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Opioid Use in Medicare Part D Remains Concerning

Key Takeaways

- ✓ Nearly one in three Part D beneficiaries received a prescription opioid in 2017.
- ✓ Overall Part D spending for opioids decreased, due in part to declining prices.
- ✓ Almost 460,000 beneficiaries received high amounts of opioids in 2017, fewer than in 2016.
- ✓ About 71,000 beneficiaries are at serious risk of opioid misuse or overdose, also fewer than in 2016.
- ✓ Almost 300 prescribers had questionable opioid prescribing for the 71,000 beneficiaries at serious risk.
- ✓ The high level of opioid use continues to call for the public and private sectors to work together to address this crisis.

The opioid crisis has been declared a public health emergency.¹ In 2016, more than 42,000 opioid-related overdose deaths occurred in the United States—115 deaths per day. This is twice the number of opioid-related overdose deaths that occurred just 6 years earlier in 2010.² Identifying patients who are at risk of overdose or abuse is key to addressing this national crisis.

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, as well as drug diversion—the redirection of prescription drugs for an illegal purpose, such as recreational use or resale. These concerns about fraud, abuse, misuse, and diversion include opioids obtained under Medicare Part D, the optional prescription drug benefit for Medicare beneficiaries. In 2017, it covered 45 million beneficiaries.

There is also growing concern about abuse of both prescription fentanyl and illicitly manufactured fentanyl. Fentanyl-related overdose deaths have drastically increased in recent years.³ Fentanyl is 30 to 50 times more powerful than heroin and is sometimes mixed with other drugs, such as cocaine or heroin, which increases the risk of overdose.⁴

In addition to these concerns, opioid use carries a number of health risks. Side effects from using opioids may include respiratory depression, confusion, increased tolerance, and physical dependence.⁵ For seniors, long-term use of prescription opioids also increases the likelihood of falls and fractures.⁶

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) published guidelines on prescribing opioids to patients with chronic pain.⁷ The guidelines recommend that prescribers use caution when ordering opioids at any dosage and avoid increasing dosages to the equivalent of 90 mg or more of morphine a day

for chronic pain.⁸ In addition, because long-term opioid use often begins with the treatment of acute pain, the guidelines recommend that prescribers order opioids for the lowest effective dose and duration, noting that more than 7 days of opioids is rarely needed to address acute pain.⁹

The Centers for Medicare & Medicaid Services (CMS) also initiated a number of actions to address opioid misuse and inappropriate prescribing. For instance, through its Overutilization Monitoring System, CMS routinely identifies Part D beneficiaries who are potentially overutilizing opioids and who may be in need of case management. It then provides each Part D sponsor with a list of these beneficiaries for follow up. CMS also expects Part D sponsors to implement controls at the point of sale to prevent unsafe dosing. In addition, CMS is taking steps to implement the Comprehensive Addiction and Recovery Act of 2016 (CARA) for 2019. CARA provides Part D sponsors the authority to restrict at-risk beneficiaries to selected pharmacies or prescribers ("lock-in") for their opioid prescriptions. In the comprehensive of the c

This data brief is part of a larger strategy by OIG to fight the opioid crisis and protect beneficiaries from prescription drug misuse and abuse. It provides 2017 data on the extent to which Medicare Part D beneficiaries receive extreme amounts of opioids or appear to be "doctor shopping" and compares these data to OIG's previous analysis of 2016.¹⁴ This data brief is being released with a toolkit that provides detailed steps for using prescription drug data to analyze patients' opioid levels and identify patients who are at risk of opioid misuse or overdose.¹⁵ OIG is also conducting a series of reviews on opioid utilization in Medicaid.¹⁶ In addition, OIG has ongoing reviews about key opioid initiatives at the Department of Health and Human Services (HHS or the Department), including access to buprenorphine for opioid use disorder; controls on opioid treatment programs, the Food and Drug Administration's oversight of programs to address opioid abuse, and a review of grants for prescription drug monitoring programs.¹⁷

RESULTS

Nearly one in three Medicare Part D Beneficiaries Received Opioids in 2017 In 2017, nearly one in three beneficiaries received at least one prescription opioid through Medicare Part D. Thirty-one percent of beneficiaries—14.1 million of the total 45.2 million enrolled in Medicare Part D—received opioids. This is a slight decrease from 2016, when 33 percent of beneficiaries—14.4 million—received opioids through Part D.

Part D paid for 76 million opioid prescriptions—an average of 5.4 prescriptions per beneficiary receiving opioids in 2017. This was a decrease from 2016, when Part D paid for 79 million opioid prescriptions—an average of 5.5 per beneficiary receiving opioids. Tramadol, hydrocodone-acetaminophen, and oxycodone-acetaminophen were the most commonly dispensed opioids in both years.¹⁸

Nearly 1 in 3
Part D beneficiaries received at least 1 prescription opioid prescriptions

Part D paid for 76 million opioid prescriptions

Part D beneficiaries received opioids for 3 or more months

Exhibit 1: Opioid Utilization in Part D, 2017.

