



October 2017

PRESCRIPTION OPIOIDS

Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm

Accessible Version

Why GAO Did This Study

Misuse of prescription opioids can lead to overdose and death. In 2016, over 14 million Medicare Part D beneficiaries received opioid prescriptions, and spending for opioids was almost \$4.1 billion. GAO and others have reported on inappropriate activities and risks associated with these prescriptions, such as receiving multiple opioid prescriptions from different providers.

GAO was asked to describe what is known about CMS's oversight of Medicare Part D opioid use and prescribing. This report examines (1) CMS oversight of beneficiaries who receive opioid prescriptions under Part D, and (2) CMS oversight of providers who prescribe opioids to Medicare Part D beneficiaries. GAO reviewed CMS opioid utilization and prescriber data, CMS guidance for plan sponsors, and CMS's strategy to prevent opioid misuse. GAO also interviewed CMS officials, the six largest Part D plan sponsors, and 12 national associations selected to represent insurance plans, pharmacy benefit managers, physicians, patients, and regulatory and law enforcement authorities.

What GAO Recommends

GAO recommends that CMS (1) gather information on the full number of at-risk beneficiaries receiving high doses of opioids, (2) identify providers who prescribe high amounts of opioids, and (3) require plan sponsors to report to CMS on actions related to providers who inappropriately prescribe opioids. HHS concurred with the first two recommendations, but not with the third. GAO continues to believe the recommendation is valid, as discussed in the report.

View [GAO-18-15](#). For more information, contact Elizabeth H. Curda at (202) 512-7114 or curdae@gao.gov.

PRESCRIPTION OPIOIDS

Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm

What GAO Found

The Centers for Medicare & Medicaid Services (CMS) provides guidance on the monitoring of Medicare beneficiaries who receive opioid prescriptions to plan sponsors—private organizations that implement the Medicare drug benefit, Part D—but lacks information on most beneficiaries at risk of harm.

- CMS provides plan sponsors guidance on how they should monitor opioid overutilization among Medicare Part D beneficiaries and requires them to implement drug utilization review systems that use criteria similar to CMS's. CMS's criteria focus on beneficiaries who (1) receive prescriptions of high doses of opioids, (2) receive prescriptions from four or more providers, and (3) fill the prescriptions at four or more pharmacies. According to CMS officials, this approach allows plan sponsors to focus their actions on those beneficiaries it determined to have the highest risk of harm from opioid use.
- CMS's criteria, including recent revisions, do not provide sufficient information about the larger population of potentially at-risk beneficiaries. CMS estimates that while 33,223 beneficiaries would have met the revised criteria in 2015, 727,016 would have received high doses of opioids regardless of the number of providers or pharmacies. In 2016, CMS began to collect information on some of these beneficiaries using a higher dosage threshold for opioid use. This approach misses some who could be at risk of harm, based on Centers for Disease Control and Prevention guidelines. As a result, CMS is limited in its ability to assess progress toward meeting the broader goals of its Opioid Misuse Strategy, which includes activities to reduce the risk of harm from opioid use.

CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria

Number of beneficiaries receiving high opioid doses (in tens of thousands)	Estimated number of beneficiaries CMS would have tracked with revised criteria (in tens of thousands)
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Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. | [GAO-18-15](#)

CMS oversees the prescribing of drugs at high risk of abuse through a variety of projects, but does not analyze data specifically on opioids. According to CMS officials, CMS and plan sponsors identify providers who prescribe large amounts of drugs with a high risk of abuse, and those suspected of fraud or abuse may be referred to law enforcement. However, GAO found that CMS does not identify providers who may be inappropriately prescribing large amounts of opioids separately from other drugs, and does not require plan sponsors to report actions they take when they identify such providers. As a result, CMS is lacking information that it could use to assess how opioid prescribing patterns are changing over time, and whether its efforts to reduce harm are effective.

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Abbreviations

CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
CPI	Center for Program Integrity
DUR	drug utilization review
HHS	Department of Health and Human Services
HHS-OIG	Department of Health and Human Services Office of Inspector General
MED	morphine equivalent dose
mg	milligrams
NBI MEDIC	National Benefit Integrity Medicare Drug Integrity Contractor
OMS	Overutilization Monitoring System
PLATO	Predictive Learning Analytics Tracking Outcome
POS	point-of-sale

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October 6, 2017

The Honorable Pat Toomey
Chairman
Subcommittee on Health Care
Committee on Finance
United States Senate

The Honorable Tim Kaine
United States Senate

Misuse of prescription opioids, which are used to treat both acute and chronic pain, has become a serious public health problem for the U.S. population, including Medicare beneficiaries. The Centers for Disease Control and Prevention (CDC) reported that from 1999 to 2013 the rate of drug poisoning deaths from prescription opioids nearly quadrupled from 1.4 to 5.1 per 100,000 people.¹ In addition, the Department of Health and Human Services (HHS) Office of Inspector General (HHS-OIG) reported that 14.4 million people (about one-third) who participate in Medicare Part D received at least one prescription for opioids in 2016, and that Part D spending for opioids in 2016 was almost \$4.1 billion.² GAO and the HHS-OIG have previously reported on inappropriate activities that can be associated with such prescriptions, including “doctor shopping” to receive multiple opioid prescriptions from different providers, the diversion of prescription drugs for uses other than intended, and questionable

¹Department of Health and Human Services, Centers for Disease Control and Prevention, *Rates of Deaths from Drug Poisoning and Drug Poisoning Involving Opioid Analgesics—United States, 1999-2013*, Morbidity and Mortality Weekly Report, vol. 64, no. 1, (Atlanta, Ga.: Jan. 16, 2015).

²Department of Health and Human Services Office of Inspector General, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing*, OE-02-17-00250 (July 2017). 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. Since 2006, Medicare Part D has offered voluntary prescription drug coverage through stand-alone prescription drug plans or through Medicare Advantage prescription drug plans, which combine medical and prescription drug benefits.

prescribing practices, including those in Medicare.³ Additionally, a staff report issued in 2016 by the Senate Permanent Subcommittee on Investigations outlined concerns associated with opioid abuse in both Medicare and private health insurance.⁴

In March 2015, HHS announced plans to make addressing opioid abuse a high priority through two broad goals: (1) decreasing opioid overdoses and overall overdose deaths, and (2) decreasing the prevalence of opioid use disorder.⁵ Further, in January 2017, the Centers for Medicare & Medicaid Services (CMS), the HHS agency that administers Medicare, issued its Opioid Misuse Strategy for the Medicaid and Medicare programs, including Part D. One of the four priority areas outlined in the strategy is implementing activities to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion.⁶ For this priority, the strategy includes the agency's plans to address concerns about beneficiary use of opioids and the prescribing of opioids by providers, such as educating and providing feedback to beneficiaries and

³See GAO, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, [GAO-02-634](#) (Washington, D.C.: May 17, 2002); GAO, *Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem*, [GAO-04-110](#) (Washington, D.C.: Dec. 19, 2003); GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, [GAO-11-699](#) (Washington, D.C.: Sept. 6, 2011); and GAO, *Medicare Program Integrity: CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse*, [GAO-15-66](#) (Washington, D.C.: Oct. 24, 2014). In response to recommendations in [GAO-11-699](#) to CMS regarding its efforts to curb drug overutilization, CMS began working with Part D sponsors and stakeholders to control payment for inappropriate overutilization of drugs. See also Department of Health and Human Services, Office of Inspector General, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, OEI-02-15-00190 (June 2015); and Department of Health and Human Services, Office of Inspector General, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, OEI-02-16-0029, (June 2016).

⁴Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, United States Senate, *Combatting the Opioid Epidemic: A Review of Anti-Abuse Efforts in Medicare and Private Health Insurance Systems* (Oct. 4, 2016).

⁵Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Death* (March 26, 2015). Opioid use disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress as indicated by at least 2 of 11 criteria occurring within a 12 month period. The criteria include opioids that are often taken in larger amounts or over a longer period of time than was intended, persistent desire or unsuccessful efforts to cut down or control opioid use, or a strong desire or urge to use opioids.

