PREScription opioids

Medicare Should Expand Oversight Efforts to Reduce the Risk of Harm

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What GAO Found

The Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (HHS), 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 from opioid use.

- CMS provides guidance to plan sponsors 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 focused on beneficiaries who do all the following: (1) receive prescriptions of high doses of opioids, (2) receive prescriptions from four or more providers, and (3) fill prescriptions at four or more pharmacies. According to CMS, this approach focused actions on beneficiaries the agency determined to have the highest risk of harm.

- 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 overutilization monitoring 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 for the Medicare and Medicaid programs, which includes activities to reduce the risk of harm to beneficiaries from opioid use.

What GAO Recommends

In the October 2017 report, GAO made three recommendations 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. CMS concurred with the first two recommendations, but not with the third. GAO continues to believe the recommendation is valid, as discussed in the report and in this statement.


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.
Chairman Jenkins, Ranking Member Lewis, and Members of the Subcommittee:

I am pleased to be here to discuss our recently released report on oversight of opioid prescribing in the Medicare program.¹ 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.² 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.³ 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 what was intended; and questionable prescribing practices by providers, including those in Medicare.⁴

³Department 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.
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. In 2016, CDC issued guidelines with recommendations for prescribing opioids in outpatient settings for chronic pain. The guidelines recommended that providers use caution when prescribing opioids at any dose, carefully reassess evidence of individual benefits and risks when increasing opioid dosage to 50 mg morphine-equivalent dose (MED) per day or more, and either avoid or carefully justify dosage at 90 mg MED or more. CDC guidelines 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. 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 Medicare Part D. The strategy includes the agency’s plans to address concerns about beneficiary use of opioids and the prescribing of opioids by providers.

My remarks today discuss the findings and recommendations from our report on CMS efforts to oversee prescription opioids. Accordingly, this testimony focuses on (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. For our report, we reviewed CMS opioid utilization and prescriber data, CMS guidance for plan sponsors, and CMS’s strategy to prevent opioid misuse. We also interviewed officials from CMS, the six largest Part D plan sponsors—private organizations, such as health insurance companies.

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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 (Mar. 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 taking opioids 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.


contracted by CMS to provide outpatient drug benefit plans to Medicare beneficiaries—and 12 national associations selected to represent insurance plans, pharmacy benefit managers, physicians, patients, and regulatory and law enforcement agencies. More detailed information on our objectives, scope, and methodology for that work can be found in the issued report. We conducted the work on which this statement is based 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 the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

CMS Delegates
Monitoring of Beneficiaries who Receive Opioid Prescriptions to Plan Sponsors, but Does Not Have Sufficient Information on Those Most at Risk for Harm
Our October 2017 report found that CMS provides guidance to Medicare Part D plan sponsors on how the plan sponsors 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. 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. 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. At the time of our review, the OMS considered beneficiaries to be at a high risk of opioid overuse when they met all three of the following criteria:

1. received a total daily MED greater than 120 mg for 90 consecutive days,
2. received opioid prescriptions from four or more providers in the previous 12 months, and

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10In 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.
3. received opioids from four or more pharmacies in the previous 12 months.\textsuperscript{11}

The criteria excluded beneficiaries with a cancer diagnosis and those in hospice care, for whom higher doses of opioids may be appropriate.

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. We found that some actions plan sponsors may take include

- **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.

- **Beneficiary-specific point-of-sale (POS) edits.** 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.

- **Formulary-level POS edits.** These edits alert providers who may not have been aware that their patients are receiving high levels of opioids from other doctors.

- **Referrals for investigation.** According to the six plan sponsors we interviewed, the referrals can be made to CMS’s National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC), which is responsible for identifying and investigating potential Part D fraud, waste, and abuse, or to the plan sponsor’s own internal investigative

\textsuperscript{11}These criteria are in effect through 2017. CMS announced in its April 3, 2017 call letter the revisions to the OMS criteria that will take effect in 2018. See \textit{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}, accessed April 4, 2017. \url{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.
unit, if they have one. After investigating a particular case, they may refer the case to the HHS-OIG or a law enforcement agency, according to CMS, NBI MEDIC, and one plan sponsor.

Based on CMS’s use of the OMS and the actions taken by plan sponsors, CMS reported a 61 percent decrease from calendar years 2011 through 2016 in the number of beneficiaries meeting the OMS criteria of high risk—from 29,404 to 11,594 beneficiaries—which agency officials consider an indication of success toward its goal of decreasing opioid use disorder.

In addition, we found that CMS relies on separate patient safety measures developed and maintained by the Pharmacy Quality Alliance to assess how well Part D plan sponsors are monitoring beneficiaries and taking appropriate actions. In 2016, CMS started tracking plan sponsors’ performance on three patient safety measures that are directly related to opioids. The three measures are similar to the OMS criteria in that they identify beneficiaries with high dosages of opioids (120 mg MED), beneficiaries that use opioids from multiple providers and pharmacies, and beneficiaries that do both. However, one difference between these approaches is that the patient safety measures separately identify beneficiaries who fulfill each criterion individually.

