U.S. Department of Health and Human Services

Office of Inspector General

Data Brief

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Opioid Use in Medicare Part D Continued To Decline in 2019, but Vigilance Is Needed as COVID-19 Raises New Concerns

Key Takeaways

- Medicare Part D has seen a steady decline in opioid use over the past several years, along with an increased use of drugs for medication-assisted treatment of opioid use disorder.
- In 2019, the number of beneficiaries at serious risk of opioid misuse or overdose was lower than in the previous 3 years.
- The number of prescribers with questionable opioid prescribing for beneficiaries at serious risk has also decreased.
- Together, these changes show progress in 2019 from the efforts of the Department of Health and Human Services (HHS)—and others—to address the opioid crisis. Nonetheless, it is critical to remain vigilant.
- The additional danger that COVID-19 poses to this population, alongside the elevated risk of opioid-related fraud and abuse that could result from recent rule changes, makes it imperative for HHS to closely monitor opioid use in 2020.

Why OIG Did This Review

The United States has been grappling with the opioid crisis for several years. In 2018, nearly 47,000 opioid-related overdose deaths occurred in the United States.¹ The Office of Inspector General (OIG) has been tracking opioid use in Medicare Part D since 2016. In particular, OIG has identified beneficiaries at serious risk of opioid misuse or overdose and prescribers with questionable opioid prescribing for these beneficiaries.²

This data brief provides important information on opioid use in Medicare Part D in 2019, before the coronavirus disease 2019 (COVID-19) pandemic. This information is critical to understanding trends in opioid use. This data brief will also provide comparison points for a forthcoming OIG data brief, which will examine changes in opioid use that occurred during the pandemic in 2020.

What OIG Found

About 1 in 4 Medicare Part D beneficiaries received opioids in 2019, a decrease from the prior 3 years. Spending for opioids in Part D also decreased to \$2.8 billion, the lowest amount in 10 years. At the same time, the number of beneficiaries receiving drugs for medication-assisted treatment (MAT) for opioid use disorder has steadily increased in recent years, reaching about 209,000 in 2019. Also, the number of beneficiaries receiving prescriptions through Part D for naloxone—a drug that can reverse the effects of an opioid overdose—has continued to grow.

Yet concerns remain. Nearly 267,000 beneficiaries received high amounts of opioids in 2019, with almost 34,000 of them at serious risk of opioid misuse or overdose. About 140 prescribers ordered opioids for large numbers of these beneficiaries at serious risk. There is also concern that some beneficiaries may be experiencing challenges in accessing MAT drugs to treat opioid use disorder. Further, additional efforts to expand access to naloxone may be needed.

What OIG Concludes

As of 2019, opioid use in Part D had decreased and the use of MAT drugs and the availability of naloxone had increased. Nonetheless, it is critical to remain vigilant. The current COVID-19 pandemic

makes the need to look at this population even more pressing. Early reports for 2020 indicate that overdose deaths are rising in some areas of the country.³ The National Institute on Drug Abuse—part of the National Institutes of Health—warned that individuals with opioid use disorder could be particularly hard hit by COVID-19 as it is a disease that attacks the lungs,⁴ and respiratory disease is known to increase the risk of fatal overdose among people taking opioids. In addition, a number of rules related to telehealth and the prescribing of opioids have been relaxed in response to COVID-19 to ensure greater access to legitimate prescribing during the pandemic. These changes may unintentionally increase the risk of doctor shopping and inappropriate opioid prescribing in 2020. Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. OIG is committed to continuing our work on opioid use and access to treatment in 2020 and beyond. Likewise, we encourage the Centers for Medicare & Medicaid Services (CMS) to also closely monitor opioid use and access to treatment in 2020 and beyond.

