United States Government Accountability Office

Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

October 2014

MEDICARE PROGRAM INTEGRITY

CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse

GAO-15-66

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GAO Highlights

Highlights of GAO-15-66, a report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

Recent media reports and law enforcement actions have highlighted the problem of prescription drug fraud, waste, and abuse in the United States. Medicare, and the Part D prescription drug benefit, are susceptible to such fraud—a risk made greater by Medicare's size, scope, and complexity. GAO and others have raised questions about CMS's oversight of its activities to address fraud, waste, and abuse in Part D, as well as oversight of the contractors tasked with this work.

GAO examined (1) practices for promoting prescription drug program integrity, and (2) the extent that CMS's oversight of Medicare Part D program integrity, including the program integrity contractors, reflects these practices. To develop a list of practices, GAO interviewed 14 stakeholder groups involved in various aspects of prescription drug program integrity, including provider, beneficiary, and anti-fraud groups; identified and reviewed related documents; and conducted a search of eight bibliographic databases that included peer-reviewed articles and government documents. GAO organized the practices based on the three categories of GAO's Fraud Prevention Framework. To determine how CMS's oversight reflects these practices, GAO analyzed agency documents, such as contracts, manuals, work products, and CMS audits of contractors; and interviewed agency officials.

View GAO-15-66. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

GAO identified 23 practices for addressing prescription drug fraud, waste, and abuse that fall within three categories based on GAO's Fraud Prevention Framework—prevention, detection and monitoring, and investigation and prosecution.

The Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services' (CMS) activities to address prescription drug fraud, waste, and abuse in the Medicare Part D prescription drug program reflect 14 of these 23 identified practices, some of which are in multiple categories, and the agency plans to implement 3 additional practices.

Practices Implemented, Planned, and Not Pursued by CMS and Its Contractors to Address Prescription Drug Fraud, Waste, and Abuse

Category	Practice[a]	Implemented	Planned	Not pursuing
Prevention	Providing clinical guidelines			●
	Practicing collaboration	●		
	Educating clinicians and others	●		
	Using health information technology			●
	Limiting supply of abused drugs			●
	Using prepayment edits	●		
	Screening participants of health insurance programs	●		
	Using Prescription Drug Monitoring Programs (PDMP)[b]			●
Detection and monitoring	Providing clinical guidelines			●
	Practicing collaboration	●		
	Having compliance programs	●		
	Conducting data analysis	●		
	Conducting drug utilization reviews	●		
	Educating patients and others	●		
	Limiting certain patients to certain providers ("lock-ins")			●
	Using PDMPs[b]		●	
	Conducting postpayment reviews	●		
Investigation and prosecution	Practicing collaboration	●		
	Educating law enforcement and others	●		
	Pursuing enforcement options		●	
	Having investigative staff	●		
	Reporting to law enforcement	●		
	Using PDMPs[b]		●	

Source: GAO analysis of relevant literature, CMS documents, and interviews with CMS officials. | GAO-15-66

[a]GAO determined that CMS had *implemented* a practice if the agency required or documented at least one activity within that practice, that CMS *planned* a practice if documentation or officials described activities as pilots or in the process of development, and that CMS was *not pursuing* a practice based on reviews of documentation and interviews with officials.

[b]PDMPs are state-based programs that operate electronic databases that gather information from pharmacies on certain dispensed prescriptions, such as whether a patient has multiple opioid prescriptions from multiple providers.

HHS generally agreed with our findings.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
CPARS	Contractor Performance Assessment Reports System
CPI	Center for Program Integrity
D&M	detection and monitoring
DEA	Drug Enforcement Administration
DUR	drug utilization review
FDR	First Tier, Downstream or Related Entity
HHS	Department of Health and Human Services
I&P	investigation and prosecution
MEDIC	Medicare Drug Integrity Contractor
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
NBI	National Benefit Integrity
O&E	outreach and education
OIG	Office of Inspector General
OMS	Overutilization Monitoring System
PDMP	Prescription Drug Monitoring Program
RAC	Recovery Audit Contractor
SIU	Special Investigation Unit

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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October 24, 2014

The Honorable Kevin Brady
Chairman
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

Recent media reports and law enforcement actions have highlighted the problem of prescription drug fraud, waste, and abuse in the United States.[1] Examples of problematic activities include beneficiaries "doctor shopping" to receive multiple prescriptions for opioids, such as OxyContin or Vicodin, from different providers; providers found to have questionable prescribing and billing practices; and diversion of prescription drugs by beneficiaries, pharmacies, and others for uses other than intended. Medicare and its prescription drug benefit, Part D, are susceptible to such fraud—a risk made greater by Medicare's size, scope, and complexity.[2]

Since 2006, the Part D program has provided voluntary, outpatient prescription drug coverage to the Medicare population. In 2013, Part D had nearly 40 million beneficiaries and cost almost $70 billion, or about

[1]Fraud involves an intentional act or representation to deceive with the knowledge that the action or representation could result in gain. Waste includes inaccurate payments for services, such as unintentional duplicate payments. Abuse represents actions inconsistent with acceptable business or medical practices. In this report, we use the term "program integrity" to refer to activities and practices that address fraud, waste, and abuse.

[2]Medicare is a federal health insurance program for people age 65 and older, individuals under age 65 with certain disabilities, and individuals diagnosed with end-stage renal disease. Medicare Parts A and B are known as original Medicare or Medicare fee-for-service; Part A covers hospital and other inpatient stays, and Part B covers hospital outpatient, physician, and other services. Part C is Medicare Advantage, under which beneficiaries receive health benefits through private health plans. In Part D, plan sponsors offer prescription drug coverage through stand-alone prescription drug plans or through Medicare Advantage prescription drug plans, which combine medical and prescription drug benefits.

In 1990, we began to report on government operations that we identified as "high risk" for serious weaknesses in areas that involve substantial resources and provide critical services to the public. Medicare has been included among such programs since 1990. See GAO, *High-Risk Series: An Update*, GAO-13-283 (Washington, D.C.: Feb. 14, 2013).

12 percent of total Medicare expenditures. The program is administered by the Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (HHS). CMS contracts with private companies to provide benefits under Part D.

GAO, the HHS Office of Inspector General (OIG), and others have raised questions about CMS's oversight of its activities to address fraud, waste, and abuse in Part D, as well as oversight of the contractors tasked with assisting in these activities, the Medicare Drug Integrity Contractors (MEDIC).[3] You asked us to examine practices for addressing fraud, waste, and abuse in prescription drug programs, and CMS's use of these practices. We examined (1) practices for promoting prescription drug program integrity, and (2) the extent that CMS's oversight of Medicare Part D program integrity, including the MEDICs, reflects these practices.

To develop a list of practices for addressing prescription drug fraud, waste, and abuse, we interviewed stakeholders involved in prescription drug program integrity, such as groups representing prescribers, pharmacies, beneficiaries, and others, to discuss program integrity practices and identify documents that describe such practices.[4] Through these interviews we identified an initial 213 documents that appeared to address program integrity practices related to prescription drug fraud, waste, and abuse. We reviewed each document to identify specific practices and any relevant activities within those practices. We then

[3]See, for example, Department of Health and Human Services Office of Inspector General, *Prescribers with Questionable Patterns in Medicare Part D*, OEI-02-09-00603 (Washington, D.C.: June 2013); *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, OEI-03-11-00310 (Washington, D.C.: January 2013); and GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, GAO-11-699 (Washington, D.C.: Sept. 6, 2011).

[4]We interviewed a total of 14 stakeholder groups: the National Health Care Anti-Fraud Association and the Health Care Compliance Association, which represent antifraud and compliance entities; AARP, which represents Medicare beneficiaries; America's Health Insurance Plans, which represents private insurers; the Academy of Managed Care Pharmacy, the American Pharmacists Association, the National Association of Chain Drug Stores, and the National Community Pharmacists Association, which represent pharmacies; the Pharmaceutical Care Management Association, which represents pharmacy benefit managers; the American Medical Association, which represents prescribers; and the Federation of State Medical Boards, the National Association of Attorneys General, the National Association of Medicaid Fraud Control Units, the National Association of Medicaid Directors, and the Prescription Drug Monitoring Programs Center for Excellence, which represent state-based programs.

conducted an additional search of eight bibliographic databases that included peer-reviewed articles and government documents that yielded an additional 642 documents that appeared to address program integrity practices related to prescription drug fraud, waste, and abuse. We reviewed the most recently published 10 percent, or 64 documents, to determine whether they were relevant and if they described additional specific practices not already determined through our review of the initial 213 documents. We did not identify any significantly different practices and therefore discontinued our review of documents. We reviewed, in total, 277 documents. We used GAO's Fraud Prevention Framework to organize the prescription drug program integrity practices we identified in our review into one of three categories: prevention, detection and monitoring, and investigation and prosecution.[5] We did not evaluate the practices we identified for their relative effectiveness.