Source: OIG analysis of Medicare Part D data, 2018.

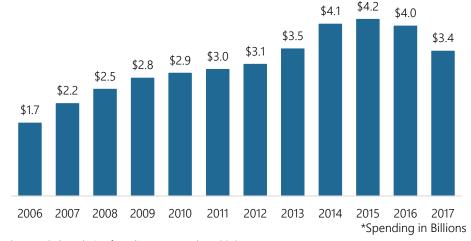
Raising concern, about 1 in 10 Part D beneficiaries received opioids on a regular basis. Specifically, 4.9 million beneficiaries received opioids for a total of 3 or more months in 2017. Opioids may have been necessary for many of these beneficiaries, but these high numbers raise questions as to whether opioids are being appropriately prescribed and used.¹⁹ Research shows that the risk of opioid dependence increases substantially for patients receiving opioids continually for 3 months.²⁰ For this reason, it is essential that Medicare beneficiaries receive the lowest effective amount of opioids.

Further, a number of States had higher proportions of beneficiaries receiving opioids than the Nation overall. Alabama, Mississippi, Arkansas, and Oklahoma had the highest proportions, with more than 40 percent of each State's Part D beneficiaries receiving at least one opioid. These States also had the highest proportion of beneficiaries who received opioids in the Nation in 2016. See Appendix A for more detailed information about each State.

Overall Part D
spending for
opioids decreased,
due in part to
declining prices

While overall opioid use decreased slightly, overall Part D spending for opioids went down more significantly. Part D paid a total of \$3.4 billion for opioids in 2017, compared to \$4.0 billion in 2016. This difference represents a 15 percent decrease. See Exhibit 2.

Exhibit 2: Overall spending for opioids in Part D decreased in 2017, but remained more than \$3 billion.



Source: OIG analysis of Medicare Part D data, 2018.

A decrease in opioid prices appears to be a main driver of the drop in spending. The average price of a month's supply decreased for 18 of the 20 most commonly prescribed opioids in 2017. For example, decreases in the price per month of the top five opioids ranged from 11 percent to 30 percent. See Exhibit 3. Notably, the price per month for hydrocodone-acetaminophen 10-325 mg dropped 30 percent from 2016 to 2017, going from \$37 to \$26. The prices of two other common strengths of hydrocodone-acetaminophen dropped 24 and 28 percent. In total, Medicare Part D paid \$220 million less in 2017 for these three commonly prescribed strengths of hydrocodone-acetaminophen than it did in 2016.²¹

The slight decreases in the number of beneficiaries receiving opioids and the number of prescriptions per beneficiary discussed above also contributed to the overall decrease in spending.

Exhibit 3: The prices of all of the most commonly prescribed opioids declined in 2017.

Drug Name [*]	Total Number of Prescriptions in 2017	Average Price per Month in 2016**	Average Price per Month in 2017**	Percent Change***
Tramadol 50 mg	14.7 million	\$11	\$9	-11%
Hydrocodone-acetaminophen 10-325 mg	10.7 million	\$37	\$26	-30%
Hydrocodone-acetaminophen 5-325 mg	10.6 million	\$33	\$24	-28%
Hydrocodone-acetaminophen 7.5-325 mg	5.3 million	\$34	\$26	-24%
Oxycodone-acetaminophen 10-325 mg	4.3 million	\$78	\$65	-16%

^{*}A drug is defined as on the active ingredient-strength-form level. All numbers are for the tablet form of the drug.

Source: OIG analysis of Medicare Part D data, 2018.

Almost 460,000
Part D beneficiaries received high amounts of opioids in 2017, fewer than in 2016

In 2017, a total of 458,935 beneficiaries received high amounts of opioids through Medicare Part D; these beneficiaries did not have cancer and were not in hospice care. The number of beneficiaries who received high amounts of opioids through Part D decreased from 501,008 beneficiaries in 2016.

Each of the 458,935 beneficiaries received high amounts of opioids, meaning they had an average morphine equivalent dose (MED) of greater than 120 mg a day for at least 3 months. MED is a measure that converts 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.²² They also exceed the 90 mg MED level that CDC recommends avoiding for patients with chronic pain.²³

The most commonly prescribed opioid for beneficiaries with high amounts—an average daily MED of greater than 120 mg for 3 months—was oxycodone 30 mg. Twenty percent of beneficiaries who received high amounts of opioids had at least one prescription for this opioid. Fourteen percent of beneficiaries who received high amounts of opioids received at least one prescription for fentanyl patch 50 mcg/hr. Oxycodone and fentanyl are among the most common opioids involved in law enforcement cases.²⁴

Although beneficiaries may receive opioids for legitimate purposes, these amounts raise concern. Many experts have noted that opioid dosages should not be increased to an MED of 90 mg a day or more without careful justification.²⁵ Opioids carry 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.²⁶

^{**}Average price per month and percent change are rounded.