⁶Centers for Medicare & Medicaid Services, *Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy 2016* (Jan.5, 2017).

providers concerning effective pain management and appropriate opioid prescribing, as well as use of evidence-based prescribing guidelines. The strategy also outlines attempts to identify providers with a high risk of fraud, waste, and abuse in prescribing opioids and other drugs. CMS contracts with the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to monitor and analyze data to detect potential fraud, waste, and abuse, and to investigate such potential fraud, waste, and abuse in Medicare Parts C and D, among other activities.⁷

You asked us for information on CMS's activities related to reducing the misuse and overprescribing of opioids. We examined

1. how CMS oversees beneficiaries who receive opioid prescriptions under Medicare Part D, and
2. how CMS oversees providers who prescribe opioids to Medicare Part D beneficiaries.

To examine CMS oversight of beneficiaries who receive opioid prescriptions under Medicare Part D, we analyzed CMS documents, such as CMS's Opioid Misuse Strategy as well as letters, guidance, and other documents on the operation of the Part D program; and CMS data about the number of beneficiaries at risk of opioid overutilization. We also reviewed CDC guidelines for prescribing opioids. Further, we interviewed CMS officials involved in these efforts. This information helped us understand CMS procedures for identifying beneficiaries at risk of overuse of opioids, as well as to assess trends in such use. We also interviewed plan sponsors—private organizations under contract with CMS that provide the Part D drug benefit to Medicare beneficiaries—about their oversight role and the compliance programs they operate to safeguard the Part D program from fraud, waste, and abuse. In addition, we interviewed other stakeholders involved in opioid use and prescribing, including organizations that represent providers, pharmacies,

⁷Medicare Part C, also known as Medicare Advantage, is a private plan alternative to traditional Medicare, and covers all traditional Medicare services.

beneficiaries, and others to further understand issues related to opioid use.⁸

To examine CMS oversight of providers who prescribe opioids to Medicare Part D beneficiaries, we analyzed CMS and NBI MEDIC documents, such as Part D program guidance, and documents sent to plan sponsors about opioid prescribing patterns, as well as data about providers who prescribe a large amount of opioids. We also interviewed CMS officials and officials from NBI MEDIC about monitoring opioid prescribing. We used this information to understand CMS's and NBI MEDIC's procedures for identifying and addressing opioid overprescribing. We also interviewed the same plan sponsors and stakeholders identified above about issues related to opioid prescribing and CMS's role in addressing opioid overprescribing.

For both objectives, we compared the information we collected to CMS's stated goals and relevant federal internal control standards.⁹ We assessed the reliability of CMS and NBI MEDIC data by reviewing documents for potential inconsistencies and discussing the methodologies used to gather the data with officials from both CMS and NBI MEDIC. We determined that these data were sufficiently reliable for the purposes of our objectives.

We conducted this performance audit from October 2016 to October 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

⁸We interviewed officials from the largest six health care plan sponsors: Aetna, Cigna, CVS Health, Express Scripts, Humana, and UnitedHealth Group. We also interviewed 12 stakeholders that represent a range of perspectives on opioid use and prescribing patterns in Medicare: AARP, American Health Insurance Plans, American Society of Interventional Pain Physicians, Brandeis Prescription Drug Monitoring Program Training and Technical Assistance Center, Federation of State Medical Boards, National Association of Drug Diversion Investigators, National Association of Medicaid Directors, National Healthcare Antifraud Association, Pew Charitable Trust, Pharmaceutical Care Management Association, Physicians for Responsible Opioid Prescribing, and one expert on opioid abuse.

⁹GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014). Internal controls is a process affected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Opioids, such as hydrocodone, oxycodone, morphine, and methadone, can be prescribed to treat both acute and chronic pain. Because many opioids have a high potential for abuse and may lead to severe psychological or physical dependence, many of them are classified as Schedule II drugs under the Controlled Substances Act.¹⁰ The abuse of opioids has been associated with serious consequences, including addiction, overdose, and death.

Responsibilities of Medicare Part D Plan Sponsors, CMS, and NBI MEDIC

Medicare Part D plan sponsors are private organizations, such as health insurance companies and pharmacy benefit managers, contracted by CMS to provide outpatient drug benefit plans to Medicare beneficiaries. CMS provides guidance to plan sponsors that are responsible for establishing reasonable and appropriate drug utilization review (DUR) programs that assist in preventing misuse of prescribed medications in general, including the unsafe use of opioid pain medications. In 2013, CMS implemented the Medicare Part D opioid overutilization policy intended to improve medication safety. Through the Overutilization Monitoring System (OMS), CMS seeks to ensure that plan sponsors establish reasonable and appropriate DUR programs to prevent overutilization of opioids. CMS uses criteria in the OMS to identify high-risk use of opioids. Plan sponsors may, but are not required to, use these guidelines as part of their DUR.

CMS's Center for Program Integrity (CPI) oversees Part D program integrity and coordinates with other parts of CMS that monitor plan sponsor compliance with the Part D program. CPI has primary responsibility for overseeing NBI MEDIC, which is responsible for identifying and investigating potential Part D fraud, waste, and abuse, in

¹⁰Under the Controlled Substances Act, which was enacted in 1970, drugs are classified as controlled substances and placed into one of five schedules based on their medicinal value, potential for abuse, and risk of dependence. Schedule II drugs have the highest potential for abuse of any drugs approved for medical use.

general. NBI MEDIC handles complaints from beneficiaries and others, as well as requests from law enforcement; investigates providers and refers them to law enforcement as appropriate; and analyzes Part D program prescription drug event records and other data to identify patterns that may indicate fraud, waste, or abuse.¹¹ NBI MEDIC's responsibilities are for all Part D drugs and are not opioid-specific.

Drug Diversion

One concern associated with prescribed opioids is their diversion—that is, the redirection of prescription drugs for an illegal purpose such as recreational use or resale. Diversion can include selling prescription drugs that were obtained legally, transferring a legitimately prescribed opioid to family or friends who may be trying to self-medicate, or pretending to be in pain to obtain a prescription opioid due to an addiction. It is often associated with “doctor shopping,” the attempt to obtain large amounts of opioids through multiple providers, or from multiple pharmacies. Doctor shopping can be used to help support an individual's addiction or to obtain opioids for resale on the black market. Drug diversion can also include illicit prescribing, whereby providers—commonly known as “pill mills”—write unnecessary prescriptions or prescribe larger quantities than are medically necessary. Opioids are among the drugs with the highest potential for drug diversion.

CDC Guidelines for Prescribing Opioids

In 2016, CDC issued guidelines with recommendations for prescribing opioids in outpatient settings for chronic pain, based on consultation with experts and a review of scientific evidence.¹² CDC noted in the guidelines that primary care physicians have reported concerns about opioid misuse and addiction, and find managing patients with chronic pain a challenge, possibly because of insufficient training in prescribing opioids. According to the guidelines, most experts agreed that long-term opioid dosage of 50 milligrams (mg) morphine equivalent dose (MED) per day or more

¹¹A prescription drug event is recorded and submitted to CMS every time a Medicare beneficiary fills a prescription covered under Part D. These records include drug cost and payment information that enables CMS to administer and monitor the Part D benefit.

¹²Department of Health and Human Services, Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, Morbidity and Mortality Weekly Report, vol. 65, no. 1, (Atlanta, Ga.: March 18, 2016).

generally increases overdose risk without necessarily adding benefits for pain control or function.¹³ Experts also noted that daily opioid dosages close to or greater than 100 mg MED per day are associated with significant risks. The guidelines therefore recommended that providers use caution when prescribing opioids at any dose, carefully reassess evidence of individual benefits and risks when increasing the dosage to 50 mg MED per day or more, and either avoid or carefully justify dosage at 90 mg MED or more. In making these recommendations, CDC noted that there is not a dosage threshold below which the risk of overdose is eliminated, but found that dosages less than 50 mg MED would reduce the risk for a large portion of patients. CDC also noted that providers should use additional caution in prescribing opioids to patients aged 65 and older, because the drugs can accumulate in the body to toxic levels.

¹³CDC uses the term morphine milligram equivalents and CMS uses the term MED to mean the same thing. For purposes of this report, we use the term MED.

