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OFFICE OF INSPECTOR GENERAL

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"OIG's Efforts to Address the Prescribing and Treatment Dimensions of the Opioid Crisis"

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Good morning, Chairman Grassley, Ranking Member Wyden, and distinguished members of the Committee. I am Gary Cantrell, Deputy Inspector General for Investigations with the Department of Health and Human Services (HHS) Office of Inspector General (OIG).

I appreciate the opportunity to appear before you to discuss OIG's enforcement efforts and other work to address the prescribing and treatment dimensions of the opioid crisis.

OIG is charged with overseeing all HHS programs and operations. We combat fraud, waste, and abuse in those programs; promote their efficiency, economy, and effectiveness; and protect the beneficiaries they serve. To accomplish this, OIG employs tools such as data analysis, audits, evaluations, and investigations. We are a multidisciplinary organization comprising investigators, auditors, evaluators, analysts, clinicians, and attorneys. We depend on our strong public and private partnerships to ensure coordinated enforcement success.

The Office of Investigations is the component of OIG that investigates fraud and abuse involving HHS programs. Our special agents have full law enforcement authority and effect a broad range of actions, including the execution of search warrants and arrests. We use traditional as well as state-of-the art investigative techniques and innovative data analysis to fulfill our mission. Our office has investigators covering every State, the District of Columbia, Puerto Rico, and other U.S. territories. We collaborate with other Federal, State, Tribal, and local law enforcement authorities to maximize our impact.

INTRODUCTION

OIG has, for several years, identified curbing the opioid crisis as one of the Department's Top Management and Performance Challenges, as well as one of OIG's four priority focus areas.[1] Key components of that challenge include addressing inappropriate prescribing of opioids, improving access to treatment, and stopping the misuse of grant funds. In addition, combating fraud issues, such as drug diversion and billing for medically unnecessary prescriptions or services not actually rendered by providers, presents a significant challenge

[1] The other three priority areas are: (1) promoting patient safety and accuracy of payments for services furnished in home and community settings, (2) strengthening Medicaid protections against fraud and abuse, and (3) ensuring health and safety of children served by grant-funded programs. For each priority focus area, OIG executives and senior-level staff develop strategies, drive action, unleash organizational creativity, and measure impact to provide solutions and improve outcomes for HHS programs and beneficiaries. OIG's current priority focus areas were selected based on past and ongoing work, top challenges facing HHS as identified annually by OIG, ability to collect data, and ability to influence outcomes.

for the Department. OIG's ongoing opioids-related work is taking a multifaceted approach, looking at a variety of issues on both the prescribing and treatment dimensions of the crisis.

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 harm patients and waste taxpayer money. For years, OIG has been acting to address a rise in fraud schemes involving opioids, as well as associated potentiator and treatment drugs and ancillary services. In addition to increasing our investigative efforts to combat prescription drug abuse, we have responded to the growing severity of the opioid crisis 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.

Today, I will highlight how OIG addresses both the prescribing and treatment dimensions of the opioid crisis through expanding law enforcement activities, led by my Office of Investigations, as well as new OIG work such as audits, evaluations, and data briefs, to combat opioid-related fraud, waste, and abuse while ensuring that both substance use disorder treatment and beneficiary continuity-of-care needs are met.

OIG'S EFFORTS TO ADDRESS THE OPIOID CRISIS ARE INCREASING THROUGH EXPANDING LAW ENFORCEMENT PARTNERSHIPS

Over the past 2 years, through expansion of Medicare Fraud Strike Force districts, establishment of the Opioid Fraud and Abuse Detection Unit Initiative, and establishment of the Appalachian Regional Prescription Opioid (ARPO) Strike Force, OIG's enforcement efforts to address the opioid crisis have increased significantly. For example, we have seen an increase of more than 100% in open opioid-related cases from 2015 to 2019.

Medicare Fraud Strike Force

The Strike Force effort began in Miami, Florida, in March 2007 and has expanded to now include a total of 12 districts. Strike Force teams effectively harness the efforts of OIG and the Department of Justice (DOJ), including Main Justice, U.S. Attorneys' Offices, the Federal Bureau of Investigation (FBI), and the Drug Enforcement Administration (DEA), as well as State and local law enforcement, to fight healthcare fraud in geographic hot spots.

Strike Force partnerships between HHS-OIG, DOJ, U.S. Attorney's Offices, the FBI, and the DEA are a force multiplier that utilize data proactively to identify high-risk districts to target the worst offenders involved in criminal conduct or fraud associated with the improper

prescription, distribution, possession, and use of opioids. This coordinated and data-driven approach to identifying, investigating, and prosecuting fraud has produced record-breaking results, including the June 2018 National Health Care Fraud Takedown, the 2019 Appalachian Regional Prescription Opioid Strike Force Takedowns, and most recently, the 2019 Regional Health Care Fraud and Genetic Testing Takedowns.

