

United States Senate

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

Committee on Homeland Security and Governmental Affairs

Rob Portman, Chairman

Claire McCaskill, Ranking Minority Member

COMBATTING THE OPIOID EPIDEMIC: A REVIEW OF ANTI-ABUSE EFFORTS IN MEDICARE AND PRIVATE HEALTH INSURANCE SYSTEMS

STAFF REPORT

**PERMANENT SUBCOMMITTEE ON
INVESTIGATIONS**

UNITED STATES SENATE



SENATOR ROB PORTMAN
Chairman

SENATOR CLAIRE McCASKILL
Ranking Minority Member

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

BRIAN CALLANAN
Staff Director & General Counsel

MATT OWEN
Chief Counsel

MARK ANGEHR
Senior Counsel

ANDREW POLESOVSKY
Counsel

WILL DARGUSCH
Investigator

MARGARET DAUM
Staff Director & Chief Counsel to the Minority

BRANDON REAVIS
Counsel to the Minority

KELSEY STROUD
Chief Clerk

COMBATTING THE OPIOID EPIDEMIC: A REVIEW OF ANTI-ABUSE EFFORTS IN MEDICARE AND PRIVATE HEALTH INSURANCE SYSTEMS

TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
BACKGROUND	3
A. The Opioid Epidemic.....	3
B. The Subcommittee’s Investigation	4
C. CMS Efforts to Combat Opioid Abuse in the Medicare Drug Benefit Program	5
D. Health Insurers’ Role in Detecting and Addressing Opioid Overutilization....	6
DISCUSSION	7
I. Review of CMS’s Oversight Efforts to Combat Opioid Abuse and Fraud in Medicare Part D	7
A. CMS’s Efforts to Reduce Opioid Overutilization	8
B. Lack of Standards for Medicare Part D Program Integrity Reporting and Referrals	10
1. CMS has Given Plan Sponsors No Clear Standard for Reporting Abuse Cases to the MEDIC, and Reporting Rates Diverge Widely.....	10
2. MEDIC Lacks Clear Standards for Investigating Abuse Complaints and Leads	12
3. MEDIC Investigations of Actionable Abuse Complaints are Declining as Complaints are Rising	14
4. The HHS Inspector General Declines Half of the MEDIC’s Referrals for Action	15
C. The MEDIC’s Current Rate of Investigations Per Beneficiary is Half the 2008 Rate	16
D. Government Database Meant to Connect the Dots on Opioid Abuse, at the Cost of Millions of Dollars, is Relatively Unused by Plan Sponsors.....	17
E. CMS has not Implemented Several HHS Inspector General Recommendations to Improve Program Integrity in Part D.....	19

II. Review of Private Insurers’ Efforts to Combat Opioid Epidemic	20
A. Drug Utilization Reviews and Case Management Programs	21
B. Insurers’ Use of Lock-Ins Varies Widely, Suggesting this Anti-Abuse Tool May Be Underutilized.....	23
C. Insurers’ Use of Beneficiary-Level Opioid Point-of-Sale Edits Varies, Suggesting this Anti-Abuse Tool May Be Underutilized	26

EXECUTIVE SUMMARY

The abuse of opioid drugs has become a national health crisis. Sixty percent of the record 47,000 drug overdose deaths in 2014 were attributable to prescription opioids or heroin.¹ Approximately 19,000 of those deaths were due to prescription opioids. Combatting this public health emergency requires a collaborative effort by treatment centers, the health care community, and law enforcement. Those integrated efforts have been the subject of many congressional hearings.

The Subcommittee has focused on the significant role that the Centers for Medicare and Medicaid Services (CMS) and private health insurers play in detecting, reporting, and addressing opioid abuse. Specifically, the Subcommittee examined the efforts undertaken by CMS and its main program integrity contractor, the Medicare Drug Integrity Contractor (MEDIC), to address opioid-related fraud and abuse in Medicare Part D—the federal prescription drug coverage program serving nearly 35 million senior citizens and 7 million Social Security disability benefit recipients.² In addition, the Subcommittee examined the anti-opioid abuse efforts of six of the nation’s largest health insurance companies—both in their commercial insurance business and in their role as Medicare Part D plan sponsors.

CMS has taken recent steps to reduce opioid overutilization in Medicare Part D. In July 2013, CMS adopted an opioid overutilization policy that encompasses a medication safety approach by which plan sponsors are “expected to reduce beneficiary overutilization of opioids.” CMS requires that Part D plan sponsors maintain systems, policies, and procedures to review the dispensation of opioids in real time and also requires plan sponsors to develop and maintain retrospective utilization review programs for their Part D business.

Our principal findings are as follows:

First, CMS’s program integrity efforts suffer from a lack of clear standards governing when plan sponsors should report cases of waste, fraud, and abuse, including abuse of opioids. The agency has provided only generalized instructions to plan sponsors, calling for reports of “pattern[s] of fraud or abuse threatening the

¹ American Society of Addiction Medicine, *Opioid Addiction 2016 Facts and Figures*, 1, <http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>.

² The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds*, 10 (June 22, 2016), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2016.pdf>.

life or well-being of beneficiaries” or “schemes with large financial risk” with no definitions of these terms or specific thresholds. The MEDIC has not elaborated on these standards by providing further written guidance to sponsors. Indeed, there are no opioid-specific MEDIC reporting standards of any kind.

Second, as a result of this lack of guidance, plan sponsors take an *ad hoc*, case-by-case approach to MEDIC reporting. Their reporting rates reflect that. The annual rates of waste, fraud, and abuse reporting among the insurers reviewed ranged from 1 report for every 2,845 Part D beneficiaries to 1 report for every 71,000 Part D beneficiaries.

Third, even when an opioid-related abuse case is reported to the MEDIC, there are no written standards governing when the MEDIC should open an investigation or refer the case to law-enforcement authorities. CMS has broadly tasked the MEDIC with “review[ing] and triag[ing]” waste, fraud, and abuse complaints in search of “compliance violations,” but the agency has left the standard for triaging to the MEDIC’s discretion. The MEDIC, in turn, informed the Subcommittee that its standards for opening an investigation and making criminal or administrative referrals are all “unwritten.”

Fourth, the MEDIC investigated only 7% of all “actionable” waste, fraud, and abuse complaints from plan sponsors. That rate is also declining. Between 2013 and 2015, even as the number of complaints from sponsors increased significantly, the MEDIC’s investigations of actionable complaints *fell* by 50%. More broadly, the MEDIC’s total number of investigations—generated both by plan sponsors’ complaints and by other leads—has been steadily declining since 2008.

Fifth, a multimillion-dollar database created at CMS’s direction to detect opioid abuse schemes across insurers remains relatively unused by plan sponsors. The Predictive Learning Analytics Tracking Outcome (PLATO) database was designed to uncover prescription drug fraud schemes, including opioid diversion, by enabling data sharing among plan sponsors. But plan sponsors use PLATO sparingly, if at all, in their anti-abuse efforts, faulting limitations of the database.

Sixth, insurers’ use of lock-ins, an important anti-opioid abuse intervention, varies widely—suggesting this tool may be underutilized. Humana made negligible use of the restriction, as it locked in only 11 patients from 2013 through 2015. By contrast, Anthem far exceeded other insurers in terms of patient lock-ins, restricting 20,956 Medicaid beneficiaries between 2013 and 2015.³

³ Although patient lock-in is permissible in certain state-specific Medicaid programs, the practice was prohibited in Medicare Part D until the passage of the Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-298, Section 704(g).

Seventh, insurers’ use of beneficiary-level opioid point-of-sale edits, another significant anti-opioid intervention, also varies widely. For example, Kaiser applied only two such beneficiary-level edits in 2015 and four in 2016 in its Medicare business. UnitedHealth has applied the largest number of opioid-specific beneficiary-level point-of-sale edits in its Medicare business, applying 26 edits in 2013, 76 in 2014, and 175 in 2016.