Our October 2017 report also found that 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 receive high doses of opioids—regardless of the number of providers and pharmacies used—and who therefore may be at risk for harm, according to CDC guidelines. These guidelines note that long-term use of high doses of opioids—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 include more at-risk beneficiaries beginning in 2018. The new OMS

12The 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.
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.\textsuperscript{13} Based on 2015 data, CMS found that 33,223 beneficiaries would have met these revised criteria. 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, OMS will not provide information on the total number of 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 total 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 to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion. However, CMS officials told us that the agency does not keep track of the total number of these beneficiaries, and does not have plans to do so as part of OMS. (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

- Number of beneficiaries receiving high opioid doses (in tens of thousands)\textsuperscript{a}
- Estimated number of beneficiaries CMS would have tracked with revised criteria (in tens of thousands)\textsuperscript{b}

Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. \textsuperscript{GAO-18-336T}

\textsuperscript{a}This number includes beneficiaries with an average opioid morphine equivalent dose of 90 milligrams or more within a 6-month measurement period.

\textsuperscript{b}This 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.

\textsuperscript{13}According 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.
We also found that 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. The patient safety measures identified 285,119 such beneficiaries—counted as member-years—in 2016.14 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 OMS criteria. Because neither the OMS criteria nor the patient safety measures include all beneficiaries potentially at risk of harm from high opioid doses, we recommended that CMS should gather information over time on the total number of beneficiaries 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 concurred with our recommendation.

Our October 2017 report found that 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 Schedule II drugs, which include but are not limited to opioids.15 Using prescription drug data, NBI MEDIC conducts a peer comparison of providers’ prescribing practices to identify outlier providers—the highest prescribers of Schedule II drugs. NBI MEDIC reports the results to CMS.

- NBI MEDIC’s other projects. NBI MEDIC gathers and analyzes data on Medicare Part C and Part D, including projects using the Predictive Learning Analytics Tracking Outcome (PLATO) system.16 According to NBI MEDIC officials, these PLATO projects seek to identify potential fraud by examining data on provider behaviors.

14Patient safety measures count member-years, which account for beneficiaries who are enrolled in a Part D plan for only part of a year.

15Under 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.

16Medicare Part C, also known as Medicare Advantage, is a private plan alternative to traditional Medicare, and covers all traditional Medicare services.
NBI MEDIC’s investigations to identify fraud, waste, and abuse. NBI MEDIC officials 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; suspected fraud, waste, or abuse reported to NBI MEDIC’s call center; NBI MEDIC’s analysis of outlier providers; or from one of its other data analysis projects.

NBI MEDIC’s referrals. After identifying providers engaged in potential fraudulent overprescribing, NBI MEDIC officials said they may refer cases to law enforcement agencies or the HHS-OIG for further investigation and potential prosecution.

Plan sponsors’ 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’s guidance focuses broadly on prescription drugs, and does not specifically address opioids.

Our report concluded that although these efforts provide valuable information, CMS lacks all the information necessary to adequately oversee opioid prescribing. 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 these drugs 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 reducing opioid use, which would be consistent with federal internal control standards. Federal internal control standards require agencies to conduct monitoring activities and to use quality information to achieve objectives and address risks. As a result, we recommended that CMS require NBI MEDIC to gather separate data on providers who prescribe high amounts of opioids. This would allow CMS to better identify those providers who are inappropriately and potentially fraudulently overprescribing opioids. HHS

17GAO, 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.
agreed, and noted that it intends to work with NBI MEDIC to identify trends in outlier prescribers of opioids.

Our report also found that 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. Plan sponsors collect information on cases of fraud, waste, and abuse, and can choose to report this information to NBI MEDIC or CMS. While CMS receives information from plan sponsors who voluntarily report their actions, it does not know the full extent to which plan sponsors have identified providers who prescribe high amounts of opioids, or the full extent to which sponsors have taken action to reduce overprescribing. We concluded that without this information, it is difficult for CMS to assess progress in this area, which would be consistent with federal internal control standards. In our report, we recommended that CMS require plan sponsors to report on investigations and other actions taken related to providers who prescribe high amounts of opioids. HHS did not concur with this recommendation. 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. However, without complete reporting—such as reporting from all plan sponsors on the actions they take to reduce overprescribing—we believe that CMS is missing key information that could help assess progress in this area. Due to the importance of this information for achieving the agency’s goals, we continue to believe that CMS should require plan sponsors to report on the actions they take to reduce overprescribing.

In conclusion, a large number of Medicare Part D beneficiaries use potentially harmful levels of 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 Medicare Part D beneficiaries, CMS lacks the

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18According 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).
necessary information to effectively determine the full number of beneficiaries at risk of harm, as well as other information that could help CMS assess whether its efforts to reduce opioid overprescribing are effective. It is important that health care providers help patients to receive appropriate pain treatment, including opioids, based on the consideration of benefits and risks. Access to information on the risks that Medicare patients face from inappropriate or poorly monitored prescriptions, as well as information on providers who may be inappropriately prescribing opioids, could help CMS as it works to improve care.

Chairman Jenkins, Ranking Member Lewis, and Members of the Subcommittee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

If you or your staff members have any questions concerning this testimony, please contact me at (202) 512-7114 or CurdaE@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this statement. Other individuals who made key contributions to this testimony include Will Simerl (Assistant Director), Carolyn Feis Korman (Analyst-in-Charge), Amy Andresen, Drew Long, Samantha Pawlak, Vikki Porter, and Emily Wilson.
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