Appalachian Regional Prescription Opioid Strike Force

In October 2018, DOJ, in partnership with HHS-OIG, FBI and DEA, launched the ARPO Strike Force. The mission of the ARPO Strike Force is to identify and investigate healthcare fraud schemes in the Appalachian region and surrounding areas, and to effectively and efficiently prosecute medical professionals and others involved in the illegal prescription and distribution of opioids. This new Strike Force is operating out of two hubs based in the Cincinnati-Northern Kentucky and Nashville, Tennessee, areas, and supports the 6 States and 10 districts that make up the ARPO Strike Force region: Eastern, Middle, and Western Districts of Tennessee; Northern District of Alabama; Eastern and Western Districts of Kentucky; Northern and Southern Districts of West Virginia; Southern District of Ohio; and most recently, Western District of Virginia. The ARPO Strike Force has spearheaded takedowns in April and September 2019, resulting in charges against 73 individuals, including 64 medical professionals.

Collaboration With Public Health Partners

As part of the ARPO takedowns, OIG and our law enforcement partners worked in close collaboration with HHS's Office of the Assistant Secretary for Health (OASH), the Centers for Disease Control and Prevention (CDC), the Commissioned Corps of the U.S. Public Health Service, and the States' respective Departments of Health to deploy Federal and State-level strategies and resources to provide assistance to patients impacted by the law enforcement operations with additional information regarding available treatment programs and where they can turn for quality assistance. I will further discuss this new effort to ensure continuity of care and prevent patient harm later in my testimony.

In addition, OIG also implemented a pilot program providing OIG special agents in the ARPO region with a nasal spray version of naloxone—a drug that reverses the effects of an opioid overdose. The special agents were equipped and trained to treat any law enforcement officer who came into accidental contact with an opioid or any individual in medical distress caused by an opioid overdose encountered as part of the operations. OIG has expanded this program nation-wide to ensure that we are prepared to address agent and public needs that could arise as we engage in enforcement efforts.

Healthcare Fraud Takedowns

Over the month of September, along with our Medicare Fraud Strike Force, several U.S.

Attorney's Offices, and various other Federal, State, and local law enforcement agencies, OIG participated in a series of healthcare fraud takedowns across the country. In total, these coordinated law enforcement activities resulted in charges against over 380 individuals, including 178 medical professionals and 105 defendants for opioid-related offenses, who allegedly billed Federal health care programs for more than $3 billion and allegedly prescribed or dispensed approximately 50 million controlled substance pills.

Overall, the 2018 National and 2019 Regional and Appalachian Regional takedown efforts demonstrate OIG's commitment to rooting out fraud in HHS's opioid prescribing and treatment programs, helping to protect patients from harmful prescribing and worthless treatment services.

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 are elaborate, involving multiple co-conspirators including healthcare professionals such as physicians, nonphysician providers, and pharmacists, and sometimes even beneficiaries or patients themselves. These investigations can be complex and often involve the use of informants, undercover operations, and surveillance.

Of particular concern is fraud involving medication-assisted treatment (MAT), sober homes, and ancillary services such as drug screening and urinalysis. Through our oversight of opioid treatment facilities, we have seen a recent increase in MAT-related prescription fraud cases, particularly those involving buprenorphine.

Case Examples

The following examples highlight common schemes involving prescription and treatment opioid-related fraud:

Prescription Fraud

In Maryland, OIG recently worked a joint case with Federal, State, and several local law enforcement agencies to investigate allegations that Starlife Wellness Center was operating as a pill mill, charging patients $400 or more in cash for each office visit in exchange for unlawful prescriptions for large quantities of narcotics. Patient deaths were attributed to the prescribing practices of Dr. Kofi Shaw-Taylor and Starlife owner/general manager Tormarco Harris. Ultimately, Dr. Shaw-Taylor and eight co-conspirators were all indicted and charged with a variety of crimes, pled guilty, and sentenced to prison. Harris was found guilty at trial and sentenced to 20 years incarceration without the possibility of parole, 5 years probation, and a $10,000 fine.