BACKGROUND

A. The Opioid Epidemic

The opioid epidemic is a public health emergency that has devastated communities across the country.⁴ Over the past ten years, while mortality rates have decreased for leading causes of death such as heart disease and cancer, the mortality rate associated with opioid drugs has “increased markedly.”⁵ According to the most recent data from the Centers for Disease Control and Prevention (CDC), out of the 47,055 drug overdose deaths in 2014, over 60% involved prescription opioids or heroin,⁶ an illegal opioid with effects similar to prescription opioids.⁷ And nearly 19,000 of those overdose deaths involved prescription opioids.⁸ Indeed, more than 165,000 people have died from prescription opioid overdoses over the last 15 years.⁹ According to the American Society of Addiction Medicine, 1.9 million Americans were addicted to prescription opioids in 2014, and 586,000 were abusing heroin.¹⁰

⁴ See generally U.S. Dep’t of Health & Human Servs., *The Opioid Epidemic: By the Numbers* (June 2016), <http://www.hhs.gov/sites/default/files/Factsheet-opioids-061516.pdf>.

⁵ Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016* (Mar. 18, 2016), <http://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁶ Centers for Disease Control and Prevention, National Center for Health Statistics, *Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014*,

https://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.

⁷ National Institute on Drug Abuse, *DrugFacts: Heroin* (Oct. 2014), <http://www.drugabuse.gov/publications/drugfacts/heroin>.

⁸ Center for Disease Control and Prevention, National Center for Health Statistics, *Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014*,

http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf.

⁹ Centers for Disease Control and Prevention, *Injury Prevention & Control: Opioid Overdose Data*, <http://www.cdc.gov/drugoverdose/data/overdose.html>.

¹⁰ American Society of Addiction Medicine, *Opioid Addiction: 2016 Facts and Figures*, 2, <http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>.

Prescription opioid abuse also serves as a gateway to heroin use.¹¹ Since 2007, heroin use in the United States has increased among both sexes, most age groups, and all income levels by 150%.¹² According to the National Institute on Drug Abuse, “nearly half of young people who inject heroin surveyed in three recent studies reported abusing prescription opioids before starting to use heroin.”¹³ Another study found that four in five new heroin users started out by misusing prescription painkillers.¹⁴

B. The Subcommittee’s Investigation

In March 2016, the Subcommittee began its inquiry into efforts by private and governmental health insurance systems to address the opioid epidemic. From the outset, the Subcommittee’s inquiry has had two areas of focus: (1) the coordinated efforts of CMS, the MEDIC, and plan sponsors to curb opioid abuse and fraud in Part D, and (2) the effectiveness of private health insurers’ programs and techniques to identify opioid abuse and fraud among patients, prescribers, and pharmacies in commercial health plans.

During its investigation, the Subcommittee interviewed and reviewed documents from private insurers and pharmacy benefit managers, all of whom have significant market share in both commercial plans as well as Medicare Part D. Those private entities included Aetna, Inc., Anthem, Inc. (formerly WellPoint, Inc.), Cigna, Humana, Inc., Kaiser Permanente, and UnitedHealth Group, Inc., as well as CVS Health and Express Scripts in their roles as pharmacy benefit managers and Part D plan sponsors.

The Subcommittee also interviewed and reviewed documents from the MEDIC about its contract with CMS, interactions with plan sponsors, investigative efforts, and overall effectiveness. In addition, the Subcommittee conducted multiple interviews with and requested documents from CMS and the Health and Human Services (HHS) Inspector General about their efforts to combat opioid abuse and ensure Medicare Part D program integrity.

¹¹ National Institute on Drug Abuse, *Drug Facts* (rev. Oct. 2014), <https://www.drugabuse.gov/publications/drugfacts/heroin>.

¹² Centers for Disease Control and Prevention, *Vital Signs: Demographic and Substance Use Trends Among Heroin Users—United States, 2002–2013* (July 10, 2015), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6426a3.htm?s_cid=mm6426a3_w.

¹³ *Id.*

¹⁴ American Society of Addiction Medicine, *Opioid Addiction: 2016 Facts and Figures*, 2, <http://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf>.

C. CMS Efforts to Combat Opioid Abuse in the Medicare Drug Benefit Program

Taxpayer dollars spent on prescription opioids has increased significantly over the last decade. In 2015, the federal drug benefit program for Medicare enrollees (known as Part D) spent \$4.1 billion on commonly abused prescription opioids,¹⁵ up from \$1.5 billion in 2006.¹⁶ A high percentage of Part D beneficiaries receive commonly abused opioids. In 2015, almost 12 million beneficiaries—or nearly 1 in 3—received at least one of these drugs.¹⁷ And on average, each beneficiary in that subset received five prescriptions for commonly abused opioids during the year.¹⁸ Between 2006 and 2015, the total number of beneficiaries receiving commonly abused opioids grew by 94%, compared to 76% for all drugs.¹⁹ The most widely prescribed drug to Part D beneficiaries in 2014 was generic Vicodin—a commonly used opioid painkiller.²⁰

The responsibility to combat opioid-related waste, fraud, and abuse in Medicare Part D is shared by CMS’s Center for Program Integrity, the MEDIC, and private health insurers acting as Part D plan sponsors.

Plan sponsors are the first line of defense in combatting waste, fraud, and abuse in Plan D. They are responsible for paying claims, monitoring billing patterns, and establishing compliance plans that specify their procedures for preventing and detecting fraud, waste, and abuse. Plan sponsors must also ensure that the entities with which they subcontract (e.g., pharmacy benefit managers and pharmacies) meet regulatory and compliance requirements.²¹

The Center for Program Integrity monitors plan sponsor compliance with the Part D program.²² Among other functions, the Center ensures contractual

¹⁵ See U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-02-16-00290, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, 3 (June 2016).

¹⁶ See U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-02-15-00190, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, 3 (June 2015).

¹⁷ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-02-16-00290, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, 4, 8 (June 2016).

¹⁸ *Id.* at 4.

¹⁹ Interview with U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., Office of Investigations (Sept. 7, 2016).

²⁰ U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Part D Prescriber Data CY 2014* (Aug. 18, 2016).

²¹ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-02-09-00603, *Ensuring the Integrity of Medicare Part D*, 1 (June 2015), <https://oig.hhs.gov/oei/reports/oei-03-15-00180.pdf>.

²² Government Accountability Office, GAO-15-66, *CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse*, 6 (Oct. 2014).

compliance through audits of the private health insurers that administer Medicare benefits and analyzes data to identify potential patient safety concerns such as overutilization of opioid drugs.²³

CMS contracts out significant program integrity work to the MEDIC, a private firm responsible for intake and handling of abuse complaints from plan sponsors and other outside entities, responding to requests for information from law enforcement, investigating providers and referring them to law enforcement, and analyzing Part D prescription drug event records to identify patterns of potential waste, fraud, and abuse.²⁴ CMS has contracted with Health Integrity, LLC, to serve as the MEDIC since September 2006.²⁵

Since the Part D program went into effect in 2006, the HHS Inspector General has expressed several concerns about abuse and diversion of Part D drugs. HHS IG reports have revealed questionable billing associated with pharmacies, prescribers, and beneficiaries—involving opioids and other controlled (and non-controlled) substances.²⁶ For example, a 2012 Inspector General report found that more than 2,600 retail pharmacies had questionable billing practices for drugs including opioids and other pain killers.²⁷ A similar report in 2013 highlighted the questionable prescribing patterns of doctors and physicians in Part D.²⁸ The Inspector General also identified specific oversight concerns regarding the MEDIC's ability to proactively identify fraud schemes and faulted the MEDIC for not starting investigations on its own initiative despite having access to valuable data.²⁹

D. Health Insurers' Role in Detecting and Addressing Opioid Overutilization

The flood of opioid prescriptions presents insurers with both a challenge and an opportunity to combat the public health crisis posed by opioid abuse. In response, insurers have developed policies and programs that harness sophisticated data analytics to monitor claims and prescription drug histories for patterns of opioid-related abuse and fraud. The goal of these programs is to ensure safe,

²³ *Id.*

²⁴ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 24, 2016) (Statement of Work).

²⁵ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 24, 2016) (Chart of Contracts for MEDIC Senate Investigation).

²⁶ See U.S. Dep't of Health & Human Servs., Office of Inspector Gen., OEI-02-09-00603, *Ensuring the Integrity of Medicare Part D* (June 2015).

²⁷ See generally U.S. Dep't of Health & Human Servs., Office of Inspector Gen., OEI-02-09-00600, *Retail Pharmacies with Questionable Part D Billing* (May 2012).

²⁸ See generally U.S. Dep't of Health & Human Servs., Office of Inspector Gen., OEI-02-09-00603, *Prescribers with Questionable Patterns in Medicare Part D* (June 2013).

