



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:

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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.