CMS Delegates Monitoring of Beneficiaries who Receive Opioid Prescriptions to Plan Sponsors, but Does Not Have Sufficient Information on Most Beneficiaries at Risk for Harm

CMS Delegates Monitoring of Individual Beneficiaries' Opioid Prescriptions to Plan Sponsors

CMS provides guidance to plan sponsors on how they should monitor opioid overutilization problems among Part D beneficiaries. The agency includes this guidance in its annual letters to plan sponsors, known as call letters; it also provided a supplemental memo to plan sponsors in 2012.¹⁴ Among other things, these guidance documents instructed plan sponsors to implement a retrospective drug utilization review (DUR) system to monitor beneficiary utilization starting in 2013.¹⁵ As part of the DUR systems, CMS requires plan sponsors to have methods to identify beneficiaries who are potentially overusing specific drugs or groups of drugs, including opioids.

Also in 2013, CMS created the Overutilization Monitoring System (OMS), which outlines criteria to identify beneficiaries with high-risk use of opioids and to oversee sponsors' compliance with CMS's opioid overutilization policy. Plan sponsors may use the OMS criteria for their DUR systems, but they have some flexibility to develop their own targeting criteria, within CMS guidance. The OMS considers beneficiaries to be at a high risk of

¹⁴Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, accessed December 21, 2016, <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf>; and Centers for Medicare & Medicaid Services, *Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D*, accessed April 25, 2017, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/HPMSSupplementalGuidanceRelated-toImprovingDURcontrols.pdf>.

¹⁵In addition to instructing plan sponsors to implement retrospective DUR systems, the guidance in the 2013 call letter includes information on other mechanisms to control overutilization. See <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf>.

opioid overuse when they meet all three of the following criteria: (1) receive a total daily MED greater than 120 mg for 90 consecutive days, (2) receive opioids prescriptions from four or more providers in the previous 12 months, and (3) receive opioids from four or more pharmacies in the previous 12 months.¹⁶ The criteria exclude beneficiaries with a cancer diagnosis and those in hospice care, for whom higher doses of opioids may be appropriate.

Officials from all six plan sponsors we interviewed confirmed they have a DUR system that specifically looks at opioids. In addition, to be consistent with CMS, all of the plan sponsors adopted criteria similar to the OMS, with some minor modifications—typically involving the number of months in which they measured beneficiaries' opioid prescriptions.

Through the OMS, CMS generates quarterly reports that list beneficiaries who meet all of the criteria and who are identified as high-risk and then distributes the reports to the plan sponsors. Plan sponsors are expected to review the list of identified beneficiaries, determine appropriate action, and then respond to CMS with information on their actions within 30 days. According to CMS officials, the agency also expects that plan sponsors will share any information with CMS on beneficiaries that they identify through their own DUR systems. Some actions plan sponsors may take include

- **Case management.** After plan sponsors identify beneficiaries with patterns of inappropriate opioid use and possible coordination of care issues through their DUR analysis, they may conduct case management. Case management may include an attempt to improve coordination issues, and often involves provider outreach, whereby the plan sponsor will contact the providers associated with the beneficiary to let them know that the beneficiary is receiving high levels of opioids and may be at risk of harm. In addition to outreach, officials from two of the six plan sponsors we interviewed told us they focus on provider education and one plan sponsor said they may

¹⁶These criteria are in effect through 2017. CMS announced in its April 3, 2017 call letter, *Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information*, revisions to the OMS criteria that will take effect in 2018, accessed April 4, 2017, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf>. Some of the beneficiaries that meet the OMS criteria may not be using the opioids themselves, but rather diverting them by either giving or selling them to others.

direct the providers to the CDC guidelines or other information to help reduce overutilization. Officials from two plan sponsors reported that they also reach out to beneficiaries to let them know they are receiving high levels of opioids and may be at risk of harm.

- **Beneficiary-specific point-of-sale (POS) edits.** When plan sponsors determine that a beneficiary is at risk for opioid harm, they may choose to implement a beneficiary-specific POS edit to prevent overutilization. Beneficiary-specific POS edits are restrictions that limit these beneficiaries to certain opioids and amounts. Pharmacists receive a message when a beneficiary attempts to fill a prescription that exceeds the limit in place for that beneficiary. CMS expects plan sponsors to report on the POS edits they use through CMS's Medicare Advantage and Prescription Drug System for information sharing and monitoring purposes. That way, if a beneficiary changes plans, the new plan sponsor will receive an alert about the beneficiary's record of POS edits. From February 2014 through March 10, 2016, there were 2,693 POS edits reported in that system for 2,520 beneficiaries.¹⁷
- **Formulary-level POS edits.** CMS expects plan sponsors to use formulary-level POS edits to prospectively prevent opioid overutilization. These edits alert providers who may not have been aware that their patients are receiving high levels of opioids from other doctors. CMS recommends these formulary-level edits to be used when a beneficiary has a cumulative opioid MED of at least 90 mg.¹⁸
- **Referrals for investigation.** According to the six plan sponsors we interviewed, the referrals can be made to NBI MEDIC or to the plan sponsor's own internal investigative unit, if they have one. After investigating a particular case, if a plan sponsor or NBI MEDIC determines that a beneficiary is suspected of diverting opioids, they may refer the case to the HHS-OIG, or a law enforcement agency, according to CMS, NBI MEDIC, and one plan sponsor.

¹⁷These are the most recent data available, because 2017 data will not be available until 2018. Some beneficiaries may be subject to multiple edits that apply in different situations.

¹⁸These edits may be soft edits, which can be overridden by the pharmacist, or hard edits, which require prescriber attestation through the coverage determination process. CMS recommends that soft edits be implemented with a threshold at levels greater than 90mg MED, and hard edits have a threshold at 200mg MED or more. While CMS expects plan sponsors to implement formulary-level edits, hard edits are not required.

- Pharmacy lock-ins.** Beginning in 2019, Medicare Part D plan sponsors will be able to restrict certain beneficiaries identified as at-risk for prescription drug abuse to a single pharmacy for all their opioid prescriptions, known as a pharmacy “lock in.”¹⁹ Some plan sponsors explained that they use pharmacy lock-ins for their commercial and Medicaid lines of business, and generally found them to be a useful tool for controlling opioid use.

Based on CMS’s use of the OMS and the actions taken by plan sponsors, CMS reported a decrease in the number of beneficiaries meeting the OMS criteria of high-risk—which agency officials consider an indication of success toward its goal of decreasing opioid use disorder. From calendar years 2011 through 2016, there was a 61 percent decrease in the number of beneficiaries meeting the OMS criteria.²⁰ (See table 1.)

Table 1: Part D Medicare Beneficiaries Who Meet Overutilization Monitoring System (OMS) Criteria for High Risk Opioid Use,^a Calendar Years 2011 and 2013-2016^b

Calendar year	Number of Part D enrollees	Number of Part D beneficiaries identified as high-risk under OMS criteria
2011	31,483,841	29,404
2013	37,842,632	25,347
2014	39,982,962	21,838
2015	41,835,016	15,651
2016	43,569,035	11,594

Source: Centers for Medicare & Medicaid Services. | GAO-18-15

^aNot all Part D beneficiaries who receive prescriptions for opioids use the drugs, but instead may divert them by giving or selling them to others. The OMS criteria in effect for these years identify beneficiaries that receive a daily morphine equivalent dose greater than 120 mg for 90 consecutive days, receive opioids from four or more providers in the previous 12 months, and receive opioids from four or more pharmacies in the previous 12 months. The criteria exclude beneficiaries with a cancer diagnosis and those in hospice care.

¹⁹A Part D beneficiary who is at-risk for prescription drug abuse is identified through the use of applicable clinical guidelines that indicate misuse or abuse of prescription drugs. See Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 704(a), 130 Stat. 695, 742 (2016). The act provides CMS with the authority to implement a lock-in program for prescribers and/or pharmacies in Medicare Part D for plan years beginning on or after January 1, 2019. CMS officials told us that they currently plan implementation by this statutory deadline.

²⁰According to CMS officials, the agency does not have 2012 data, because it used 2011 data as a benchmark to develop the OMS and did not officially implement the OMS until 2013.