To determine the extent to which CMS's oversight of Medicare Part D, including the MEDICs, reflects the practices we identified, we interviewed agency officials involved in the oversight of the MEDICs and plan sponsors. We also analyzed agency documents, such as the MEDIC contracts and manuals; MEDIC work products, including the MEDICs' most recent performance evaluations; plan sponsor contract materials and memos; CMS findings from its 2013 audits of selected plan sponsors; and CMS regulations. We used the reviewed materials and interviews with CMS officials to determine which of the practices we identified that CMS incorporates into its oversight of the Part D program, as well as the practices CMS does not incorporate or plans to incorporate in the future. We determined that CMS had implemented a practice if the agency required or documented at least one activity within that practice, that CMS planned a practice if documentation or officials described activities as pilots or in the process of development, and that CMS was not pursuing practices based on reviews of documentation and interviews with officials.

We conducted this performance audit from January 2014 to October 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain

[5]The Fraud Prevention Framework was developed by GAO and informed by GAO's internal control standards for the federal government. See GAO, *Individual Disaster Assistance Programs: Framework for Fraud Prevention, Detection, and Prosecution,* GAO-06-954T (Washington, D.C.: July 12, 2006). We are currently considering revisions to the Fraud Prevention Framework, which we plan to publish in 2015.

sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

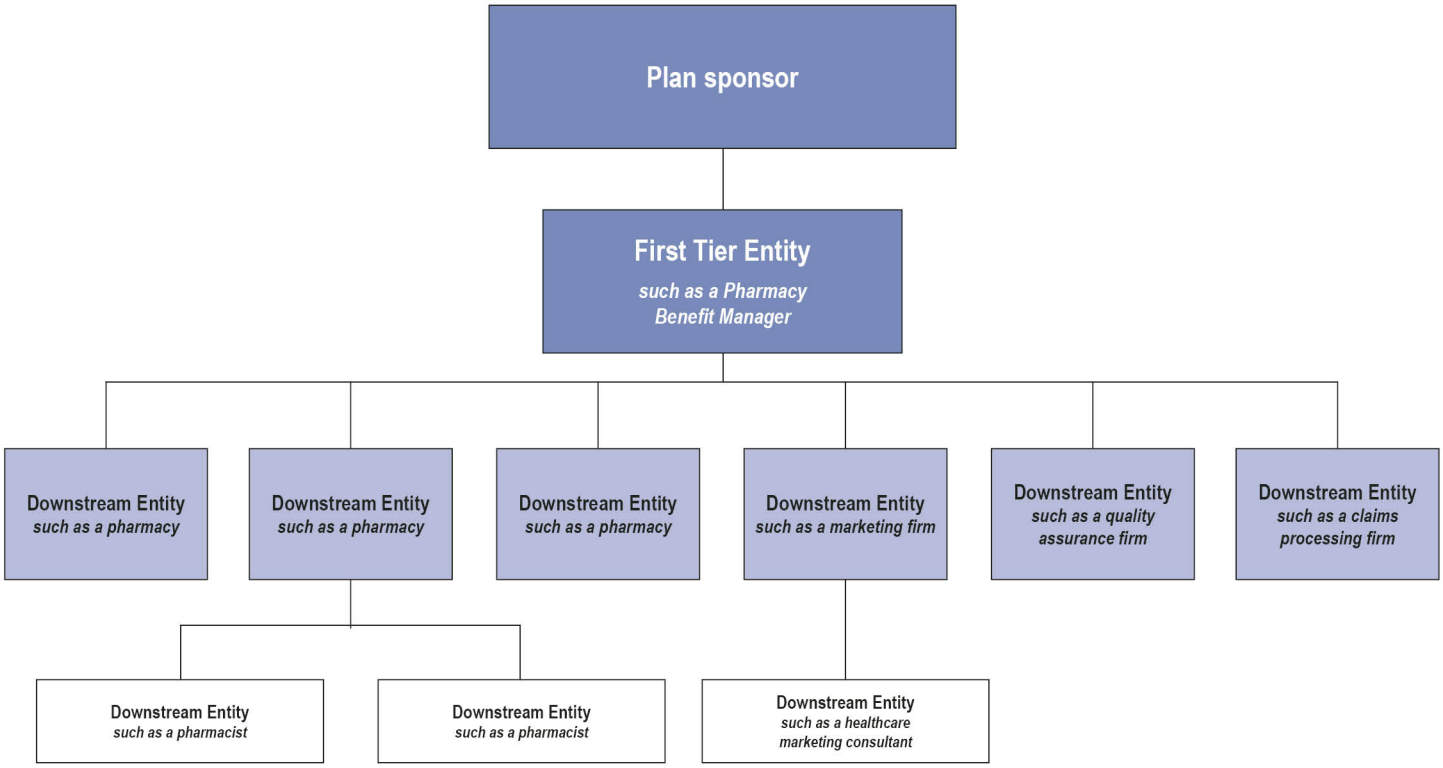
Background

Part D Plan Sponsors

The Medicare Part D program was designed to be administered by private organizations—referred to as plan sponsors—that CMS contracts with to provide outpatient prescription drug benefit plans to Medicare beneficiaries.[6] These sponsors may contract with other entities—called First Tier, Downstream or Related Entities (FDR)—to help provide these benefits. (See fig. 1.) FDRs include pharmacy benefit managers—companies that provide services such as contracting with a network of pharmacies, managing formularies, and performing drug utilization reviews on behalf of the sponsors—and pharmacies. CMS holds plan sponsors responsible for oversight of their FDRs.

[6]In this report, we use the term "plan sponsors" to refer to both stand-alone Part D plan sponsors as well as Medicare Advantage prescription drug sponsors.

Figure 1: Example of How a Part D Plan Sponsor Contracts with Other Entities



Source: GAO analysis of CMS information. | GAO-15-66

Part D Program Integrity

Program integrity responsibilities in Medicare Part D are shared by plan sponsors, CMS's Center for Program Integrity (CPI) and Center for Medicare, and CMS's program integrity contractors.

Plan Sponsors' Responsibilities

Plan sponsors are required to have comprehensive compliance programs that include elements intended to safeguard the Part D program from fraud, waste, and abuse.[7] CMS issued requirements for these programs based on input from various sources, including plan sponsors and industry representatives.[8] CMS requires plan sponsors to

- monitor and audit their FDRs;
- analyze data to detect and prevent potential fraud, waste, and abuse; and
- have a unit, such as a Special Investigation Unit (SIU), specifically tasked with identifying and addressing fraud, waste, and abuse, or ensure that the responsibilities generally conducted by an SIU are conducted by a plan sponsor's compliance department.

CMS's Oversight

CMS's CPI oversees Part D program integrity and coordinates with other groups within CMS's Center for Medicare that monitor plan sponsor compliance with the Part D program. (See fig. 2.) Within the Center for Medicare, one such group is the Medicare Parts C and D Oversight and Enforcement Group, which ensures contractual compliance through audits of plan sponsors. If those audits identify noncompliance with the terms of the Part D contract, CMS may take a variety of actions that include requiring corrective action plans, sending warning letters, assessing civil money penalties, and terminating or not renewing a contract. The other group, the Medicare Drug Benefit and C & D Data Group, analyzes data to identify potential patient safety concerns, such as overutilization of opioid drugs, that may also indicate potential fraud or abuse.

[7]To protect beneficiaries and the fiscal integrity of the Medicare program, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which established the Part D program, requires all Part D sponsors to have programs to safeguard Part D from fraud, waste, and abuse. Pub. L. No. 108-173 § 101, 117 Stat. 2066, 2086 (codified at 42 U.S.C. § 1395w-104(c)(1)(D)). As a result, CMS issued regulations requiring that sponsors adopt and implement a compliance program that includes measures to prevent, detect, and correct fraud, waste, and abuse. 42 C.F.R. § 423.504(b)(4)(vi).

[8]CMS Compliance Program Guidelines appear in Chapter 9 of the *Medicare Prescription Drug Benefit Manual*, revised January 11, 2013. CMS issues this manual in tandem with Chapter 21 of the *Medicare Managed Care Manual*, which includes the Compliance Program Guidelines for Medicare Advantage.