^{***}Percent change was calculated before the values were rounded.

About 71,000 beneficiaries are at serious risk of opioid misuse or overdose, fewer than in 2016

Two groups of beneficiaries that are at serious risk of opioid misuse or overdose are the focus of this review. They include: (1) beneficiaries who receive extreme amounts of opioids and (2) beneficiaries who appear to be doctor shopping. Other Part D beneficiaries also may be at serious risk of opioid misuse or overdose but do not meet these criteria.

A total of 71,260 beneficiaries were in these two groups in 2017. This does not include beneficiaries who have cancer or were in hospice care. Specifically, 57,611 beneficiaries received extreme amounts of opioids, and 14,814 beneficiaries appeared to be doctor shopping (i.e., received high amounts of opioids and had multiple

Beneficiaries at serious risk of opioid misuse or overdose include:

- Beneficiaries who receive extreme amounts of opioids—i.e., an average daily MED greater than 240 mg for 12 months.
- 2. Beneficiaries who appear to be doctor shopping—i.e., receive a high amount of opioids (an average daily MED greater than 120 mg for 3 months) and have four or more prescribers and four or more pharmacies.

prescribers and pharmacies). A total of 1,165 beneficiaries were in both groups. Most of the beneficiaries at serious risk were under the age of 65. Seventy-four percent of beneficiaries were under 65 years old, 22 percent were between 65 and 75, and 4 percent were over 75. In addition to the elderly, individuals with disabilities may also be eligible for Medicare coverage.²⁷

Fewer beneficiaries were identified as being at serious risk of opioid misuse or overdose in 2017 compared to 2016, when OIG identified 89,843 beneficiaries at serious risk.²⁸ The numbers in each group declined, with the larger drop—34 percent—in the number of beneficiaries who appeared to be doctor shopping. See Appendix B for more detailed information. Despite the decrease, a high number of beneficiaries in these two groups is still at serious risk.

About 58,000 beneficiaries received extreme amounts of opioids

A total of 57,611 beneficiaries received extreme amounts of opioids, putting them at serious risk of opioid misuse or overdose.²⁹ 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. Research has shown that patients who receive an MED at such a level are at increased risk of overdose death.³⁰

Of note, 890 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.

Receiving extreme amounts of opioids raises concerns. It may signal that a beneficiary's care is not being monitored or coordinated properly or that the beneficiary's care needs to be reassessed.³¹ It may also 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.

Examples of Beneficiaries Receiving Extreme Amounts of Opioids

A beneficiary in California received 48 prescriptions during the year—12 months each of 4 different powerful opioids—all ordered by one physician. In total, the beneficiary had an average daily MED of 3,460 mg for the entire year, which is 38 times the level that CDC recommends avoiding.

A beneficiary in South Carolina received 60 opioid prescriptions during the year—an average of more than one a week—from one physician. His prescriptions included a year's supply each of three different strengths of oxycodone. This beneficiary had an average daily MED of 3,068 mg for the entire year, which is 34 times the level that the CDC recommends avoiding.

About 15,000 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 prescriptions from multiple prescribers and multiple pharmacies. A total of 14,814 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 had four or more prescribers *and* four or more pharmacies in 2017. It is uncommon for a beneficiary to have multiple prescribers or pharmacies. Most beneficiaries who received opioids in 2017 had just one prescriber and one pharmacy.³² Although beneficiaries may receive opioids from multiple prescribers or pharmacies for legitimate reasons, these patterns raise concern.

Notably, 69 beneficiaries had particularly high numbers of prescribers and pharmacies. Each received opioids from more than 10 prescribers and more than 10 pharmacies in 2017.

Receiving high amounts of opioids and having multiple prescribers and pharmacies may signal that the beneficiary's care is not being monitored or coordinated properly. It may also indicate that a beneficiary is seeking medically unnecessary drugs, perhaps to use them recreationally or to divert them. It could also mean that the beneficiary's identification number was stolen, sold, or otherwise compromised.

Furthermore, receiving high amounts of opioids and having multiple prescribers and pharmacies 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, which track prescriptions for controlled substances.³³ Prescribers can check these databases before ordering opioids to determine if the beneficiary is already receiving opioids ordered by other prescribers.³⁴

Examples of Beneficiaries Who Appear To Be Doctor Shopping

A beneficiary in Washington, D.C. received 101 opioid prescriptions from 26 prescribers and filled them at 28 pharmacies in 2017. Many of these prescriptions were for various strengths of oxycodone. Over the course of the year, this beneficiary received more than 10,000 pills containing oxycodone. In 1 month alone, this beneficiary received 16 opioid prescriptions from 11 different prescribers and filled them at 12 pharmacies.

A beneficiary in Louisiana received 52 opioid prescriptions from 30 prescribers and filled these prescriptions at 23 separate pharmacies located across New Jersey, New York, Louisiana, and Texas. Over one-half of these prescriptions were for fentanyl patches. In total, this beneficiary received 165 fentanyl patches in 2017. This beneficiary also received prescriptions for oxycodone, hydrocodone-acetaminophen, morphine, oxycodone-acetaminophen, and hydromorphone.