^bCMS does not have 2012 data, because it used 2011 data as a benchmark to develop the OMS and did not officially implement OMS until 2013.

In addition to using the OMS as a monitoring tool to oversee plan sponsors' compliance with their DUR system requirements, CMS relies on patient safety measures to assess how well Part D plan sponsors are monitoring beneficiaries and taking appropriate actions. Specifically, CMS tracks data on plan sponsors' performance for 15 measures related to Part D patient safety that are developed and maintained by the Pharmacy Quality Alliance, and CMS communicates with plan sponsors about their performance.²¹ In 2016, CMS started tracking plan sponsors' performance on three Pharmacy Quality Alliance-approved patient safety measures that are directly related to opioids, which were

1. The proportion of beneficiaries that use opioids at high dosages (more than 120 mg MED for 90 days or longer) in persons without cancer or not in hospice care.
2. The proportion of beneficiaries that use opioids from multiple providers (four or more providers and four or more pharmacies) in persons without cancer or not in hospice care.
3. The proportion of beneficiaries that use opioids at high dosage and from multiple providers in persons without cancer or not in hospice care, and that meet both of the other measures.

The three measures are similar to the OMS criteria in that they identify beneficiaries with high dosages of opioids (120 mg MED) from multiple providers and pharmacies (four or more of each). However, there are a number of differences between these measures and the OMS. For example, the OMS counts actual beneficiaries, while the patient safety measures report member-years, which are adjusted to account for beneficiaries who are enrolled in a plan for only part of a year.²² In addition, these measures separately identify beneficiaries who fulfill each of those criteria individually. For example, data gathered on the first measure indicate that about 285,119 beneficiaries, counted as member-

²¹The Pharmacy Quality Alliance is a consensus-based, multi-stakeholder membership organization that collaboratively promotes appropriate medication use and develops strategies for measuring and reporting performance information related to medications. The alliance developed all but one of CMS's Part D patient safety measures, and that one measure is not related to opioid safety.

²²According to officials, in counting member-years, for example, if a beneficiary is enrolled in a plan for 6 out of 12 months of the year, he or she would count as only 0.5 member years.

years across all Part D plans, received high doses (more than 120 mg MED) of opioids for 90 days or longer during calendar year 2016. CMS also uses these data in different ways from how it uses OMS data. The OMS criteria were developed and maintained by CMS to identify patients at risk for harm who may warrant case management and to examine opioid use trends across the Part D program, including progress toward its goal of decreasing opioid use disorder. In contrast, CMS officials told us that the agency uses the patient safety measures to assess plan sponsor performance. The patient safety measures also serve as a tool for Part D sponsors to compare their performance to overall averages, and to track progress in improving these measures over time. CMS also tracks sponsors' progress in improving the measures, according to agency officials. Each quarter, CMS contacts plan sponsors who have the lowest performance on each measure and expects them to respond about actions they take to improve performance. Beginning in April 2017, the agency began distributing to plan sponsors the beneficiary-level files for the patient safety measures. CMS officials said that these files provide a complete list of beneficiaries included in each of the measures.²³

CMS Does Not Have Sufficient Information on Most Beneficiaries Potentially at Risk for Harm

While CMS tracks the total number of beneficiaries who meet all three OMS criteria as part of its opioid overutilization oversight across the Part D program, it does not have comparable information on most beneficiaries who may be at risk for harm. CMS has goals to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion in its Opioid Misuse Strategy, but OMS does not track the number of beneficiaries with prescriptions for high doses of opioids unless those beneficiaries are also receiving them both from four or more providers and from four or more pharmacies; and agency officials told us that CMS has no plans for OMS to begin doing so. According to CDC guidelines, long-term use of high opioid dosages—those above a MED of 90 mg per day—are associated with significant risk of harm and should be avoided if possible.

Based on the CDC guidelines, outreach to Part D plan sponsors, and CMS analyses of Part D data, CMS has revised its current OMS criteria to

²³The list of beneficiaries based on patient safety measure data is different from that provided to plan sponsors under OMS.

include more at-risk beneficiaries beginning in 2018. The new OMS criteria define a high user as having an average daily MED greater than 90 mg for any duration, and who receives opioids from four or more providers and four or more pharmacies, or from six or more providers regardless of the number of pharmacies, for the prior 6 months.²⁴

According to CMS officials, the revised OMS criteria, like the current criteria, are intended to identify the beneficiaries it determined are at the greatest risk of harm: those who may lack coordinated care as a result of using multiple pharmacies and providers. CMS officials also noted that the revised criteria are intended to limit the increase in the number of beneficiaries for whom plan sponsors are expected to take action, such as case management, to avoid overburdening plan sponsors with unreasonable workload levels.²⁵

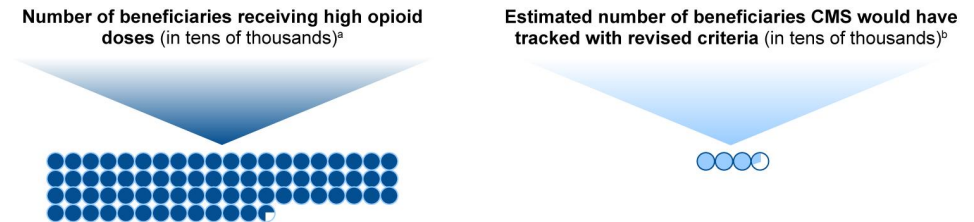
While the revised criteria will help identify beneficiaries who CMS determined are at the highest risk of opioid misuse and therefore may need case management by plan sponsors, they will not provide information on most Part D beneficiaries who may also be at risk of harm. In developing the revised criteria, CMS conducted a one-time analysis that estimated there were 727,016 beneficiaries with an average MED of 90 mg or more, for any length of time during a 6 month measurement period in 2015, regardless of the number of providers or pharmacies used. These beneficiaries may be at risk of harm from opioids, according to CDC guidelines, and therefore tracking the number of these beneficiaries over time could help CMS to determine whether it is making progress toward meeting the goals specified in its Opioid Misuse Strategy. However, CMS officials told us that the agency does not keep track of these beneficiaries, and does not have plans to do so as part of OMS. Instead, CMS uses the number of beneficiaries who meet the OMS criteria as an indicator of progress toward its goals. CMS estimated that 33,223 beneficiaries would have met its revised criteria based on 2015

²⁴According to CMS officials, the changes are partially in response to CDC's 2016 guidelines. The CDC guidelines noted that patients are at risk of harm above 50 mg MED and that providers should generally avoid increasing dosage to more than 90 mg MED of opioids, regardless the number of providers or pharmacies.

²⁵The revised OMS criteria are expected to more than double the number of beneficiaries that plan sponsors are expected to review, determine appropriate actions to take, and respond to CMS. Based on 2015 data, CMS found that 15,651 beneficiaries met the current OMS criteria and 33,223 beneficiaries would have met the revised criteria. CMS officials told us that, based on information gathered in a pilot in 2012, providers were not receptive to case-management in cases involving high doses of opioids with a single prescriber.

data, which is a much smaller number than the estimated 727,016 beneficiaries at risk of harm from opioids.²⁶ (See fig. 1.)

Figure 1: CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria



Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. | GAO-18-15

^aThis number includes beneficiaries with an average opioid morphine equivalent dose of 90 milligrams or more within a 6-month measurement period.

^bThis number is an estimate of how many beneficiaries would have met CMS’s revised Overutilization Monitoring System (OMS) criteria. CMS calculated these totals by applying the revised OMS criteria to 2015 Part D data.