CPI has primary responsibility for overseeing the two MEDICs tasked with promoting program integrity in Medicare Part D:[9]

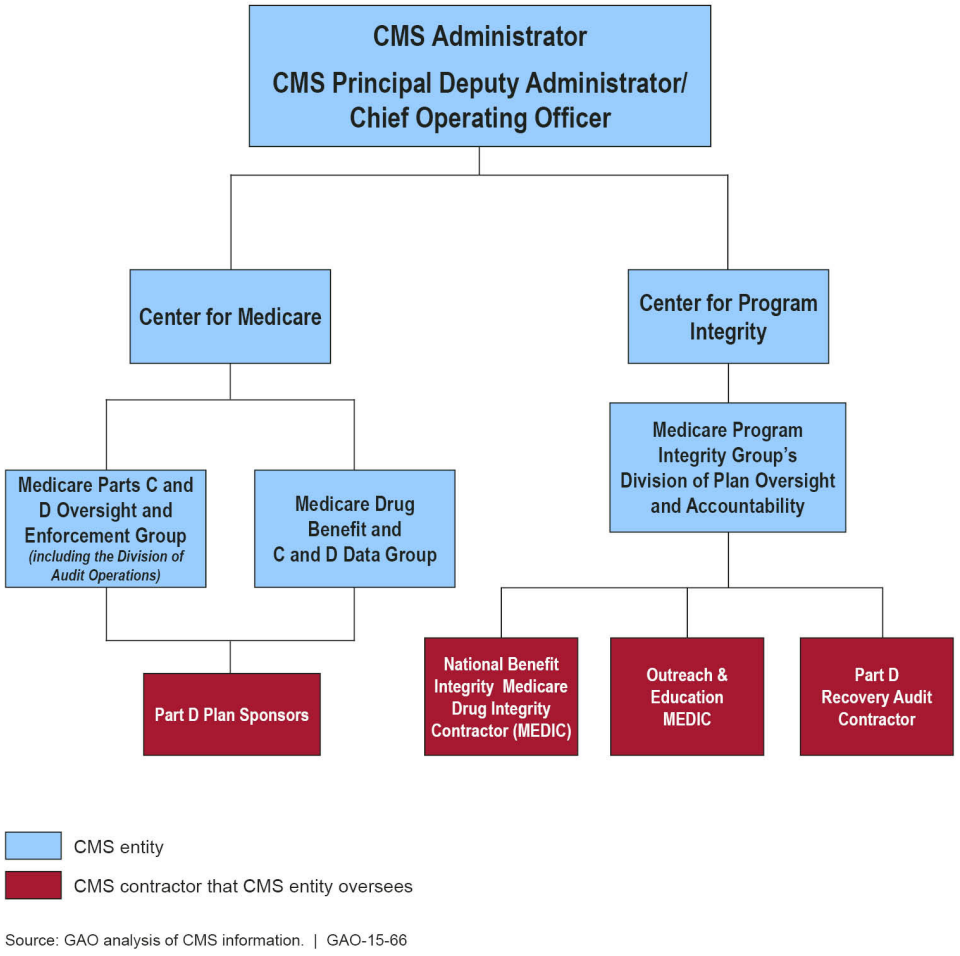
- The National Benefit Integrity (NBI) MEDIC is responsible for preventing, detecting, and deterring Part D fraud, waste, and abuse. This includes intake and handling of complaints from beneficiaries and others as well as requests for information from law enforcement; investigating providers and others and referring them to law enforcement; and analyzing Part D program prescription drug event records and other data to identify patterns indicative of potential fraud, waste, or abuse.[10]
- The Outreach & Education (O&E) MEDIC provides Part D fraud, waste, and abuse education to plan sponsors and other stakeholders by working in concert with CMS to develop educational and training tools, and by facilitating information-sharing opportunities, such as fraud alerts, conferences, and other meetings.

CPI also oversees the Part D Recovery Audit Contractor (RAC) program, which is tasked with reviewing paid Medicare claims—or, for Part D, prescription drug event data—from plan sponsors and their pharmacies to determine overpayments and underpayments; providing information to CPI to help prevent future improper payments; and referring any potential fraud identified during the auditing process to the NBI MEDIC to investigate. While the Part D RAC may conduct work similar to the NBI MEDIC, the focus of the RAC is improper payments—such as overpayments—while the MEDIC's focus is potential fraud, waste, and abuse.

[9]Beginning in fiscal year 2007, CMS awarded contracts to MEDICs to address potential fraud and abuse related to the Part D benefit. In fiscal year 2009, CMS added oversight of Part C to the MEDICs' responsibilities.

[10]Every time a Medicare beneficiary fills a prescription covered under Part D, the sponsor must submit a prescription drug event record to CMS. These records include drug cost and payment information that enables CMS to administer and monitor the Part D benefit.

Figure 2: CMS Entities with Primary Responsibility for Part D Plan Sponsor Oversight



Source: GAO analysis of CMS information. | GAO-15-66

We Identified Multiple Prevention, Detection, and Investigation Practices to Address Prescription Drug Fraud, Waste, and Abuse

We identified a total of 23 practices for addressing prescription drug fraud, waste, and abuse that fall within one or more of the three categories based on the Fraud Prevention Framework: (1) prevention, (2) detection and monitoring, and (3) investigation and prosecution. Counting only once the practices that fall within more than one category, we identified 16 unique practices.

Prevention

We identified eight practices related to the prevention of prescription drug fraud, waste, and abuse that can include multiple activities, as shown in table 1. For example, one prevention practice, limiting the supply of abused drugs, can help prevent abuse by restricting the amount of potentially abused drugs that are available. This is done by conducting the following activities:

- offering “take-back” programs where patients can safely dispose of any unused medications, preventing use or abuse by others;
- securing information and materials, such as Drug Enforcement Administration (DEA) registration numbers and prescription pads,[11] that could prevent bad actors from illegally obtaining prescription drugs; and
- developing abuse-resistant drugs that could hamper efforts to abuse them.

[11]Among other things, the Controlled Substances Act requires those who manufacture, distribute, prescribe, import, or export controlled substances to register with the DEA. 21 U.S.C. §§ 822, 957. Once registered, DEA provides a certificate with a registration number.

Table 1: Prevention Practices for Prescription Drug Fraud, Waste, and Abuse

Practice	Description/examples
Clinical guidelines	Providing clinical guidance to prescribers and pharmacies regarding topics such as • using the lowest effective dose and judicious prescribing; • encouraging use of generic drugs as alternatives to brand drugs; • alternatives to opioid drugs, such as physical therapy; and • appropriate prescribing of noncontrolled substances, such as to reduce inappropriate prescribing of antibiotics.
Collaboration	Establishing mutually reinforcing or joint strategies among stakeholders when developing programs and/or strategies to address prevention of prescription drug fraud, waste, and abuse.
Education	Providing education or training to clinicians, patients, and others on how to prevent abuse, such as • training clinicians on appropriate prescribing of opioid drugs and • educating the public on correct use and safe disposal of prescription drugs.
Health information technology	Adopting health information technology, such as • electronic prescribing and • electronic health records.

Limit the supply of abused drugs	Limiting the supply of abused drugs, including
	• "take back" programs for safe prescription drug disposal;
	• physical and information security, including
	  • safe storage of drugs;
	  • safeguarding Drug Enforcement Administration, Medicare National Provider Identifier, and other identifiers that can be used to obtain prescription drugs fraudulently;
	  • securing the prescription drug supply chain; and
	  • restricting distribution of certain prescription drugs to appropriate entities;
	• developing abuse-resistant drugs, including generic versions; and
	• prescription verification (by provider or pharmacist), including
	  • using tamper-resistant prescription pads,
	  • checking patients' identification prior to dispensing certain drugs, and
	  • verifying certain prescriptions with the prescriber.

Prepayment edits	Using prepayment edits—controls built into payment systems—to deny claims that should not be paid or to flag claims for additional review before payment.
Prescription Drug Monitoring Programs (PDMP)[a]	Having clinicians use their states' PDMPs to ensure patients are not inappropriately receiving multiple prescriptions, including • prescribers checking PDMPs prior to first prescribing certain prescription drugs and • pharmacists checking PDMPs prior to dispensing those drugs.
Screening	Screening the eligibility of beneficiaries, prescribers, pharmacies, and other entities to ensure that they have coverage under or participate in a health insurance program. (Note: This does not include screening for potential drug abuse.)

Source: GAO analysis of relevant literature. | GAO-15-66

[a]PDMPs are state-based programs that operate electronic databases that gather information from pharmacies on certain dispensed prescriptions. Authorized users access the information about a patient's prescription drug history, such as whether a patient has multiple opioid prescriptions from multiple providers.

Detection and Monitoring

We identified nine practices related to the detection and monitoring of prescription drug fraud, waste, and abuse, as shown in table 2. For example, the collaboration practice includes sharing information about specific fraud schemes and potentially fraudulent providers that can help other interested parties—such as other insurers—find those schemes and providers within their own systems. These practices also help monitor individuals who have been identified as potentially abusing drugs or health care benefits. For example, one practice we identified is recipient restriction programs—called "lock-ins"—that typically require certain patients to use one prescribing physician and one dispensing pharmacy—to better track their prescription drug use.

