U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

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Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing

Key Takeaways:

- ✓ *One in three Medicare Part D beneficiaries received a prescription opioid in 2016*
- ✓ *About 500,000 beneficiaries received high amounts of opioids*
- ✓ *Almost 90,000 beneficiaries are at serious risk; some received extreme amounts of opioids, while others appeared to be doctor shopping*
- ✓ *About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk*

Opioid abuse and overdose deaths are at epidemic levels in the United States. In 2015, the number of opioid-related deaths exceeded 33,000 for the first time.[1] Nearly half of these deaths involved prescription opioids.

Opioids include narcotics intended to manage pain from surgery, injury, or illness. They can create a euphoric effect, which makes them vulnerable to abuse and misuse (i.e., taking opioids in a way other than prescribed). Although opioids can be appropriate under certain circumstances, the Office of Inspector General (OIG) and others are concerned about fraud, abuse, and misuse of opioids, including those obtained under Medicare Part D. Part D is the optional prescription drug benefit for Medicare beneficiaries. In 2016, it covered 43.6 million beneficiaries.

This data brief is part of a larger strategy by OIG to fight the opioid crisis and address one of its top priority outcomes—to protect Medicare beneficiaries—and the community as a whole—from prescription drug abuse. Previous OIG work called attention to increased spending for commonly abused opioids.[2] OIG has also highlighted the problem of drug diversion—the redirection of prescription drugs for an illegal purpose, such as recreational use or resale.[3]

In addition to the risk of abuse, misuse, and diversion, opioids carry a number of health risks. Side effects from using opioids may include respiratory depression, confusion, tolerance, and physical dependence.[4] For seniors, long-term use of prescription opioids also increases the likelihood of falls and fractures.[5] For these reasons, it is essential that Medicare Part D beneficiaries only receive medically necessary opioids in the appropriate amounts.

Prescribers play a crucial role in ensuring that beneficiaries receive appropriate amounts of opioids. To help inform prescribers, the Centers for Disease Control and Prevention (CDC)

recently published guidelines on prescribing opioids to patients with chronic pain.[6] The guidelines recommend that prescribers use caution when ordering opioids at any dosage and avoid dosages that are equivalent to 90 mg or more of morphine a day.[7] In addition, the Centers for Medicare & Medicaid Services (CMS) has initiated a number of projects to address opioid misuse and inappropriate prescribing. For instance, CMS identifies Part D beneficiaries who are potentially overutilizing opioids and who may be in need of case management.[8] Despite these efforts, concerns remain about beneficiaries receiving high amounts of opioids through Part D.

This data brief builds on OIG's previous work and includes in-depth analysis of opioid utilization among Medicare Part D beneficiaries.[9] It provides baseline data on the extent to which beneficiaries receive extreme amounts of opioids and appear to be "doctor shopping." The analysis looks at the morphine equivalent dose (MED) received by each beneficiary, which equates all of the various opioids and strengths into one standard value. This data brief also identifies prescribers who have questionable opioid prescribing patterns.

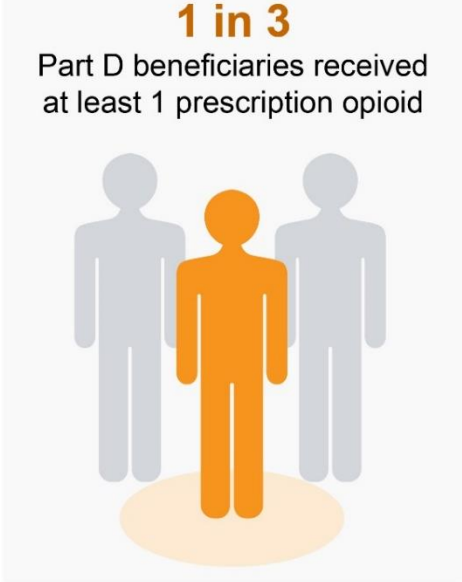
RESULTS

One in three Medicare Part D beneficiaries received opioids in 2016

In 2016, one out of every three beneficiaries received at least one prescription opioid through Medicare Part D. In total, 14.4 million of the 43.6 million beneficiaries enrolled in Medicare Part D received opioids. Medicare Part D paid almost $4.1 billion for 79.4 million opioid prescriptions for these beneficiaries. The vast majority of these opioids (80 percent) were Schedule II or III controlled substances, meaning they have the highest potential for abuse among legally available drugs.[10]

The most commonly prescribed opioids were tramadol, hydrocodone-acetaminophen (including the brand-name version, Vicodin), and oxycodone-acetaminophen (including the brand-name version, Percocet). Part D beneficiaries received about 15 million prescriptions for tramadol 50 mg, which is a Schedule IV drug.[11] Beneficiaries also received several million prescriptions for various strengths of hydrocodone-acetaminophen, a Schedule II drug, and for oxycodone-acetaminophen 5 mg, another Schedule II drug. See Exhibit 2.

