3</sup>

Much of OIG's investigative 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. More than 60,000 Americans died from drug overdoses in 2016, of which 66 percent reportedly involved opioids. Deaths from prescription pain medication remain far too high, and in 2016, there was a sharp increase in deaths involving synthetic opioids such as fentanyl and an increase in heroin-involved deaths. 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 elaborate, involving complicit

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> Centers for Disease Control and Prevention, <u>Prescription Painkiller Overdoses at Epidemic Levels</u> [press release], Nov. 1, 2011.

<sup>&</sup>lt;sup>5</sup> Centers for Disease Control and Prevention, Data Brief 294, *Drug Overdose Deaths in the United States, 1999-2016*, December 2017, and supplement tables. <sup>6</sup>Ibid.

patients or beneficiaries who are not ill, kickbacks, medical identity theft, money laundering, and other criminal enterprises. Some schemes also involve multiple co-conspirators and health care professionals such as physicians, nonphysician providers, and pharmacists. These investigations 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. 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

OIG agents have investigated the following cases. These examples highlight opioid schemes involving patient harm and prescription and treatment fraud:

#### Patient Harm

• In Philadelphia, Dr. Norman Werther was sentenced to 25 years in prison for distribution of a controlled substance resulting in death and more than 300 counts stemming from his operation of a pill mill. Werther was part of a multimillion-dollar drug conspiracy involving illegal prescriptions, phony patients, and multiple drug trafficking organizations. The drug traffickers recruited large numbers of pseudo-patients who were transported to Werther's medical office for cursory examinations. The "patients" paid an office visit fee, usually \$150, by cash, check, or money order, and Werther wrote prescriptions for them to obtain oxycodone-based drugs without a legitimate medical purpose and outside the usual course of professional practice. The phony patients were then driven to various pharmacies to have their prescriptions filled. The drugs were then turned over to drug traffickers so their organizations could sell them to numerous drug dealers who resold them on the street. At one point, Werther knowingly dispensed approximately 150 pills containing 30 milligrams each of oxycodone, and 30 pills containing 15 milligrams each of oxycodone, to a patient for no legitimate medical purpose, ultimately resulting in the individual's death from overdose.

# Prescription Fraud

• In Williamsport, Dr. John Terry was sentenced to 20 months in prison for writing fraudulent prescriptions for oxycodone. Along with Terry, Thomas Ray was sentenced to

<sup>&</sup>lt;sup>7</sup> Department of Justice, <u>National Health Care Fraud Takedown Results in Charges Against Over 412 Individuals Responsible for \$1.3 Billion in Fraud Losses</u>, July 2017.

71 months in prison on charges of possession with intent to distribute a controlled substance. Terry wrote prescriptions for oxycodone and other narcotics for Ray in reckless disregard of the fact that the drugs were not being used by Ray for legitimate medical purposes, but being diverted and sold on the street. Medicaid paid for the fraudulent prescriptions written for Ray. Terry also wrote prescriptions for oxycodone in Stephen Heffner's name knowing that Heffner was not his patient and the drugs would later be diverted to another individual, David Hatch. Because Medicare paid for these drugs, Heffner and Hatch were both sentenced to 6 months of probation for theft from the Medicare Program.

• In Pittsburgh, Dr. Brent Clark was sentenced to 60 months in prison on charges of distribution of oxycodone and amphetamine outside the usual course of professional practice and health care fraud. He was also ordered to pay more than \$225,000 in restitution and forfeit \$131,000, the building he owned where he conducted his medical practice and where the offenses were committed, his Drug Enforcement Administration prescribing number, his Pennsylvania State medical license, and a vehicle he owned. Clark distributed oxycodone on 13 occasions and amphetamine on 3 occasions outside the usual course of professional practice.