In 2016, CMS began to gather information from its patient safety measures on the number of beneficiaries who use more than 120 mg MED of opioids for 90 days or longer, regardless of the number of providers and pharmacies. However, this information does not include all at-risk beneficiaries, because the threshold is more lenient than indicated in CDC guidelines and CMS’s new criteria for OMS. Specifically, CMS’s one-time analysis of 2015 data indicated that 727,016 beneficiaries received prescriptions with an average MED of 90 mg or more for any length of time during a 6-month measurement period. In contrast, the 2016 patient safety measures reports identified significantly fewer beneficiaries, 285,119, in its most comparable measure—member years for opioid prescriptions at 120 mg MED for 90 consecutive days or longer. According to CMS officials, CMS shared feedback with the Pharmacy Quality Alliance to consider updating the threshold to 90 mg MED to align with CDC guidelines and the revised OMS criteria. CMS officials said the agency will consider adopting these updates once complete. In addition, while CMS monitors the patient safety measure data, these data are relatively new. CMS officials told us that, as a result, the agency does not

²⁶In July 2017, the HHS-OIG conducted a separate review using an MED of 120 mg, while CMS’s review used an MED of 90 mg. HHS-OIG compared the number of beneficiaries who received an average MED of greater than 120 mg a day for at least three months (501,008 beneficiaries) with the number of beneficiaries considered to be “doctor shopping”, which the HHS-OIG defined as meeting CMS’s initial OMS criteria (22,308 beneficiaries).

yet have enough data to report changes over time toward its goals to reduce the risk of opioid use disorders, overdoses, and inappropriate prescribing.

Neither the data gathered as part of OMS, nor patient safety measures gathered so far are adequate to provide CMS with the information necessary to track progress toward meeting its goal of reducing harm from opioids. While tracking a smaller number of beneficiaries in OMS is useful for targeting resource-intensive plan sponsor actions, keeping track of the larger number of beneficiaries at risk of harm from high doses of opioids—greater than 90 mg MED for any duration regardless of the number of providers and pharmacies—could provide CMS with information on progress toward its goals without additional monitoring by plan sponsors. Doing so would also be consistent with federal internal control standards, which require agencies to use quality information to achieve objectives and address risks.²⁷ Without tracking the number of beneficiaries who receive potentially dangerous levels of opioids regardless of the number of providers or pharmacies, and then examining changes in that number over time, CMS lacks key information that would be useful to determine if it is making progress toward reducing the risk of opioid harm for Part D beneficiaries.

²⁷See [GAO-14-704G](#).

CMS Oversees Providers through its Contractor and Plan Sponsors, but Efforts Do Not Specifically Monitor Opioid Prescriptions

CMS's Contractor and Plan Sponsors Seek to Identify Inappropriate Prescribing of Drugs with High Potential for Abuse, Including Opioids

CMS oversees providers who prescribe opioids to Medicare Part D beneficiaries through its contractor, NBI MEDIC, and the Part D plan sponsors.

NBI MEDIC's Data Analyses to Identify Outlier Providers

CMS requires NBI MEDIC to identify providers who prescribe high amounts of drugs classified as Schedule II under the Controlled Substances Act, which indicates a high potential for abuse and includes many opioids. Using prescription drug event data, NBI MEDIC conducts a peer comparison of providers' prescribing practices to identify outlier providers—the highest prescribers of Schedule II drugs, which include, but are not limited to, opioids. NBI MEDIC's initial analyses focuses on providers associated with at least 100 prescription drug event records or at least \$100,000 in total Part D payments for Schedule II drugs over the course of one year.²⁸ These providers are then classified as outliers if they are listed as high in both the number of prescription drug records per prescriber and prescriptions per beneficiary by specialty within each state.²⁹ NBI MEDIC reports to CMS on the providers with the highest number of prescriptions identified by the analysis. Beginning with the October 2016 report, CMS began sharing NBI MEDIC's prescriber outlier report with the plan sponsors quarterly to supplement their own investigations of potential fraud, waste, and abuse. According to data from NBI MEDIC, the number of outlier providers identified has generally

²⁸Every time a beneficiary fills a prescription under Medicare Part D, a prescription drug plan sponsor must submit a summary record called the prescription drug event data to CMS. The PDE data are not the same as individual drug claim transactions, but are summary extracts using CMS-defined standard fields.

²⁹The 30-day equivalent was used to normalize prescriptions of varying durations by totaling the days' supply from the prescription drug event records and dividing it by 30.

remained stable except for an increase in 2015. NBI MEDIC and CMS officials said this increase occurred when a commonly used opioid, hydrocodone, was added to the analysis after it was reclassified as a Schedule II drug.

NBI MEDIC's Other Projects

NBI MEDIC gathers data on Medicare Part C and Part D and uses its Predictive Learning Analytics Tracking Outcome (PLATO) system to conduct a number of data analysis projects. According to NBI MEDIC officials, these PLATO projects seek to identify potential fraud by examining data on provider behaviors. In addition, according to officials, PLATO is capable of allowing NBI MEDIC to share information on providers with plan sponsors. NBI MEDIC officials stated there are two current PLATO projects that include a focus on some opioids.

- **The TRIO data project** identifies providers who prescribe beneficiaries a combination of an opioid, a benzodiazepine, and the muscle relaxant Carisoprodol.³⁰ This well-known combination of drugs is used to increase the effects of opioids.
- **The Pill Mill data project** identifies providers with abnormal prescribing behavior in authorizing controlled substances, including opioids, absent medical necessity. To identify providers potentially operating a pill mill, 17 risk factors are considered, including the number of beneficiaries for whom a provider prescribed controlled substances, the quantity of these medications, the number of beneficiaries who travel long distances to receive medications, and the number of beneficiaries treated for drug abuse or misuse at emergency rooms.

Another analysis that NBI MEDIC conducts, according to its officials, is the Transmucosal Immediate Release Fentanyl project, which identifies potential improper payments for medicines containing fentanyl, a prescription opioid pain reliever. NBI MEDIC looks for instances of this

³⁰Benzodiazepines are drugs prescribed to treat conditions like anxiety, insomnia, and seizures. Examples of these drugs include alprazolam, clonazepam, and lorazepam.

drug being prescribed to beneficiaries who do not have cancer combined with breakthrough pain, the only approved use for this drug.³¹

NBI MEDIC's Investigations to Identify Fraud, Waste, and Abuse

NBI MEDIC officials said they conduct investigations to assist CMS in identifying cases of potential fraud, waste, and abuse among providers for Medicare Part C and Part D. The investigations are prompted by complaints from plan sponsors, calls to NBI MEDIC's call center, NBI MEDIC's analysis of outlier providers, or from one of its other data analysis projects.³² As part of its investigations, NBI MEDIC officials said they may access data from Medicare Part B, which includes coverage for doctors' services and outpatient care, to determine whether providers' diagnoses coincide with their prescriptions. Officials added that they investigate inappropriate prescribing by reviewing Part D prescription records, medical records, or PLATO data; or by conducting background checks, interviewing beneficiaries, or conducting site visits, among other activities. NBI MEDIC data indicates that the total number of its investigations decreased from 2013 to 2016, which, according to NBI MEDIC officials, occurred because it increased activities related to data analysis and collaboration with plan sponsors.

NBI MEDIC's Referrals

After identifying providers engaged in potential fraudulent overprescribing, NBI MEDIC officials said they may refer cases to agencies for further investigation and potential prosecution, such as the HHS-OIG, state and local law enforcement, the Federal Bureau of Investigations, or the Drug Enforcement Administration.³³ In 2016, NBI MEDIC data showed that it

³¹According to the Food and Drug Administration, Transmucosal Immediate Release Fentanyl medicines are used to manage breakthrough pain in adults with cancer who are routinely taking other opioid pain medicines around-the-clock for pain. Breakthrough pain is pain that comes on suddenly for short periods of time and is not alleviated by a patient's normal pain management plan.

³²The NBI MEDIC call center is designed to receive complaints regarding any suspected fraud, waste, and abuse in Medicare Parts C or D.

³³For cases of inappropriate prescribing, CMS can revoke a provider's eligibility for Medicare Part B payments. Providers do not currently enroll in Medicare Part D, but will be required to do so by January 2019. After that time, CMS expects to have the ability to remove providers inappropriately prescribing from the Medicare Part D program. 79 Fed. Reg. 29844 (May 23, 2014); 80 Fed. Reg. 25958 (May 6, 2015) (enforcement delayed until January 1, 2019).

referred a total of 119 cases to the HHS-OIG and 48 to agencies within the Department of Justice, including the Federal Bureau of Investigations and the Drug Enforcement Agency. CMS officials told us that they do not routinely track the results of individual cases referred by NBI MEDIC to other agencies. A 2016 Senate committee report indicated that the HHS-OIG declined and returned more than half of the cases referred to it from 2013 through 2015.³⁴ According to NBI MEDIC officials, cases may be rejected for reasons such as not meeting prosecutorial thresholds for evidence, or HHS-OIG does not having enough staff to take on the workload. NBI MEDIC officials told us that HHS-OIG does not always inform NBI MEDIC of its reasons for declining the referrals.