RESULTS

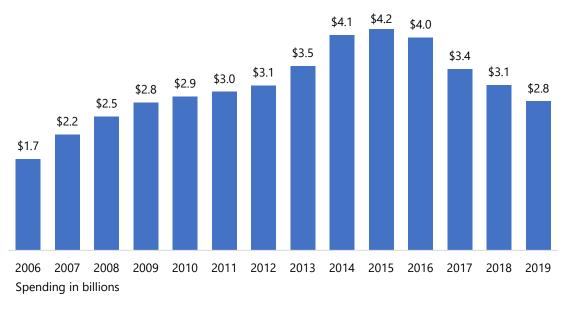
About 1 in 4 Medicare Part D beneficiaries received opioids in 2019, a decrease from the previous 3 years

In 2019, about 1 in 4 beneficiaries received at least one prescription opioid through Medicare Part D. Twenty-six percent of beneficiaries—almost 13 million of the total of 48 million beneficiaries enrolled in Medicare Part D—received opioids. This is a decrease from 2018, when 29 percent of beneficiaries received opioids through Part D; a decrease from 2017, when 31 percent did; and a decrease from 2016, when 33 percent did. (See Appendix A for information about opioid use in each State.)

Part D paid for almost 67 million opioid prescriptions—an average of 5.3 prescriptions per beneficiary receiving opioids in 2019.⁵ This too is a decrease from 2018, 2017, and 2016, when Part D paid for 71 million, 76 million, and 79 million opioid prescriptions, respectively. Tramadol was the most commonly dispensed opioid in each of the 4 years.⁶

Overall Part D spending for opioids also went down. Part D paid \$2.8 billion for opioids in 2019, compared to \$3.1 billion in 2018, \$3.4 billion in 2017, and \$4.0 billion in 2016. As Exhibit 1 shows, \$2.8 billion is the lowest amount that Part D has spent annually on opioids in the past 10 years.

Exhibit 1: Spending for opioids in Part D decreased to \$2.8 billion in 2019, the lowest amount since 2009.

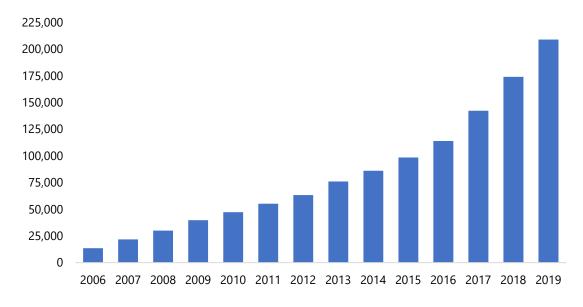


Beneficiaries' use of drugs for medication-assisted treatment has steadily increased in Part D

Beneficiaries' use of drugs for MAT in Part D has steadily increased in recent years. These drugs help treat opioid use disorder (OUD)—a problematic pattern of opioid use that leads to clinically significant impairment or distress.⁷ These medications should be prescribed in combination with counseling and behavioral health therapies. Research shows that this combination can successfully treat OUD and prevent relapse.⁸ Part D covers two drugs indicated for the treatment of OUD: buprenorphine and naltrexone.⁹ We refer to these drugs as "MAT drugs."

In 2019, the number of Medicare beneficiaries receiving MAT drugs through Part D reached 209,090, an increase of 20 percent from 2018. See Exhibit 2.

Exhibit 2: The number of beneficiaries receiving MAT drugs through Part D has increased each year.



Source: OIG analysis of Medicare Part D data, 2020.

The number of prescriptions for MAT drugs has also increased steadily in Part D. From 2018 to 2019, this number rose from 1.6 million to 1.9 million prescriptions, an increase of 21 percent. Congress and the Department of Health and Human Services (HHS) have taken steps to increase access to MAT drugs, which may have contributed to these increases. (See Appendix B for more information on the use of MAT drugs in Part D.)

Despite these increases, concerns about access to MAT drugs remain. In 2019, about 960,000 Medicare Part D beneficiaries had a diagnosis of opioid use disorder, yet just 13 percent of these beneficiaries received MAT drugs through Part D.¹¹ The limited number of beneficiaries with opioid use disorder who received MAT drugs through Part D may result, in part, from beneficiaries having challenges in accessing providers

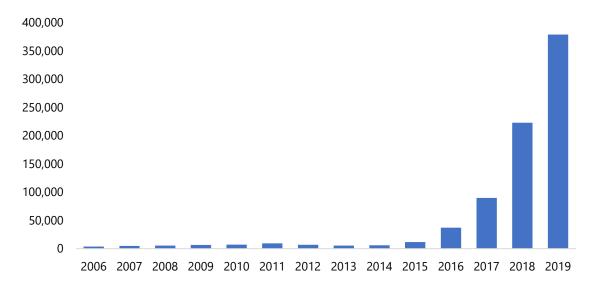
who can prescribe buprenorphine; only certain health care practitioners who have waivers from the Substance Abuse and Mental Health Services Administration (SAMHSA) may prescribe buprenorphine for MAT.¹² A recent OIG report found that 40 percent of U.S. counties did not have providers with a waiver. ¹³