Almost 300 prescribers had questionable opioid prescribing for the 71,000 beneficiaries at serious risk

Almost 90,000 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) in 2017.³⁵ 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 282 prescribers stand out as having questionable prescribing; these prescribers ordered opioids for the highest numbers of beneficiaries at serious risk. This total is lower than the 401 prescribers identified in 2016, as there were fewer beneficiaries identified as being at serious risk in 2017.³⁶ Like the prescribers identified in 2016, the patterns of the 282 prescribers are far outside the norm and warrant further scrutiny.

Specifically, 145 prescribers ordered opioids for a high number of beneficiaries who received extreme amounts in 2017. These prescribers each ordered opioids for at least 45 beneficiaries who received an average daily MED of more than 240 mg for the entire year, did not have cancer or were not in hospice care. Beneficiaries who receive these extreme amounts of opioids are at serious risk. CDC recommends that prescribers avoid increasing dosages to 90 mg or more MED a day for chronic pain, yet these beneficiaries are receiving more than two and a half times that amount.

Further, 169 prescribers ordered opioids for a high number of beneficiaries who appeared to be doctor shopping.³⁷ Each prescriber ordered opioids for at least 18 beneficiaries who appeared to be doctor shopping. These beneficiaries received high amounts of opioids, had four or more prescribers and four or more pharmacies, did not have cancer and were not in hospice care. Like beneficiaries who receive extreme amounts, beneficiaries who appear to be doctor shopping are at serious risk of opioid misuse or overdose.

Although these opioids may be necessary for some patients, prescribing to an unusually high number of beneficiaries at serious risk raises concerns. It may indicate that beneficiaries are receiving poorly coordinated care and could be in danger of overdose or dependence. It may also signal that prescribers are not checking State prescription drug monitoring databases, or that these databases do not have current data.

Prescribing to an unusually high number of beneficiaries at serious risk could also indicate that the prescriber is ordering medically unnecessary drugs, which could be diverted for resale or recreational use. The 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. Another possibility is that the prescriber's identification was sold or stolen and is being used for illegal purposes.

In total, these 282 prescribers with questionable ordered 178,091 opioid prescriptions for beneficiaries at serious risk, costing Part D a total of \$47 million. A little more than one-third of these prescribers were nurse practitioners or physician assistants. In total, 64 were nurse practitioners and 37 were physician assistants.

Examples of Prescribers With Questionable Prescribing

A physician in Florida ordered opioids for 192 beneficiaries who received extreme amounts during the year. For one of these beneficiaries, the physician ordered 33 prescriptions, including 11 months each of fentanyl patches and oxycodone. This beneficiary had an average daily MED of 535 mg over the entire year, about 6 times the level CDC recommends avoiding. In total, this physician ordered 2,692 opioid prescriptions for beneficiaries who received extreme amounts of opioids, costing Part D \$570,000.

In the first 7 months of 2017, a physician in Texas ordered opioids for 53 different beneficiaries who appeared to be doctor shopping. Most of these prescriptions were for hydrocodone, oxycodone, or morphine. In total, this prescriber ordered more than 600 opioid prescriptions for these beneficiaries.

CONCLUSION

Opioid use among Medicare Part D beneficiaries has decreased slightly but remains concerning. Nearly one in three beneficiaries received a prescription opioid through Part D in 2017. Despite this decrease, the high level of opioid use in Part D continues to raise concerns.

During the year, close to 460,000 beneficiaries received high amounts of opioids—an average daily MED of greater than 120 mg for at least 3 months of the year—through Part D. About 71,000 of these beneficiaries are at serious risk of misuse or overdose. Beneficiaries at serious risk include those who received extreme amounts of opioids—more than an average daily MED of 240 mg 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). Although the number decreased from 2016, a high number of beneficiaries are at serious risk in 2017. In addition, almost 300 prescribers had questionable prescribing for the 71,000 beneficiaries at serious risk. This prescribing is far outside the norm and warrants 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. These patterns may indicate that a beneficiary is receiving poorly coordinated care or that the beneficiary's care may need to be reassessed. They may also indicate that opioids are being prescribed for medically unnecessary purposes and could be diverted for resale or recreational use.

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. However, focusing on prescribers alone is not enough.

The severity of the opioid crisis makes it imperative that HHS, including CMS and OIG, continues to work together to develop new strategies to address this epidemic. 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.³⁸

As part of these efforts, CMS is implementing a number of new initiatives in 2019 to address opioid overutilization in Part D.³⁹ For instance, Part D sponsors will be able to restrict certain "at-risk" beneficiaries to selected pharmacies or prescribers for their opioid prescriptions (a practice known as "lock in").⁴⁰ Also, Part D sponsors will be expected to implement care coordination alerts at the point of sale when a beneficiary's total daily MED reaches or exceeds 90 mg. Further, for beneficiaries starting opioids, Part D sponsors will be expected to limit initial opioid prescriptions to no more than 7 days for the treatment of acute pain. These policies aim to increase patient safety in Part D by addressing multiple facets of the issue.