Treatment-Related Fraud

Dr. Rajaa Nebbari and Dr. Chethan Byadgi, owners/operators of a medical practice in Pennsylvania that operated as an urgent-care medical clinic and a Suboxone treatment facility, both pled guilty to one count each of Medicaid Fraud, Theft by Deception and Insurance Fraud. Dr. Nebbari and Dr. Byadgi admitted to defrauding Medicaid, Medicare Part D, Medicare Part B, and various private health insurers of between $100,000 and $500,000. The doctors admitted to directing unlicensed "Suboxone coordinators" to see, treat, counsel and prescribe Suboxone to opioid-addicted patients. As part of the scheme, the doctors provided the Suboxone coordinators with pre-signed prescription pads and let the Suboxone coordinators use Google to find information on how to treat drug-addicted patients with Suboxone and how to determine the dosage of Suboxone for the prescription. Both doctors were sentenced to 9–23 months imprisonment, 7 years probation, and 1,000 hours of community service to be directed toward those impacted by drug addiction. Additionally, both doctors were ordered to pay $198,189.06 in restitution to the Medical Assistance program, the Medicare Part B and D programs, and various private health insurance companies.

Enforcement Actions Against Manufacturers

Since first taking action against executives with Purdue Pharma in 2007, OIG has been at the forefront of enforcement efforts to hold opioid manufacturers accountable for the illegal marketing and distribution of opioids. Notably, OIG has been heavily involved with investigation of Insys Therapeutics, which in June of this year agreed to a global resolution to settle the government's separate criminal and civil investigations. Both the criminal and civil investigations, as well as the conviction of seven former executives (including the company's billionaire founder and CEO) in May, stemmed from Insys's payment of kickbacks and other unlawful marketing practices to illegally promote sales of Subsys, a sublingual fentanyl spray that is only approved by the Food and Drug Administration for the treatment of persistent breakthrough pain in adult cancer patients who are already receiving, and tolerant to, around-the-clock opioid therapy. Many of these kickbacks allegedly took the form of sham speaker programs designed to reward high-prescribing physicians with jobs for the prescribers' relatives and friends, and lavish meals and entertainment. Insys also is alleged to have improperly encouraged physicians to prescribe Subsys for patients who did not have cancer and lied to insurers about patients' diagnoses to obtain reimbursement for Subsys prescriptions that had been written for Medicare and TRICARE beneficiaries. This was the first successful prosecution of top pharmaceutical executives for crimes related to the prescribing of opioids.

Sentencing for the executives and the plea hearing for the global resolution have been set for next January. As part of the criminal resolution, Insys will agree to a detailed statement of facts outlining its criminal conduct and pay a $2 million fine and forfeiture of $28 million,

while its operating subsidiary will plead guilty to five counts of mail fraud. As part of the civil resolution, Insys agreed to pay $195 million to settle allegations that it violated the False Claims Act. Insys also has entered into an unprecented 5-year Corporate Integrity Agreement and Conditional Exclusion Release with OIG.[2]

OIG has been heavily involved with the indictment of pharmaceutical company Indivior and subsequent resolution with its former parent company,[3] Reckitt Benckiser Group plc (RB Group) this year. In April 2019, a Federal grand jury indicted Indivior for allegedly engaging in an illicit nation-wide scheme to increase prescriptions of Suboxone. According to the indictment, Indivior—including during the time when it was a subsidiary of RB Group—promoted the film version of Suboxone (Suboxone Film) to physicians, pharmacists, Medicaid administrators, and others across the country as less divertible and less abusable and safer around children, families, and communities than other buprenorphine drugs, even though such claims have never been established. The indictment further alleges that Indivior touted its "Here to Help" internet and telephone program as a resource for opioid-addicted patients. Instead, however, Indivior used the program, in part, to connect patients to doctors it knew were prescribing Suboxone and other opioids to more patients than allowed by Federal law, at high doses, and in a careless and clinically unwarranted manner. The United States' criminal trial against Indivior is scheduled to begin in May 2020.

In the meantime, in July 2019 RB Group has agreed to pay $1.4 billion to resolve its potential criminal and civil liability related to a Federal investigation of the marketing of the opioid addiction treatment drug Suboxone. The resolution—the largest recovery by the United States in a case concerning an opioid drug—includes the forfeiture of proceeds totaling $647 million, civil settlements with the Federal Government and the States totaling $700 million, and an administrative resolution with the Federal Trade Commission for $50 million. The $700 million settlement amount includes $500 million to the Federal Government and up to $200 million to States that opt to participate in the agreement. As I said at the time of the resolution in July, with the Nation continuing to battle the opioid crisis, the availability of quality addiction treatment options is critical. When treatment medications are used, it is essential that they are prescribed carefully, legally, and based on

[2] Because of the extensive cooperation provided by Insys in the prosecution of culpable individuals and its agreement to enhanced CIA requirements, OIG elected not to pursue exclusion of Insys at this time. The CIA includes several novel provisions, including enhanced material breach provisions, designed to protect Federal health care programs and beneficiaries. In addition, Insys admitted to a Statement of Facts and acknowledged that the facts provide a basis for permissive exclusion. OIG did not release its permissive exclusion authority, as it generally does for CIA parties in False Claims Act settlements. Instead, OIG will provide such a release only after Insys satisfies its obligations under the CIA (https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal).

