Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts by Federal Authorities and Private Insurers

Testimony before the

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by

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Good morning, Chairman Portman, Ranking Member McCaskill, and members of the subcommittee. I am Sandy Love, President of Health Integrity, LLC and I appreciate the opportunity to tell the committee about the important work we do to support the Centers for Medicare & Medicaid Services (CMS) in protecting the integrity of the Medicare and Medicaid programs. Created in 2006, Health Integrity is a non-profit, program integrity contractor.

Our contracts with CMS include the National Benefit Integrity Medicare Prescription Drug Contractor (NBI MEDIC). It is our responsibility to identify and investigate incidents of fraud, waste, and abuse in the Medicare Advantage (Part C) and Medicare Prescription Drug (Part D) programs. Additional CMS contracts include the Audit Medicaid Integrity Contractor (Audit MIC) that identifies Medicaid overpayments and the Zone Program Integrity Contractor (ZPIC) that reviews Medicare fee-for-service claims for the states of Texas, Colorado, Oklahoma, and New Mexico.

Since 2009, we have been the only NBI MEDIC and my testimony will focus on our work identifying, investigating, and proactively preventing potential fraud, waste, and abuse in Medicare's prescription drug programs. Also since 2009, Health Integrity has worked as a partner to CMS, the Health and Human Services' Office of Inspector General (HHS/OIG), and other federal and state law enforcement agencies in the fight against Medicare prescription drug fraud. I am proud to say that CMS and the NBI MEDIC have made great strides in improving operations and expanding authorities since the last time Health Integrity testified before the Committee in 2010. I want to make clear that we evaluate every lead we receive from plan sponsors. We bring our expertise and a detailed prioritization process to every decision of whether or not to refer a lead to law enforcement. Further, we retain all the information we receive and factor it into subsequent reviews of new plan leads and our ongoing integrity work.

Health Integrity is acutely aware of the opioid epidemic seizing this nation and shares the committee's concerns about the abuse and diversion of Part D drugs as detailed in the OIG report[1] released in July 2016. As you may know, the HHS/OIG reported that 30% of beneficiaries have at least one prescription for widely abused opioids and the median number of scripts per beneficiary is five over one year. The NBI MEDIC and CMS have been collaborating on attacking the opioid epidemic prior to the OIG report issuance and have developed and completed numerous, proactive projects to identify potential fraud, waste, and abuse involving controlled substances. These projects focus on identifying aberrant billing patterns, trends, and anomalies as well as questionable physician and pharmacy practices involving prescription drugs, including opioids and include:

[1] HHS OIG. "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns" (OEI-02-16-00290). 6/21/2016. http://oig.hhs.gov/oei/reports/oei-02-16-00290.asp

- The Quarterly Pharmacy Risk Assessment that uses 16 different measures to identify high-, medium-, or low-risk pharmacies leads for investigation and referral to law enforcement and for sharing with plan sponsors. Two of the 16 measures include Schedule II Controlled Substances (or opioids) metrics.
- The Prescriber Risk Assessment compares prescribers against their peers by their primary specialty and geographically by state to identify outliers. Specifically, it focuses on Schedule II controlled substances (or opioids) prescription drug event record count and Schedule II controlled substances 30-day equivalents.
- The Quarterly Pharmacy Spike Analysis identifies rapid changes in the billing patterns for pharmacies by quarter. It includes Schedule II and Schedule III-V controlled substances' metrics to identify pharmacy outliers.
- The Quarterly Prescriber Spike Analysis detects unusual billing trends of nationwide prescribers of Controlled Substances, Human Immunodeficiency Virus Medications, and Antipsychotics. It includes specific analysis of Schedule II and Schedule III-V controlled substances to identify prescribers who have unusual spikes in billing.
- The Quarterly Drug Trend Analysis detects sudden increases and emerging issues surfacing between the analyzed periods. It includes specific analysis of Schedule II and Schedule III-V controlled substances.
- The Transmucosal Immediate Release Fentanyl (TIRF) Drug Project involved the identification of improper payments made by Prescription Drug Plans (PDP) and Medicare Advantage-Prescription Drug (MA-PD) Plans for unapproved uses of these drugs. TIRF drugs are potent opioids indicated only for the management of breakthrough pain in adult patients with cancer.