²⁹ See generally U.S. Dep't of Health & Human Servs., Office of Inspector Gen., OEI-03-11-00310, *MEDIC Benefit Integrity Activities in Medicare Parts C and D* (Jan. 2013).

appropriate, and cost-effective use of opioid drugs by limiting the dispensing of harmful drugs to opioid abusers in the first instance and generating effective treatment options as soon as potential opioid overutilization is detected.

Potential opioid overutilizers are often referred to as “outliers”—that is, individuals whose pattern of opioid use is outside the clinically-determined normal range. Once outliers have been identified, insurers deploy case management strategies such as outreach and education to the prescribers and pharmacies involved in an overutilizing patient’s care, as well as (in some cases) direct communication with the patient.³⁰ These communications inform prescribers and pharmacies that patients may be abusing opioids and ensure that each provider is aware of the full scope of the patient’s prescription drug history.³¹ Depending on the severity of the overutilization, insurers may request that prescribers justify the course of treatment or agree on a plan to reduce utilization.³²

Insurers sometimes restrict opioid abusers to a single pharmacy or prescriber.³³ This technique, known as a “lock-in,” cuts down on “doctor shopping” or “pharmacy shopping,” which is the practice of “obtaining controlled substances from multiple healthcare practitioners without the prescribers’ knowledge of the other prescriptions.”³⁴ Insurers carefully administer lock-ins to ensure that patients maintain appropriate access to drugs; accordingly, patients receive notification of the lock-ins, have an ability to contest the restriction, and are given a choice of primary prescriber or pharmacy.³⁵ Insurers may also flag problematic opioid prescriptions at the point-of-sale, either rejecting or modifying the prescription or simply warning the pharmacist to verify that the prescription is clinically appropriate.³⁶

DISCUSSION

I. Review of CMS’s Oversight Efforts to Combat Opioid Abuse and Fraud in Medicare Part D

CMS has implemented various safeguards designed to curb opioid abuse and fraud in Part D. For example, CMS has required that plan sponsors have review

³⁰ See, e.g., AETNA-PSI-0000078-79 (sample provider letter); AETNA-PSI-0000076-77 (sample member letter); CIGNA000163-64 (sample provider letter).

³¹ See, e.g., AETNA-PSI-0000078-79.

³² See, e.g., UnitedHealth000134-140.

³³ See, e.g., UnitedHealth000130-34 (pharmacy lock-in program); Letter from Anthem to the Permanent Subcommittee on Investigations at 7 (June 8, 2016) (discussing lock-in program). Beneficiary lock-in was not permitted in Part D until the passage of the Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-298, Section 704(g).

³⁴ Centers for Disease Control and Prevention, *Doctor Shopping Laws*, <https://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf>.

³⁵ UnitedHealth000131.

³⁶ See, e.g., AETNA-PSI-000124-25.

systems in place to monitor beneficiaries' opioid utilization at the point of sale (when pharmacies actually dispense prescriptions) and to identify and address beneficiaries engaged in potential opioid abuse. CMS also is responsible for oversight of its main Part D integrity contractor, the MEDIC. The Subcommittee found that both CMS and the MEDIC have failed to give plan sponsors clear standards for when to refer potential waste, fraud, and abuse to the MEDIC. CMS has also failed to provide the MEDIC with written guidance as to when the MEDIC should open an investigation or refer a matter for further action to law enforcement or CMS. The Subcommittee's review also found that the MEDIC is opening fewer investigations per year even as it is receiving more actionable complaints. The MEDIC's rate of investigations per beneficiary is half the 2008 rate.

A. CMS's Efforts to Reduce Opioid Overutilization

In July 2013, CMS adopted an opioid overutilization policy that encompasses a medication safety approach by which plan sponsors are "expected to reduce beneficiary overutilization of opioids."³⁷ The Overutilization Monitoring System provides plan sponsors with quarterly reports on high-risk beneficiaries; plan sponsors then must provide CMS with the outcome of their review of each case.³⁸

In addition, CMS requires that Part D plan sponsors maintain systems, policies, and procedures to review the dispensing of opioids in real time—a process that it calls concurrent drug utilization review.³⁹ The sponsors must administer a processing system that flags potentially harmful prescriptions at the point of sale or point of service.

Part D sponsors also use prior authorization review—under which certain prescriptions require additional approval from an insurer or its pharmacy benefit manager before dispensing—to prevent opioid waste, fraud, and abuse. In the Part D context, as CMS has explained, "sponsors determine the scope of their own prior authorization programs subject to CMS review to ensure that such programs have a sound medical basis and do not discriminate against beneficiaries with certain medical conditions."⁴⁰

³⁷ U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Medicare Part D Overutilization Monitoring System (OMS) Summary* (Nov. 3, 2015), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-11-03.html>.

³⁸ *Id.*

³⁹ 42 CFR § 423.153 (promulgating requirements for drug utilization management, quality assurance, and medication therapy management programs); *see also* U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual: Chapter 7—Medication Therapy Management and Quality Improvement Program*, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter7.pdf>.

⁴⁰ Centers for Medicare and Medicaid Servs., *Medicare Prescription Drug Benefit Manual*:

CMS also requires plan sponsors to develop and maintain retrospective utilization review programs for their Part D business.⁴¹ Retrospective drug utilization reviews examine utilization and prescribing patterns after dispensing to ensure that a patient's prescriptions are clinically appropriate and medically necessary.⁴² These types of programs analyze large amounts of historic prescription data in an effort to identify patterns of inappropriate prescriptions and outlier patients who exhibit signs of misusing prescription drugs.⁴³

Because opioids vary in strength, CMS has set the threshold for potential opioid overutilization using morphine dosage as the benchmark.⁴⁴ Specifically, CMS identifies beneficiaries at high risk of overutilizing opioids as those who have a daily morphine equivalent dose exceeding 120 mg over at least 90 consecutive days, see three or more prescribers, and submit claims at three or more pharmacies in the same 90-day period.⁴⁵ CMS uses this threshold to identify cases for inclusion on the quarterly reports it generates as part of its Overutilization Monitoring System.⁴⁶

Chapter 6—Part D Drugs and Formulary Requirements (rev. Jan. 15, 2016),

[https://www.cms.gov/Medicare/Prescription-Drug-](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf)

[Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf).

⁴¹ 42 CFR § 423.153(c)(3).

⁴² See, e.g., KAISER PERMANENTE 0008; UnitedHealth000107; see also U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual: Chapter 7—Medication Therapy Management and Quality Improvement Program* (Jan. 15, 2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter7.pdf>.

⁴³ See, e.g., UnitedHealth000107.

⁴⁴ U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Improving Drug Utilization Review Controls in Part D*, 2 (Sept. 6, 2012), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf>.

⁴⁵ See U.S. Dep't of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Supplemental Guidance Related to Medicare Part D Overutilization Monitoring System (OMS) Summary*, 2 (Nov. 3, 2015), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Fact-Sheet-Overutilization-Monitoring-System-11032015.pdf>.

⁴⁶ *Id.*

B. Lack of Standards for Medicare Part D Program Integrity Reporting and Referrals

1. CMS has Given Plan Sponsors No Clear Standard for Reporting Abuse Cases to the MEDIC, and Reporting Rates Diverge Widely

CMS provides general guidance for reporting possible instances of Medicare waste, fraud or abuse to the MEDIC.⁴⁷ These standards are detailed in the Compliance Program Guidelines found in the CMS Prescription Drug Benefit Manual and the CMS Medicare Managed Care Manual. The benefit manual states that plan sponsors

may refer an issue of non-compliance when any of the following conditions exist: (1) suspected, detected or reported criminal, civil, or administrative law violations; (2) allegations that extend beyond the Parts C and D plans, involving multiple health plans, multiple states, or widespread schemes; (3) allegations involving known patterns of fraud; (4) pattern of fraud or abuse threatening the life or well-being of beneficiaries; and (5) schemes with large financial risk to the Medicare Program or beneficiaries.⁴⁸

Neither CMS nor the MEDIC has provided other written guidance concerning circumstances in which such reporting to the MEDIC is warranted.⁴⁹ As a result, insurers have received no standard for assessing, for example, what constitutes a “large financial risk” to Medicare or when a “pattern of fraud or abuse” threatens the “life or well-being of beneficiaries.” Moreover, the insurers themselves report that they have developed no more specific internal standards for when to report to

⁴⁷ Letter from Aetna to the Permanent Subcommittee on Investigations (June 3, 2016); Letter from Anthem to the Permanent Subcommittee on Investigations (June 8, 2016); Letter from Cigna to the Permanent Subcommittee on Investigations (June 7, 2016); Letter from Humana to the Permanent Subcommittee on Investigations (June 3, 2016); Letter from UnitedHealth to the Permanent Subcommittee on Investigations (June 14, 2016).