The number of beneficiaries receiving drugs through Part D to reverse opioid overdoses has also continued to grow

The number of beneficiaries receiving naloxone prescriptions through Part D grew in 2019, as it has for the past several years. Naloxone is a medication that can reverse the effects of an opioid overdose. Overdoses occur when high doses of opioids—alone or in combination with other substances—cause breathing to slow to dangerous levels or to stop altogether. When naloxone (such as the brand-name drug Narcan) is administered in a timely fashion, it can save lives by blocking the effects of opioids and restoring normal breathing. Ensuring that individuals have naloxone on hand in the event of an overdose is critical for reducing the number of overdose deaths.

About 379,000 beneficiaries received a naloxone prescription in 2019, a 70-percent increase from 2018.¹⁴ (See Exhibit 3.)

Exhibit 3: The number of beneficiaries receiving prescriptions for naloxone—a drug that can reverse an opioid overdose—continued to increase in 2019.



The total number of prescriptions for naloxone also increased, reaching 414,079 prescriptions in 2019—a 73-percent increase from 2018. Congress and HHS have taken steps to increase the availability of naloxone—as they have done with MAT drugs—which may be contributing to these increases.¹⁵

Despite the increases in naloxone prescribing, additional efforts to expand access to this life-saving drug may be needed. HHS recommends that providers strongly consider prescribing naloxone to patients with an increased risk of opioid overdose, such as those who receive higher opioid amounts. Yet a recent OIG report found that only about one-quarter of beneficiaries at serious risk of opioid misuse or overdose received naloxone through Part D over a 2-year period. (See Appendix B for more information on the use of naloxone in Part D.)

Nearly 267,000 Part D beneficiaries received high amounts of opioids in 2019

In 2019, a total of 266,728 beneficiaries received high amounts of opioids through Medicare Part D; these beneficiaries did not have cancer and were not in hospice care. This is a decrease of 25 percent from 2018, when 353,751 beneficiaries received high amounts of opioids. In 2017, a total of 458,935 beneficiaries received high amounts of opioids; in 2016, 501,008 beneficiaries received high amounts of opioids.¹⁷

Each of the 266,728 beneficiaries who received high amounts of opioids in 2019 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.

Although beneficiaries may receive opioids for legitimate purposes, these amounts raise concern as opioids carry a number of health risks. The Centers for Disease Control and Prevention (CDC) recommends that prescribers use caution when ordering opioids at any dosage and avoid increasing dosages to the equivalent of 90 mg or more MED a day for chronic pain. For patients who are already taking high dosages of opioids, prescribers should offer them the opportunity to re-evaluate their continued use of these dosages, and prescribers should offer to work with them to taper their opioids to safer dosages.

Almost 34,000 beneficiaries were at serious risk of opioid misuse or overdose, fewer than in the previous 3 years

Two groups of beneficiaries that are at serious risk of opioid misuse or overdose are (1) beneficiaries who receive extreme amounts of opioids and (2) beneficiaries who appear to be doctor shopping. Other Part D beneficiaries may also be at serious risk of opioid misuse or overdose but do not fall into either group.

A total of 33,809 beneficiaries were in these two groups in 2019.²¹ (This does not include beneficiaries who have cancer or were in hospice care.) Specifically, 29,734 beneficiaries received extreme amounts of opioids (i.e., an average daily MED greater than 240 mg for 12 months) and 4,346 beneficiaries appeared to be doctor shopping (i.e., received high amounts of opioids and had 4 or more prescribers and 4 or more pharmacies). A total of 271 beneficiaries were in both groups.

The number of beneficiaries at serious risk (33,809) was lower in 2019 than in any of the previous 3 years. OIG identified 48,558 beneficiaries at serious risk of opioid misuse or overdose in 2018, 71,260 in 2017, and 89,843 in 2016.²² The numbers of beneficiaries in each of the two groups has decreased each year, with the larger drops occurring with beneficiaries who appear to be doctor shopping. (See Appendix C for more detailed information.) Despite the decrease, tens of thousands of beneficiaries are still at serious risk.