Plan Sponsor Monitoring of Providers

CMS requires all plan sponsors to adopt and implement an effective compliance program, which must include measures to prevent, detect, and correct Part C or Part D program noncompliance, as well as fraud, waste, and abuse. CMS communicates guidance for plan sponsor's compliance programs through Chapter 9 of CMS's Prescription Drug Benefit Manual and in annual letters.³⁵ CMS's guidance focuses broadly on prescription drugs, and does not specifically address opioids.

To detect fraud, waste, and abuse among providers, plan sponsors told us they use their own data analysis and criteria, as well as NBI MEDIC's list of outlier providers. For example, plan sponsors identify providers suspected of fraud, waste, or abuse by looking for certain characteristics, such as providers who have a large number of beneficiaries traveling from a different zip code to receive prescriptions, or providers who prescribe large quantities of commonly abused drugs with no associated medical claims to support the prescriptions. Once the suspected providers are identified, plan sponsors said that they conduct their own investigations to determine if there is sufficient evidence of inappropriate prescribing.

Plan sponsors told us they may choose to take a number of actions based on these investigations, including choosing to refer the case to NBI MEDIC. Additionally, if appropriate, plan sponsors can educate providers

³⁴Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, United States Senate, *Combating the Opioid Epidemic*.

³⁵Chapter 9-Rev. 16, 01-11-13

about prescribing guidelines and best practices, or notify them that their patients may be doctor shopping, in order to improve coordination of care. They may also terminate a provider from their plan if they find evidence of fraud or abuse.

CMS Lacks Information Necessary for Oversight of Opioid Prescribing and Plan Sponsors' Monitoring Activities

CMS lacks the information necessary to adequately determine the number providers potentially overprescribing opioids, and therefore cannot determine the effectiveness of efforts to achieve the agency's goals of reducing the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion. CMS's oversight actions focus broadly on Schedule II drugs rather than specifically on opioids. For example, NBI MEDIC's analyses to identify outlier providers do not indicate the extent to which they may be overprescribing opioids specifically. According to CMS officials, they direct NBI MEDIC to focus on Schedule II drugs, because they have a high potential for abuse, whether they are opioids or other drugs. However, without specifically identifying opioids in these analyses—or an alternate source of data—CMS lacks data on providers who prescribe high amounts of opioids, and therefore cannot assess progress toward meeting its goals related to opioid use.

CMS also lacks key information necessary for oversight of opioid prescribing, because it does not require plan sponsors to report to NBI MEDIC or CMS cases of fraud, waste, and abuse; cases of overprescribing; or any actions taken against providers.³⁶ Plan sponsors collect information on cases of fraud, waste, and abuse, and can choose to report this information to NBI MEDIC or CMS. PLATO, a voluntary reporting system, is one way that plan sponsors can report information to NBI MEDIC or CMS, and share with other plan sponsors about providers they investigate and about actions they take. While CMS receives some information from plan sponsors who voluntarily report their actions, it does not know the full extent to which plan sponsors have identified providers who have prescribed high amounts of opioids and taken action to reduce overprescribing. Without this information, CMS cannot determine the extent to which plan sponsors are taking action to reduce overprescribing, making it difficult to assess progress in this area. CMS officials told us that they receive reports on what information plan sponsors enter into PLATO. However, according to these officials, they do not have information on all actions taken by plan sponsors; therefore, CMS does

³⁶According to CMS officials, the agency's regulations currently make reporting inappropriate prescribing and any actions against providers voluntary for plan sponsors. See 42 C.F.R. § 423.504(b)(4)(vi)(G)(3).

not know how often plan sponsors use PLATO or what proportion of actions they report.³⁷

A 2015 HHS-OIG report recommended that CMS require plan sponsors to report all potential fraud and abuse to CMS and/or NBI MEDIC.³⁸ CMS disagreed with this recommendation, and stated that plan sponsors currently have several options for referring incidents, that CMS has worked with plan sponsors to improve organizational performance, and that plan sponsors regularly share information on best practices for prevention and detection of fraud. The HHS-OIG continues to recommend that CMS require reporting due to the lack of a comprehensive set of data needed to monitor providers' inappropriate prescribing.

Without specifically monitoring providers' overprescribing of opioids, CMS cannot determine if its efforts, or the efforts of NBI MEDIC and plan sponsors, are helping to contribute to its goals related to opioid use. Federal internal control standards require agencies to conduct monitoring activities and to use quality information to achieve objectives and address risks.³⁹ Without adequate information on providers' opioid prescribing patterns in Part D, CMS is unable to determine whether its related oversight efforts—including such efforts by NBI MEDIC or Part D plan sponsors—are effective or should be adjusted.

Conclusions

A large number of Medicare Part D beneficiaries use prescription opioids, and reducing the inappropriate prescribing of these drugs is a key part of CMS's strategy to decrease the risk of opioid use disorder, overdoses, and deaths. Despite working to identify and decrease egregious opioid use behavior—such as doctor shopping—among beneficiaries in Medicare Part D, CMS lacks the necessary information to effectively determine the full number of beneficiaries at risk of opioid harm. CMS

³⁷CMS places some limits on access to PLATO, and officials from four out of the six plan sponsors we interviewed told us that these limits make it challenging to use and update PLATO as effectively as possible. CMS officials told us that they would consider any requests from plan sponsors to remove these limits, but also indicated that CMS and plan sponsors have not communicated about this possibility.

³⁸Department of Health and Human Services, Office of Inspector General, *Ensuring the Integrity of Medicare Part D*, OEI-03-15-00180 (Washington, D.C.: June 2015).

³⁹See [GAO-14-704G](#).

recently expanded the number of beneficiaries for whom it expects plan sponsors to conduct intervention efforts, such as case management, and has begun to collect additional patient safety measure data on beneficiaries at risk of harm from opioids. However, these efforts have not yet provided CMS with sufficient data to track how many beneficiaries are receiving large doses of opioids, and therefore are at risk of harm. Without expanding and enhancing its data collection efforts to include information on more at-risk beneficiaries, CMS cannot fully assess whether it is making sufficient progress toward its goals of reducing opioid use disorders, overdoses, inappropriate prescribing, and drug diversion.

CMS's efforts to oversee opioid prescribing specifically are also inadequate. CMS directs NBI MEDIC to focus its analyses on providers who prescribe any drugs with a high risk of abuse, but NBI MEDIC does not specifically track those providers who prescribe opioids. Absent opioid-specific monitoring, CMS cannot assess whether its efforts to reduce opioid overprescribing are effective, or if opioid prescribing patterns are changing over time. In addition, neither CMS nor NBI MEDIC can be sure they have complete information about providers potentially overprescribing opioids to Part D beneficiaries, because plan sponsors are not required to report to CMS or NBI MEDIC all potential fraud and abuse incidents or actions sponsors have taken against providers. As a result, CMS lacks information about plan sponsors' monitoring of providers who overprescribe opioids, and is therefore unable to determine if the agency's and plan sponsors' efforts are successful in achieving CMS's goals.

Recommendations

We are making the following three recommendations to CMS.