⁴⁸ U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Prescription Drug Benefit Manual, Chapter 9—Compliance Program Guidelines* (Jan. 11, 2013), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf>.

⁴⁹ Letter from Aetna to the Permanent Subcommittee on Investigations (June 3, 2016); Letter from Anthem to the Permanent Subcommittee on Investigations (June 8, 2016); Letter from Cigna to the Permanent Subcommittee on Investigations (June 7, 2016); Letter from Humana to the Permanent Subcommittee on Investigations (June 2, 2016); Letter from UnitedHealth to the Permanent Subcommittee on Investigations (June 14, 2016).

MEDIC.⁵⁰ Instead, the insurers take an *ad hoc*, case-by-case approach to MEDIC reporting, and their reporting rates reflect it.

Based on the Subcommittee’s review of information obtained from the MEDIC, reporting of actionable complaints among insurers and pharmacy benefit managers varies widely. For example, in 2015 UnitedHealth accounted for 33.7% of the actionable waste, fraud, and abuse complaints sent by plan sponsors to the MEDIC.⁵¹ Express Scripts nearly matches Aetna with 9% of actionable complaints, but percentages for the remaining reporters in the top 15 entities range from 6.75% to as low as 0.86%.⁵² These differences in reporting volume are not explained by the varying numbers of Medicare beneficiaries enrolled in each health plan. For example, UnitedHealth Group and Humana have similar numbers of Medicare beneficiaries—approximately 9.5 million and 8.2 million, respectively—but UnitedHealth submits 15 times more reports to the MEDIC than Humana. To put reporting rates in further context, the Subcommittee compared the number of waste, fraud, and abuse reports to the Medicare beneficiaries for each insurer to yield a report-to-beneficiary ratio. The result shows ratios ranging from 1 report for every 2,845 beneficiaries to 1 report for every 71,102 beneficiaries.

Waste, Fraud & Abuse Reporting Rates to CMS⁵³		
2015		
<i>Plan Sponsor</i>	<i>Cases Reported to CMS</i>	<i>Report to Medicare Beneficiary Ratio</i>
Anthem	492	1 : 2,845
UnitedHealth Group	2,219	1 : 5,556
Aetna	64	1 : 28,125
Kaiser	29	1 : 46,367
Humana	120	1 : 65,709
Cigna	28	1 : 71,102

The share of all plan sponsors that did not make a single referral to the MEDIC has also risen over the past two years. In 2013, 60% of plan sponsors made zero referrals to MEDIC. By 2015, the number of non-referring plan sponsors climbed to two-thirds (66.77%).⁵⁴

⁵⁰ *Id.*

⁵¹ Production from the MEDIC to the Permanent Subcommittee on Investigations (July 5, 2016).

⁵² *Id.*

⁵³ Letter from Aetna to the Permanent Subcommittee on Investigations (June 24, 2016); Letter from Anthem to the Permanent Subcommittee on Investigations (June 24, 2016); Letter from Cigna to the Permanent Subcommittee on Investigations (June 24, 2016); Letter from Humana to the Permanent Subcommittee on Investigations (June 3, 2016); Letter from UnitedHealth to the Permanent Subcommittee on Investigations (June 14, 2016); Letter from Kaiser Permanente to the Permanent Subcommittee on Investigations (May 13, 2016).

⁵⁴ Production from the MEDIC to the Permanent Subcommittee on Investigations (Sept. 16, 2016).

2. MEDIC Lacks Clear Standards for Investigating Abuse Complaints and Leads

CMS has paid more than \$129 million to Health Integrity LLC, which serves as the MEDIC, since it began performing Medicare program integrity work in 2005.⁵⁵ According to the most recent statement of work for the MEDIC contract, the MEDIC is responsible for the “intake and handling of all complaints, requests for information, and sending and tracking referrals to law enforcement,” as well as “all investigations; benefit integrity; and data analysis.”⁵⁶

Based on the Subcommittee’s review, CMS has not provided clear standards to govern when the MEDIC should open investigations upon receipt of a complaint or refer a case for criminal or other administrative action. CMS’s written guidance instead broadly directs the MEDIC to “review and triage complaints” alleging Medicare fraud, waste and abuse.⁵⁷ Without carefully defined standards from CMS outlining when to open an investigation or refer a case to the HHS Inspector General, law enforcement, or CMS for administrative action, the MEDIC must make *ad hoc* determinations about investigations and referrals. CMS has also not provided the MEDIC with any specific instructions concerning opioid overutilization complaints.

CMS is capable of providing more clear guidance. Indeed, it has done so for circumstances that warrant an “immediate advisement” to the Inspector General. Immediate advisements are fraud or abuse allegations that benefit integrity contractors are required to send directly and immediately to the Inspector General upon receipt from a third party.⁵⁸ CMS has carefully defined the circumstances in which the MEDIC is to make an immediate advisement, which include “indications a Medicare employee is engaged in fraud,” cases “with, or likely to get, widespread publicity or involving sensitive issues,” cases with allegations of “kickbacks or bribes,” and cases with indications that “organized crime may be involved.”⁵⁹

The MEDIC told the Subcommittee that it has unwritten standards for accepting and investigating complaints and making criminal or administrative referrals.⁶⁰ In an interview with the Subcommittee, Douglas Quave, the MEDIC’s

⁵⁵ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 27, 2016) (review of funding contracts).

⁵⁶ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 27, 2016) (2015 Task Order to the Statement of Work).

⁵⁷ *Id.*

⁵⁸ U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual: Chapter 4—Benefit Integrity*, § 4.18.1.2 (Feb. 19, 2016), <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c04.pdf>.

⁵⁹ *Id.*

⁶⁰ The MEDIC did produce a “scoring tool” after reviewing a draft of this report. This “scoring tool” is used by its staff to attempt to prioritize complaints for further action based on some factors including

Senior Vice President and Program Director, stated that the MEDIC itself does not have or issue written guidelines or templates for these actions.⁶¹ Mr. Quave further stated that the MEDIC instead relies on the “independent judgment and experience” of its investigators to determine whether or not to ultimately open an investigation. Mr. Quave also told the Subcommittee that CMS has not issued specific standards for when the MEDIC should take action on opioid-specific cases.⁶²

Despite that lack of standards, the MEDIC will “reject” complaints by stating that the referrals do not meet “prosecutorial guidelines.” For example, a January 2016 rejection letter received by a plan sponsor after submitting a complaint reads as follows:

Thank you for sharing your findings of your review regarding [SUBJECT OF PLAN SPONSOR INVESTIGATION]. Based on the fact that, at this time, the complaint does not meet prosecutorial guidelines established by the United States Attorney’s Office and/or other law enforcement agencies, this matter is being returned to you for any administrative actions you deem necessary.⁶³

Such language about “prosecutorial guidelines” is standard in MEDIC rejection letters.⁶⁴ Yet, when asked what “guidelines” these letters reference, the MEDIC was unable to point to any written guidance.

According to Mr. Quave, the MEDIC’s investigators can reject plan sponsor complaints if the dollar amount or harm to the Medicare program is too small.⁶⁵ Yet while there are no set dollar amounts or thresholds for when a specific case is opened or referred, the rough monetary threshold applied by the MEDIC’s staff often differs depending on geographic location. For example, Mr. Quave stated that the MEDIC would not open an investigation or refer a “million dollar case” in Miami, Florida, because the prosecutorial standards to bring a case in Miami are higher. However, a million dollar case elsewhere, like in the Midwest, would likely be referred. According to Mr. Quave, the MEDIC investigators determine these unwritten dollar thresholds using their experience and judgment.⁶⁶

geographic area, source of the complaint, prior criminal background of the subject, and the possible dollar harm. Production from the MEDIC to the Permanent Subcommittee on Investigations (Sept. 19, 2016).

⁶¹ Interview with Doug Quave, Program Director and Sr. Vice President, MEDIC (Aug. 29, 2016).

⁶² *Id.*

⁶³ AETNA-PSI-0000007 (emphasis added).

⁶⁴ Interview with Sandra Love, President, MEDIC (Sept. 16, 2016).

⁶⁵ Interview with Doug Quave, Program Director and Sr. Vice President, MEDIC (Aug. 29, 2016).