- The Pill Mill Doctor Project identifies prescribers with a high risk of fraud, waste, and abuse in prescribing Schedule II-IV controlled substances. These high-risk prescribers may be engaged in what is commonly referred to as a "pill mill" scheme, which involves prescribing medications without a legitimate medical purpose. This project identifies prescribers from all specialties with an aggregated risk score above established thresholds. High-risk leads are investigated and referred to law enforcement and also shared with plan sponsors and law enforcement through PLATO.
- The Trio Prescriber Project focuses on identifying providers that prescribe all three of the following components to a beneficiary, an Opioid, a Benzodiazepine, and the Muscle Relaxant carisoprodol. This combination comprises a well-known drug cocktail prone to abuse as both benzodiazepines and carisoprodol can potentiate the effects of opioids.
- The Compounding Pharmacy Project applies statistical outlier detection methods to identify high-risk pharmacies billing Medicare Part D for compounded prescription drugs. The underlying risk factors of this project are based on the known compounding pharmacy fraud and abuse schemes uncovered in our investigative work and institutional knowledge of Health Integrity's clinical pharmacists.
- The Brand Name Drug Project is designed to uncover abnormal or aberrant billing practices by independent community/retail pharmacies concerning Medicare Part D payments for brand-name prescription drugs, including opioids sold under brand names, such as OxyContin®, Percocet®, Vicodin®, Percodan®, Tylox®, and Demerol® among others.

It is a very long list of projects so let me drill down on the results of the TIRF project to give you a sense of what each project entails. Started in 2013, this national project was initiated

after Health Integrity reported to CMS a program vulnerability involving TIRF. The problems we noted were found despite the U.S. Food and Drug Administration's (FDA) TIRF Risk Evaluation and Mitigation Strategy (REMS) program that was initiated in 2011 to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications due to medication errors. Our project found that drugs were prescribed and dispensed to beneficiaries lacking the required cancer diagnosis.

The initial project, which focused on standalone prescription drugs plans, covering January 2010 to June 2013 identified about $77.5 million in improper payments. Later, a follow-up project covering July 2013 to June 2015 identified about $33.9 million in improper payments attributed to standalone prescription drug plans. The project was later expanded to Medicare Advantage-Prescription Drug Plans, which covered January 2010 to December 2013, and identified $20.5 million in improper payments.

The results of each of these project periods were shared with the sponsors so they could take action to recoup the improper payments and institute changes in their approval and payment processes. Misuse of these drugs not only has a financial effect but also potential patient harm as the drugs are not oriented to treatment of non-cancer diagnoses. Problems noted from these types of reviews also result in our referral of the prescriber and pharmacist to the state boards of pharmacy and physician licensing. From 2013 to 2015, we have made over 400 such referrals to these boards.

NBI MEDIC Contractual Operations

The NBI MEDIC maintains a toll-free hotline to receive complaints alleging fraud, waste, and abuse in the Medicare Part C and D programs. During the calendar years of 2013, 2014, and 2015, the NBI MEDIC received over 37,000 calls to our toll-free hotline. Complaints are also received via fax, mail, and encrypted email using the NBI MEDIC Fraud Referral Complaint form found on our website.

Of these numbers, the NBI MEDIC has received over 24,000 actionable complaints from many sources including Medicare beneficiaries, plan sponsors, Pharmacy Benefit Managers (PBMs), law enforcement, and CMS. The complaints are about allegations of fraud, waste, and abuse, including services not rendered and drug diversion. These reactive complaints remain a sizeable portion of the NBI MEDIC workload. However, beginning September 2013, CMS directed the NBI MEDIC to perform more proactive data analysis to identify and investigate potential program vulnerabilities including those projects outlined above. The use of available records of prescriptions written provider and supplier data and innovative analytical methodologies (such as the PLATO tool, which we discuss in detail below) resulted in an increase of 174% in proactive investigations and an increase of 520% in proactive referrals to law enforcement agencies during the last quarter of 2013.