- The Administrator of CMS should gather information over time on the number of beneficiaries at risk of harm from opioids, including those who receive high opioid morphine equivalent doses regardless of the number of pharmacies or providers, as part of assessing progress over time in reaching the agency's goals related to reducing opioid use. (Recommendation 1)
- The Administrator of CMS should require its contractor, NBI MEDIC, to identify and conduct analyses on providers who prescribe high amounts of opioids separately from providers who prescribe high amounts of any Schedule II drug. (Recommendation 2)

-
- The Administrator of CMS should require plan sponsors to report to CMS on investigations and other actions taken related to providers who prescribe high amounts of opioids. (Recommendation 3)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for comment. HHS provided written comments, which are reprinted in appendix I, and technical comments, which we incorporated as appropriate. In its written comments, HHS described its efforts to reduce opioid overutilization in Medicare Part D. HHS noted that these efforts include a medication safety approach to improve care coordination for high-risk beneficiaries using opioids, quality metrics for plan sponsors, and data analysis of prescribing patterns to target potential fraud, waste, and abuse. For example, HHS noted that CMS adopted a Medicare Part D opioid overutilization policy in 2013 that provided specific guidance to Part D plans on effective drug utilization review programs to reduce overutilization of opioids. As described in our report, CMS's opioid overutilization policy requires sponsors to implement retrospective drug utilization review programs to identify beneficiaries who are potentially overusing opioids. Among other things, sponsors may choose to implement beneficiary-specific edits that limit high-risk beneficiaries to certain opioids and amounts, and CMS expects them to use formulary-level edits to alert providers when their patients are receiving high levels of opioids from other doctors.

HHS also concurred with two of our three recommendations.

- HHS concurred with our recommendation that CMS gather information over time on the number of beneficiaries at risk of harm from opioids, as part of assessing progress toward agency goals. HHS commented that CMS tracks beneficiaries who meet these criteria through the patient safety measures. However, while these patient safety measures are a potential source of this information, they currently do not include all at-risk beneficiaries, because the opioid use threshold they use (120 mg MED for 90 days or longer) is more lenient than indicated in CDC guidelines or in CMS's revised OMS criteria. In addition, while CMS uses the patient safety measures to assess plan sponsor performance, the data are relatively new, and CMS has not yet used them to report progress over time toward its goals.

- HHS concurred with our recommendation that CMS require NBI MEDIC to gather separate data on providers who prescribe high amounts of opioids, and HHS noted that it intends to work with NBI MEDIC to identify trends in outlier prescribers of opioids.
- HHS did not concur with our recommendation that CMS require plan sponsors to report on investigations and other actions taken related to providers who prescribe high amounts of opioids. HHS noted that plan sponsors have the responsibility to detect and prevent fraud, waste, and abuse and that CMS reviews cases when it conducts audits. HHS also stated that it seeks to balance requirements on plan sponsors when considering new regulatory requirements. As noted in our report, plan sponsors conduct investigations and take actions against providers, and some plan sponsors report actions to CMS and NBI MEDIC. However, without complete reporting, such as reporting from all plan sponsors on the actions they take to reduce overprescribing, CMS is missing key information that could help assess progress in this area. Due to the importance of this information, we continue to believe that CMS should require plan sponsors to report on the actions they take.

As agreed with your offices, 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 HHS and the Administrator of CMS. 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 CurdaE@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 II.



Elizabeth H. Curda
Director, Health Care

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

**Appendix I: 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

SEP 07 2017

Elizabeth Curda
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Curda:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm*" (GAO-18-15).

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

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: PRESCRIPTION OPIOIDS: MEDICARE NEEDS TO EXPAND OVERSIGHT EFFORTS TO REDUCE THE RISK OF HARM (GAO-18-15)

The Department of Health & Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. HHS recognizes that the epidemic use of opioids among Medicare beneficiaries is a pressing challenge.

Medicare beneficiaries enrolled in Part D receive prescription drug coverage through private health plans (Part D plans); either through standalone prescription drug plans that add this coverage to traditional Medicare or through Medicare Advantage Prescription Drug plans that combine prescription drug and medical coverage. Therefore, Medicare Advantage plans and Part D sponsors are a key part of HHS' opioid risk reduction strategy.

HHS has implemented multiple initiatives that work together to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion in the Medicare program. These strategies include a medication safety approach to improve care coordination for high risk beneficiaries using opioids, quality metrics for plan sponsors, and data analysis of prescribing patterns to target potential fraud, waste, and abuse.

HHS has significantly expanded its oversight efforts of Part D plans to ensure that they identify and address opioid overutilization among beneficiaries. In 2013, CMS adopted a robust Medicare Part D opioid overutilization policy to provide specific guidance to plans on how to employ more effective drug utilization review programs to reduce overutilization of opioids and maintain access to needed medications among beneficiaries. Part D plans are expected to use multiple tools including safety edits at the point of dispensing, better formulary management, and case management with beneficiaries' physicians aimed at coordinated care. The Comprehensive Addiction and Recovery Act provides HHS with the authority to allow Part D plans to implement pharmacy and prescriber lock-in for their Medicare Part D beneficiaries, subject to appropriate protections. Pharmacy and prescriber lock-in will enable plans and providers to better coordinate care for the beneficiaries who meet the guidelines for lock-in. HHS plans to implement pharmacy and prescriber lock-in by the statutory deadline.

In addition, HHS created the Overutilization Monitoring System in 2013 which helps HHS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications. To assist the plans in their efforts, HHS provides quarterly reports of high risk beneficiaries to Part D plans through the Overutilization Monitoring System, and plans update HHS on their actions taken to reduce the risk of overutilization. There has been a 61 percent decrease in beneficiaries meeting the Overutilization Monitoring System criteria from calendar years 2011-2016. It is an encouraging sign that there has been a reduction in enrollees who are at the highest risk of harm for opioid overuse.

HHS also uses quality measures developed by the Pharmacy Quality Alliance to assess reductions in opioid overuse across the Medicare Part D program. HHS tracks overall statistics and progress, as well as plan performance, related to the proportion of beneficiaries using high doses of opioids, those receiving opioids from multiple providers or pharmacies, and those who

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: PRESCRIPTION OPIOIDS: MEDICARE NEEDS TO EXPAND OVERSIGHT EFFORTS TO REDUCE THE RISK OF HARM (GAO-18-15)

meet both measures' criteria. HHS communicates with plans about their performance on each of these measures, including sharing information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure should report actions they will take to improve performance.

HHS also has a number of ongoing data initiatives focused on providers. HHS utilizes the Medicare Drug Integrity Contractor to identify and investigate potential fraud and abuse and to refer cases to law enforcement agencies when necessary. In particular, the Medicare Drug Integrity Contractor identifies prescribers of drug combinations known to increase the effects of opioids, those with prescribing behavior that indicates they may be operating a pill mill, and those who prescribe Transmucosal Immediate-Release Fentanyl to non-cancer patients. HHS shares this information with plans to assist in their investigation of fraud, waste, and abuse.

HHS has a number of authorities to help curtail prescribing practices which maliciously place patients at risk of harm. These authorities are employed judiciously to prevent bad actors who fail to meet Medicare requirements from harming beneficiaries. These efforts have helped HHS protect the most vulnerable beneficiaries from the harms associated with opioid overuse.

HHS is actively engaged in addressing the opioid abuse epidemic and is committed to implementing effective tools in Medicare Part D. We will continue to work with beneficiary and advocacy groups, health plans, our federal partners, and other interested stakeholders to address this devastating epidemic.

GAO's recommendations and HHS' responses are below.

GAO Recommendation

HHS should gather information over time on the number of beneficiaries at risk of harm from opioids, including those who receive high opioid morphine equivalent doses regardless of the number of pharmacies or providers, as part of assessing progress over time in reaching the agency's goals related to reducing opioid use.

HHS Response

HHS concurs with this recommendation.

Through the Pharmacy Quality Alliance patient safety measures, HHS currently tracks beneficiaries in each Medicare Part D plan who meet the individual risk criteria, which includes those receiving high doses of opioids regardless of number of providers or pharmacies. HHS shares this information with plans and monitors rates for the program as a whole.

GAO Recommendation

HHS should require its contractor, the Medicare Drug Integrity Contractor, to identify and conduct analyses on providers who prescribe high amounts of opioids separately from providers who prescribe high amounts of any of any Schedule II drug.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: PRESCRIPTION OPIOIDS: MEDICARE NEEDS TO EXPAND OVERSIGHT EFFORTS TO REDUCE THE RISK OF HARM (GAO-18-15)

HHS Response

HHS concurs with this recommendation.

HHS appreciates the severity of the opioid crisis, and has a vested interest in partnering with providers to develop innovative solutions to address this challenge. HHS intends to work with the Medicare Drug Integrity Contractor to identify trends in which types of providers are outlier prescribers of opioids.