⁶⁶ *Id.*

3. MEDIC Investigations of Actionable Abuse Complaints are Declining as Complaints are Rising

The lack of written standards described above is troubling because the MEDIC is entrusted with making significant determinations about when to investigate and refer thousands of actionable complaints. The MEDIC does not have the resources to investigate every single complaint—nor is that the job it has contracted to do. Nonetheless, the number of investigations that the MEDIC has opened is declining overall and as a share of actionable complaints.

Data provided to the Subcommittee shows that in 2015 the MEDIC only opened investigations on 7% of all actionable complaints received.⁶⁷ The chart below shows the number of actionable complaints the MEDIC received and the number of investigations it opened in response over the last three years.

Year	Total Actionable Complaints Received	Actionable Complaint Investigations Opened	Share of Actionable Complaints Investigated
2013	6,879	1,135	16%
2014	8,519	681	8%
2015	8,892	597	7%

The Subcommittee also reviewed a selected group of opioid-related plan sponsor complaints that the MEDIC has rejected. This limited review revealed cases in which the MEDIC declined to undertake a genuine investigation and instead relied on a cursory review before rejecting the complaint. The most common tasks in this cursory review included noting the monetary harm to Medicare, the status of a medical or pharmacy license, the existence of other complaints to the MEDIC, and whether CMS had suspended payments to the provider at issue. Following this cursory review, the MEDIC has in some cases rejected complaints that, on their face, presented a high risk of opioid abuse by beneficiaries, prescribers, or pharmacies.⁶⁸

For example, in a 2014 case reviewed by the Subcommittee, the MEDIC rejected a complaint identifying a prescriber that was possibly overprescribing controlled substances.⁶⁹ The complaint found that 74% of the prescriber's Schedule II and III prescriptions were for the narcotic oxycodone and the amount of Schedule

⁶⁷ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 30, 2016) (review of investigations statistics).

⁶⁸ Production from the MEDIC to the Permanent Subcommittee on Investigations (Sept. 14, 2016).

⁶⁹ Production from the MEDIC to the Permanent Subcommittee on Investigations (Sept. 14, 2016) (review of Case File 27234).

II prescriptions was five and a half times the average of the prescriber's peers.⁷⁰ After concluding that the doctor's medical license was active, that there were no additional complaints in the MEDIC system, and that there were no suspended Medicare payments on the doctor's record, the MEDIC investigator sent the plan sponsor a letter indicating the complaint did not "not meet prosecutorial guidelines established by the United States Attorney's Office and/or other law enforcement agencies," and the file was closed.⁷¹ One month later, however, the MEDIC received a similar complaint from a different plan sponsor regarding the same doctor. The MEDIC opened an investigation, was notified that the doctor had been formally charged with 27 counts of illegally distributing controlled substances by running a pill mill, and then sent the HHS IG an immediate advisement two months later.⁷² After that notification, the MEDIC ran a report of the doctor's prescribing patterns with all available prescription drug event data. That report showed suspect prescribing patterns and a monetary exposure to Medicare of roughly \$150,000. Eventually, a federal jury convicted the doctor of "running a multimillion-dollar pill mill" leading to an overdose death of at least one of his patients.⁷³

4. The HHS Inspector General Declines Half of the MEDIC's Referrals for Action

The HHS Inspector General is at the center of the federal government's efforts to combat Medicare fraud. The Office of Investigations "conducts criminal, civil and administrative investigations of fraud and misconduct" related to HHS programs—including the Medicare Part D Prescription Drug benefit.⁷⁴ The Inspector General is also responsible for coordinating the Medicare Fraud Strike Force Teams designed to coordinate federal, state, and local law enforcement resources to identify fraud and prosecute offenders.

According to a review of data provided to the Subcommittee, the HHS Inspector General declined and returned more than half of the MEDIC's referrals from 2013 to 2015.⁷⁵ This is significant because the Inspector General is the number-one recipient of MEDIC referrals, and the MEDIC spends substantial time and resources preparing them—only to have over half declined by the receiving

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² U.S. Dep't. of Justice, *Pennsylvania Doctor and Receptionist Charged with Running Pill Mill* (Jan. 29, 2015), <https://www.fbi.gov/contact-us/field-offices/philadelphia/news/press-releases/pennsylvania-doctor-and-receptionist-charged-with-running-pill-mill>.

⁷³ Steve Bohnel, *Jury Convicts Doctor Accused of Running Pill-Mill with Pagans' Help*, *Philadelphia Inquirer* (June 30, 2016), http://articles.philly.com/2016-06-30/news/74098311_1_jury-drug-dealer-verdict.

⁷⁴ See U.S. Dep't of Health & Human Servs., Office of Inspector Gen., *About Us*, <https://oig.hhs.gov/about-oig/about-us/office-of-investigations.asp>.

⁷⁵ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 30, 2016).

agency. The table below shows the total number of referrals and the receiving agency.⁷⁶

MEDIC Referrals by Agency				
Receiving Agency	2013	2014	2015	Total
HHS IG	134	199	186	519
DOJ	50	82	121	253
Other	1	21	169	191
State and Local Law Enforcement	17	32	26	75
Other Non-Law Enforcement Agencies	10	19	16	45
Contractors	1	2	4	7
DOI/SIC ⁷⁷	0	4	0	4
Total	213	359	522	1,094

When interviewed by Subcommittee staff, the HHS Inspector General’s Office of Investigations stated that the ultimate goal was a 100% acceptance rate of MEDIC referrals and that the current acceptance rate of less than half “should probably be higher.”⁷⁸ According to the Office of Investigations, the “baseline” for acceptance is the “quality” and “completeness” of the MEDIC’s investigation.⁷⁹ Substantial gaps in the MEDIC’s investigation, or in cases in which the MEDIC simply forwarded a plan sponsor’s referral without adding supplemental information, increase the odds of rejection by the Inspector General. The low rate of the Inspector General’s acceptance has persisted since 2013 despite the fact that the MEDIC and the Inspector General have quarterly meetings to discuss individual cases before referrals are even made.⁸⁰

C. The MEDIC’s Current Rate of Investigations Per Beneficiary is Half the 2008 Rate

According to the MEDIC, the most important tool to root out waste, fraud, and abuse is its process for investigating complaints from plan sponsors or other

⁷⁶ *Id.*

⁷⁷ “DOI” and “SIC” refers to Department of Insurance and State Insurance Commission, respectively.

⁷⁸ Interview with Dep’t of Health & Human Servs., Office of Inspector Gen., Office of Investigations (Sept. 7, 2016); Interview with U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., Office of Evaluation and Inspections (Sept. 7, 2016).

⁷⁹ *Id.* A representative from the HHS Inspector General later noted that referral acceptance “also is dependent upon OIG investigative resources.” Email from the HHS Inspector to the Permanent Subcommittee on Investigations (Sept. 19, 2016).

⁸⁰ *Id.*; Production from the MEDIC to the Permanent Subcommittee on Investigations (June 30, 2016).

outside entities.⁸¹ “Investigat[ing] complaints alleging fraud” is also a key part of the MEDIC contract, as well as a statutory responsibility.⁸² Despite this statutory and contractual obligation and a funding increase of more than 25% over the past two years the number of MEDIC investigations continues to decline.

According to data reviewed by the Subcommittee, the MEDIC opened 31% fewer investigations in 2015 than in 2013. The chart below shows the total number of MEDIC investigations and the federal funding it received for each of the past three years.⁸³

	2013	2014	2015	Total
Total Number of Investigations	1,349	1,041 (23% decrease)	929 (11% decrease)	3,319
Federal Funding	\$15,730,588	\$18,871,279	\$19,546,327	\$54,148,194

The MEDIC conducted roughly 2.4 investigations of potential fraud and abuse for every 100,000 beneficiaries in 2015. By contrast, the MEDIC conducted 5 investigations for every 100,000 beneficiaries in 2008, according to an HHS Inspector General report.⁸⁴ In other words, the MEDIC conducted less than half as many investigations per beneficiary in 2015 as it had seven years earlier.

D. Government Database Meant to Connect the Dots on Opioid Abuse, at the Cost of Millions of Dollars, is Relatively Unused by Plan Sponsors

Sharing information across health insurance plans is crucial to uncovering fraud and abuse—especially those involving multiple plans. Because a prescriber or pharmacy may defraud several different plan sponsors at the same time, access to reports from multiple plans may be necessary to detect the fraud and understand its full scope.