Exhibit 1



Source: OIG analysis of Medicare Part D data, 2017.

Several States had higher proportions of beneficiaries receiving opioids than the Nation overall, which was 33 percent. Alabama and Mississippi had the highest proportions, with almost half of the State's Part D beneficiaries receiving at least one opioid—46 percent and 45 percent,

Exhibit 2: Most Common Opioids in Part D, by Number of Prescriptions, 2016

* Tablets also contain 325 mg of acetaminophen.
Source: OIG analysis of Medicare Part D data, 2017.

respectively. Arkansas had 44 percent of beneficiaries receiving opioids, while Oklahoma, Tennessee, and Louisiana each had 42 percent. The lowest proportions were in Hawaii (21 percent) and New York (22 percent).

In addition, 1 in 10 Medicare Part D beneficiaries nationwide received opioids on a regular basis. Specifically, 5 million beneficiaries received opioids for 3 months or more in 2016. Research shows that the risk of opioid dependence increases substantially for patients receiving opioids continuously for 3 months.[12] Of these 5 million beneficiaries, 3.6 million received opioids for 6 or more months and nearly 610,000 received opioids for the entire year.

Half a million Part D beneficiaries received high amounts of opioids in 2016

A total of 501,008 beneficiaries received high amounts of opioids through Medicare Part D in 2016. This does not include beneficiaries who had cancer or were in hospice care. Each of the 501,008 beneficiaries received an average morphine equivalent dose (MED) of greater than 120 mg a day for at least 3 months. MED is a measure that equates all the various opioids and strengths into one standard value. A daily MED of 120 mg is equivalent to taking 12 tablets a day of Vicodin 10 mg or 16 tablets a day of Percocet 5 mg. These dosages far exceed the amounts that the manufacturers recommend for both of these drugs.[13] They also exceed the 90 mg MED level that CDC recommends avoiding for patients with chronic pain.[14]

The most commonly prescribed opioid for beneficiaries with high amounts was oxycodone 30 mg. One in five beneficiaries who received a high amount of opioids had at least one prescription for oxycodone 30 mg. Oxycodone is one of the prescription opioids most commonly involved in law enforcement cases.[15]

Although beneficiaries may receive opioids for legitimate purposes, these high amounts raise concern. Many experts have noted that opioid dosages should not be increased over a MED of 90 mg a day without careful justification.[16] Moreover, opioids carry other health risks including respiratory depression, constipation, drowsiness, and confusion. Older adults may also be at an increased risk of injury, as research has shown that the risk of fracture may increase as drug dosage increases.[17]

Almost 90,000 beneficiaries are at serious risk of opioid misuse or overdose

Two groups of beneficiaries are at serious risk of opioid misuse or overdose: (1) beneficiaries who received extreme amounts of opioids and (2) beneficiaries who appeared to be doctor shopping.

A total of 89,843 beneficiaries were in these two groups in 2016. Specifically, 69,563 beneficiaries received extreme amounts of opioids, and 22,308 beneficiaries appeared to be doctor shopping (i.e., received high amounts of opioids and had multiple prescribers and pharmacies). A total of 2,028 beneficiaries were in both groups. Other beneficiaries may also be at serious risk of opioid misuse or overdose, but they are not the focus of this data brief.

Two Groups of Beneficiaries at Serious Risk of Opioid Misuse or Overdose:

1. Beneficiaries who received extreme amounts of opioids—i.e., an average daily MED greater than 240 mg for 12 months.

2. Beneficiaries who appeared to be doctor shopping—i.e., received a high amount of opioids (an average daily MED greater than 120 mg for 3 months) *and* had four or more prescribers and four or more pharmacies.