[3] In December 2014, RB Group spun off Indivior Inc., and the two companies are no longer affiliated.

accurate information, to protect the health and safety of patients in Federal health care programs.

Exclusions Actions

OIG protects federally funded health care programs by excluding certain dangerous or unscrupulous individuals and entities. Excluded providers cannot receive payment from Federal health care programs for any items or services they furnish, order, or prescribe. OIG's criminal law enforcement efforts are complemented by its efforts to exclude problem providers from participating in Federal health care programs. From the start of fiscal year 2018 through the end of fiscal year 2019, OIG has issued exclusion notices to 1,348 individuals (doctors, nurses, other providers, business owners/employees, etc.)—including 161 physicians, 896 nurses, and 87 pharmacists/technicians—and 15 entities (physicians' practices and other businesses) because of conduct related to opioid diversion and abuse.

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

OIG continues to augment its robust portfolio of work related to the opioid crisis, with new and ongoing work that identifies opportunities to strengthen program integrity and protect at-risk beneficiaries across both the prescribing and treatment dimensions of the crisis. OIG currently has numerous opioid-related audits and evaluations underway covering multiple departmental programs, including questionable opioid prescribing patterns in Medicaid and Medicare; characteristics of Part D beneficiaries at serious risk of opioid misuse or overdose; beneficiary access to MAT through SAMHSA's Buprenorphine Waiver Program; SAMHSA's awarding of Opioid State Targeted Response (STR) grants; and opioid prescribing practices in the Indian Health Service.

Prescribing Oversight

In a series of reviews targeting provider oversight, OIG examined actions that selected States have taken using CDC and SAMHSA funds for enhancing prescription drug monitoring plans (PDMPs) to achieve program goals toward improving safe prescribing practices and preventing prescription drug abuse and misuse. In another series of reviews, OIG identified actions that selected States took related to their oversight of opioid prescribing and their monitoring of opioid use. Specifically, OIG reviewed the States' policies and procedures, data analytics, programs, outreach, and other efforts.

Treatment Oversight

SAMHSA estimates that 2 million people have an opioid use disorder related to prescription pain relievers and/or heroin. MAT provided by opioid treatment programs (OTPs) is a significant component of the treatment protocols for opioid use disorder (OUD) and plays a large role in combating the opioid crisis in the United States. SAMHSA issued final

regulations to establish an oversight system for the treatment of substance use disorders with MAT. These regulations (42 CFR Part 8) established procedures for an entity to become an approved accreditation body, which evaluates OTPs and ensures that SAMHSA's opioid dependency treatment standards are met. OIG has an ongoing review that examines whether SAMHSA's oversight of accreditation bodies complied with Federal requirements.

Separately, OIG is reviewing potential geographic disparities in access to MAT through SAMSHA's Buprenorphine Waiver Program, which enables patients to access MAT through regular doctor's offices—instead of limiting this service to OTPs. In this review, we are determining how many providers have received waivers to prescribe buprenorphine for MAT and whether they are located in counties likely to have high needs for opioid treatment services.

In July 2019, building on our extensive body of work related to the opioid crisis, which includes annual data briefs on opioid prescribing in Medicare Part D, OIG released a data brief on the 2018 Part D data, *Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased*. We found that nearly 3 in 10 Medicare Part D beneficiaries received an opioid in 2018, a significant decrease from the previous 2 years. At the same time, the number of beneficiaries receiving Part D drugs for MAT for OUD and the number of beneficiaries receiving prescriptions through Part D for naloxone both increased. The number of beneficiaries at serious risk of opioid misuse or overdose also decreased, along with the number of prescribers with questionable opioid prescribing for these beneficiaries. Despite this seeming progress, concerns remain. About 354,000 beneficiaries received high amounts of opioids in 2018, with almost 49,000 of them at serious risk of opioid misuse or overdose. Further, about 200 prescribers had questionable opioid prescribing for the beneficiaries at serious risk.

The data briefs help OIG and OIG's law enforcement partners investigate high prescribers for possible fraud. We are also referring actionable information with program integrity partners including the Centers for Medicare & Medicaid Services (CMS), States, and the Healthcare Fraud Prevention Partnership (HFPP), so that they can use tools at their disposal to address high-risk beneficiaries and prescribers that have questionable billing.