#### Treatment Related Fraud

- In Philadelphia, Dr. Alan Summers was sentenced to 48 months in prison and ordered to pay over \$4.6 million in restitution after pleading guilty to charges of conspiracy to distribute controlled substances, distribution of controlled substances, health care fraud, and money laundering. Dr. Summers ran a clinic that sometimes operated under the business name NASAPT (National Association for Substance Abuse-Prevention & Treatment). Co-defendants Dr. Azad Khan and Dr. Keyhosrow Parsia were employed by Dr. Summers. The defendants executed a scheme in which they sold prescriptions for large doses of Suboxone and Klonopin in exchange for cash payments. Experts testified at trial that Suboxone and Klonopin should never be prescribed together except in rare cases when absolutely necessary. At the clinic, virtually all customers received prescriptions for both Suboxone and Klonopin regardless of their medical need. During the duration of the conspiracy, Dr. Khan and other doctors at the clinic illegally sold more than \$5 million worth of these controlled substances. Almost all of the prescriptions for Suboxone and Klonopin were preprinted before the customer met with a doctor. Khan and the other doctors working at the clinic failed to conduct medical examinations or mental health examinations as required by law to legally prescribe these controlled substances. Several customers who frequented the clinic testified that they were, in fact, drug dealers or drug addicts who sold the prescribed medications. Three other doctors involved in the scheme have pleaded guilty and have either already been sentenced or await sentencing.
- In Johnstown, Dr. John Johnson was sentenced to 84 months in prison and ordered to pay more than \$3 million in restitution after pleading guilty to charges of paying kickbacks and tax fraud. Johnson owned and operated a group of pain management clinics and entered into an agreement with Universal Oral Fluid Labs (UOFL) and its owner,

William Hughes, to refer patients to UOFL in exchange for kickback payments. UOFL was a clinical drug testing and drug screening lab located in Greensburg, Pennsylvania. Johnson received cash payments and monthly checks from Hughes and UOFL in exchange for referring patients, including Medicare and Medicaid beneficiaries, to UOFL. Johnson referred all of his patients to UOFL for drug testing and related services. He received more than \$2,300,000 in kickbacks from Hughes and UOFL for these referrals. As a result of Johnson's referrals, UOFL received millions of dollars from third-party payors, including approximately \$3,443,528 from Medicare and \$1,147,768 from Pennsylvania Medicaid.

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

Data analysis to identify questionable prescribing, dispensing, and utilization of opioids

OIG uses data analytics to detect and investigate health care fraud, waste, and abuse. We analyze 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 indepth analysis and efficiently target investigations.

In July 2017, OIG released a data brief entitled *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*<sup>8</sup> 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. Beneficiaries with a cancer diagnosis and those enrolled in hospice were excluded from the analysis. 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. Although beneficiaries may receive opioids for legitimate purposes, these high amounts raise concern due to the health risks associated with opioids.
- Within that group, 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

<sup>&</sup>lt;sup>8</sup> OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, OEI-02-17-00250, July 2017.

misuse or overdose: (1) beneficiaries who received extreme amounts of opioids and (2) beneficiaries who appeared to be "doctor shopping." <sup>9</sup>

- 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 for beneficiaries at serious risk. In the data brief, a total of 401 prescribers stood out as having questionable prescribing because they ordered opioids for higher 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 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 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 levels of prescribing also raise significant concern that prescribers may be operating pill mills.

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.

Identify opportunities to improve HHS programs

Across multiple operating divisions and programs, HHS has many opportunities to help curb this epidemic. Medicare provides prescription drug coverage for 41 million Part D beneficiaries and

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<sup>&</sup>lt;sup>9</sup> Other beneficiaries may also be at serious risk of opioid misuse or overdose, but they were not the focus of this data brief.

Medicaid for almost 69 million beneficiaries. The U.S. Food and Drug Administration (FDA) oversees the approval and safe use of prescription drugs. Agencies such as the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), and the CDC award grants to support health care providers, researchers, and States in their efforts to combat the epidemic.

OIG audits and evaluations address opioid issues by identifying opportunities to strengthen program integrity and protect at-risk beneficiaries across HHS programs. OIG currently has numerous opioid-related audits or evaluations underway. They address the following issues:

- questionable prescribing patterns in Medicaid;
- Medicaid program integrity controls;
- Medicare program integrity controls in the prescription drug benefit;
- CDC's oversight of grants to support programs to monitor prescription drugs;
- FDA's oversight of opioid prescribing through its risk management programs;
- SAMHSA's oversight of opioid treatment program grants;
- beneficiary access to buprenorphine medication-assisted treatment; and
- opioid prescribing practices in the Indian Health Service.