About 70,000 beneficiaries received extreme amounts of opioids

Exhibit 3: Average Daily MED

* *CDC Guidelines for Prescribing Opioids for Chronic Pain*, March 2016

A total of 69,563 beneficiaries received extreme amounts of opioids for the entire year, putting them at serious risk of opioid misuse or overdose.[18] Each of these beneficiaries had an average daily MED that exceeded 240 mg for the entire year. This extreme amount is more than two and a half times the dose CDC recommends avoiding for chronic pain patients. (See Exhibit 3.) Research has shown that patients who receive an MED at such a level are at increased risk of overdose death.[19]

Of note, 678 beneficiaries received even more extreme amounts of opioids. These beneficiaries each received an average daily MED greater than 1,000 mg for the entire year. In one case, a beneficiary from New Hampshire received 134 prescriptions for opioids from one prescriber in 2016, including 13 months of OxyContin 80 mg, 13 months of OxyContin 60 mg, 13 months of OxyContin 40 mg, 14 months of oxycodone 30 mg, and 13 months of fentanyl patches.

Receiving extreme amounts of opioids raises concerns. It may indicate that the beneficiary is receiving medically unnecessary drugs, which could be diverted for resale. It

may also indicate that the beneficiary is addicted to opioids and at risk of overdose. Alternatively, it may indicate that a beneficiary's identification number has been stolen or sold.

Example of Beneficiary Receiving Extreme Amounts of Opioids

One beneficiary in New York received 62 opioid prescriptions during the year, which is more than one prescription per week. All of the prescriptions were for fentanyl or oxycodone. The beneficiary had an average daily MED of over 3,130 mg for the entire year, which is almost 35 times the level that CDC recommends avoiding. All but one of these opioids were prescribed by one family medicine physician.

About 22,000 beneficiaries appear to be doctor shopping

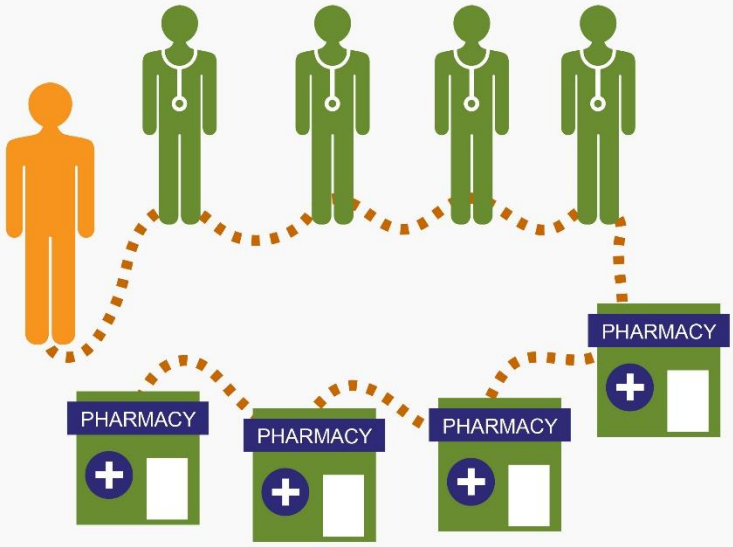
A second group of beneficiaries—those who appear to be doctor shopping (i.e., received high amounts of opioids and had multiple prescribers and pharmacies)—are also at serious risk of opioid misuse or overdose. Doctor shoppers are beneficiaries who seek medically unnecessary prescriptions from multiple prescribers and multiple pharmacies. A total of 22,308 beneficiaries appear to be doctor shopping. Each of these beneficiaries received a high amount of opioids—an average daily MED that exceeded 120 mg for at least 3 months—and have four or more prescribers *and* four or more pharmacies in 2016.[20] Typically, beneficiaries who receive opioids have just one prescriber and one pharmacy.[21] Although beneficiaries may receive opioids from multiple prescribers or pharmacies for legitimate reasons, these patterns raise concern.

Notably, 162 beneficiaries each received opioids from more than 10 prescribers and more than 10 pharmacies in 2016. One beneficiary received opioids from 46 different prescribers and 20 different pharmacies. In August alone, this beneficiary received 11 different opioid prescriptions from 8 prescribers in 5 different States; this beneficiary filled these prescriptions at 6 different pharmacies.

Receiving high amounts of opioids and having multiple prescribers and pharmacies may indicate that a beneficiary is seeking medically unnecessary

Exhibit 4

Beneficiaries who appear to be DOCTOR SHOPPING received high amounts of opioids and had ≥4 prescribers and ≥4 pharmacies



drugs, perhaps to use them recreationally or to divert them. It could mean that the beneficiary's identification number was stolen or sold. It may also signal that the beneficiary's care is not being monitored or coordinated properly. Furthermore, it may indicate that prescribers are not checking the beneficiary's opioid history before prescribing. All but one State maintain databases, called prescription drug monitoring programs, that track prescriptions for controlled substances. Prescribers can check these databases before ordering opioids to determine if the beneficiary is already receiving opioids ordered by other prescribers.[22]

Examples of Beneficiaries Who Appear to be Doctor Shopping

A beneficiary in Washington, D.C. received prescriptions for opioids from 42 different prescribers and filled them at 37 different pharmacies in a year. In a single month, this beneficiary received 2,330 pills from prescriptions written by just one prescriber. These drugs included oxycodone, hydromorphone, and morphine.