GAO Recommendation

HHS should require plan sponsors to report to HHS on investigations and other actions taken related to providers who prescribe high amounts of opioids.

HHS Response

HHS does not concur with this recommendation.

Plan sponsors are already held accountable for detecting and preventing fraud and abuse as CMS requires plan sponsors to have effective compliance measures that include measures to detect, correct, and prevent fraud, waste, and abuse. During compliance program audits, CMS reviews cases of reported fraud, waste, and abuse. Audit results provide an indication of plan sponsors' performance and allow CMS to target guidance and education. In addition, plan sponsors report potential fraud to the Medicare Drug Integrity Contractor.

HHS seeks to balance requirements on plans and providers when considering new regulatory requirements. HHS will continue to measure and report to plans those providers who prescribe high amounts of opioids.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Elizabeth H. Curda, (202) 512-7114 or CurdaE@gao.gov

Staff Acknowledgments

In addition to the contact named above, Will Simerl (Assistant Director), Carolyn Feis Korman (Analyst-in-Charge), Amy Andresen, Samantha Pawlak, and Patricia Roy made key contributions to this report. Also contributing were Muriel Brown, Drew Long, and Emily Wilson.

Appendix III: Accessible Data

Data Tables

Accessible Data for CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria

Number of beneficiaries receiving high opioid doses:

- 727,016

Estimated number of beneficiaries CMS would have tracked with revised criteria:

- 33,223

Accessible Data for Figure 1: CMS Estimates of 2015 Part D Beneficiaries with High Opioid Doses and Those Who Would Have Met Revised Overutilization Monitoring Criteria

Number of beneficiaries receiving high opioid doses:

- 727,016

Estimated number of beneficiaries CMS would have tracked with revised criteria:

- 33,223

Agency Comment Letter

Accessible Text for Appendix I: Comments from the
Department of Health and Human Services

Page 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation

Washington, DC 20201

SEP 07 2017

Elizabeth Curda

Director, Health Care

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

Dear Ms. Curda:

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

Sincerely,

Barbara Pisaro Clark

Acting Assistant Secretary for Legislation

Attachment

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GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: PRESCRIPTION OPIOIDS: MEDICARE NEEDS TO EXPAND OVERSIGHT EFFORTS TO REDUCE THE RISK OF HARM (GAO-18-15)

The Department of Health & Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. HHS recognizes that the epidemic use of opioids among Medicare beneficiaries is a pressing challenge.

Medicare beneficiaries enrolled in Part D receive prescription drug coverage through private health plans (Part D plans); either through standalone prescription drug plans that add this coverage to traditional Medicare or through Medicare Advantage Prescription Drug plans that combine prescription drug and medical coverage. Therefore, Medicare Advantage plans and Part D sponsors are a key part of HHS' opioid risk reduction strategy.

HHS has implemented multiple initiatives that work together to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion in the Medicare program. These strategies include a medication safety approach to improve care coordination for high risk beneficiaries using opioids, quality metrics for plan sponsors, and data analysis of prescribing patterns to target potential fraud, waste, and abuse.

HHS has significantly expanded its oversight efforts of Part D plans to ensure that they identify and address opioid overutilization among beneficiaries. In 2013, CMS adopted a robust Medicare Part D opioid overutilization policy to provide specific guidance to plans on how to employ more effective drug utilization review programs to reduce overutilization of opioids and maintain access to needed medications among beneficiaries. Part D plans are expected to use multiple tools including safety edits at the point of dispensing, better formulary management, and case management with beneficiaries' physicians aimed at coordinated care. The Comprehensive Addiction and Recovery Act provides HHS with the authority to allow Part D plans to implement pharmacy and prescriber lock-in for their Medicare Part D beneficiaries, subject to appropriate protections. Pharmacy and prescriber lock-in will enable plans and providers to better coordinate care for the beneficiaries who meet the guidelines for lock-in. HHS plans to implement pharmacy and prescriber lock-in by the statutory deadline.

In addition, HHS created the Overutilization Monitoring System in 2013 which helps HHS ensure that sponsors have established reasonable and appropriate drug utilization management programs to assist in preventing overutilization of certain prescribed medications. To assist the plans in their efforts, HHS provides quarterly reports of high risk beneficiaries to Part D plans through the Overutilization Monitoring System, and plans update HHS on their actions taken to reduce the risk of overutilization. There has been a 61 percent decrease in beneficiaries meeting the Overutilization Monitoring System criteria from calendar years 2011-2016.

It is an encouraging sign that there has been a reduction in enrollees who are at the highest risk of harm for opioid overuse.

HHS also uses quality measures developed by the Pharmacy Quality Alliance to assess reductions in opioid overuse across the Medicare Part D program. HHS tracks overall statistics and progress, as well as plan performance, related to the proportion of beneficiaries using high doses of opioids, those receiving opioids from multiple providers or pharmacies, and those who

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meet both measures' criteria. HHS communicates with plans about their performance on each of these measures, including sharing information about specific beneficiaries identified, and plan sponsors with the lowest rating on each measure should report actions they will take to improve performance.

HHS also has a number of ongoing data initiatives focused on providers. HHS utilizes the Medicare Drug Integrity Contractor to identify and investigate potential fraud and abuse and to refer cases to law enforcement agencies when necessary. In particular, the Medicare Drug Integrity Contractor identifies prescribers of drug combinations known to increase the effects of opioids, those with prescribing behavior that indicates they may be operating a pill mill, and those who prescribe Transmucosal Immediate-Release Fentanyl to non-cancer patients. HHS shares this information with plans to assist in their investigation of fraud, waste, and abuse.

HHS has a number of authorities to help curtail prescribing practices which maliciously place patients at risk of harm. These authorities are employed judiciously to prevent bad actors who fail to meet Medicare requirements from harming beneficiaries. These efforts have helped HHS protect the most vulnerable beneficiaries from the harms associated with opioid overuse.

HHS is actively engaged in addressing the opioid abuse epidemic and is committed to implementing effective tools in Medicare Part D. We will continue to work with beneficiary and advocacy groups, health plans, our federal partners, and other interested stakeholders to address this devastating epidemic.

GAO's recommendations and HHS' responses are below.

GAO Recommendation

HHS should gather information over time on the number of beneficiaries at risk of harm from opioids, including those who receive high opioid morphine equivalent doses regardless of the number of pharmacies or providers, as part of assessing progress over time in reaching the agency's goals related to reducing opioid use.

HHS Response

HHS concurs with this recommendation.

Through the Pharmacy Quality Alliance patient safety measures, HHS currently tracks beneficiaries in each Medicare Part D plan who meet the individual risk criteria, which includes those receiving high doses of opioids regardless of number of providers or pharmacies. HHS shares this information with plans and monitors rates for the program as a whole.

GAO Recommendation

HHS should require its contractor, the Medicare Drug Integrity Contractor, to identify and conduct analyses on providers who prescribe high amounts of opioids separately from providers who prescribe high amounts of any of any Schedule II drug.

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HHS Response

HHS concurs with this recommendation.

HHS appreciates the severity of the opioid crisis, and has a vested interest in partnering with providers to develop innovative solutions to address this challenge. HHS intends to work with the Medicare Drug Integrity Contractor to identify trends in which types of providers are outlier prescribers of opioids.

GAO Recommendation

HHS should require plan sponsors to report to HHS on investigations and other actions taken related to providers who prescribe high amounts of opioids.

HHS Response

HHS does not concur with this recommendation.

Plan sponsors are already held accountable for detecting and preventing fraud and abuse as CMS requires plan sponsors to have effective compliance measures that include measures to detect, correct, and prevent fraud, waste, and abuse. During compliance program audits, CMS reviews cases of reported fraud, waste, and abuse. Audit results provide an indication of plan sponsors' performance and allow CMS to target guidance and education. In addition, plan sponsors report potential fraud to the Medicare Drug Integrity Contractor.

HHS seeks to balance requirements on plans and providers when considering new regulatory requirements. HHS will continue to measure and report to plans those providers who prescribe high amounts of opioids.

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