For calendar years 2013, 2014, and 2015, NBI MEDIC investigations have referred over 1,000 cases to law enforcement, of which 45% have been the result of proactive investigations. Almost 20% of these cases involve the diversion of controlled substances such as opioids.

Notable cases include Dr. Norman Werther, a Philadelphia physician sentenced to 25 years in prison for more than 300 counts stemming from his pill mill operation. This operation distributed controlled substances to patients, given cursory examinations, who were then

transported to pharmacies to fill prescriptions for oxycodone-based drugs that were turned over to drug dealers who resold the drugs on the street.

Another NBI MEDIC case involved Babubhai Patel, the owner and controller of 26 metropolitan Detroit pharmacies. Mr. Patel sent people to soup kitchens and homeless shelters to offer inhabitants cash in exchange for their Medicare or Medicaid number. He then paid doctors to write prescriptions for drugs he never intended to provide these pseudo-patients. Twenty-six co-conspirators were arrested and Mr. Patel was sentenced to 17 years of prison and ordered to pay nearly $20 million in restitution.

These are but two examples of investigative successes. There are many more that depict the NBI MEDIC's efforts to combat fraud, waste, and abuse in the Part C and D programs.

While criminal prosecutions rarely quantify the amount of recovery specifically to Medicare, NBI MEDIC referrals to law enforcement have resulted in a total recovery of over $111 million in fines, restitution and civil settlements in fiscal year (FY) 2015, alone.

Additionally, in FY 2015, the NBI MEDIC identified in excess of $155 million in inappropriate Medicare payments through proactive data analysis projects, the identification of program vulnerabilities and desk audits targeting specific issues. To date, CMS and health plans have recovered over $98 million of these inappropriate Medicare payments.

Reporting NBI MEDIC Results

The NBI MEDIC and CMS have recently collaborated to create and manage a Provider Peer Activity Report (PAR) for the Medicare Parts C and D programs. These reports focus on educating providers, examining utilization trends and patterns, and generating comparative data reports for healthcare providers to show them how their prescribing patterns compare to their

peers. For example, Health Integrity sent a notification which targeted doctors identified as outliers prescribing the atypical antipsychotic (AAP) drug quetiapine (generic), Seroquel® or Seroquel XR®, reduced overprescribing of this drug by 11 percent. PAR also is intended to have a sentinel effect and deter fraud, waste, and abuse by making providers aware that their billing practices, trends, and patterns are being monitored. This activity eventually is expected to curb and reduce drug overutilization and improper payments.

Development of PLATO: Advanced Analytic Solution and Communication Tool

In response to the growing need to share information with plan sponsors and PBMs, Health Integrity and CMS worked together to refine Health Integrity's PLATO® to share leads with plan sponsors. PLATO is a web-based, fraud-fighting tool we designed to help users identify potential leads using data projects based on nationwide data and identify fraud schemes. In the past, plan sponsors only had access to data on their own plan members. But now with PLATO, national, summary data information is available to the PLATO users. Additionally, plan sponsor activities involving ongoing investigations of pharmacies and prescribers, referenced as providers in PLATO, can be entered and tracked in the PLATO application.

Plan sponsors began to use PLATO in April 2015. As of August 26, 2016, there are 413 plan sponsor users of PLATO who have entered more than 4,000 activities involving Medicare providers into PLATO. In addition, law enforcement has also begun to use PLATO as part of their work involving the Part D program.