A second beneficiary in Illinois received 73 prescriptions for opioids from 11 different prescribers and filled them at 20 different pharmacies in a year. On multiple occasions, this beneficiary filled opioid prescriptions at multiple pharmacies on the same day. For example, one day he filled two 30-day prescriptions for fentanyl patches at two nearby pharmacies and another 30-day prescription for morphine at a third pharmacy more than 40 miles away.

About 400 prescribers had questionable opioid prescribing patterns for beneficiaries at serious risk

In total, 115,851 prescribers ordered opioids for at least one beneficiary at serious risk of opioid misuse or overdose (i.e., a beneficiary who has received extreme amounts or appeared to be doctor shopping). The vast majority of these prescribers each ordered opioids for only one or two of these beneficiaries. Some prescribers ordered for many more. A total of 401 prescribers stand out as having questionable prescribing patterns; these prescribers ordered opioids for the highest numbers of beneficiaries at serious risk. The patterns of these 401 prescribers are far outside the norm and warrant further scrutiny.

Specifically, 198 prescribers ordered opioids for a high number of beneficiaries who received extreme amounts, while 264 prescribers ordered opioids for a high number of beneficiaries who appeared to be doctor shopping. Sixty-one prescribers ordered opioids for high numbers from both groups of beneficiaries at serious risk. In total, prescribers with questionable patterns wrote 256,260 opioid prescriptions for beneficiaries at serious risk, costing Part D a total of $66.5 million.

Nearly 200 prescribers each ordered opioids for dozens of beneficiaries who received extreme amounts of opioids

There were 198 prescribers with questionable prescribing patterns for beneficiaries who received extreme amounts of opioids. Each of these prescribers ordered opioids for at least 44 beneficiaries who received extreme amounts. As noted earlier, beneficiaries who receive extreme amounts of opioids are at serious risk. They each had an average daily MED of more than 240 mg for the entire year and did not have cancer or hospice care. CDC recommends avoiding a daily MED of more than 90 mg, but beneficiaries with extreme amounts are receiving more than two and a half times that amount.

Although high amounts of opioids may be necessary for some patients, questionable prescribing patterns may indicate that the prescriber is ordering medically unnecessary drugs. These drugs may be diverted for resale or recreational use. Furthermore, beneficiaries who receive extreme amounts of opioids are at serious risk of misuse or overdose; therefore, it is important for prescribers to pay close attention to the amount of these drugs that they order and the frequency in which they order them.

Fifteen prescribers stand out. Each ordered opioids for more than 98 beneficiaries who received extreme amounts during the year. In one case, a prescriber in Missouri wrote an average of 31 opioid prescriptions each for 112 beneficiaries. Half of these beneficiaries had an average daily MED that exceeded 375 mg for the entire year. Another prescriber in Indiana wrote an average of 24 opioid prescriptions each for 108 beneficiaries who received extreme amounts; these drugs cost Part D $1.1 million.

Examples of Prescribers with Questionable Prescribing Patterns for Beneficiaries Who Received Extreme Amounts of Opioids

One Florida physician repeatedly ordered extreme amounts of opioids for multiple beneficiaries. For one beneficiary in a single day, this physician ordered three opioids—oxycodone and two different forms of fentanyl—that had a daily MED of 1,239 mg. In total, this physician prescribed opioids to 125 beneficiaries who received extreme amounts. Part D paid $1.6 million for these drugs.

A family medicine physician in Texas wrote 1,199 opioid prescriptions for 103 beneficiaries. For one beneficiary, this physician wrote 27 opioid prescriptions—9 months each of oxycodone, methadone, and hydrocodone-acetaminophen. For another beneficiary, this physician wrote 24 opioid prescriptions—8 months each of oxycodone, morphine, and hydrocodone-acetaminophen. In total, Part D paid $192,000 for opioids prescribed by this physician for beneficiaries who received extreme amounts.

Over 260 prescribers each ordered opioids for numerous beneficiaries who appeared to be doctor shopping

There were 264 prescribers with questionable prescribing patterns for beneficiaries who appeared to be doctor shopping. These beneficiaries received high amounts of opioids and had four or more prescribers *and* four or more pharmacies. Each of the 264 prescribers ordered opioids for at least 21 of these beneficiaries. Like beneficiaries who receive extreme amounts, beneficiaries who appear to be doctor shopping are at serious risk of opioid misuse or overdose.