Receiving extreme amounts of opioids or high amounts of opioids from multiple prescribers and pharmacies raises concern. It may signal that a beneficiary's care is not being monitored or coordinated properly or that a beneficiary's care needs to be reassessed.²³ It may also indicate that a beneficiary is seeking medically unnecessary drugs—perhaps to use them recreationally or to divert them—or that a beneficiary is addicted to opioids and at risk of overdose.

Furthermore, a beneficiary's 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 States but Missouri maintain databases—called prescription drug monitoring programs—that track prescriptions for controlled substances.²⁴ Prescribers can check these databases before ordering opioids to determine whether a beneficiary is already receiving opioids ordered by other prescribers.²⁵

Examples of Beneficiaries at Serious Risk of Misuse or Overdose

A Missouri beneficiary received 64 opioid prescriptions in 2019. In total, this beneficiary received 12,330 opioid pills and had an average daily MED of 2,151 mg for the year. All of these prescriptions were ordered by just two prescribers: a family medicine physician and a nurse practitioner.

A beneficiary from Colorado received 36 opioid prescriptions from 10 prescribers and filled these prescriptions at 14 different pharmacies. In 1 month alone, this beneficiary filled seven opioid prescriptions at six pharmacies. These included prescriptions for hydromorphone and both short- and long-acting oxycodone. They were ordered by four different prescribers.

About 140 prescribers had questionable opioid prescribing for beneficiaries at serious risk

About 39,000 prescribers ordered opioids for at least 1 beneficiary at serious risk of opioid misuse or overdose (i.e., a beneficiary who received extreme amounts of opioids or appeared to be doctor shopping) in 2019.²⁶ 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 142 prescribers stand out as having questionable prescribing; they were far outside the norm with their prescribing and warrant further scrutiny. They ordered opioids for the highest numbers of beneficiaries at serious risk. Specifically, 84 prescribers each ordered opioids for at least 32 beneficiaries who received extreme amounts of opioids in 2019. Further, 62 prescribers each ordered opioids for at least 10 beneficiaries who appeared to be doctor shopping.²⁷

The number of prescribers with questionable prescribing for beneficiaries at serious risk decreased in 2019. There were 142 of these prescribers in 2019, down from 198 in 2018, 282 in 2017, and 401 in 2016.²⁸

Although 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 that could be diverted for resale or recreational use. Another possibility is that the prescriber's identification was sold or stolen and is being used for illegal purposes.

In total, these 142 prescribers ordered 74,820 opioids in 2019 for beneficiaries at serious risk, costing Part D a total of \$22.1 million. As in previous years, about one-third of these prescribers were nurse practitioners or physician assistants. In total, 25 were physician assistants and 23 were nurse practitioners.

Examples of Prescribers Who Ordered Opioids for Large Numbers of Beneficiaries At Serious Risk

A Florida physician ordered 1,707 opioids for 72 beneficiaries who received extreme amounts of opioids in 2019. Almost half of these prescriptions were for oxycodone. In total, Part D paid almost \$600,000 for these prescriptions.

A South Carolina physician ordered 130 opioids for 28 beneficiaries who appeared to be doctor shopping. This doctor ordered 14 prescriptions for fentanyl and oxycodone for a beneficiary who received extreme amounts of opioids and appeared to be doctor shopping.

CONCLUSION

Opioid use in Medicare Part D has steadily decreased over the past several years, with about 1 in 4 Part D beneficiaries receiving an opioid in 2019. At the same time, the use of drugs for medication-assisted treatment has steadily increased. In addition, the number of beneficiaries receiving prescriptions through Part D for naloxone—a drug that can reverse the effects of an opioid overdose—has continued to grow. In 2019, there were fewer Part D beneficiaries receiving high amounts of opioids and fewer beneficiaries at serious risk of opioid misuse or overdose than in the previous 3 years. The number of prescribers with questionable opioid prescribing for beneficiaries at serious risk has also decreased. These changes show progress in 2019 from the efforts of HHS and others to address the opioid crisis.²⁹