The MEDIC developed a database called the Predictive Learning Analytics Tracking Outcome (PLATO), which is designed to address this issue by collecting information from plans and providing a more robust dataset for review and

⁸¹ Interview with Julio Arias, Deputy Program Director, MEDIC (June 24, 2016).

⁸² Production from MEDIC to the Permanent Subcommittee on Investigations (June 27, 2016) (2015 Task Order to the Statement of Work).

⁸³ Production from MEDIC to the Permanent Subcommittee on Investigations (June 24, 2016) (Investigations Statistics documentation).

⁸⁴ See U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-03-08-00420, *Medicare Drug Integrity Contractors’ Identification of Potential Part D Fraud and Abuse*, 9 (Oct. 2009).

analysis.⁸⁵ PLATO first became accessible to private insurers in April 2015, and a budget proposal from the MEDIC estimates a fiscal year 2016 cost of more than \$5 million for PLATO and predictive modeling data analysis.⁸⁶

In order for PLATO to be effective, the database must rely on continuous updates from plan sponsors with detailed prescription drug event information and potential fraud schemes. As the Subcommittee's investigation revealed, however, plan sponsors appear to use PLATO sparingly, if at all. Since PLATO's launch in April 2015, for example, 11 plan sponsors are responsible for more than 50% of the roughly 4,000 individual data entries, and 57 plan sponsors submitted 10 or fewer entries in the system.⁸⁷ Anthem, for example, only entered four cases in PLATO in 2015 and three cases in 2016.⁸⁸ Kaiser Permanente only entered one case.⁸⁹ Humana, for its part, lacks the capability to track the number of cases entered in PLATO,⁹⁰ and UnitedHealth only "periodically" uses PLATO to collect information on waste, fraud, and abuse.⁹¹ Only Aetna reported a comparatively robust reporting history, with 78 pharmacy-related cases entered in PLATO.⁹²

Some plan sponsors faulted PLATO's limitations for their relatively light usage. Several sponsors noted that CMS has limited the number of log-ins to only two access points per plan sponsor.⁹³ For example, Humana and Aetna indicated that their entire Special Investigative Units had only two access points and that this limited the companies' ability to use PLATO effectively.⁹⁴ According to Humana, PLATO lacks the capacity to provide proactive notices to plan sponsors about suspected cases of opioid waste, fraud, and abuse.⁹⁵ One plan sponsor further elaborated on this point in an interview with the Subcommittee, stating that PLATO itself does not have sufficient analytical tools—it simply stores the data and investigators must actively run their own queries. The Subcommittee heard from at

⁸⁵ Government Accountability Office, GAO-15-66, *CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse*, 20 (Oct. 2014).

⁸⁶ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 24, 2016) (Sept. 29, 2015 – Sept. 28, 2016 Option Year 10).

⁸⁷ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 24, 2016) (PLATO documentation).

⁸⁸ Letter from Anthem to the Permanent Subcommittee on Investigations (June 8, 2016).

⁸⁹ Letter from Kaiser Permanente to the Permanent Subcommittee on Investigations (June 2, 2016).

⁹⁰ Letter from Humana to the Permanent Subcommittee on Investigations (June 3, 2016).

⁹¹ Letter from UnitedHealth to the Permanent Subcommittee on Investigations (June 3, 2016).

⁹² Letter from Aetna to the Permanent Subcommittee on Investigations (June 3, 2016).

⁹³ Interview with Doug Quave, Program Director and Sr. Vice President, MEDIC (May 20, 2016); Interview with Aetna (June 29, 2016); Interview with Humana (Apr. 15, 2016).

⁹⁴ Production from the MEDIC to the Permanent Subcommittee on Investigations (June 24, 2016) (PLATO Documentation).

⁹⁵ Letter from Humana to the Permanent Subcommittee on Investigations (June 3, 2016).

least two plan sponsors that PLATO was not as “proactive” or “productive” as originally planned by CMS.⁹⁶

E. CMS has not Implemented Several HHS Inspector General Recommendations to Improve Program Integrity in Part D

Since Part D’s implementation in 2006, the HHS Inspector General has released a series of recommendations and findings⁹⁷ designed to improve program integrity controls, including measures to combat opioid overutilization. To date, CMS has not implemented the recommendations detailed below. In some cases, CMS has attempted to implement changes based on the Inspector General’s findings, but has failed to complete implementation as of this report.

(1) ***Require Reporting by Plan Sponsors of Potential Fraud and Abuse.*** The HHS Inspector General recommended that CMS require mandatory reporting by plan sponsors of statistical information concerning waste, fraud, and abuse to CMS and specific matters of waste, fraud, and abuse to the MEDIC for further investigation. If plan sponsors were required to consistently report this information, the Inspector General explained, CMS and the MEDIC could more effectively monitor plan sponsors’ efforts to combat fraud, waste, and abuse in Part D.⁹⁸ As recently as April 2016, CMS did not concur with this recommendation.⁹⁹

(2) ***Determine Effectiveness of Plan Sponsors’ Fraud and Abuse Detection Programs.*** The HHS Inspector General recommended that CMS require plan sponsors to consistently report information related to their fraud and abuse detection programs. Consistent reporting of that information would allow CMS, for example, to determine whether variations in reported data actually indicate program vulnerabilities.¹⁰⁰ CMS did not concur with this recommendation, stating that it has conducted “outreach and education activities for plan sponsors to improve organizational performance.”¹⁰¹

(3) ***Prevent Illegal Refills of Schedule II Drugs.*** In 2012, the HHS Inspector General found that Part D paid \$25 million for illegal refills of Schedule II

⁹⁶ Interview with Anthem (May 2, 2016); Interview with Cigna (May 17, 2016).

⁹⁷ See generally U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-03-15-00180, *Ensuring the Integrity of Medicare Part D* (June 2015).

⁹⁸ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-03-13-00030, *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse*, 16 (Mar. 2014).

⁹⁹ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., *Compendium of Unimplemented Recommendations*, 15 (Apr. 2016).

¹⁰⁰ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-03-15-00180, *Ensuring the Integrity of Medicare Part D*, 18 (June 2015).

¹⁰¹ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., *Compendium of Unimplemented Recommendations*, 15 (Apr. 2016).

drugs.¹⁰² Due to the high risk of abuse, federal law prohibits the refilling of Schedule II prescriptions, including those for most opioids, except in rare instances.¹⁰³ Despite this prohibition, the Inspector General found that Part D inappropriately paid for these drugs billed as refills, “raising concerns for public health and the potential for diversion.”¹⁰⁴ Furthermore, CMS does not exclude these inappropriate claims when calculating its final payments to plan sponsors at the end of each year.¹⁰⁵ Despite the fact that the Inspector General made its recommendation in 2012, CMS has failed to fully implement changes necessary to address it.¹⁰⁶

(4) ***Implement Lock-Ins for Medicare Beneficiaries.*** In numerous reports, the Inspector General recommended that CMS permit plan sponsors to “lock-in” beneficiaries who exhibit drug-seeking behavior.¹⁰⁷ According to the Inspector General, restricting these beneficiaries to a limited number of pharmacies or prescribers could reduce program costs and inappropriate utilization, as well as improve coordination of services and quality of care.¹⁰⁸ Recent legislative changes grant CMS the authority to implement lock-ins for Medicare beneficiaries.¹⁰⁹ Under the law, CMS is required to begin holding stakeholder meetings no later than January 1, 2017, to receive input on the impact of lock-in, thus ensuring that beneficiaries maintain appropriate access to needed medication.¹¹⁰ The lock-in provision must be fully implemented by January 1, 2019.¹¹¹

II. Review of Private Insurers’ Efforts to Combat Opioid Epidemic

Private insurers have developed and implemented programs to combat the opioid epidemic in both their government and commercial health plans. Certain

¹⁰² U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-02-09-00605, *Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills*, 9 (Sept. 2012).

¹⁰³ *Id.*

¹⁰⁴ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-03-15-00180, *Ensuring the Integrity of Medicare Part D*, 17 (June 2015).

¹⁰⁵ *Id.*

¹⁰⁶ *Medicare Part D: Measures Needed To Strengthen Program Integrity: Hearing Before the Subcomm. on Oversight and Investigation of the H. Comm. on Energy and Commerce*, 114th Cong. 22-23 (2015) (statement of Dr. Shantanu Agrawal, Center for Program Integrity, Centers for Medicare & Medicaid Services).