Questionable prescribing may indicate that beneficiaries are receiving poorly coordinated care and could be in danger of overdose or dependence. It may also mean that prescribers are not checking the State prescription drug monitoring databases, or that these databases do not have current data. Another possibility is that the prescriber's identification was sold or stolen and is being used for illegal purposes. Questionable patterns also raise significant concern that prescribers may be operating "pill mills." A pill mill is a doctor's office, clinic, or health care facility that routinely prescribes controlled substances—such as oxycodone—outside the scope of professional practice and without a legitimate medical purpose.

Eighteen prescribers stand out in that each ordered opioids for more than 45 beneficiaries who appeared to be doctor shopping. Of note, four physicians in the same practice in Texas each ordered opioids for more than 56 beneficiaries who appeared to be doctor shopping.

Example of Prescribers with Questionable Prescribing Patterns for Beneficiaries Who Appear to be Doctor Shopping

Four practitioners from the same practice in Wisconsin—1 physician and 3 nurse practitioners—each prescribed opioids to more than 136 beneficiaries who appeared to be doctor shopping. Together, these practitioners wrote 2,823 opioid prescriptions during the year for beneficiaries who appeared to be doctor shopping, costing Part D $336,000. Two-thirds of these prescriptions—1,885—were for oxycodone, a commonly diverted drug.

Nurse practitioners and physician assistants make up one-third of the prescribers with questionable prescribing patterns for beneficiaries at serious risk

One-third (133 of 401) of the prescribers who had questionable prescribing patterns for beneficiaries at serious risk were nurse practitioners or physician assistants. In total, 81 of these prescribers were nurse practitioners and 52 were physician assistants. Most of the nurse practitioners specialized in family or adult health and just two specialized in acute care.

CONCLUSION

In 2016, one out of every three beneficiaries received a prescription opioid through Medicare Part D. Half a million of them received high amounts of opioids—an average daily MED of 120 mg for at least 3 months of the year. Even more concerning, almost 90,000 beneficiaries are at serious risk of misuse or overdose. These include beneficiaries who received extreme amounts of opioids—more than two and a half times the level that CDC recommends avoiding—for the entire year. They also include beneficiaries who appeared to be doctor shopping (i.e., received high amounts of opioids and had multiple prescribers and pharmacies). Moreover, 401 prescribers had questionable prescribing patterns for beneficiaries who are at serious risk. These patterns are far outside the norm and warrant further scrutiny.

Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. The extreme use of opioids and apparent doctor shopping described in this study put beneficiaries at risk and may indicate that opioids are being prescribed for medically unnecessary purposes and then diverted for resale or recreational use. It may also indicate that beneficiaries are receiving poorly coordinated care.

Prescribers play a key role in combatting opioid misuse. They must be given the information and tools needed to appropriately prescribe opioids when medically necessary. States' prescription drug monitoring programs can provide invaluable information to prescribers about a patient's opioid prescription history. Prescribers must be vigilant about checking the State monitoring databases to ensure that their patients are receiving appropriate doses of opioids and to better coordinate patient care. At the same time, we must address prescribers with questionable prescribing patterns for opioids to ensure that Medicare Part D is not paying for unnecessary drugs that are being diverted for resale or recreational use.

But focusing on prescribers alone is not enough. A multifaceted approach is necessary. As the Department has highlighted—strengthening public health surveillance, advancing the practice of pain management, improving access to treatment and recovery services, targeting availability and distribution of overdose-reversing drugs, and supporting cutting-edge research—all need to be part of the strategy to fight the opioid crisis.[23]

OIG is committed to fighting the opioid crisis and protecting beneficiaries from prescription drug abuse and misuse. It has formed a multidisciplinary team dedicated to addressing this issue. As a part of that effort, we will work with our law enforcement partners and CMS to follow up on the specific prescribers who we identified in this review. We will also continue to conduct investigations and reviews that address the ongoing problems created by opioid misuse. In addition to enforcement, we will identify other approaches to support prevention and treatment efforts. We are also committed to conducting reviews to improve the efficiency and effectiveness of the broader Department efforts.