Nonetheless, it is critical for HHS and others to remain vigilant. Nearly 267,000 beneficiaries received high amounts of opioids during the year, with almost 34,000 of them at serious risk of opioid misuse or overdose. Although opioids may be necessary for some patients, the extreme use of opioids and apparent doctor shopping described in this study raise concern. These patterns may indicate that opioids are being prescribed for medically unnecessary purposes and could be diverted for resale or recreational use. They may also indicate that a beneficiary is receiving poorly coordinated care or that the beneficiary's care may need to be reassessed. In addition, there is also concern that some beneficiaries may be experiencing challenges in accessing MAT drugs to treat opioid use disorder. Further, additional efforts to expand access to naloxone may be needed. A recent OIG data brief recommended that CMS educate Part D beneficiaries and providers about access to MAT drugs and naloxone.³⁰ We continue to encourage CMS to take these steps.

The concerns raised in this data brief are even more pressing in light of the current COVID-19 pandemic. Early reports for 2020 indicate that overdose deaths are rising in many areas of the country. The National Institute on Drug Abuse—part of the National Institutes of Health—warned that individuals with opioid use disorder could be particularly hard hit by COVID-19 as it is a disease that attacks the lungs, ³¹ and respiratory disease is known to increase the risk of fatal overdose among people taking opioids. In addition, in response to COVID-19, a number of rules related to telehealth and the prescribing of opioids have been relaxed to ensure greater access to legitimate prescribing during the pandemic.³² These changes may unintentionally increase the risk of doctor shopping and inappropriate opioid prescribing in 2020.

The danger that COVID-19 poses to this population and the elevated risk of opioid-related fraud and abuse from the recent rule changes make it imperative for HHS—including CMS and OIG—to continue its efforts to address the opioid crisis. OIG is committed to working with our law enforcement partners and with CMS to follow up on prescribers with questionable opioid prescribing. We are also committed to

continuing our work on opioid use and access to treatment in 2020 and beyond.³³ Likewise, we encourage CMS to closely monitor opioid use and access to treatment in 2020 and beyond.

METHODOLOGY

We based this data brief on an analysis of prescription drug event (PDE) records for Part D drugs. These PDE records are for prescriptions that beneficiaries received through Part D. They do not include prescriptions paid for 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.

To obtain descriptive information about the drugs, beneficiaries, and prescribers, we matched PDE records to data from the First DataBank, the National Claims History File, Part C Encounter Data, CDC's Morphine Milligram Equivalent (MME) conversion file, and the National Plan and Provider Enumeration System (NPPES). 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 diagnosis 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 drug's morphine milligram equivalence.³⁴ The NPPES contains information about prescribers, such as their name, address, and taxonomy (i.e., specialty). For the purposes of this study, we use the term "prescription" to mean one PDE record.

Analysis of Part D Utilization of Opioids, Drugs for MAT, and Naloxone

We identified all PDE records for opioids that beneficiaries received in 2019.³⁵ We calculated the total number of Part D beneficiaries who received opioids in 2019. We then calculated the total number of opioid prescriptions paid for by Part D in 2019 and the average number of opioid prescriptions per beneficiary. We compared the 2019 data to the data from 2016, 2017, and 2018 in our previous data briefs, which used the same methodology. Next, we calculated total Part D spending for opioids from 2006 (the first year of Part D) to 2019. 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 2019. We based this analysis on the PDE records and Medicare enrollment data. We then identified the most commonly prescribed opioids by calculating the total number of prescriptions for each drug name (delineated by strength and form).

We then identified all PDE records for (1) MAT drugs indicated for the treatment of OUD and (2) naloxone (the opioid overdose reversal drug). We first calculated the total number of beneficiaries who received MAT drugs and the number of prescriptions for these drugs from 2006 through 2019.³⁶ Next, we calculated the total number of beneficiaries who received naloxone and the number of prescriptions for naloxone from 2006 through 2019.³⁷

We calculated the proportion of beneficiaries with opioid use disorder who received MAT drugs in 2019. We identified beneficiaries with opioid use disorder in 2019 by using CMS's National Claims History File and Part C Encounter data. We considered a beneficiary to have opioid use disorder if he or she had a diagnosis of "opioid abuse" (F11.1) or "opioid dependence" (F11.2).³⁸ For beneficiaries with opioid use disorder, we calculated the total number of beneficiaries who received MAT drugs in 2019 using PDE records.

