



## Testimony

Before the Subcommittee on Health  
Care, Committee on Finance, U.S.  
Senate

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# PRESCRIPTION OPIOIDS

## Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries

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# GAO Highlights

Highlights of [GAO-18-585T](#), a testimony before the Subcommittee on Health Care, Committee on Finance, U.S. Senate

## Why GAO Did This Study

Misuse of prescription opioids can lead to overdose and death. Medicare and Medicaid, two of the nation's largest health care programs, provide prescription drug coverage that can include opioids. GAO and others have reported on inappropriate activities and risks associated with these prescriptions.

This statement is based on GAO's October 2017 report (GAO-18-15) and discusses (1) CMS oversight of Medicare beneficiaries who receive opioid prescriptions under Part D, and (2) CMS oversight of providers who prescribe opioids to Medicare Part D beneficiaries. For the October 2017 report, 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

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. 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 and in this statement.

View [GAO-18-585T](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or [deniganmacauleym@gao.gov](mailto:deniganmacauleym@gao.gov).

May 29, 2018

# PRESCRIPTION OPIOIDS

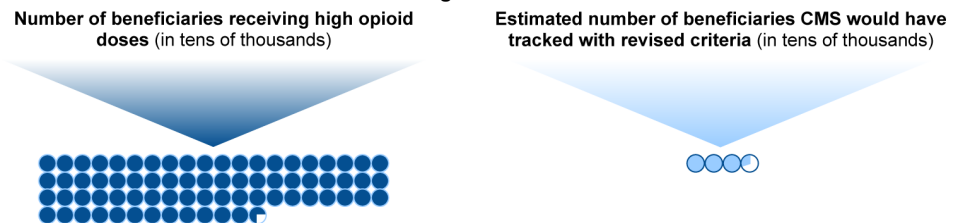
## Medicare Needs Better Information to Reduce the Risk of Harm to Beneficiaries

### What GAO Found

In October 2017, GAO found that the Centers for Medicare & Medicaid Services (CMS) provided guidance on the monitoring of Medicare beneficiaries who received opioid prescriptions to plan sponsors—private organizations that implement the Medicare drug benefit, Part D—but it lacked information on most beneficiaries at risk of harm from opioid use. Specifically, GAO found that

- CMS provided guidance to plan sponsors on how they should monitor opioid overutilization among Medicare Part D beneficiaries, and required them to implement drug utilization review systems that use criteria similar to CMS's. Prior to 2018, the agency's criteria focused on beneficiaries who did all the following: (1) received prescriptions of high doses of opioids, (2) received prescriptions from four or more providers, and (3) filled 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. For 2018, CMS revised the criteria to include more at-risk beneficiaries.
- CMS's criteria, including recent revisions, did not provide sufficient information about the larger population of potentially at-risk beneficiaries. CMS estimated that, in 2015, 727,016 beneficiaries would have received high doses of opioids regardless of the number of providers or pharmacies, but only 33,223 would have met its revised criteria. In 2016, CMS began to collect information on some of these beneficiaries using a higher dosage threshold for opioid use. However, based on Centers for Disease Control and Prevention guidelines, CMS's approach also missed some who could be at risk of harm. As a result, CMS had limited information to assess progress against the goals of the Medicare and Medicaid programs' Opioid Misuse Strategy, which includes activities to reduce risk of harm to beneficiaries.

### 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-18-585T

CMS provided oversight on prescribing of drugs at high risk of abuse through a variety of projects, but did not analyze data specifically on opioids. According to CMS officials, CMS and plan sponsors identified providers who prescribed 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 did not identify providers who may be inappropriately prescribing large amounts of opioids separately from other drugs, and did not require plan sponsors to report actions they take when they identified such providers. As a result, CMS lacked 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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Chairman Toomey, Ranking Member Stabenow, and Members of the Subcommittee:

I am pleased to be here to discuss our October 2017 report on oversight of opioid prescribing in the Medicare program.<sup>1</sup> 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 and Medicaid beneficiaries. The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), reported that from 1999 to 2013 the rate of drug poisoning deaths from prescription opioids nearly quadrupled, and that in 2016, alone, there were more than 17,000 overdose deaths from prescription opioids.<sup>2</sup>