In addition, we are committed to forging expanded partnerships among Federal agencies, States, and private sector partners. We specifically call on Part D sponsors to work with OIG and CMS to further improve efforts to combat opioid misuse in Medicare. These efforts include Part D sponsors' program integrity activities to address prescription drug and pharmacy fraud. We also

specifically encourage Part D sponsors to effectively use CMS's Overutilization Monitoring System, which identifies beneficiaries who are potentially overutilizing opioids. We further encourage sponsors to implement drug management programs for at-risk beneficiaries, following additional guidance from CMS.[24] In addition, we continue to support our private and public sector partners as part of the Healthcare Fraud Prevention Partnership and our shared commitment to reducing the harms of opioids.[25] By working together and expanding our efforts in Part D, we can help curb the opioid crisis in our Nation.

METHODOLOGY

We based this data brief on an analysis of prescription drug event (PDE) records for Part D drugs. This data brief includes prescriptions that beneficiaries received through Part D. It does not include prescriptions received through other programs or through only paying cash. Part D sponsors submit a PDE record to CMS each time a drug is dispensed to a beneficiary enrolled in their plans. Each record contains information about the drug and beneficiary, as well as the identification numbers for the pharmacy and the prescriber.

We matched PDE records to data from the First Databank, National Plan and Provider Enumeration System (NPPES), National Claims History File, and Part C Encounter Data file to obtain descriptive information about the drugs, prescribers, and beneficiaries. First Databank contains information about each drug, such as the drug name, strength of the drug, therapeutic class (e.g., an opioid), and controlled substance schedule (e.g., Schedule II or III). NPPES contains information about prescribers, such as their name, address, and taxonomy (i.e., specialty). The National Claims History File contains claims data from Medicare Parts A and B, including diagnoses codes. Part C Encounter Data contains medical claims data for beneficiaries enrolled in Medicare Advantage plans. For the purposes of this study, we use the term "prescription" to mean one PDE record.

Analysis of Opioid Utilization

We identified PDE records for opioids that beneficiaries received in 2016.[26] We calculated total Part D spending, the total number of beneficiaries, and the total number of prescriptions for all opioids and all Schedule II and III opioids. To determine total spending, we summed four fields on the PDE records that represent the total gross drug costs: ingredient cost, dispensing fee, vaccine administration fee, and sales tax. Next, using PDE data and Medicare enrollment data, we determined the proportion of Part D beneficiaries who received opioids in the Nation and in each State. We then identified the most commonly prescribed opioids by calculating the total number of prescriptions for each generic drug name (delineated by strength and form). Lastly, we counted the total number of days during the year that each beneficiary received opioids.

Beneficiary Analysis

Next, we determined the amount of opioids that each beneficiary received. To do this, we calculated each beneficiary's average daily morphine equivalent dose (MED).[27] The MED converts opioids of different ingredients, strengths, and forms into equivalent milligrams of morphine. It allows us to sum dosages of different opioids to determine a beneficiary's daily opioid level.

To calculate each beneficiary's average daily MED, we first calculated the MED for each prescription (i.e., PDE record).[28] To do this, we used the following equation:

$$MED = \frac{(strength\ per\ unit) \times (quantity\ dispensed) \times (MED\ conversion\ factor)}{(Days\ supply)}$$

We then summed each beneficiary's MED for each day of the year based on the dates of service and days supply on each PDE record. We refer to this as the daily MED. We excluded from this analysis beneficiaries with a diagnosis of cancer or a hospice stay in 2016.[29]

Next, we determined the extent to which beneficiaries received high amounts of opioids. We calculated each beneficiary's average daily MED over each 90-day period in 2016. We determined that a beneficiary received high amounts of opioids if he or she exceeded an average daily MED of 120 mg for any 90-day period *and* had received opioids for 90 or more days in the year. We used these criteria because they closely align with the current criteria used by CMS for its Overutilization Monitoring System.[30] The MED of 120 mg also exceeds the level CDC recommends avoiding for patients with chronic pain—an MED of 90 mg.

We then determined the extent to which beneficiaries received extreme amounts of opioids. We calculated each beneficiary's average daily MED over the entire year. We considered a beneficiary who exceeded an average daily MED of 240 mg for the entire year *and* had received opioids for 360 days or more to have received an extreme amount of opioids.

Lastly, we determined the extent to which beneficiaries appeared to be doctor shopping. To do this, we calculated the total number of prescribers and pharmacies from which each beneficiary received opioids in 2016. We considered beneficiaries to have appeared to be doctor shopping if they exceeded an average daily MED of 120 mg for any 90-day period, received opioids for 90 or more days in the year, and received opioids from four or more prescribers *and* four or more pharmacies.