In addition, as part of its strategy to fight the opioid crisis and protect beneficiaries, OIG will soon release a new data brief on opioid use in Medicare Part D. <sup>10</sup> It is a followup to a previous data brief, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing* (OEI-02-17-00250), which was based on 2016 data. The new data brief is based on 2017 data and, like the previous one, will (1) determine the extent to which Medicare Part D beneficiaries received high amounts of opioids, (2) identify beneficiaries who are at serious risk of opioid misuse or overdose, and (3) identify prescribers with questionable opioid prescribing patterns for these beneficiaries.

In conjunction with the new data brief, OIG will also release an analysis toolkit.<sup>11</sup> It is based on the methodology that OIG has developed in our extensive work on opioids. The toolkit provides detailed steps for using prescription drug data to analyze patients' opioid levels and identify those at risk of opioid misuse or overdose, such as those who receive extreme amounts of opioids or appear to be doctor shopping. The purpose of the toolkit is to assist our public and private sector partners with analyzing their own prescription drug claims data to help combat the opioid crisis.

OIG is also focused on effective public health approaches to prevention and treatment. Currently, we are conducting an evaluation to examine access to Medication-Assisted Treatment (MAT) for opioid use disorder. MAT, including buprenorphine, is a key component of effective treatment for opioid use disorder. Congress has taken sustained action to support MAT services through broadened prescribing authorities and increased Federal funding. However, a treatment gap continues to exist where an estimated 10 percent of the people in the United States who need treatment receive it.

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<sup>&</sup>lt;sup>10</sup> OIG, Opioid Use in Medicare Part D, OEI-02-18-00220, forthcoming.

<sup>&</sup>lt;sup>11</sup> OIG, Toolkit to Identify Patients at Risk of Opioid Misuse, OEI-07-00560, forthcoming.

To address this treatment gap, we are examining access to MAT through the SAMHSA buprenorphine waiver program, which permits providers to prescribe buprenorphine to patients in office settings rather than traditional opioid treatment facilities. We are determining the number, location, and patient capacity of providers who have obtained buprenorphine waivers from SAMHSA. We will also determine the extent to which waivered providers are located in areas with high indicators of opioid misuse and abuse (i.e., areas that likely have large numbers of residents in need of treatment services), including whether any of these areas are without waivered providers. We anticipate that this report, when finalized, will highlight counties in need of MAT services that do not now have adequate access.

# 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 <a href="Healthcare Fraud Prevention Partnership">Healthcare Fraud Prevention Partnership</a> (HFPP) and collaboration with the <a href="National Health Care Anti-Fraud Association">National Health Care Anti-Fraud Association</a> (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 DEA 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

OIG has made numerous recommendations to improve HHS programs to better protect beneficiaries at risk of opioid misuse or overdose. Specifically, ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Medicare Part D.

As a result of OIG recommendations, Part D has strengthened its monitoring of beneficiaries at risk of opioid misuse. CMS has expanded drug utilization review programs to include non-opioid "potentiator" drugs. These euphoria-enhancing potentiator drugs are often abused in conjunction with opioids and increase the risk of negative outcomes including overdose. CMS now identifies beneficiaries with concurrent opioid and benzodiazepine prescription drug use and will, beginning in 2019, identify beneficiaries who receive high doses of gabapentin in addition to opioids. CMS also expects that when plan sponsors perform case management they would consider the use of these potentiator drugs in their own review processes. Further, CMS has committed to perform analyses to proactively identify other potentiator drugs, meet biannually with OIG to discuss emerging issues, and consider additional enhancements to drug utilization review programs in the future.

Despite the progress made, there are other improvements OIG recommends to protect Medicare beneficiaries.

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.

In 2018, CMS promulgated regulations that govern how Part D sponsors should implement the new lock-in authority under CARA, beginning in 2019. However, the decision of whether to implement this program rests with the Part D sponsors.

2) 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.

3) 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.