The Centers for Medicare and Medicaid Services (CMS), also within HHS, administers Medicare and Medicaid, two of the nation's largest health care programs. 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. Within Medicare is Part D, the program's outpatient prescription drug benefit.<sup>3</sup> Medicaid is a joint federal-state program that finances health care coverage for

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<sup>1</sup>See GAO, *Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm*, [GAO-18-15](#) (Washington, D.C.: Oct. 6, 2017). In January of 2018, we also testified before the Subcommittee on Oversight, Committee on Ways and Means, House of Representatives on the findings and recommendations from this report. See GAO, *Prescription Opioids: Medicare Should Expand Oversight Efforts to Reduce the Risk of Harm*, [GAO-18-336T](#) (Washington, D.C.: Jan. 17, 2018).

<sup>2</sup>See Department 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); and P. Seth, L. Scholl, et. al., *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants—United States, 2015-2016*, Morbidity and Mortality Weekly Report, vol. 67, no. 12, Centers for Disease Control and Prevention (Mar. 30, 2018).

<sup>3</sup>Medicare consists of Parts A, B, C, and the Part D prescription drug program. Parts A and B are known as traditional Medicare or Medicare fee-for-service. Medicare Part C, also known as Medicare Advantage, is a private plan alternative to traditional Medicare, and covers all traditional Medicare services.

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certain low-income and medically needy individuals.<sup>4</sup> Due to concerns about adequacy of oversight, both Medicare and Medicaid are on our list of high-risk programs.<sup>5</sup>

HHS's Office of Inspector General (HHS-OIG) reported that 14.4 million people (about one-third) who participated in Medicare Part D in 2016 received at least one prescription for opioids, and that Part D spending for opioids in 2016 was almost \$4.1 billion.<sup>6</sup> We 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.<sup>7</sup>

The Medicaid program also covers opioid prescriptions for its beneficiaries. In our prior work, we have reported on potentially inappropriate activities involving Medicaid's prescription drug coverage. In 2017, for example, we reported on prescriptions for opioid pain medication among Medicaid beneficiaries. In that report, we noted that while opioid pain medication can constitute proper medical care for beneficiaries suffering from painful conditions, the use of these medications among Medicaid beneficiaries with diagnosed opioid abuse or dependence raises concerns about potential inappropriate

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<sup>4</sup>Within broad federal requirements, states have significant flexibility to design and implement their Medicaid programs based on their unique needs, resulting in 56 distinct programs. Medicaid programs are administered by the 50 states, the District of Columbia, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. These programs are administered at the state level and overseen at the federal level by CMS.

<sup>5</sup>See GAO, *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, [GAO-17-317](#) (Washington, D.C.: Feb. 15, 2017).

<sup>6</sup>Department 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).

<sup>7</sup>See GAO, *Medicare Part D: Instances of Questionable Access to Prescription Drugs*, [GAO-11-699](#) (Washington, D.C.: Sept. 6, 2011); and *Medicare Program Integrity: CMS Pursues Many Practices to Address Prescription Drug Fraud, Waste, and Abuse*, [GAO-15-66](#) (Washington, D.C.: Oct. 24, 2014). See also 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).

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prescribing.<sup>8</sup> In addition, in a July 2015 report, we found indicators of potential Medicaid prescription-drug fraud and abuse, such as doctor shopping.<sup>9</sup>

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.<sup>10</sup> In 2016, CDC issued guidelines with recommendations for prescribing opioids in outpatient settings for chronic pain.<sup>11</sup> 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 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, CMS issued its Opioid Misuse Strategy for the Medicare and Medicaid programs, including Medicare Part D.<sup>12</sup> The strategy includes the agency's plans to address concerns about beneficiary use of opioids and the prescribing of opioids by providers.

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<sup>8</sup>GAO, *Medicaid Expansion: Behavioral Health Treatment Use in Selected States in 2014*, [GAO-17-529](#) (Washington, D.C.: June 22, 2017).

<sup>9</sup>GAO, *Medicaid: Additional Reporting May Help CMS Oversee Prescription-Drug Fraud Controls*, [GAO-15-390](#) (Washington, D.C.: July 8, 2015).