Prescriber Analysis

For this analysis, we identified prescribers who ordered opioids for a high number of beneficiaries at serious risk: beneficiaries who received extreme amounts of opioids and beneficiaries who appeared to be doctor shopping. We considered these prescribers to have questionable prescribing patterns that warrant further scrutiny.

In total, 60,742 prescribers ordered opioids for beneficiaries who received extreme amounts and 79,175 prescribers ordered opioids for beneficiaries who appeared to be doctor shopping. For each of these prescribers, we calculated the number of beneficiaries in each group for whom the prescriber ordered opioids. We then identified the prescribers who ordered opioids for the highest number of beneficiaries in each group.[31]

Lastly, we calculated the average number of prescriptions that each prescriber ordered for beneficiaries in each group. We also calculated the average daily MED for beneficiaries for each prescriber for each group.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

ACKNOWLEDGMENTS

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ENDNOTES

[1] CDC, "Increases in Drug and Opioid-Involved Overdose Deaths: United States, 2010–2015." *MMWR Morb Mortal Wkly Rep*, December 30, 2016, pp. 1445–52. Accessed at https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm on May 4, 2017.

[2] OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, OEI-02-16-00290, June 2016. Also see OIG, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, OEI-02-15-00190, June 2015.

[3] Maxwell, Ann, Assistant Inspector General for Evaluations and Inspections, Office of Inspector General, U.S. Department of Health and Human Services, "Opioid Use Among Seniors: Issues and Emerging Trends" (Congressional testimony), February 24, 2016. Also see Cantrell, Gary, Deputy Inspector General for Investigations, Office of Inspector General, U.S. Department of Health and Human Services, "Fraud in Medicare" (Congressional testimony), March 24, 2015.

[4] Chau, Diane L. et al. "Opiates and Elderly: Use and Side Effects." *Clinical Interventions in Aging*, 2008, p. 276. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546472/ on April 17, 2017. Also see CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016." *MMWR Recomm Rep*, March 18, 2016.

[5] Saunders, Kathleen W. et al. "Relationship of Opioid Use and Dosage Levels to Fractures in Older Chronic Pain Patients." *Journal of General Internal Medicine*, 2010, pp. 310–15. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842546/ on April 17, 2017.

[6] CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016." *MMWR Recomm Rep*, March 18, 2016, pp. 1–49. Accessed at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm on May 4, 2017.

[7] Ibid, p. 16. The CDC guidelines recommend that prescribers avoid increasing opioids to morphine equivalent dosages of 90 mg a day or more or carefully justify the decision to increase to this level.

[8] CMS identifies beneficiaries who are at high risk for opioid overutilization. On a quarterly basis, CMS provides each Part D sponsor with a list of these beneficiaries through its Overutilization Monitoring System. For more information about CMS's complete efforts to address opioids misuse, see CMS, *CMS Opioid Misuse Strategy 2016.* Accessed at https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf on April 20, 2017.

[9] OIG, *Ensuring the Integrity of Medicare Part D*, OEI-03-15-00180, June 2015. Also see OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, OEI-02-16-00290, June 2016.

[10] Controlled substances are drugs regulated by the Controlled Substances Act, which established five schedules based on the medical use and the potential for abuse. Schedule I drugs, such as heroin, have no currently accepted medical use. Schedule II drugs, such as oxycodone, hydrocodone, and fentanyl, have a high potential for abuse and may lead to severe psychological or physical dependence. Schedule V have the lowest potential for abuse among controlled substances. See 21 U.S.C. § 812. In total, Part D paid $3.9 billion for Schedule II and III opioids in 2016.

[11] Although tramadol is a Schedule IV drug, which means it has low potential for abuse and low risk of dependence, recent research raised concern about a link between tramadol and long-term use of opioids. The research found that initial treatment with tramadol increases the probability of long-term use. In addition, the Substance Abuse and Mental Health Services Administration reports that emergency department visits associated with tramadol increased 145 percent from 2005 to 2011. See CDC, "Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use: United States, 2006–2015." *MMWR Morb Mortal Wkly Rep*, March 17, 2017, pp. 265-69. Accessed at https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm on May 4, 2017.

[12] CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016." *MMWR Recomm Rep*, March 18, 2016, p. 25.

[13] According to the manufacturer labels, the maximal daily dose for Percocet 5 mg is 12 tablets and the daily dosage for Vicodin 10 mg should not exceed 6 tablets. For more information about Percocet, see page 2 at https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf and for Vicodin see page 20 at http://www.rxabbvie.com/pdf/vicodin_apap_300mg_hydrocodone_5mg-7_5mg-10mg_PI.pdf.