¹⁰⁷ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-02-11-00170, *Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs*, 22 (Aug. 2014). <https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2016.pdf>

¹⁰⁸ U.S. Dep’t of Health & Human Servs., Office of Inspector Gen., OEI-03-15-00180, *Ensuring the Integrity of Medicare Part D*, 8 (June 2015).

¹⁰⁹ Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-298 (Section 704(g)).

¹¹⁰ *Id.*

¹¹¹ *Id.*

programs are specific to Medicare Part D, and are therefore overseen by CMS.¹¹² But insurers use other programs on the commercial side of their business. These clinically-based programs vary in a number of ways, including the thresholds used to identify potential opioid overuse, the point-of-sale restrictions employed, and case management strategies. Both commercial and Part D programs share the common goal of ensuring the safe, appropriate, and cost-effective use of opioid drugs by reducing abuse and preventing diversion.

A. Drug Utilization Reviews and Case Management Programs

As discussed above, CMS requires that Part D plan sponsors maintain systems, policies, and procedures concerning utilization review processes. While these programs are required only for Part D plans, every insurer the Subcommittee examined had similar programs for its non-government health plans. A key feature of the utilization review process is the safety alert—called an “edit”—that results in the rejection or modification of a prescription at the point of sale. Edits are designed to flag prescriptions for several types of potential harm, including overutilization and clinical abuse. CMS mandates certain types of safety edits, but plan sponsors may implement additional edits, including checks for multiple prescribers, multiple pharmacies, or early refills, among other factors.¹¹³

Utilization-review systems also include “formulary level” edits relating to quantity limits.¹¹⁴ Each plan studied by the Subcommittee has established quantity limits for opioid analgesics and other long-acting controlled substances in both their commercial and governmental health plans. Quantity limits generally adhere to FDA recommended doses, where available, or to recommendations in clinical literature in cases where the FDA has not provided a recommended dose limit.¹¹⁵

Insurers also promote safe prescribing practices through the use of prior authorization, a program that requires additional approval from an insurer or its

¹¹² See 42 CFR § 423.153 (requiring Part D plan sponsors to adopt and implement “a drug utilization management program, quality assurance measures and systems, and [a medication therapy management program]”); see generally U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual: Chapter 7—Medication Therapy Management and Quality Improvement Program*, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter7.pdf>.

¹¹³ U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual: Chapter 7—Medication Therapy Management and Quality Improvement Program*, 5-6, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/chapter7.pdf>.

¹¹⁴ See U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., *Medicare Prescription Drug Benefit Manual: Chapter 6—Part D Drugs and Formulary Requirements*, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

¹¹⁵ See, e.g., CIGNA000123-25 (noting “rationale” for quantity limits as adhering to FDA recommended daily dose, if one exists).

pharmacy benefit manager before dispensing. Through prior authorization, insurers can limit the drug quantity beneficiaries can obtain with each refill, limit early refills, and limit the total opioid daily dose a beneficiary receives. Prior authorization policies can also impose “step therapy,” which requires beneficiaries to first use less expensive medications before moving on to a more expensive approach.¹¹⁶ Insurers can impose a wide variety of triggers for prior authorization, including metrics for quantity and high dosage, in their policies. Blue Cross Blue Shield of Massachusetts, for example, limits its beneficiaries to two 15-day prescriptions of opioids and requires authorization before allowing beneficiaries to receive more than 30 days of opioids in any two-month period.¹¹⁷ Through this program, Blue Cross Blue Shield reduced prescriptions for opioids by 6 million pills over an 18-month period.¹¹⁸

As discussed above, insurers also use retrospective drug utilization reviews to examine utilization and prescribing patterns after dispensing and ensure that a patient’s prescriptions are clinically appropriate and medically necessary.¹¹⁹ All the insurers the Subcommittee examined in this investigation maintain similar programs for their commercial plans. At their most basic level, these programs function by analyzing prescription data according to a set of parameters designed to identify at-risk patients. Aetna, for example, has a number of utilization review programs under its umbrella program known as Aetna RxCheck.¹²⁰ Although each program tests the same claims data, each has a different threshold or algorithm that identifies suspect patients according to a specific set of parameters.¹²¹

Once insurers identify at-risk patients as potential opioid abusers, they conduct outreach and education to the prescriber, pharmacy, and/or patient concerned. Prescriber and pharmacy outreach, which may occur by letter or by phone, draws attention to potential overuse and lists the patient’s recent prescription drug history.¹²² Depending on the level of potential overutilization, the letter may simply present these findings or may request from prescribers a response regarding the appropriate course of treatment going forward.¹²³ Letters sent

¹¹⁶ U.S. Dep’t of Health & Human Servs., Centers for Medicare & Medicaid Servs., *How Medicare Prescription Drug Plans & Medicare Advantage Plans with Prescription Drug Coverage (MA-PDs) Use Pharmacies, Formularies, & Common Coverage Rules*, 4 (Oct. 2015).

¹¹⁷ Substance Abuse and Mental Health Servs. Admin., Preventing Prescription Abuse in the Workplace Technical Assistance Center, *The Role of Insurers in Preventing Misuse and Abuse of Controlled Substances*, 3 (Feb. 11, 2015).

¹¹⁸ *Id.*

¹¹⁹ *See, e.g.*, KAISER PERMANENTE 0008.

¹²⁰ AETNA-PSI-000008-13.

¹²¹ *Id.*

¹²² *See, e.g.*, AETNA-PSI-0000078-79 (sample provider letter); AETNA-PSI-0000076-77 (sample member letter); CIGNA000163-64 (sample provider letter); UnitedHealth000134-140 (sample provider letter).

¹²³ *See, e.g.*, UnitedHealth000134-140 (sample provider letter requesting a response).

directly to patients alert them to potential overutilization and list recent drug prescriptions.¹²⁴ Caseworkers and clinical pharmacists will then monitor the patient's opioid utilization and continue to communicate with him and his prescriber.¹²⁵ Ultimately, if this outreach and education process fails to reduce opioid use, the insurer may implement further restrictions on the patient's utilization or refer the matter to enforcement authorities.¹²⁶ For instance, if an insurer repeatedly is unable to reach a prescriber to discuss reducing opioid utilization, the insurer may unilaterally restrict a patient's opioid use by implementing a beneficiary-level point-of-sale edit.¹²⁷

For example, Humana's doctor shopping model monitors cases for three months after it makes initial contact with the relevant prescriber, pharmacy, and patient.¹²⁸ Humana's letters to providers include a prescription drug history; its letters to patients contain a prescription history and encourage the use of only one pharmacy so that Humana can more safely review and manage medications.¹²⁹ If the patient's opioid usage drops below the policy threshold after these actions, Humana will close the case.¹³⁰ But if the patient's usage continues to exceed the threshold, Humana will send another round of letters and begin a new three-month monitoring period.¹³¹ If three such rounds of monitoring pass without improvement, Humana will refer the matter to the MEDIC for further review.¹³² After four rounds without improvement, Humana may refer the matter to its SIU for investigation.¹³³

B. Insurers' Use of Lock-Ins Varies Widely, Suggesting this Anti-Abuse Tool May Be Underutilized

The restriction or "lock-in" of a patient who is abusing opioids to a single prescriber or pharmacy is a clinically-proven method to reduce opioid abuse.¹³⁴

¹²⁴ See, e.g., AETNA-PSI-0000076-77 (sample member letter).

¹²⁵ HUMANA-PSI-0059-60 (discussing monitoring usage and communicating with prescribers and / or members).

¹²⁶ HUMANA-PSI-0055.

¹²⁷ UnitedHealth000141 (informing prescriber of the need to "implement an opioid restriction" for a patient after attempts to contact the prescriber had failed).

¹²⁸ HUMANA-PSI-0054.

¹²⁹ HUMANA-PSI-0053-54.

¹³⁰ HUMANA-PSI-0054.

¹³¹ HUMANA-PSI-0054-55.

¹³² HUMANA-PSI-0055.

¹³³ *Id.*

¹³⁴ See, e.g., Sarah G. Kachur et al., *Impact of a Single-Provider Lock-In Program for Opiates in a Managed Medicaid Population*, Johns Hopkins University School of Medicine (concluding that "Enrollment in a single-provider lock-in program decreases opiate prescriptions and associated cost among health plan members who exhibit signs of opiate overuse").