Table 2: Detection and Monitoring Practices for Prescription Drug Fraud, Waste, and Abuse

Practice	Description/examples
Clinical guidelines	Providing clinical guidance to prescribers and pharmacies regarding topics such as • screening patients for potential drug abuse, such as through urine testing or other screening tools, and • more frequent evaluations of patients who are prescribed certain drugs.
Collaboration	Establishing mutually reinforcing or joint strategies among stakeholders to help in detection and monitoring efforts, such as sharing information on specific fraud schemes, results of data analysis, and disciplinary actions taken against providers.
Compliance program	Establishing effective compliance programs that include the following elements: • written policies, procedures, and standards of conduct; • designation of a compliance officer and committee; • effective training and education; • effective lines of communication; • enforcing standards; • internal monitoring and auditing; and • responding promptly to offenses and developing corrective actions.
Data analysis	Having dedicated and appropriate staff for collecting and actively analyzing data to identify outliers or other markers of potential fraud, waste, or abuse.
Drug utilization review (DUR)	Having authorized, structured, ongoing reviews of prescribing, dispensing, and use of medication, which can include • prospective reviews, such as requiring prior authorization for certain drugs, high drug doses, or large drug quantities before the drugs are dispensed; • concurrent reviews; and • retrospective or retroactive reviews.
Education	Educating insurers, providers, patients, and others on how to detect potential prescription drug fraud, waste, and abuse. This can include alerting providers to their prescribing patterns.
Postpayment reviews	Reviewing claims and other documents after payment to ensure compliance with payment rules and that the prescription was medically necessary, including the ability to suspend payments and obtain and review medical records. Alerting providers and beneficiaries to potential errors in services provided or received, such as by sending explanation of benefit reports to beneficiaries for their review.
Prescription Drug Monitoring Programs (PDMP)[a]	Using PDMP reports to help detect potential problems, which can be solicited reports, such as prescribers requesting a report about a particular patient, or unsolicited reports, such as a PDMP system automatically sending a prescriber a report on his or her patients and prescribing patterns.
Recipient restriction programs (“lock- ins”)	Requiring certain patients—such as those at risk for abusing drugs, high-users of controlled substances, and others—typically to use only one prescribing physician and one dispensing pharmacy.

Source: GAO analysis of relevant literature. | GAO-15-66

[a]PDMPs are state-based programs that operate electronic databases that gather information from pharmacies on certain dispensed prescriptions. Authorized users access the information about a patient’s prescription drug history, such as whether a patient has multiple opioid prescriptions from multiple providers.

Investigation and Prosecution

We identified six practices related to the investigation and prosecution of prescription drug fraud, waste, and abuse, as shown in table 3. Practices include having investigative staff knowledgeable of prescription drug schemes and experienced in investigating them, as well as having the ability to take actions to enforce prescription drug rules.

Table 3: Investigation and Prosecution Practices for Prescription Drug Fraud, Waste, and Abuse

Practice	Description/examples
Collaboration	Participating in joint investigations, task forces, and other investigative efforts. Sharing information, as appropriate, regarding ongoing fraud investigations, including information about the providers under investigation.
Education	Providing education to law enforcement and other investigators on how to investigate prescription drug fraud, waste, and abuse.
Enforcement	Having and using punitive measures against those involved in potential fraud, waste, or abuse of prescription drugs, such as • restricting providers' or beneficiaries' access to or removing them from insurance programs and • pursuing prosecutions.
Investigations/investigative staff	Having in-house investigators, such as a Special Investigative Unit, which take investigative steps such as on-site audits, medical record reviews, and other actions.
Prescription Drug Monitoring Programs (PDMP)[a]	Accessing and/or analyzing PDMP data in support of investigations and/or prosecutions.
Reporting to law enforcement	Reporting suspect bad actors and problems to law enforcement agencies.

Source: GAO analysis of relevant literature. | GAO-15-66

[a]PDMPs are state-based programs that operate electronic databases that gather information from pharmacies on certain dispensed prescriptions. Authorized users access the information about a patient's prescription drug history, such as whether a patient has multiple opioid prescriptions from multiple providers.

CMS's Part D Program Integrity Efforts Reflect Many of the Practices We Identified

CMS pursues many of the practices we identified that can be used to prevent, detect, and investigate prescription drug fraud, waste, and abuse. In addition, CMS plans to add new and strengthen certain existing practices, but will not adopt certain other practices for a variety of reasons.

CMS, with Its Contractors, Has Implemented Many Program Integrity Practices, Particularly within the Categories of Detection and Monitoring and Investigation and Prosecution

CMS activities to address prescription drug fraud, waste, and abuse reflect 14 of the 23 total practices we identified, based on interviews with officials and review of agency documents. Most of the practices CMS pursues—10 of its 14 practices—relate to the detection and monitoring, and investigation and prosecution categories.

CMS implements its prescription drug program integrity practices by assigning activities to and working with plan sponsors, the MEDICs, and others. For example,

- for prevention, CMS works with the O&E MEDIC to develop educational materials that plan sponsors can download from the O&E MEDIC's website and customize for their beneficiaries;
- for detection and monitoring, CMS requires plan sponsors to have compliance programs, which incorporate multiple practices we identified, such as data analysis, collaboration, and education; the NBI MEDIC also analyzes data and shares the results with plan sponsors; and
- for investigations and prosecutions, plan sponsors and the NBI MEDIC are expected to have staff who can identify and investigate potential fraud, waste, and abuse.

The NBI and O&E MEDICs reported completing work for a variety of practices, and CMS rated elements of the MEDICs' work from satisfactory to exceptional on their most recent performance assessments.[12]

NBI MEDIC

CMS paid approximately $17 million in 2013 to the NBI MEDIC to analyze data, process and review complaints, and develop investigations to promote Part D program integrity. In the most recently completed contract year, the NBI MEDIC reported the following:

[12]CMS evaluates each MEDIC's performance annually based on metrics it sets for each contractor, primarily related to the timeliness of contractors' work. For example, CMS expects that the NBI MEDIC will send an acknowledgment letter to complainants within 5 days of receiving the complaint, and expects that the O&E MEDIC will conduct a minimum of 10 training presentations each contract year. Scores are based on a five-point scale: (1) unsatisfactory, (2) marginal, (3) satisfactory, (4) very good, and (5) exceptional.

CMS rated the contractors on additional elements not included in the examples we described.

- processing almost 7,000 complaints to determine whether they identified potential fraud, for which CMS most recently rated the contractor "exceptional";
- completing 7 data analysis projects and initiating 41 new projects, for which CMS most recently rated the contractor "exceptional"; and
- referring almost 400 cases that represented approximately $5.1 billion in potential fraud to law enforcement, for which CMS most recently rated the contractor "satisfactory" for its investigations and "exceptional" for its law enforcement referrals.[13]

O&E MEDIC

CMS paid approximately $1.7 million in 2013 to the O&E MEDIC to provide outreach and education that assists CMS in communicating program integrity efforts as well as supporting fraud, waste, and abuse oversight audits. In the most recently completed contract year, the O&E MEDIC reported the following:

- developing 59 outreach and education materials, such as fraud awareness flyers and frequently asked questions;
- developing 33 training products, such as webinars and job aids; and
- executing 8 conferences, including with stakeholders we interviewed, and providing 22 presentations at other conferences and meetings.

CMS rated each element of the O&E MEDIC's work as "satisfactory."[14]

Table 4 identifies the practices implemented by CMS and its contractors.

[13]The NBI MEDIC's most recently completed Contractor Performance Assessment Reports System (CPARS) evaluation was for April 2011 through March 2012. While CMS has conducted two subsequent reviews, the ratings had not been posted to CPARS as of August 2014. Therefore, we report the MEDIC's 2013 activities from the most recently completed contract year, and the CPARS ratings as of March 2012, since those are the most recently available results.

[14]The O&E MEDIC's most recently completed contract year for which its CPARS ratings are available was October 2012 through September 2013.