[14] In addition, CMS uses a daily MED of 120 mg for 90 days—as well as beneficiaries having four or more prescribers and four or more pharmacies—to identify beneficiaries who are potentially overutilizing opioids for its

Overutilization Monitoring System. Beginning in 2018, CMS is changing its criteria to an average daily MED of 90 mg plus four or more prescribers and four or more pharmacies *or* six or more prescribers, regardless of the number of pharmacies. See CMS, 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 at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf on April 25, 2017. Note that the guidance uses the term "more than 3 prescribers and more than 3 pharmacies," which is which equivalent to "4 or more prescribers and 4 or more pharmacies."

[15] U.S. Drug Enforcement Administration, Diversion Control Division, *National Forensic Laboratory Information System: Year 2015 Annual Report*, 2016. Accessed at https://www.deadiversion.usdoj.gov/nflis/2015_annual_rpt.pdf on April 24, 2017.

[16] CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016." *MMWR Recomm Rep*, March 18, 2016, p. 23. Accessed at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm on May 4, 2017.

[17] Ibid, p. 13, 44.

[18] This does not include beneficiaries who had cancer or were in hospice care.

[19] Ibid, p. 10.

[20] As mentioned above, CMS uses a daily MED of 120 mg for 90 days—in addition to beneficiaries having four or more prescribers and four or more pharmacies—to identify beneficiaries who are potentially overutilizing opioids for its Overutilization Monitoring System.

[21] Specifically, 58 percent of beneficiaries who received opioids have one prescriber and 78 percent have one pharmacy. This does not include beneficiaries who had cancer or hospice care.

[22] State requirements for checking this information vary. For more information about these programs, see Prescription Drug Monitoring Program Training and Technical Assistance Center, *Tracking PDMP Enhancement: The Best Practice Checklist*, 2017. Accessed at http://www.pdmpassist.org/pdf/2016_Best_Practice_Checklist_Report_20170228.pdf on April 26, 2017. Also see PEW, *Prescription Drug Monitoring Programs: Evidence-based practices to optimize prescriber use*, 2016. Accessed at http://www.pewtrusts.org/~/media/assets/2016/12/prescription_drug_monitoring_programs.pdf on April 21, 2017.

[23] Price, Tom, Secretary, U.S. Department of Health and Human Services, "Secretary Price Announces HHS Strategy for Fighting Opioid Crisis." Speech to the National Rx Drug Abuse and Heroin Summit, April 19, 2017. Accessed at https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html on May 3, 2017.

[24] The Comprehensive Addiction Recovery Act of 2016 allows Part D sponsors to establish drug management programs for beneficiaries who are at risk for prescription drug abuse. Under these programs, sponsors may limit at-risk beneficiaries' coverage of frequently abused drugs to one or more selected prescribers and one or more selected pharmacies. Comprehensive Addiction and Recovery Act of 2016, Pub. L. No. 114-198, § 704 (July 22, 2016).

[25] Healthcare Fraud Prevention Partnership, *Health Payer Strategies to Reduce the Harms of Opioids*, January 2017. Accessed at https://downloads.cms.gov/files/hfpp/hfpp-opioid-white-paper.pdf on March 7, 2017.

[26] Using CMS's Integrated Data Repository, we identified a total of 79,425,530 PDE records for opioids with dates of service in 2016.

[27] To calculate MED, we used CDC's Morphine Milligram Equivalent (MME) file, which is available at https://www.cdc.gov/drugoverdose/media/index.html. It contains MED conversion factors for each National Drug Code. MED and MME are interchangeable terms. For more information on calculating opioid dosage, see CDC, *Calculating Total Daily Dose of Opioids for Safer Dosage*. Accessed at https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf on June 26, 2017.

[28] We included PDE records dispensed in 2015 with days of use in 2016. We excluded PDE records for injection, intravenous, and intrathecal opioids from this analysis.

[29] We identified beneficiaries with a cancer diagnosis or hospice stay using CMS's National Claims History File and Part C Encounter data. In total, we identified 2,658,350 beneficiaries with cancer or hospice who received at least one opioid.

[30] As stated above, CMS currently uses a daily MED of 120 mg for 90 days—in addition to beneficiaries having four or more prescribers and four or more pharmacies—to identify beneficiaries who are potentially overutilizing opioids for its Overutilization Monitoring System.

[31] Each of these prescribers is an extreme outlier in terms of the number of beneficiaries to whom they prescribed opioids in one of the groups at serious risk. These prescribers were more than 3 standard deviations above the mean and in the top 0.3 percent.