Beneficiary Analysis

We determined the amount of opioids that each beneficiary received in 2019. To do this, we calculated each beneficiary's average daily morphine equivalent dose (MED).³⁹ 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., for each PDE record).⁴⁰ To do this, we used the following equation:

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

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 who had a diagnosis of cancer or a hospice stay at any point in 2019.⁴¹

We analyzed the MED data using the same criteria that we used in our previous analysis of the 2016, 2017, and 2018 data.⁴² 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 2019. 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. The MED of 120 mg exceeds the 90-mg MED level that CDC recommends avoiding for patients with chronic pain.

We then determined the extent to which these 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 2019. 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 numbers of beneficiaries that we had previously identified in our analyses of the 2016, 2017, and 2018 data.

Prescriber Analysis

For this analysis, we identified prescribers who ordered opioids for a high number of beneficiaries at serious risk—i.e., 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. We used the National Provider Identifiers (NPIs) on the PDE records to identify prescribers. We considered each NPI to be a unique prescriber.⁴³

In total, 25,906 prescribers ordered opioids for beneficiaries who received extreme amounts of opioids and 18,351 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 he or she 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, MAT drugs, or naloxone that beneficiaries may have received from sources other than Part D.

Standards

We conducted this study 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.

Alabama	39%	Florida	25%
Arkansas	37%	Ohio	25%
ouisiana.	35%	Iowa	25%
Mississippi	35%	Illinois	25%
Oklahoma	34%	New Mexico	25%
Georgia	33%	Alaska	24%
ennessee	33%	Nevada	24%
Kentucky	32%	Wisconsin	24%
South Carolina	31%	Maryland	24%
Missouri	31%	South Dakota	24%
exas	30%	California	23%
North Carolina	30%	North Dakota	23%
ndiana	30%	Delaware	23%
(ansas	30%	Pennsylvania	22%
Jtah	29%	Minnesota	22%
daho	29%	District of Columbia	21%
West Virginia	28%	Maine	20%
Oregon	27%	Connecticut	20%
Wyoming	27%	New Jersey	20%
Washington	26%	Massachusetts	20%
Michigan	26%	New Hampshire	19%
Montana	26%	Rhode Island	19%
Colorado	26%	New York	17%
lebraska	26%	Vermont	17%
rizona	26%	Hawaii	15%
/irginia	25%		

APPENDIX B

Use of Medication-Assisted Treatment Drugs and Naloxone in Part D

Exhibit B-1: Both the number of beneficiaries and the number of prescriptions for medication-assisted treatment (MAT) drugs for opioid use disorder increased between 2016 and 2019.

	2016	2017	2018	2019	Percent Change From 2016 to 2017	Percent Change From 2017 to 2018	Percent Change From 2018 to 2019
Beneficiaries who received a MAT drug through Part D	113,967	142,258	174,109	209,090	25%	22%	20%
Part D prescriptions for drugs for MAT	1,030,755	1,278,557	1,591,262	1,925,730	24%	24%	21%

Source: OIG analysis of Medicare Part D data, 2020.

Exhibit B-2: The number of beneficiaries and the number of prescriptions for naloxone continued to increase in 2019.

	2016	2017	2018	2019	Percent Change From 2016 to 2017	Percent Change From 2017 to 2018	Percent Change From 2018 to 2019
Beneficiaries who received naloxone through Part D	37,039	89,871	222,736	378,740	143%	148%	70%
Part D prescriptions for naloxone	39,902	96,295	239,283	414,079	141%	148%	73%

APPENDIX C

Beneficiaries Receiving Opioids Through Part D

Exhibit C-1: Almost 267,000 beneficiaries received high amounts of opioids through Part D in 2019, a decrease from the previous 3 years.

	2016	2017	2018	2019	Percent Change From 2016 to 2017	Percent Change From 2017 to 2018	Percent Change From 2018 to 2019
Beneficiaries who received high amounts of opioids	501,008	458,935	353,751	266,728	-8%	-23%	-25%

Source: OIG analysis of Medicare Part D data, 2020.

Exhibit C-2: About 34,000 beneficiaries are at serious risk of opioid misuse or overdose in 2019, a decrease from the previous 3 years.