OIG is also working to increase its efforts to fight the opioid crisis. We are working with our law enforcement partners and with CMS to follow up on identified prescribers. We are also working in new ways to conduct investigations and reviews that address the ongoing problems of opioid misuse. This includes working closely with the Department of Justice's new Opioid Fraud and Abuse Detection Units. In addition to enforcement, we continue to identify other approaches to support prevention and treatment efforts and to improve the effectiveness of broader Department efforts. For example, as noted earlier, OIG is conducting a series of reviews on opioid use in Medicaid and has ongoing reviews about key opioid initiatives in the Department.⁴¹

OIG is also committed to continue forging relationships with States and with private sector partners to address this crisis. OIG continues to support our State and private sector partners through the Healthcare Fraud Prevention Partnership and our shared commitment to reducing the harms of opioids.⁴²

In addition, we encourage Part D sponsors to work with OIG and CMS to improve efforts to combat opioid misuse in Medicare. Sponsors are on the front lines of fighting the opioid crisis in Medicare Part D. More specifically, we call on Part D sponsors to implement their new lock-in authority, as appropriate. We also call on Part D sponsors to work with pharmacies to ensure that the new point-of-sale care coordination alerts are implemented and effective. Specifically, sponsors should ensure that when these controls are triggered, the pharmacists consult with the prescribers before dispensing additional opioids.

We also support States' efforts to implement and enforce strong prescription drug monitoring programs that require prescribers and pharmacies to check the State database before prescribing and dispensing opioids. Further, we encourage States to provide greater access to these data, including sharing these data with entities such as State Medicaid agencies. We also encourage States to analyze these data to help identify patients who may be at risk and to promote appropriate opioid prescribing practices. For example, States could provide reports to prescribers about

their opioid prescribing patterns. 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 paid through other programs, prescriptions paid for in cash, or illicitly purchased drugs. 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 Claims History File, Part C Encounter Data, CDC's morphine milligram equivalent (MME) conversion file, National Plan and Provider Enumeration System (NPPES), and the National Council for Prescription Drug Programs (NCPDP) database to obtain descriptive information about the drugs, beneficiaries, and pharmacies. First Databank contains information about each drug, such as the drug name, strength of the drug, and therapeutic class (e.g., an opioid). 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, including diagnosis codes, for beneficiaries enrolled in Medicare Advantage plans. CDC's MME conversion file contains information about each opioid's drug morphine milligram equivalence.⁴³ NPPES contains information about prescribers, such as their name, address, and taxonomy (i.e., specialty). The NCPDP database contains information about pharmacies, such as their name and address. For the purposes of this study, we use the term "prescription" to mean one PDE record.

Analysis of Part D Opioid Utilization and Spending

We identified all PDE records for opioids that beneficiaries received in 2017.⁴⁴ We calculated the total number of Part D beneficiaries who received opioids in 2017. We then calculated the total number of opioid prescriptions paid for by Part D in 2017 and the average number of opioid prescriptions per beneficiary. We compared the 2017 data to the data from 2016 in our prior data brief. Next we calculated total Part D spending for opioids from 2006 to 2017. To do this, 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 we calculated the proportion of beneficiaries who received opioids in the Nation and in each State in 2017. We based this analysis on the PDE records and the Medicare Enrollment Database. We then identified the most commonly prescribed opioids by calculating the total number of prescriptions for each drug name (delineated by strength and form) and determined that average price per 30-day supply for each of these drugs in

2016 and 2017. (When calculating these drug prices, we analyzed brandname and generic drugs separately.) We use the term "month" to refer to a 30-day supply. Lastly, we counted the total number of days during the year that each beneficiary received opioids and determined the proportion that received opioids for at least 3 months.

Beneficiary Analysis

Next we determined the amount of opioids that each beneficiary received in 2017. To do this, we calculated each beneficiary's average daily morphine equivalent dose (MED). ⁴⁵ 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).⁴⁶ To do this, we used the following equation:

$$MED = \frac{(Strength \ per \ unit) \times (Quantity \ dispensed) \times (MME \ conversion \ factor)}{(Days \ supply)}$$

Next we 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 at any point in 2017.⁴⁷

We analyzed the MED data using the same criteria that we used in our previous analysis of the 2016 data. We began by determining the extent to which beneficiaries received high amounts of opioids. To do this, we calculated each beneficiary's average daily MED over each 90-day period in 2017. 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 criteria used by CMS in 2016 and 2017 for its Overutilization Monitoring System. 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.

Next 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 2017. 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.

Lastly, we compared the number of beneficiaries who received high amounts of opioids and who were at serious risk of opioid misuse or overdose to the number of beneficiaries we identified in our previous analysis of the 2016 data.

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 that warrants further scrutiny.