Table 4: Practices Implemented by CMS and Its Contractors for Addressing Prescription Drug Fraud, Waste, and Abuse

Category	Practice	Responsible entities and examples of activities[a]
Prevention	Collaboration (prevention)	CMS has established relationships with a variety of stakeholders to help develop programs and strategies to address prescription drug fraud, waste, and abuse, including, for example, the agency's participation in the Public-Private Partnership to Prevent Health Care Fraud and as a member of the National Health Care Anti-Fraud Association.
	Education (prevention)	Outreach & Education Medicare Drug Integrity Contractor (O&E MEDIC), in concert with CMS Center for Program Integrity, offers a variety of materials and events, such as an insert on safe drug disposal that plan sponsors can provide to their beneficiaries, and training to Medicare beneficiaries on how to prevent potential fraud.
	Prepayment edits	Plan sponsors may implement edits at the point of sale to control specific beneficiaries' access to certain medications (see also drug utilization review (DUR) below). For every prescription, plan sponsors must check a range of information, typically at the point of sale or distribution, such as drug interactions, incorrect amounts, and age or gender contraindications, such as a woman receiving medications prescribed only to men.
	Screening	Plan sponsors must verify beneficiaries' Part D eligibility. CMS finalized a rule in May 2014 establishing a Medicare enrollment requirement for Part D prescribers effective June 1, 2015, and strengthening screening for ineligible incarcerated beneficiaries starting January 1, 2015.[b]
Detection and monitoring (D&M)	Collaboration (D&M)	Plan sponsors are to share information with CMS regarding potentially fraudulent providers or schemes. National Benefit Integrity (NBI) and O&E MEDICs convene conferences and share information on prescription drug fraud, waste, and abuse with plan sponsors, law enforcement, beneficiaries, and other stakeholders. CMS sends memos to all plan sponsors about new Part D fraud schemes and potentially fraudulent providers that are also made available on the O&E MEDIC website. In addition, CMS sends the results of the NBI MEDIC's data analyses directly to a plan sponsor if the NBI MEDIC identifies particular issues for that sponsor to address.
	Compliance program	Plan sponsors are to have effective compliance programs.
	Data analysis	The NBI MEDIC conducts data analysis projects, such as identifying deceased prescribers across all plan sponsors, and is to have clinical and analytic staff to conduct that work. The NBI MEDIC is also implementing predictive analytic models to identify potential fraud in the Part D program. Plan sponsors are to have clinical and analytic staff, or contract with an entity that can provide such staff, to monitor and analyze data as part of their compliance programs.
	Drug utilization review (DUR)	Plan sponsors are to review beneficiaries' drug utilization patterns to identify potential patient harm and beneficiaries at risk for overutilization, and refer those beneficiaries for case management. Plan sponsors are to share information on these beneficiaries when they move from one Part D plan to another. CMS also reports quarterly to plan sponsors the names of beneficiaries overutilizing opioids and certain other drugs through CMS's Overutilization Monitoring System. Plan sponsors must report to CMS quarterly on how each identified case is addressed.

Category	Practice	Responsible entities and examples of activities[a]
	Education (D&M)	O&E MEDIC, in coordination with CMS and the NBI MEDIC, provides training and materials to plan sponsors and others on how to identify potential fraud, waste, and abuse. For example, the O&E MEDIC, with CMS oversight, developed a Fraud Handbook that plan sponsors can access to learn about practical techniques and approaches on preventing, detecting, and investigating potential prescription drug fraud.
	Postpayment reviews	Plan sponsors are to conduct certain postpayment reviews (see also DUR above). Plan sponsors are also to provide beneficiaries with an explanation-of-benefits document to review for potential errors that also has a telephone number to report potential fraud. Part D Recovery Audit Contractor is to review paid Part D claims to identify over- and underpayments and recoup overpayments, and refer potential fraud identified during that postpayment review to the NBI MEDIC.
Investigation and prosecution (I&P)	Collaboration (I&P)	The NBI MEDIC responds to law enforcement requests for information and has participated in task forces and other investigative efforts. The O&E MEDIC trains insurance investigators, law enforcement, and others. CMS hosts quarterly meetings with a variety of stakeholders on prescription drug fraud, waste, and abuse.
	Education (I&P)	O&E MEDIC, in consultation with the NBI MEDIC, provides educational materials on how to investigate potential fraud.
	Investigations/ investigative staff	Plan sponsors are to have staff who can identify potential fraud. The NBI MEDIC is to have investigative staff knowledgeable of prescription drug fraud.
	Reporting to law enforcement	The NBI MEDIC is required to refer investigations to law enforcement. CMS encourages but does not require plan sponsors to refer potential fraud to law enforcement and/or CMS, including the NBI MEDIC.[c]

Source: GAO analysis of CMS documents and interviews with CMS officials. | GAO-15-66

[a]This table does not include all instances of CMS's activities to implement the practices we identified.

[b]Once prescribers are enrolled, the rule provides that CMS will be able to revoke prescriber billing privileges for certain abuses of the program or noncompliance with applicable licensure requirements. To implement the exclusion of incarcerated individuals from Part D coverage, the rule redefined eligible Medicare service areas to exclude facilities in which individuals are incarcerated. See *Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*. 79 Fed. Reg. 29,844 (May 23, 2014).

[c]In a March 2014 report, OIG reiterated previous recommendations that it had made to CMS to amend regulations to require Part D plan sponsors to report to CMS their identification of and response to potential fraud and abuse incidents. CMS did not concur with this recommendation, citing concerns about creating duplicative reporting. See Department of Health and Human Services Office of Inspector General, *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse*, OEI-03-13-00030 (Washington, D.C.: March 2014). CMS officials told us in September 2014 that if the agency were to impose such a requirement, it would be able to evaluate sponsors' compliance with the reporting requirement, but not whether the reports identified actual fraud as defined by law enforcement.

CMS May Adopt Some Practices, but Not Others, for a Number of Reasons

CMS is planning to implement another 3 of the 23 total practices and to strengthen 4 that it has already implemented, but officials stated that the agency is not pursuing 6 practices for a number of reasons.

The three additional practices CMS plans to implement are the following:

- *Detection and Monitoring: Prescription Drug Monitoring Program (PDMP)*. CMS officials said the agency is seeking access to PDMP data through several avenues.[15] For example, CMS and the NBI MEDIC are working with the PDMP Center of Excellence to obtain de-identified PDMP data to assist the MEDIC in detecting potential patterns of prescription drug fraud, waste, and abuse.
- *Investigation and Prosecution: PDMPs*. CMS officials said CMS and the NBI MEDIC are also working with four states—Idaho, Indiana, Massachusetts, and New York—to obtain PDMP data as another data source to help investigate potential prescription drug diversion. Idaho currently is the only state that allows Medicare access to its PDMP, while the other states have expressed interest in providing information to CMS.
- *Investigation and Prosecution: Enforcement*. Under the recently issued rule, which established a Medicare enrollment requirement for prescribers of drugs covered by Part D,[16] CMS can revoke a physician's or eligible professional's Medicare enrollment if the DEA or a state agency has suspended or revoked the individual's prescriber privileges. CMS may also revoke enrollment where it determines the individual has prescribing patterns or conducts practices that are abusive or represent a threat to the health and safety of Medicare beneficiaries, or both. Prior to this new requirement, CMS could not directly take administrative actions against a Part D provider. CMS officials also reported that they are working with OIG on how best to pursue other enforcement options, such as "permissive exclusions," which allow OIG to exclude

[15]PDMPs are state-based programs that operate electronic databases that gather information from pharmacies on certain dispensed prescriptions, such as whether a patient has multiple opioid prescriptions from multiple providers. Authorized users access the information about a patient's prescription drug history. Each state determines what data are collected, and who may access the PDMP and for what purpose. For example, some states only allow health care providers to access the PDMP as a patient-safety tool for their patients, while others allow law enforcement access for active investigations. According to Brandeis University's PDMP Training and Technical Assistance Center, as of June 2014, 49 of 50 states and the District of Columbia had legislation authorizing PDMPs, and 48 of those have operational PDMPs.

[16]*Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.* 79 Fed. Reg. 29,844 (May 23, 2014).

providers from federal health programs for certain other actions, such as misdemeanor convictions for certain offenses.[17]

CMS is planning to strengthen four practices that it has already implemented, which correspond to all three categories.

- *Prevention: Screening*. CMS issued a final rule in May 2014 that is intended to strengthen Part D prescriber and beneficiary screening. The rule establishes a Medicare enrollment requirement for prescribers of drugs covered by Part D, effective June 2015.[18] As a result, CMS is to screen these prescribers during the Medicare enrollment process to verify that they meet specific requirements, such as having current licenses or accreditation and valid Social Security numbers. Additionally, this final rule authorizes CMS to revoke a physician's or eligible professional's Medicare enrollment for certain abuses of the program, or based upon a suspension or revocation of the prescriber's DEA certificate or state authority to prescribe drugs. As with fee-for-service providers, CMS will revalidate enrollment information when changes or updates are submitted and during a 5-year revalidation process. CMS is still considering whether to require pharmacies that dispense covered Part D drugs to enroll into the Medicare program.

  The rule is also intended to strengthen screening of Part D beneficiaries.[19] Currently, plan sponsors are to verify beneficiaries' Part D eligibility. While incarcerated or confined beneficiaries are generally ineligible for Part D coverage, recent OIG reports found that

[17]Under section 1128 of the Social Security Act, exclusions from federal health programs are permissive under certain circumstances and mandatory in others. 42 U.S.C. § 1320a-7. Permissive exclusions are allowed for a variety of reasons, including licensure suspension, surrender, or revocation, or misdemeanor controlled substance conviction. Mandatory exclusions are required for felony convictions relating to health care fraud or controlled substances, and any convictions relating to patient abuse/neglect or to the delivery of Medicare or state health care programs.

[18]*Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*. 79 Fed. Reg. 29,844 (May 23, 2014).

[19]Id.

CMS paid for prescription drugs for such beneficiaries.[20] The new rule implements the exclusion of beneficiaries incarcerated for 30 days or more from receiving Part D benefits starting January 1, 2015, by removing the facilities where individuals are incarcerated from the definition of a plan's service area.