	2016	2017	2018	2019	Percent Change From 2016 to 2017	Percent Change From 2017 to 2018	Percent Change From 2018 to 2019
Beneficiaries who received an extreme amount of opioids	69,563	57,611	40,374	29,734	-17%	-30%	-26%
Beneficiaries who appear to be doctor shopping	22,308	14,814	8,796	4,346	-34%	-41%	-51%
Total beneficiaries at serious risk	89,843*	71,260**	48,558***	33,809****	-21%	-32%	-30%

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

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

^{***} A total of 612 beneficiaries were in both groups in 2018.

^{****} A total of 271 beneficiaries were in both groups in 2019.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Nancy Harrison and Meridith Seife, Deputy Regional Inspectors General.

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To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

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ENDNOTES

- ¹ CDC, Drug Overdose Deaths. Accessed at https://www.cdc.gov/drugoverdose/data/statedeaths.html on June 8, 2020.
- ² OIG first began tracking opioid use in Part D in 2014. In 2016 OIG began to conduct more in-depth reviews that determined the number of beneficiaries who were receiving high amounts of opioids, as well as the number of beneficiaries who were at serious risk for opioid misuse or overdose and the number of prescribers with questionable opioid prescribing for these beneficiaries. OIG has subsequently released additional data briefs in 2017, 2018, and 2019. See OIG, *Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D*, OEI-02-15-00190, June 2015; OIG, *High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns*, OEI-02-16-00290, June 2016; OIG, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing*, OEI-02-17-00250, July 2017; OIG, *Opioid Use in Medicare Part D Remains Concerning*, OEI-02-18-00220, June 2018; OIG, *Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased*, OEI-02-19-00390, July 2019.
- ³ For example, Maryland, Vermont, and Rhode Island have released preliminary data that indicate opioid-related overdose deaths were higher in the beginning of 2020, compared to the same time in 2019. See Maryland Opioid Operational Command Center, *Quarterly Report, January 1, 2020–March 31, 2020*, June 10, 2020. Also see Vermont Department of Health, *Monthly Opioid Update—June 2020*, June 23, 2020, and Rhode Island, *Increase in Overdose Deaths Identified in the Early Months of 2020*, June 23, 2020.
- ⁴ Dr. Nora Volkow, Director, National Institute on Drug Abuse, National Institutes of Health, *COVID-19: Potential Implications for Individuals with Substance Abuse Disorders*, April 6, 2020. Accessed at https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders on April 9, 2020.
- ⁵ This represents the total number of opioid prescriptions paid for under Part D, including those in the deductible stage of the benefit when some beneficiaries pay the full cost. For the purposes of this study, we use the term "prescription" to mean one PDE record.
- ⁶ In each year from 2016 to 2019, the most commonly dispensed opioids included tramadol 50 mg, hydrocodone-acetaminophen 10-325 mg, and hydrocodone-acetaminophen 5-325 mg.
- ⁷ Diagnostic and Statistical Manual of Mental Disorders: DSM-5. Arlington, VA: American Psychiatric Publishing, 2013.
- ⁸ SAMHSA, *Medication and Counseling Treatment*. Accessed at https://www.samhsa.gov/medication-assisted-treatment on May 8, 2020.
- ⁹ Methadone is another drug used for MAT. However, methadone used for MAT is not covered by Part D. See *Medicare Prescription Drug Benefit Manual*, ch. 6, § 10.8. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf on May 8, 2020. In 2020, Medicare Part B began covering methadone provided by opioid treatment programs.
- ¹⁰ For example, Section 303 of the Comprehensive Addiction and Recovery Act of 2016 (CARA), P.L. No. 114-198 (enacted July 22, 2016), and Section 3201 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act), P.L. No. 115-271 (enacted October 24, 2018), expanded prescribing authority for MAT drugs. The Department's five-point strategy to combat opioid misuse and overdose also emphasizes increasing access to medication-assisted treatment. See HHS, *Strategy to Combat Opioid Abuse, Misuse, and Overdose*, September 2018. Accessed at https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf on May 8, 2020.
- ¹¹ A diagnosis of opioid use disorder indicates that an individual has a problematic pattern of opioid use that leads to clinically significant impairment or distress. We identified beneficiaries with a diagnosis of opioid use disorder in 2019 using CMS's National Claims History File and Part C Encounter data.
- ¹² 21 U.S.C. § 823(g).