In total, 47,985 prescribers ordered opioids for beneficiaries who received extreme amounts, and 53,933 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. 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.

Limitations

This analysis is based on Part D PDE records; it is not based on a review of medical records. The analysis does not include data on opioids that beneficiaries may have received from sources other than Part D.

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.

APPENDIX A: STATE DATA

Exhibit A-1: Alabama had the highest proportion of beneficiaries receiving opioids through Medicare Part D, while Hawaii had the lowest proportion.

Proportion of Beneficiaries per State That Received Opioids Through Medicare Part D in 2017				
Alabama	44%	Colorado	31%	
Mississippi	43%	Ohio	30%	
Arkansas	42%	Nebraska	30%	
Oklahoma	41%	Montana	30%	
Louisiana	40%	lowa	29%	
Tennessee	40%	New Mexico	29%	
Georgia	39%	Illinois	29%	
South Carolina	38%	Maryland	28%	
Kentucky	37%	Wisconsin	28%	
North Carolina	36%	Delaware	28%	
Missouri	36%	South Dakota	28%	
Indiana	35%	California	28%	
Texas	35%	Pennsylvania	27%	
West Virginia	35%	North Dakota	26%	
Kansas	34%	District of Columbia	26%	
Utah	34%	Minnesota	26%	
Idaho	34%	Maine	25%	
Michigan	34%	Connecticut	24%	
Nevada	33%	Rhode Island	24%	
Alaska	32%	New Jersey	24%	
Oregon	32%	Massachusetts	23%	
Arizona	32%	New Hampshire	23%	
Washington	31%	Vermont	22%	
Virginia	31%	New York	21%	
Florida	31%	Hawaii	20%	
Wyoming	31%			

Source: OIG analysis of Medicare Part D data, 2018.

APPENDIX B: DATA ON BENEFICIARIES RECEIVING OPIOIDS THROUGH PART D

Exhibit B-1: Almost 460,000 beneficiaries received high amounts of opioids through Part D in 2017, fewer than in 2016.

	Number of	Number of	
	Beneficiaries	Beneficiaries	Percent
	in 2016	in 2017	Change
Beneficiaries who received high amounts of opioids	501,008	458,935	-8%

Source: OIG analyses of Medicare Part D data, 2017 and 2018.

Exhibit B-2: About 71,000 beneficiaries are at serious risk of opioid misuse or overdose, fewer than in 2016.

	Number of	Number of	
	Beneficiaries	Beneficiaries	Percent
	in 2016	in 2017	Change
Beneficiaries who received an extreme amount of opioids	69,563	57,611	-17%
Beneficiaries who appear to be doctor shopping	22,308	14,814	-34%
Total beneficiaries at serious risk	89,843*	71,260**	-21%

Source: OIG analyses of Medicare Part D data, 2017 and 2018.

^{*} A total of 2,028 beneficiaries were in both groups in 2016.

^{**} A total of 1,165 beneficiaries were in both groups in 2017.

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ENDNOTES

- ¹ Eric D. Hargan, Acting Secretary, U.S. Department of Health and Human Services, *HHS Acting Secretary Declares Public Health Emergency to Address National Opioid Crisis*, October 26, 2017. Accessed at https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html on April 13, 2018.
- ² In 2016, there were 42,249 opioid-related overdose deaths; in 2010, there were 21,089. See Holly Hedegaard, Margaret Warner, and Arialdi M. Miniño, CDC, National Center for Health Statistics (NCHS), *NCHS Data Brief 294, Drug Overdose Deaths in the United States, 1999–2016* and supplement tables, December 2017. Accessed at https://www.cdc.gov/nchs/data/databriefs/db294.pdf and https://www.cdc.gov/nchs/data/databriefs/db294_table.pdf#page=1 on February 23, 2018.
- ³ Wilson M. Compton, Deputy Director, National Institute on Drug Abuse, National Institutes of Health, U.S. Department of Health and Human Services, "Research on the Use and Misuse of Fentanyl and Other Synthetic Opioids" Congressional testimony, June 30, 2017. Accessed at https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2017/research-use-misuse-fentanyl-other-synthetic-opioids on March 26, 2018. In addition, according to CDC, between 2015 and 2016 overdose deaths related to the category of opioids that includes fentanyl increased from 9,580 to 19,413 raising significant concern about diversion of fentanyl. CDC, NCHS Data Brief 294. Drug Overdose Deaths in the United States, 1999–2016, December 2017. Accessed at https://www.cdc.gov/nchs/data/databriefs/db294 table.pdf#page=1 on February 23, 2018.
- ⁴ U.S. Drug Enforcement Administration, *FAQ's Fentanyl and Fentanyl-Related Substances*. Accessed at https://www.dea.gov/druginfo/fentanyl-faq.shtml on April 19, 2018.
- ⁵ Diane L. Chau, Vanessa Walker, Latha Pai, et al., "Opiates and Elderly: Use and Side Effects," *Clinical Interventions in Aging* 3, no. 2 (2008): 276. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546472/ on March 29, 2018. Also see CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," *Morbidity and Mortality Weekly Report (MMWR): Recommendations and Reports* 65, no. 1, March 18, 2016. Accessed at https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf on March 27, 2018.
- ⁶ Kathleen W. Saunders, Kate M. Dunn, Joseph O. Merrill, et al., "Relationship of Opioid Use and Dosage Levels to Fractures in Older Chronic Pain Patients," *Journal of General Internal Medicine* 25, no. 4 (2010): 310–315. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842546/ on March 27, 2018.
- ⁷ These guidelines provide recommendations for prescribing opioids for chronic pain outside of cancer treatment, palliative care, and end-of-life care. See CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016." *MMWR Recommendations and Reports* 65, no. 1, March 18, 2016, 1–49. Accessed at https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf on March 27, 2018.
- ⁸ Ibid. 16. The CDC guidelines recommend that prescribers avoid increasing opioids to morphine equivalent dosages of greater than or equal to 90 mg a day or carefully justify the decision to increase to this level.