- *Detection and Monitoring: Collaboration*. CMS is seeking to strengthen collaboration through a new voluntary web-based system created by the NBI MEDIC—PLATO—that is intended to allow CMS and plan sponsors to more easily share information on fraud schemes and potential bad actors.[21] For example, plan sponsors may use the system to share information on specific suspect providers so that other plan sponsors can determine whether they should also investigate or take actions against those providers. CMS officials said that they anticipate that PLATO will be accessible to plan sponsors by the end of 2014. In addition, according to agency officials, CMS is working with the NBI MEDIC to develop and implement predictive models in PLATO to help identify potential fraud schemes that can be shared with plan sponsors, such as a model for identifying prescribers who provide certain controlled substances to patients without a valid medical need.
- *Detection and Monitoring: Compliance Program*. CMS is pursuing options for improving its oversight of plan sponsors' compliance programs. In 2013, among the plan sponsors that it audited, CMS found weaknesses in the majority of plan sponsors' compliance programs for addressing fraud, waste, and abuse. During that year, CMS audited 29 plan sponsors, representing 14 percent of all plan sponsors and, of those, nearly all (94 percent) had findings related to

[20]See Department of Health and Human Services Office of Inspector General, *Medicare Improperly Paid Millions of Dollars for Prescription Drugs Provided to Incarcerated Beneficiaries during 2006 through 2010*, A-07-12-06035 (Washington, D.C.: January 2014); and *The Centers for Medicare & Medicaid Services Provided Medicare Part D Coverage to Beneficiaries Confined in Mental Health Facilities for Court-Ordered Purposes,* A-07-13-06041 (Washington, D.C.: July 2014).

[21]PLATO stands for "predictive learning analytics tracking outcome." Predictive analytic technologies are a variety of automated systems and tools that can be used to identify particular types of behavior, including fraud, before transactions are completed.

fraud, waste, and abuse activities, according to officials.[22] These officials also reported that almost all weaknesses were addressed through a corrective action plan.[23] In January 2014, CMS proposed a rule that would require, among other things, that plan sponsors hire an independent auditor to verify that any required corrective action plans addressed deficiencies found during a program audit.[24] CMS did not finalize this requirement in the final rule issued in May 2014, and as of October 2014, CMS officials did not provide a proposed completion date.

In addition, CMS officials reported that the agency has an initiative under way to gather information that could help improve oversight of plan sponsors' practices to address fraud, waste, and abuse. As part of this initiative, CMS interviewed five plan sponsors about how they use the information CMS provided to them on new fraud schemes and potentially fraudulent providers. Based on this information, CMS officials reported that they could change how the agency audits plan sponsors' fraud, waste, and abuse activities, or increase the

[22]CMS selects sponsors to audit based on size, past audit findings, and risk, selecting both sponsors that may serve as role models, as well as those that are at risk. As of August 2014, CMS officials reported that 97 percent of beneficiaries are enrolled with plan sponsors that have been audited.CMS's 2013 audit findings included a lack of evidence that plan sponsors' FDRs or governing bodies were trained in compliance or in how to identify and report potential fraud, waste, or abuse; a lack of evidence that plan sponsors were conducting reasonable inquiries of potential fraud, waste, or abuse in a timely manner; and a lack of evidence that plan sponsors were implementing procedures to ensure appropriate corrective actions were taken in response to potential fraud, waste, or abuse.

[23]Corrective action plans are developed by the plan sponsor to address deficiencies identified by CMS. Plans are to provide an attainable time frame for implementing corrective actions, and include a process for validating and monitoring that the corrective actions were taken and remain effective.

A CMS official noted that stricter penalties—specifically, civil money penalties—are reserved for weaknesses that result in direct adverse effects on beneficiaries, such as not being able to access medications and care.

[24]*Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.* 79 Fed. Reg. 1,918 (proposed Jan. 10, 2014).

requirements for sponsors' activities, in order to improve oversight.[25] However, CMS officials noted that any changes will be based on the agency's final assessment of lessons learned from the initiative, which was still in progress as of August 2014.

- *Investigation and Prosecution: Collaboration*. CMS is working to develop a more formal way to share information about fraudulent providers with relevant state medical boards, CMS officials said, so that the medical boards can conduct additional investigations to determine whether the board should impose sanctions on those providers, such as revoking a provider's medical license.

CMS is not pursuing six practices that appear in two categories, prevention and detection and monitoring, because the agency considers the practices to be outside the scope of its program integrity activities, is concerned about limiting beneficiaries' access to services, or for other reasons.

- *Prevention, and Detection and Monitoring: Clinical Guidelines*. While CMS uses clinical guidelines to review plan sponsors' formularies to ensure access to certain drugs, CMS does not require plan sponsors to carry out activities within these program integrity practices, such as filling only the prescriptions for the lowest effective dose, promoting alternatives to opioids, or screening their patients for potential drug abuse. However, CMS provides training materials to providers on such topics to promote patient safety, and other parts of Medicare cover screening for drug abuse under certain conditions.
- *Prevention: Health Information Technology*. CMS does not use health information technology for program integrity purposes, but encourages its use by, for example, providing information to Medicare beneficiaries on the benefits of electronic health records.
- *Prevention: PDMPs*. CMS guidance to physicians has encouraged prescribers to check their states' PDMP prior to prescribing certain drugs; however, variations in state practices regarding access to

[25]Both GAO and OIG have reported problems with CMS's audits of Part D plan sponsors. See GAO, *Medicare Part D: Some Plan Sponsors Have Not Completely Implemented Fraud and Abuse Programs, and CMS Oversight Has Been Limited*, GAO-08-760 (Washington, D.C.: July 21, 2008), and Department of Health and Human Services Office of Inspector General, *Audits of Medicare Prescription Drug Plan Sponsors*, OEI-03-09-00330 (Washington, D.C.: December 2011).

PDMPs means that not all prescribers may be able to conduct checks, according to CMS officials.

- *Prevention: Limit the Supply of Abused Drugs*. CMS officials told us that the agency does not conduct activities to limit the supply of abused drugs because this practice is beyond the scope of Part D program integrity efforts. For example, CMS does not operate "take back" days where beneficiaries can dispose of any unneeded prescription drugs, since, until recently, DEA required a law enforcement presence at such events, which CMS cannot provide.[26] CMS also does not address the supply of abuse-resistant drugs, officials said, since that is the responsibility of the Food and Drug Administration and pharmaceutical manufacturers.
- *Detection and Monitoring: Lock-ins*. CMS does not monitor Medicare beneficiaries through a "lock-in" or restricted recipient program. We previously recommended that CMS consider a restricted recipient program for Medicare Part D that would limit certain beneficiaries to one prescriber, one pharmacy, or both for receiving prescriptions, and that the agency should seek congressional authority, as appropriate, to do so.[27] CMS, in responding to our recommendation, stated that it did not agree that a restricted recipient program was necessarily the appropriate control for the Part D program, and raised concerns about restricting beneficiaries' access to services.[28] However, in August 2014, OIG recommended that CMS restrict certain beneficiaries to a limited number of pharmacies and prescribers, and CMS concurred

[26]DEA finalized a rule effective October 9, 2014, expanding the options available to dispose of controlled substances. See *Disposal of Controlled Substances.* 79 Fed. Reg. 53,520 (Sept. 9, 2014).

[27]See GAO-11-699. In that report, CMS policy officials stated that Part D cannot have a restricted recipient program because MMA, which established the Part D program, did not authorize CMS to establish such restrictions on beneficiaries.

[28]Following our report, in 2012 CMS conducted a study that identified few beneficiaries (less than 1 percent) who would merit a lock-in program. CMS analyzed Part D data to identify beneficiaries receiving potentially unsafe doses of prescription opioids for 90 or more consecutive days, excluding beneficiaries with cancer or in hospice care. CMS concluded that .71 percent (224,964) of all Part D beneficiaries were at high risk for potential adverse effects and had a high likelihood of inappropriately using opioids. CMS also analyzed the number of prescribers and pharmacies associated with these beneficiaries' opioid prescriptions and found that .07 percent (22,222) of Part D beneficiaries received high dosages of opioids from at least four prescribers and at least four pharmacies.

with the recommendation, but stated the agency needs—and is receptive to—legislative authority to "lock in" beneficiaries in Part D.[29]

Currently, the agency requires plan sponsors to review data to identify beneficiaries potentially at risk for overutilization of certain drugs, including opioids, and to monitor those beneficiaries.[30] Monitoring may include notifying their prescribers of the overutilization, case management, and point-of-sale edits, which are beneficiary-specific edits that can vary based on the situation. For example, the edits may prevent a beneficiary from receiving certain types of prescription drugs or an excessive amount of a particular drug.[31]

See appendix I for the status of all 23 program integrity practices we identified and whether CMS and its contractors have implemented, planned to implement, or are not pursuing them.