Data Analysis To Identify Questionable Prescribing, Dispensing, and Utilization of Opioids
OIG uses data analytics to detect and investigate healthcare 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 in-depth analysis and efficiently target investigations.

Although OIG's increased utilization of data analytics enhances our enforcement and oversight efforts, there are still areas where we lack access to reliable data that hinders our work. For example, historically, Medicaid data have not been complete, accurate, and timely, and have not been adequate for national analysis and oversight. In August 2018, CMS announced that all States were submitting data to the national Medicaid database, known as the Transformed Medicaid Statistical Information System (T-MSIS), and that it was prioritizing T-MSIS data quality. OIG has a history of advocating for complete and accurate Medicaid data and is now monitoring whether the quality of T-MSIS is suitable for program enforcement and oversight activities. In fact, we have recently completed work assessing the completeness of variables needed to monitor national opioid prescribing in Medicaid. Complete and accurate T-MSIS data are critical for effective monitoring of the opioid crisis in Medicaid, as well as general program integrity efforts.

OIG MAXIMIZES IMPACT THROUGH STRONG COLLABORATION WITH PUBLIC AND PRIVATE PARTNERS

In addition to the Strike Force Operations and Opioid Fraud and Abuse Detection Unit law enforcement collaborations addressed earlier, OIG works closely with several HHS agencies on initiatives to prevent prescription drug and opioid-related fraud and abuse covering both the prescribing and treatment dimensions of the opioid crisis.

Collaboration With CDC on Opioid Rapid Response Teams

As our enforcement and oversight efforts to address the opioid crisis have expanded, we have come to understand the impact our enforcement work can have on the beneficiaries we serve. We recognize that when a clinic whose patients are prescribed opioids is shut down , access to care for patients, including many suffering from substance use disorders, can be disrupted. Rather than leaving these patients to potentially turn to another fraudulent provider or street drugs to meet their needs, we believe that it is vital that those struggling with substance use disorder have access to treatment and that patients who need pain treatment do not see their care disrupted. The potential dangers of abrupt opioid withdrawal are well established and thoughtful dose tapering may help patients discontinue opioid use safely.

Ensuring that these patients have continuity of care requires a collaborative approach with our Federal, State, and local partners, which has led OIG to work closely with CDC on standing up their new Opioid Rapid Response Teams (ORRTs). The mission of this team is to work alongside law enforcement partners to address disruptions in care after a clinic closure by providing support to State, local, and Tribal jurisdictions; providing clinicians with resources; conducting targeted outreach; expanding access MAT; and building response capacity. OIG worked closely with CDC in the planning and development of the ORRTs.

We advised them on protocols, connected them with other law enforcement partners, prepared data and support/educational materials, and continue to coordinate with them on deployment preparations to help focus their efforts to maximize impact. As part of the recent ARPO takedowns, OIG and our law enforcement partners coordinated closely with the CDC to make sure they were able to share their technical expertise with State and local officials and ensure that all impacted jurisdictions had sufficient response capacity to address the impact of takedown operations. OIG will continue to work hand-in-hand with our public health partners at the CDC to ensure access to treatment and continuity of care for beneficiaries impacted by our opioid-related law enforcement efforts moving forward.

Other Collaboration With the Department

OIG collaborates with a number of other HHS agencies, including 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 followup 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.

Additionally, in June 2018 OIG published a data analysis toolkit that our Federal, State, and private insurance partners can use to translate opioid prescriptions into a morphine equivalent does (MED) and identify patients who are at risk of opioid misuse or overdose. The CDC posted the toolkit to its public website aimed at researchers and analysts.

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

OIG also engages with private-sector stakeholders to enhance the relevance and impact of our work to combat healthcare fraud. The HFPP and NHCAA are public-private partnerships that address healthcare fraud by sharing data and information for the purposes of detecting and combating 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 healthcare fraud. We also share our expertise in data analytics, including the aforementioned toolkit and specific data resulting from takedown operations. Through our partnership in the HFPP and collaboration with the NHCAA, OIG strives to educate and empower private-sector insurers to best leverage data analytics and intelligence from the field to protect their own insured customer population. Likewise, OIG benefits from hearing directly from private and public partners about schemes and techniques used by other payers to combat healthcare fraud.

CONCLUSION

OIG has made combating 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 with law enforcement, the program integrity community, and the Department to maximize our efforts to address both the prescribing and treatment dimensions of the crisis. OIG will remain vigilant in identifying and investigating emerging opioid fraud trends, especially schemes involving patient harm and abuse.

Thank you for affording me the opportunity to discuss this important topic with you.