 ⁹ Ibid. 24.
- ¹⁰ CMS, CMS Opioid Misuse Strategy 2016, Strategy Paper, January 2017. Accessed at https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf on March 27, 2018.
- ¹¹ 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. CMS, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2018. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf on April 3, 2018. Also see CMS, *Analysis of Proposed Opioid Overutilization Criteria Modifications in Medicare Part D*, April 2017. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Revised-OMS-

Criteria-Modification-Analysis.pdf on March 29, 2018.

- ¹² Beginning in 2017, CMS expects Part D sponsors to implement controls at the point of sale that alert pharmacists when a beneficiary's opioid level (across all Part D prescriptions) exceeds certain levels. For more information, see CMS, *Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2016. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf on May 8, 2018.
- ¹³ Federal Register, 83 F.R. 16440 (April 16, 2018). Accessed at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf on April 18, 2018.
- ¹⁴ OIG, Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing, OEI-02-17-00250, July 2017.
- ¹⁵ The toolkit is based on the methodology OIG developed in its extensive work on opioids. It provides technical information and is intended to assist our public and private sector partners with analyzing prescription drug claims data to help combat the opioid crisis. See OIG, *Toolkit: Using Data Analysis to Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose*, OEI-02-17-00560, June 2018.
- ¹⁶ OIG, Opioids in Medicaid: Concerns about Extreme Use and Questionable Prescribing in Selected States, OEI-05-18-00010, forthcoming.
- ¹⁷ OIG, Work Plan, 2018 at https://oig.hhs.gov/reports-and-publications/workplan/index.asp.
- ¹⁸ In both years, the five most commonly dispensed opioids included tramadol 50mg, hydrocodone-acetaminophen 10-325 mg, hydrocodone-acetaminophen 5-325 mg, hydrocodone-acetaminophen 7.5-325 mg, and oxycodone-acetaminophen 10-325 mg.
- ¹⁹ In total, 2.7 million of the 14.1 million beneficiaries who received at least one opioid had a cancer diagnosis or hospice care in 2017.
- ²⁰ CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," *MMWR Recommendations and Reports* 65, no. 1, March 18, 2016, 25.
- ²¹ In 2017, Part D paid a total of \$481 million for these three strengths of hydrocodone-acetaminophen tablets.
- ²² 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 Endo Pharmaceuticals, PERCOCET® (Oxycodone and Acetaminophen Tablets, USP), 2. Accessed at
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/040330s015,040341s013,040434s003lbl.pdf; for Vicodin, see page 20 at http://www.rxabbvie.com/pdf/vicodin_apap_300mg_hydrocodone_5mg-7_5mg-10mg_Pl.pdf.
- ²³ An additional 180,160 beneficiaries had an average daily MED that exceeded 90 mg—but did not exceed 120 mg—for 3 months. These levels also exceed the MED levels that CDC recommends avoiding for patients with chronic pain. See CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," *MMWR Recommendations and Reports* 65, no. 1, March 18, 2016, 25.
- ²⁴ U.S. Drug Enforcement Administration, Diversion Control Division, *National Forensic Laboratory Information System,* 2016 Annual Report, 2017. Accessed at
- https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS2016AR.pdf on March 28, 2018.
- ²⁵ This is based on a summary of the research CDC reviewed to develop its prescribing guidelines. CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," *MMWR Recommendations and Reports* 65, no. 1, March 18, 2016, 23.
- ²⁶ Ibid. 13, 44.
- ²⁷In addition to people over the age of 65, Medicare is available to younger people with disabilities and those with end-stage renal disease. U.S. Department of Health and Human Services, *Who Is Eligible for Medicare?* Accessed at https://www.hhs.gov/answers/medicare-and-medicaid/who-is-elibible-for-medicare/index.html on April 12, 2018.
- ²⁸ A total of 38,994 of the same beneficiaries were identified as being at serious risk in both 2016 and 2017.
- ²⁹ This does not include beneficiaries who had cancer or were in hospice care.