Agency Comments

We provided a draft of this report to the Department of Health and Human Services (HHS) for comment and HHS provided written comments, which are reprinted in appendix II. In its comments, HHS generally agreed with our findings, and provided more information regarding our finding that CMS is not pursuing 6 of the 23 practices we identified for prescription drug fraud, waste, and abuse. Generally, the agency provided additional information for why CMS is not pursuing certain practices as part of its

[29]See Department of Health and Human Services Office of Inspector General, *Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs*, OEI-02-11-00170 (Washington, D.C.: August 2014).

[30]CMS requires plan sponsors to have drug utilization review (DUR) programs that include retrospective reviews of claims and case management for drugs susceptible to abuse, including opioids. 42 C.F.R § 423.153. Starting in 2013, CMS implemented a Medicare Part D Overutilization Monitoring System (OMS). OMS is similar and in addition to the DUR programs, but is focused on opioids and certain other drugs, and includes CMS sending quarterly reports to plan sponsors to alert them to their beneficiaries who are receiving excessive amounts of those drugs.

OIG recommended in August 2014 that CMS expand both the plan sponsors' DUR programs and OMS to include additional drugs susceptible to fraud, waste, and abuse. CMS concurred with the recommendation to expand DUR programs, noting the agency already encourages plan sponsors to examine nonopioids as part of those programs. CMS did not concur that it should similarly expand OMS, stating that the program is a "safety-focused tool," not a "fraud identification tool." See OEI-02-11-00170.

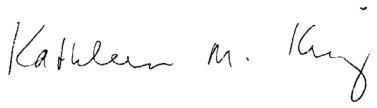
[31]Beneficiaries have a right to appeal the use of these edits, as set forth at 42 C.F.R. Part 423, Subpart M, and Chapter 18 of the *Medicare Prescription Drug Benefit Manual*.

program integrity efforts, such as the use of clinical guidelines, PDMPs, and lock-in programs. Regarding the practice of health information technology, while HHS noted that CMS requires the development by Part D sponsors of electronic prescription drug programs and the use of e-prescribing is encouraged, these activities were not identified by CMS officials as specific program integrity efforts. Regarding the practice of limiting the supply of abused drugs, HHS described CMS activities that we considered under a different practice—the use of prepayment edits. Our descriptions and examples of these practices, as well as the other 17 practices, are included in tables 1, 2, and 3 in this report. HHS also provided a recent example of its program integrity efforts to address fraud, waste, and abuse in the Part D program, in which HHS sent letters to providers identified as very high prescribers of certain controlled substances to give information to these providers to help them evaluate whether their high prescribing level of these drugs is appropriate for their patient population, and to identify areas where their prescribing could be modified. HHS also provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, appropriate congressional committees, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

Sincerely yours,



Kathleen King
Director, Health Care

Appendix I: Status of Practices by CMS and Its Contractors to Address Prescription Drug Fraud, Waste, and Abuse

Table 5 shows the 23 prevention, detection and monitoring, and investigation and prosecution practices we identified, their CMS status (implemented, planned, or not pursuing), and examples of the activities. We determined that CMS had implemented a practice if the agency required or documented at least one activity within that practice, that CMS planned a practice if documentation or officials described activities as pilots or in the process of development, and that CMS was not pursuing practices based on reviews of documentation and interviews with officials.

Table 5: CMS Implementation Status and Examples of 23 Prevention, Detection and Monitoring, and Investigation and Prosecution Practices GAO Identified

Category	Practice	Status ● Implemented ☼ Planned ○ Not pursuing	Responsible entities, examples of activities,[a] or explanation of status
Prevention	Clinical guidelines (prevention)	○	The Centers for Medicare & Medicaid Services (CMS) does not use clinical guidelines for program integrity purposes, but the agency provides educational materials related to appropriate prescribing.
	Collaboration (prevention)	●	CMS has established relationships with a variety of stakeholders to help develop programs and strategies to address prescription drug fraud, waste, and abuse, including, for example, the agency's participation in the Public-Private Partnership to Prevent Health Care Fraud and as a member of the National Health Care Anti-Fraud Association.
	Education (prevention)	●	Outreach & Education Medicare Drug Integrity Contractor (O&E MEDIC), in concert with CMS Center for Program Integrity, offers a variety of materials and events, such as an insert on safe drug disposal that plan sponsors can provide to their beneficiaries and training to Medicare beneficiaries on how to prevent potential fraud.
	Health information technology	○	CMS does not use health information technology for program integrity purposes, but has encouraged its use, such as by providing information to Medicare beneficiaries on the benefits of electronic health records.
	Limit the supply of abused drugs	○	CMS does not limit the supply of abused drugs because the associated activities of this practice are beyond the scope of Part D program integrity efforts, according to CMS officials. For example, until recently, to accept unneeded controlled substances in a "take back" program, the Drug Enforcement Administration required a law enforcement presence, which CMS cannot provide.

Category	Practice	Status ● Implemented ☼ Planned ○ Not pursuing	Responsible entities, examples of activities,[a] or explanation of status
	Prepayment edits	●	Plan sponsors may implement edits at the point of sale to control specific beneficiaries' access to certain medications (see also drug utilization review (DUR) below). For every prescription, plan sponsors must check a range of information, typically at the point of sale or distribution, such as drug interactions, incorrect amounts, and age or gender contraindications, such as a woman receiving medications prescribed only to men.
	Screening	●	Plan sponsors must verify beneficiaries' Part D eligibility. CMS finalized a rule in May 2014 establishing a Medicare enrollment requirement for Part D prescribers effective June 1, 2015, and strengthening screening for ineligible incarcerated beneficiaries starting January 1, 2015.[b]
	Prescription Drug Monitoring Programs (PDMP)[c] (Prevention)	○	CMS guidance encourages but does not require prescribers to check PDMPs prior to prescribing and variations in state practices mean not all prescribers may be able to conduct checks.
Detection and monitoring (D&M)	Clinical guidelines (D&M)	○	CMS does not use clinical guidelines for Part D program integrity purposes, but other parts of Medicare provide training materials to providers, such as on the topic of coverage for Screening, Brief Intervention, and Referral to Treatment services to identify, reduce, and prevent problematic substance use, abuse, and dependence.
	Collaboration (D&M)	●	Plan sponsors are to share information with CMS regarding potentially fraudulent providers or schemes. National Benefit Integrity (NBI) and O&E MEDICs convene conferences and share information on prescription drug fraud, waste, and abuse with plan sponsors, law enforcement, beneficiaries, and other stakeholders. CMS sends memos to all plan sponsors about new Part D fraud schemes and potentially fraudulent providers that are also made available on the O&E MEDIC website. In addition, CMS sends the results of the NBI MEDIC's data analyses directly to a plan sponsor if the NBI MEDIC identifies particular issues for that sponsor to address.
	Compliance program	●	Plan sponsors are to have effective compliance programs.
	Data analysis	●	The NBI MEDIC conducts data analysis projects, such as identifying deceased prescribers across all plan sponsors, and is to have clinical and analytic staff to conduct that work. The NBI MEDIC is also implementing predictive analytic models to identify potential fraud in the Part D program. Plan sponsors are to have clinical and analytic staff, or contract with an entity that can provide such staff, to monitor and analyze data as part of their compliance programs.

Category	Practice	Status ● Implemented ☼ Planned ○ Not pursuing	Responsible entities, examples of activities,[a] or explanation of status
	Drug utilization review (DUR)	●	Plan sponsors are to review beneficiaries' drug utilization patterns to identify potential patient harm and beneficiaries at risk for overutilization, and refer those beneficiaries for case management. Plan sponsors are to share information on these beneficiaries when they move from one Part D plan to another. CMS also reports quarterly to plan sponsors the names of their beneficiaries overutilizing opioids and certain other drugs through CMS's Overutilization Monitoring System. Plan sponsors must report to CMS quarterly how each identified case is addressed.
	Education (D&M)	●	O&E MEDIC, in coordination with CMS and the NBI MEDIC, provides training and materials to plan sponsors and others on how to identify potential fraud, waste, and abuse. For example, the O&E MEDIC, with CMS oversight, developed a Fraud Handbook that plan sponsors can access to learn about practical techniques and approaches on preventing, detecting, and investigating potential prescription drug fraud.
	Recipient restriction programs ("lock-ins")	○	CMS does not monitor Medicare beneficiaries through a "lock-in" program. The agency has reported that it has taken a beneficiary-centric approach that discourages such restrictions, and lacks the legislative authority to implement such a program, although the agency has stated that it is receptive to such authority. In addition, in 2012, CMS conducted a study that identified few beneficiaries (less than 1 percent) who would merit such a program[d] (see also DUR above).
	PDMPs[c] (D&M)	☼	CMS is negotiating with a national organization to obtain access to its PDMP data.
	Postpayment reviews	●	Plan sponsors are to conduct certain postpayment reviews (see also DUR above). Plan sponsors are also to provide beneficiaries with an explanation-of-benefits document to review for potential errors that also has a telephone number to report potential fraud. Part D Recovery Audit Contractor is to review paid Part D claims to identify over- and underpayments and recoup overpayments, and refer potential fraud identified during that postpayment review to the NBI MEDIC.
Investigation and prosecution (I&P)	Collaboration (I&P)	●	The NBI MEDIC responds to law enforcement requests for information and has participated in task forces and other investigative efforts. The O&E MEDIC trains insurance investigators, law enforcement, and others. CMS hosts quarterly meetings with a variety of stakeholders on prescription drug fraud, waste, and abuse.