<sup>10</sup>Department 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.

<sup>11</sup>Department 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.: Mar. 18, 2016).

<sup>12</sup>Centers for Medicare & Medicaid Services, *Centers for Medicare & Medicaid Services (CMS) Opioid Misuse Strategy 2016* (Jan. 5, 2017).

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My remarks today discuss the findings and recommendations from our 2017 report on CMS efforts to oversee prescription opioids in Medicare.<sup>13</sup> Accordingly, this testimony focuses on how:

- (1) CMS oversees beneficiaries who receive opioid prescriptions under Medicare Part D, and
- (2) 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—private organizations, such as health insurance companies, contracted by CMS to provide outpatient drug benefit plans to Medicare beneficiaries—and CMS’s strategy to prevent opioid misuse. We also interviewed officials from CMS, 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 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.

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<sup>13</sup>See [GAO-18-15](#).

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## CMS Delegated Monitoring of Beneficiaries who Receive Opioid Prescriptions to Plan Sponsors, but Did Not Have Sufficient Information on Those Most at Risk for Harm

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### CMS Delegated Monitoring of Individual Beneficiaries' Opioid Prescriptions to Plan Sponsors

Our October 2017 report found that CMS provided guidance to Medicare Part D plan sponsors on how they should monitor opioid overutilization problems among Part D beneficiaries. The agency included this guidance in its annual letters to plan sponsors, known as call letters; it also provided a supplemental memo to plan sponsors in 2012.<sup>14</sup> 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.<sup>15</sup> As part of the DUR systems, CMS required plan sponsors to have methods to identify beneficiaries who were potentially overusing specific drugs or groups of drugs, including opioids.

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<sup>14</sup>Centers 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>.

<sup>15</sup>In 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>.

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Also in 2013, CMS created the Overutilization Monitoring System (OMS), which outlined 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 had 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 health care providers in the previous 12 months, and
3. received opioids from four or more pharmacies in the previous 12 months.<sup>16</sup>

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

We found that through the OMS, CMS generated quarterly reports that list beneficiaries who met all of the criteria and who were identified as high-risk, and then distributed the reports to the plan sponsors. Plan sponsors were 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 expected plan sponsors to share any information with CMS on beneficiaries that they identified through their own DUR systems. We found that some actions plan sponsors may take included the following:

- **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

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<sup>16</sup>These criteria were 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 *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. <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.



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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 was responsible for identifying and investigating potential Part D fraud, waste, and abuse, or to the plan sponsor's own internal investigative 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 considered an indication of success toward its goal of decreasing opioid use disorder.

In addition, we found that CMS relied on separate patient safety measures developed and maintained by the Pharmacy Quality Alliance to assess how well Part D plan sponsors were monitoring beneficiaries and taking appropriate actions.<sup>17</sup> In 2016, CMS started tracking plan sponsors' performance on three patient safety measures that were directly related to opioids. The three measures were similar to the OMS criteria in that they identified 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

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<sup>17</sup>The 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.

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approaches was that the patient safety measures separately identified beneficiaries who fulfill each criterion individually.

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

Our October 2017 report also found that CMS tracked the total number of beneficiaries who met all three OMS criteria as part of its opioid overutilization oversight across the Part D program. However, the agency did 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’s 2016 guidelines. These guidelines noted 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 criteria define a high user as an individual

- having an average daily MED greater than 90 mg for any duration; and
- receiving 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.<sup>18</sup>

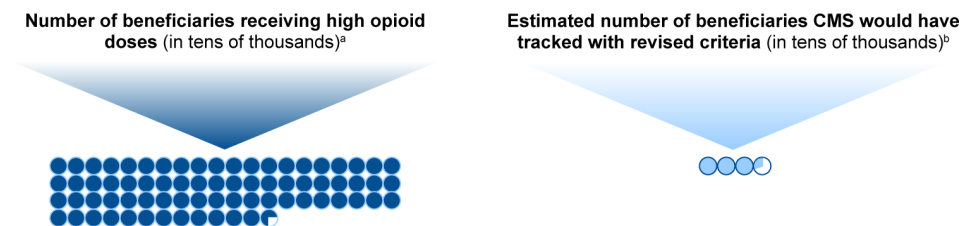
Based on 2015 data, CMS found that 33,223 beneficiaries would have met these revised criteria. While the revised criteria would help identify beneficiaries who CMS determined are at the highest risk of opioid misuse and therefore may need case management by plan sponsors, they did not provide information on the total number of Part D beneficiaries who may 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. According to the CDC guidelines, these beneficiaries may be at risk of harm from opioids, and

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<sup>18</sup>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.