- ³⁰ CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," *MMWR Recommendations and Reports* 65, no. 1, March 18, 2016, 10.
- ³¹ CDC recommends that clinicians evaluate opioid use at least every 3 months for patients with chronic pain. If the benefits of continued use do not outweigh the harm, clinicians should work with the patients to taper the opioids to a lower dosage or to discontinue use. CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," *MMWR Recommendations and Reports* 65, no. 1, March 18, 2016, 16.
- ³² Specifically, in 2017, 60 percent of Medicare Part D beneficiaries who received opioids have one prescriber and 79 percent have one pharmacy. This does not include beneficiaries who had cancer or hospice care.
- ³³ Although a statewide prescription drug management program for Missouri was authorized in 2017, it is not yet operational. Currently, St. Louis County, Missouri, operates a program. For more information, see Prescription Drug Monitoring Program, Training and Technical Assistance Center, Brandeis University. Accessed at http://www.pdmpassist.org/ on March 20, 2018. Also see Mo. Exec. Order 17-18. Accessed at https://www.sos.mo.gov/library/reference/orders/2017/eo18 on June 7, 2018.
- ³⁴ 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*, Brandeis University, 2017. Accessed at http://www.pdmpassist.org/pdf/2016 Best Practice Checklist Report 20170228.pdf on March 29, 2018. Also see The PEW Charitable Trusts, *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 March 29, 2018.
- ³⁵ A total of 86,461 prescribers ordered opioids for at least one beneficiary at serious risk of opioid misuse or overdose in 2017.
- ³⁶ In total, 166 of the same prescribers were identified as having questionable opioid prescribing in both 2016 and 2017. OIG identified 401 prescribers with questionable opioid prescribing in 2016. These prescribers each ordered opioids for at least 44 beneficiaries who received extreme amounts of opioids or 21 beneficiaries who appeared to be doctor shopping. See OIG, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing*, OEI-02-17-00250, July 2017.
- ³⁷ Thirty-two prescribers ordered opioids for high numbers of beneficiaries in both groups at serious risk.
- ³⁸ Thomas E. Price, "Secretary Price Announces HHS Strategy for Fighting Opioid Crisis," speech at the National Rx Drug Abuse and Heroin Summit, April 19, 2017, Atlanta, Georgia. Accessed at https://www.hhs.gov/about/leadership/secretary/speeches/2017-speeches/secretary-price-announces-hhs-strategy-for-fighting-opioid-crisis/index.html on March 30, 2018.
- ³⁹ CMS, Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 2018. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf on April 3, 2018.
- ⁴⁰ Under CARA, the Secretary of Health and Human Services has the authority to develop the guidelines under which beneficiaries are determined to be 'at-risk' as well as which drugs are considered frequently abused. See Pub. L. No. 114-198, § 704 (July 22, 2016). Accessed at https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf on June 7, 2018. For the 2019 plan year, at-risk beneficiaries will be, at minimum, defined as those who are considered high risk in the Overutilization Monitoring System, and most opioids and benzodiazepines will be designated as frequently abused drugs. See Federal Register, 83 F.R. 16452 (April 16, 2018). Accessed at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf on April 18, 2018.
- ⁴¹ OIG, Opioids in Medicaid: Concerns about Extreme Use and Questionable Prescribing in Selected States, OEI-05-18-00010, forthcoming. Also, see OIG, Work Plan, 2018 at https://oig.hhs.gov/reports-and-publications/workplan/index.asp.
- ⁴² Healthcare Fraud Prevention Partnership, *Health Payer Strategies to Reduce the Harms of Opioids*, White Paper, January 2017. Accessed at https://downloads.cms.gov/files/hfpp/hfpp-opioid-white-paper.pdf on March 29, 2018.

- ⁴⁵ 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 March 28, 2018.
- ⁴⁶ We included opioids dispensed in 2016 with days of use in 2017. This analysis excludes PDE records for injection, intravenous, and intrathecal opioids, as well as opioids indicated for medication-assisted treatment.
- ⁴⁷ 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 2,667,678 beneficiaries with cancer or in hospice care who received at least one opioid.
- ⁴⁸ Through 2017, CMS's Overutilization Monitoring System identified beneficiaries who had a daily MED of 120 mg for 90 days plus 4 or more prescribers and 4 or more pharmacies. Note that the guidance uses the phrase "more than 3 prescribers and more than 3 pharmacies" which is equivalent to "4 or more prescribers and 4 or more pharmacies." The criteria for the Overutilization Monitoring System changed in 2018. 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, April 2017. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf on March 29, 2018.

⁴³ These files contain MME conversion factors for each National Drug Code (NDC). MED and MME are interchangeable terms.

⁴⁴ Using CMS's Integrated Data Repository, we reviewed 75,976,074 PDE records for opioids with dates of service in 2017. To identify PDE records for opioids, we matched the NDCs on the PDE records with two files—First Databank and CDC's MME conversion file.