Category	Practice	Status ● Implemented ☼ Planned ○ Not pursuing	Responsible entities, examples of activities,[a] or explanation of status
	Education (I&P)	●	The O&E MEDIC, in consultation with the NBI MEDIC, provides educational materials on how to investigate potential fraud.
	Enforcement	☼	Starting June 1, 2015, CMS may revoke prescribers' Medicare enrollment[b] and CMS officials reported they are starting to work with the Health and Human Services Office of Inspector General (OIG) to remove more providers from Medicare through "permissive exclusions."[e]
	Investigations/ investigative staff	●	Plan sponsors are to have staff who can identify potential fraud. The NBI MEDIC is to have investigative staff knowledgeable of prescription drug fraud.
	Reporting to law enforcement	●	The NBI MEDIC is required to refer investigations to law enforcement. CMS encourages but does not require plan sponsors to refer potential fraud to law enforcement and/or CMS, including the NBI MEDIC.[f]
	PDMPs[c] (I&P)	☼	CMS is negotiating with certain states to obtain access to their PDMP data.

Source: GAO analysis of CMS documents and interviews with officials. | GAO-15-66

[a]This table does not include all instances of CMS's activities to implement the practices we identified.

[b]Once prescribers are enrolled, the rule provides that CMS will be able to revoke prescriber billing privileges for certain abuses of the program or noncompliance with applicable licensure requirements. To implement the exclusion of incarcerated individuals from Part D coverage, the rule redefined eligible Medicare service areas to exclude facilities in which individuals are incarcerated. See *Medicare Program: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*. 79 Fed. Reg. 29,844 (May 23, 2014).

[c]PDMPs are state-based programs that operate electronic databases that gather information from pharmacies on certain dispensed prescriptions. Authorized users access the information about a patients' prescription drug history, such as whether a patient has multiple opioid prescriptions from multiple providers.

[d]In 2012, CMS analyzed Part D data to identify beneficiaries receiving potentially unsafe doses of prescription opioids for 90 or more consecutive days, excluding beneficiaries with cancer or in hospice care. CMS concluded that .71 percent (224,964) of all Part D beneficiaries were at high risk for potential adverse effects and had a high likelihood of inappropriately using opioids. CMS also analyzed the number of prescribers and pharmacies associated with these beneficiaries' opioid prescriptions and found that .07 percent (22,222) of Part D beneficiaries received high dosages of opioids from at least four prescribers and at least four pharmacies.

[e]Under section 1128 of the Social Security Act, exclusions from federal health programs are permissive under certain circumstances and mandatory in others. 42 U.S.C. § 1320a-7. Permissive exclusions are allowed for a variety of reasons, including licensure suspension, surrender, or revocation, or misdemeanor controlled substance conviction. Mandatory exclusions are required for felony convictions relating to health care fraud or controlled substances and any convictions relating to patient abuse/neglect or to the delivery of Medicare or state health care programs.

[f]In a March 2014 report, OIG reiterated previous recommendations that it had made to CMS to amend regulations to require Part D plan sponsors to report to CMS their identification of and response to potential fraud and abuse incidents. CMS did not concur with this recommendation, citing concerns about creating duplicative reporting. See Department of Health and Human Services Office of Inspector General, *Less than Half of Part D Sponsors Voluntarily Reported Data on Potential Fraud and Abuse*, OEI-03-13-00030 (Washington, D.C.: March 2014). CMS officials told us in September 2014 that if the agency were to impose such a requirement, it would be able to evaluate sponsors' compliance with the reporting requirement, but not whether the reports identified actual fraud as defined by law enforcement.

Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

OCT 10 2014

Kathleen M. King
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Medicare Program Integrity: CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse" (GAO-15-66).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S REPORT ENTITLED: MEDICARE PROGRAM INTEGRITY: CMS PURSUES MANY PRACTICES TO ADDRESS PRESCRIPTION DRUG FRAUD, WASTE, AND ABUSE

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

HHS is strongly committed to program integrity efforts in Medicare and has a number of ongoing activities to address fraud, waste and abuse in the Part D program. For instance, HHS recently sent letters to providers who have been identified as very high prescribers of Schedule II controlled substances under Part D compared to other providers in their specialty and state. The letter informs the prescribers of the extent of their outlier status for Schedule II drugs in order to provide insight into their prescribing practices. The letter is intended to provide information to help these prescribers evaluate whether their high prescribing level for these drugs is appropriate for their patient population and identify areas where their prescribing could be modified. The letter encourages the providers to share the information in the letter with other clinicians.

As the report notes, HHS has implemented or plans to implement a majority of the program integrity practices identified by GAO to curb prescription drug fraud, waste, and abuse. In addition, CMS is addressing the other practices identified by GAO through coordination with Part D sponsors, prescribers, and beneficiaries.

These practices and HHS' responses to the GAO are below.

Clinical Guidelines
CMS does not use clinical guidelines for program integrity purposes, but the agency provides educational materials related to appropriate prescribing.

HHS Response
Part D plan sponsors have relationships with pharmacies. They generally do not have relationships with prescribers that would allow them to require their adherence to clinical guidelines.

Health Information Technology (Prevention)
CMS does not use health information technology for program integrity purposes, but has encouraged its use, such as by providing information to Medicare beneficiaries on the benefits of electronic health records.

HHS Response
HHS recognizes that technologies such as e-prescribing can be a helpful tool in protecting program integrity and has encouraged their use. For instance, Part D sponsors must establish and maintain an electronic prescription drug program, and e-prescribing is generally required of eligible professionals and hospitals for achieving meaningful use in the Medicare electronic health record incentive program. In addition, HHS has consulted on Drug Enforcement Agency rulemaking that allows for the use of e-prescribing for controlled substances.

Limit the Supply of Abused Drugs (Prevention)

CMS does not limit the supply of abused drugs because the associated activities of this practice are beyond the scope of Part D program integrity efforts, according to CMS officials. For example, until recently, to accept unneeded controlled substances in a "take back" program, the Drug Enforcement Administration required a law enforcement presence, which CMS cannot provide.

HHS Response
HHS has worked to limit the supply of abused drugs while maintaining access for beneficiaries. HHS has promulgated regulations that require short-cycle dispensing of brand drugs in long-term care. Also, under our guidance, plan sponsors may provide quantity limits of drugs, including on those drugs that have no U.S. Food and Drug Administration quantity limits.

Prescription Drug Monitoring Programs (PDMP) (Prevention)
CMS guidance encourages but does not require prescribers to check PDMPs prior to prescribing and variations in state practices mean not all prescribers may be able to conduct checks.

HHS Response
As noted by GAO, variations in state practices and in Part D plan sponsors relationships with prescribers make it difficult for HHS to develop a national requirement for prescribers to check PDMPs prior to prescribing.

Recipient Restriction Programs ("lock ins")
CMS does not monitor Medicare beneficiaries through a "lock in" program. The agency has reported that it has taken a beneficiary-centric approach that discourages such restrictions, and lacks the legislative authority to implement such a program, although the agency has stated that it is receptive to such authority. In addition, in 2012, CMS conducted a study that identified few beneficiaries (less than 1 percent) who would merit such a program.

HHS Response
As noted by GAO, HHS would need legislative authority to implement "lock in" programs in Part D. HHS currently responds to abuse identified at the beneficiary level through other programs. Part D sponsors review reports to identify the number of prescriptions for opioids and acetaminophen filled by individual enrollees, typically with multiple prescribers and pharmacies, to identify possible abuse or illegal activity. Prescribers for enrollees with abnormal prescription patterns for these drugs are contacted by their Part D plan sponsors to confirm the medical necessity of the prescription patterns. When medical necessity is not confirmed, Part D sponsors may impose beneficiary-level claim edits to prevent the coverage of an unsafe level of opioids and acetaminophen. The sponsor also notifies HHS has systems in place to notify a new sponsor of the edit if the beneficiary changes plans.

HHS thanks GAO for their efforts on this issue and looks forward to working with GAO on this and other issues in the future.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Karen Doran, Assistant Director; Elizabeth Morrison; Lisa Rogers; Eden Savino; and Jennifer Whitworth made key contributions to this report.