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 did not keep track of the total number of these beneficiaries, and did 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**



Source: GAO analysis of Centers for Medicare & Medicaid Service (CMS) data. | GAO-18-585T

<sup>a</sup>This number includes beneficiaries with an average opioid morphine equivalent dose of 90 milligrams or more within a 6-month measurement period.

<sup>b</sup>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.

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.<sup>19</sup> However, this information did not include all at-risk beneficiaries, because the threshold was more lenient than indicated in CDC guidelines and CMS’s new OMS criteria. Because neither the OMS criteria nor the patient safety measures included 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.

<sup>19</sup>Patient safety measures count member-years, which account for beneficiaries who are enrolled in a Part D plan for only part of a year.

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

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 required NBI MEDIC to identify providers who prescribe high amounts of Schedule II drugs, which include but are not limited to opioids.<sup>20</sup> Using prescription drug data, NBI MEDIC conducted a peer comparison of providers’ prescribing practices to identify outlier providers—the highest prescribers of Schedule II drugs—and reported the results to CMS.
- **NBI MEDIC’s other projects.** NBI MEDIC gathered and analyzed data on Medicare Part C and Part D, including projects using the Predictive Learning Analytics Tracking Outcome (PLATO) system. According to NBI MEDIC officials, these PLATO projects sought to identify potential fraud by examining data on provider behaviors.
- **NBI MEDIC’s investigations to identify fraud, waste, and abuse.** NBI MEDIC officials conducted investigations to assist CMS in identifying cases of potential fraud, waste, and abuse among providers for Medicare Part C and Part D. The investigations were 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 required 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 focused broadly on prescription drugs, and did not specifically address opioids.

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<sup>20</sup>Under 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.

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Our report concluded that although these efforts provided valuable information, CMS lacked information necessary to adequately oversee opioid prescribing. CMS's oversight actions focused broadly on Schedule II drugs rather than specifically on opioids. For example, NBI MEDIC's analyses to identify outlier providers did not indicate the extent to which they may be overprescribing opioids specifically. According to CMS officials, they directed 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 lacked 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.<sup>21</sup> 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 agreed, and in April 2018 reported that it is working with NBI MEDIC to separately identify outlier prescribers of opioids.

In addition, our 2017 report found that CMS also lacked key information necessary for oversight of opioid prescribing, because it did 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.<sup>22</sup> Plan sponsors collected information on cases of fraud, waste, and abuse, and could choose to report this information to NBI MEDIC or CMS. While CMS receives information from plan sponsors who voluntarily reported their actions, it did not know the full extent to which plan sponsors had identified providers who prescribed high amounts of opioids, or the full extent to which sponsors had taken action to reduce overprescribing. We concluded that without this information, it was difficult for CMS to assess progress in this area, which would be consistent with federal internal

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<sup>21</sup>GAO, *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.

<sup>22</sup>According 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).

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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.

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## Conclusions

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 has been 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 lacked the 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.

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Chairman Toomey, Ranking Member Stabenow, 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.

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## GAO Contacts and Staff Acknowledgements

If you or your staff members have any questions concerning this testimony, please contact me at (202) 512-7114 or [DeniganMacauleyM@gao.gov](mailto:DeniganMacauleyM@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) and Carolyn Feis Korman (Analyst-in-Charge). Also contributing were Amy Andresen, George Bogart, Andrew Furillo, Drew Long, and Vikki Porter.

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## Congressional Relations

Orice Williams Brown, Managing Director, [WilliamsO@gao.gov](mailto:WilliamsO@gao.gov), (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

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## Public Affairs

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