PLATO projects currently available to plan sponsors for their review, analysis, outcome documentation, and use in their operations are the ones I previously described. Two projects were recently approved by CMS including a project on compounding pharmacies' improper

billings and a project on HIV retroviral prescriber and pharmacy outliers. The inclusion of this work in PLATO will aid in sharing information across Part C and D plan sponsors. For example, if a plan sponsor conducts an audit of a suspect pharmacy within their network and determines the pharmacy does not maintain a sufficient inventory of prescription drugs to coincide with the quantity of prescriptions billed, they may terminate that pharmacy from their network. The documentation of their investigation in PLATO alerts other plan sponsors to conduct their own investigation into the pharmacy.

Improvement in NBI MEDIC Functions and Operations

In November 2013, CMS worked with Health Integrity to grant the NBI MEDIC the authority to refer providers for exclusion from the Medicare program. OIG exclusion removes a health practice or individuals from billing any federal healthcare program, including all four parts of Medicare. Since April 2014, the NBI MEDIC has recommended the exclusion of 186 providers to the Office of Inspector General/Office of Counsel to the Inspector General (OCIG). The potential five-year Part B and Part D cost avoidance for these providers totaled over $306 million. Additional authorities under which a revocation can be recommended include the suspension or revocation of a provider's Drug Enforcement Administration (DEA) Certificate of Registration or if the applicable licensing or administrative body for any state in which a provider practices has suspended or revoked the provider's ability to prescribe drugs. In 2015, CMS again worked with the NBI MEDIC to extend its authority to recommend the revocation of a provider's Medicare enrollment if it is determined that the provider demonstrates a pattern or practice of prescribing Part D drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

Since August 2015, the NBI MEDIC has recommended the revocation of Medicare enrollment for 169 providers. The potential five-year Part B and Part D cost avoidance for these providers totaled nearly $300 million. The five-year Part B and Part D cost avoidance for those recommendations that have been accepted thus far totals over $165 million.

The NBI MEDIC has closely followed hearings such as this to learn about your concerns and to improve our processes and offer suggestions to CMS to implement recommendations made by members of the committee and the HHS/OIG.

Previous hearings highlighted the need to better communicate with plan sponsors regarding their referrals, and the schemes under investigation by the NBI MEDIC. Health Integrity's procedures include acknowledging the receipt of all referrals from plan sponsors within five business days and resolution letters advising the outcome of the investigation. As noted earlier, we evaluate every lead we receive from plan sponsors. Our decision process is comprehensive, detailed oriented and uses the experience and technical knowledge of seasoned investigative staff to every decision of whether or not to refer a lead to law enforcement. All the information received and gathered is factored into subsequent reviews of new plan leads and our continuing program integrity work. Additionally, if our investigation of the plan lead extends beyond 45 days, interim letters are provided to the plan advising the investigation is continuing.

Additional collaboration work with the plans includes CMS, the NBI MEDIC and the Outreach and Education MEDIC conducting quarterly training sessions for plan sponsors to provide presentations on current fraud trends, schemes, and techniques for fighting fraud, waste, and abuse in Medicare Parts C and D.

Improvements in the Part D Program Oversight

CMS and the NBI MEDIC have made vast improvements to the Parts C and D program integrity efforts.

Previous reports by the OIG have highlighted barriers experienced by the NBI MEDIC in obtaining information from plan sponsors, subcontractors such as physicians, and networks' members including PBMs, pharmacies, and claims processors [known as First Tier, Downstream and Related Entities or (FDRs)]. To address this data problem, CMS, as part of Final Rule 4159, established the authority for the NBI MEDIC to directly request information from these FDR entities.

Another highlight in previous reports included the need to expand Part D data sharing. To improve data sharing, CMS and the NBI MEDIC established Joint Operating Agreements (JOAs) with each of the ZPICs, enabling the request and exchange of claims data across Medicare Parts A and B, including Home Health, Hospice and Durable Medical Equipment. This is an important step to enhance the work and outcomes of the Medicare program integrity program.

This concludes my prepared statement, including our recommendations for improvements, and I welcome your questions.