Despite the demonstrated clinical success of such lock-ins,¹³⁵ Medicare Part D did not permit lock-ins of beneficiaries until the passage of the Comprehensive Addiction and Recovery Act of 2016 (P.L. 114-198); that provision takes effect in 2019.¹³⁶ Many Medicaid programs, however, permit lock-in on a state-by-state basis.¹³⁷ And there is no legal or regulatory impediment preventing insurers from using lock-ins in their commercial business. Against this backdrop, the Subcommittee examined the use of this important tool by requesting lock-in information from the six largest health insurers.

The Subcommittee found that the use of lock-ins varies widely among insurers. Humana made negligible use of pharmacy and prescriber lock-ins, as it locked in only 11 patients from 2013 through 2015.¹³⁸ Cigna locked in only four commercial patients¹³⁹ and 229 Medicaid beneficiaries in the same time period.¹⁴⁰ Aetna, by contrast, in the same period locked in 25 commercial patients to a single pharmacy and 659 patients to a single prescriber.¹⁴¹ Aetna has made increasing use of prescriber lock-in, with 133 in 2013, 219 in 2014, and 307 in 2015.¹⁴² UnitedHealth, for its part, makes even more significant use of pharmacy lock-ins; it locked in 4,776 Medicaid beneficiaries to a single pharmacy from 2013 to 2015.¹⁴³

¹³⁵ *Id.*

¹³⁶ The statute provides that the lock-in provision for Part D will take effect on January 1, 2019. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198 (Section 704(g)).

¹³⁷ See, e.g., Megan Olsen, *Medicaid Lock-in Programs: What do they look like and do they have an impact?* (Apr. 30, 2015) (on file with the Subcommittee) (examining lock-in programs across several states).

¹³⁸ Letter from Humana to the Permanent Subcommittee on Investigations at 15 (June 3, 2016). Compared to other insurers in the Subcommittee's inquiry, Humana has by far the highest proportion of its business concentrated in Medicare Part D, which as of the writing of this report does not permit lock-in. See Letter from Humana to the Permanent Subcommittee on Investigations at 5-6 (June 3, 2016) (providing patient and beneficiary statistics); see also Submission from Humana to the Permanent Subcommittee on Investigations at 1 (Sept. 12, 2016) (explaining that Humana only uses lock-in for its Medicaid beneficiaries).

¹³⁹ Letter from Cigna to the Permanent Subcommittee on Investigations at 22 (June 7, 2016). Lock-in is available to providers in Cigna's commercial business, but the company said that the determination to lock-in is "left up to the provider's discretion" and is "not a tool that is often utilized by providers." Letter from Cigna to the Permanent Subcommittee on Investigations at 11 (Sept. 17, 2016). Cigna also noted that the four commercial lock-ins represent only lock-ins that are the product of adjudications and that the company does not track non-adjudicated lock-ins. Email from Cigna to the Permanent Subcommittee on Investigations (Sept. 21, 2016).

¹⁴⁰ Letter from Cigna to the Permanent Subcommittee on Investigations at 18 (June 7, 2016). The 229 figure pertains only to Cigna's Medicaid beneficiaries in Texas, which is Cigna's only state Medicaid program that permits lock-in. Email from Cigna to the Permanent Subcommittee on Investigations (Sept. 20, 2016).

¹⁴¹ Letter from Aetna to the Permanent Subcommittee on Investigations at 2 (June 15, 2016).

¹⁴² *Id.*

¹⁴³ Letter from UnitedHealth to the Permanent Subcommittee on Investigations at 8 (June 14, 2016). UnitedHealth also has a pharmacy lock-in policy in its High Utilization Narcotic Program as part of its commercial business, and as part of that program has locked in 120 patients in 2014 and 83 in

Anthem exceeded other insurers in terms of patient lock-ins, restricting 20,956 Medicaid beneficiaries between 2013 and 2015.¹⁴⁴ It also made increasing use of lock-ins over time: its lock-in numbers rose each year from 5,350 in 2013, to 6,337 in 2014, and finally to 9,269 in 2015.¹⁴⁵ Anthem told the Subcommittee that “data shows that [its] lock-in programs are strong[.]”¹⁴⁶

Overall spending for members assigned to a single pharmacy and/or prescriber through such a program in Anthem’s Medicaid plan in Maryland declined by approximately 17 percent. It was driven by a decline in unnecessary pharmaceutical prescriptions and avoidable medical incidents such as inpatient admissions and non-emergent emergency room visits. Across Anthem, the program helped improve overall health care for members who were assigned to a single pharmacy and/or prescriber. Emergency room visits dropped by over 21 percent, which was likely driven in part by a reduction of 28 percent in the number of prescriptions written for opiates, and a reduction of 15 percent in prescriptions for non-opiate prescription drugs.¹⁴⁷

Having experienced success with lock-ins in its Medicaid business, Anthem recently introduced pharmacy lock-in for its large commercial business.¹⁴⁸ The criteria for inclusion in the program includes, but is not limited to, three or more prescribers and/or three or more pharmacies, and five or more controlled substances (including opioids) over a 90-day period.¹⁴⁹ The process Anthem has crafted for its commercial lock-in program requires communication with the prescriber, pharmacy, and the patient, who is given an opportunity to appeal the lock-in determination.¹⁵⁰ Anthem reported that during the first three months of its commercial pharmacy lock-in program, which was implemented in April 2016, it locked in 147 patients.¹⁵¹

2015. See UnitedHealth000130-33; Email from UnitedHealth to the Permanent Subcommittee on Investigations (Sept. 16, 2016).

¹⁴⁴ Letter from Anthem to the Permanent Subcommittee on Investigations at 7 (June 8, 2016); Letter from Anthem to the Permanent Subcommittee on Investigations at 3 (Sept. 15, 2015).

¹⁴⁵ Letter from Anthem to the Permanent Subcommittee on Investigations at 7 (June 8, 2016); Email from Anthem to the Permanent Subcommittee on Investigations (Sept. 20, 2015). Anthem’s pharmacy lock-in program excludes cancer patients. Submission from Anthem to the Permanent Subcommittee on Investigations at 3 (June 24, 2016) (Attachment #1).

¹⁴⁶ Letter from Anthem to the Permanent Subcommittee on Investigations at 5 (June 8, 2016).

¹⁴⁷ *Id.*

¹⁴⁸ According to Anthem, this “Pharmacy Home Program” became effective in April 2016. Letter from Anthem to the Permanent Subcommittee on Investigations at 2 (Sept. 15, 2015).

¹⁴⁹ Submission from Anthem to the Permanent Subcommittee on Investigations at 3 (June 24, 2016) (Attachment #1).

¹⁵⁰ *Id.*

¹⁵¹ Letter from Anthem to the Permanent Subcommittee on Investigations at 2-3 (Sept. 15, 2016).

C. Insurers' Use of Beneficiary-Level Opioid Point-of-Sale Edits Varies, Suggesting this Anti-Abuse Tool May Be Underutilized

As discussed above, upon detecting opioid overutilization by a particular patient, insurers may implement a beneficiary-level point-of-sale edit that restricts that patient's access to opioids. Such edits restrict patients' access to opioids by, for instance, limiting quantities or requiring prior authorization. The insurers the Subcommittee reviewed varied in how often they employed this restriction. For example, Humana implemented opioid-specific edits in its Medicare business starting in 2014 and proceeded to apply three such edits in 2014, three in 2015, and 15 in 2016 (as of September 2016).¹⁵² Humana does not utilize such edits in its commercial line of business.¹⁵³ Kaiser, for its part, applied only two such beneficiary-level edits in 2015 and four in 2016 in its Medicare business.¹⁵⁴ Cigna has made increasing use of the tool, implementing opioid edits on 43 Medicare beneficiaries from 2013 to 2015 and 47 such edits in 2016 (as of August 2016).¹⁵⁵

The Subcommittee found, however, that UnitedHealth has applied the largest number of opioid-specific beneficiary-level point-of-sale edits in its Medicare business, applying 26 such edits in 2013, 76 in 2014, and 175 in 2015.¹⁵⁶

¹⁵² Submission from Humana to the Permanent Subcommittee on Investigations at 3 (Sept. 12, 2016).

¹⁵³ *Id.*

¹⁵⁴ KAISER PERMANENTE 0615.

¹⁵⁵ Letter from Cigna to the Permanent Subcommittee on Investigations at 9 (Sept. 17, 2016).

¹⁵⁶ Email from UnitedHealth to the Permanent Subcommittee on Investigations (Sept. 16, 2016).