- ¹³ OIG, Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder, OEI-12-17-00240 (January 2020). See also OIG, Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look, OEI-02-19-00130 (May 2020).
- ¹⁴ The total number of beneficiaries who received naloxone may be underestimated. This number includes only naloxone prescriptions that were paid for by Part D. Beneficiaries may receive naloxone from sources other than Part D. Notably, most States allow for third-party prescriptions, which means that family members or friends of an at-risk patient can get a prescription for naloxone in their own name. In addition, a number of recent initiatives have increased community-based distribution of naloxone.
- ¹⁵ For example, Section 107 of CARA, P.L. No. 114-198 (enacted July 22, 2016) authorized the Department to award grants to expand access to opioid-overdose reversal drugs, e.g. naloxone. The Department's five-point strategy to combat opioid misuse and overdose also emphasizes increasing availability of overdose-reversal drugs. See HHS, *Strategy to Combat Opioid Abuse, Misuse, and Overdose*, September 2018. Accessed at https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf on May 8, 2020. In addition, in April 2019 the Food and Drug Administration (FDA) approved the first generic naloxone nasal spray. See FDA, *FDA approves first generic naloxone nasal spray to treat opioid overdose*, April 19, 2019. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-naloxone-nasal-spray-treat-opioid-overdose on April 29, 2020.
- ¹⁶ Specifically, 23 percent of beneficiaries at serious risk of opioid misuse or overdose in 2017 received naloxone in 2017 or 2018 through Part D. OIG, *Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look*, OEI-02-19-00130, March 2020.
- ¹⁷ In addition, a smaller percentage of beneficiaries who received an opioid received high amounts of opioids. In 2019, 2.1 percent of beneficiaries who received an opioid received high amounts, down from 2.7 percent in 2018, 3.3 percent in 2017, and 3.5 percent in 2016.
- ¹⁸ In addition to the risk of dependence and overdose, 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. See Diane L. Chau, Vanessa Walker, Latha Pai, et al., "Opiates and Elderly: Use and Side Effects," *Clinical Interventions in Aging*, Vol. 3, No. 2 (2008), p. 276. CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," *MMWR* [Morbidity and Mortality Weekly Report] Recommendations and Reports, Vol. 65, No. 1, March 18, 2016, pp. 1–49. Accessed at https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf on May 8, 2020. 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*, Vol. 25, No. 4 (2010), pp. 310–315.
- ¹⁹ The CDC Guideline provides recommendations for prescribing opioids for chronic pain outside of cancer treatment, palliative care, and end-of-life care. It recommends 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. CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016." (See endnote 18 for full *MMWR* citation and link.)
- ²⁰ In September 2019, HHS issued a guide for clinicians on how to appropriately reduce or discontinue long-term use of opioids. The guide provides insights for clinicians on when and how to work with patients to taper opioids. The guide emphasizes that prescribers should decide based on the patient's individual circumstances whether tapering is appropriate. It also reiterates that under most circumstances, HHS does not recommend abrupt opioid dose reduction or discontinuation. See HHS, HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, September 2019. Accessed at https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf on May 8, 2020.
- ²¹ This group of beneficiaries is a subset of the 266,728 beneficiaries who received high amounts of opioids.
- ²² A total of 10,237 of the beneficiaries identified as being at serious risk in 2019 were also identified as such in 2016, 2017, and 2018. This represents 30 percent of the beneficiaries identified as being at serious risk in 2019.

- ²³ 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 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." (See endnote 18 for full *MMWR* citation and link.)
- ²⁴ Missouri is the only State that lacks a Statewide prescription drug monitoring program. Instead, St. Louis County operates a program.
- ²⁵ State requirements for checking this information vary. For more information about prescription drug monitoring programs, see the website of the Prescription Drug Monitoring Program Training and Technical Assistance Center, Brandeis University, at http://www.pdmpassist.org/.
- ²⁶ A total of 39,259 prescribers ordered opioids for at least 1 beneficiary at serious risk of opioid misuse or overdose in 2019.
- ²⁷ Four prescribers ordered opioids for high numbers of beneficiaries in both groups at serious risk.
- ²⁸ In total, we identified 33 prescribers as having questionable opioid prescribing in 2016, 2017, 2018, and 2019. OIG identified 198 prescribers with questionable opioid prescribing in 2018. These prescribers each ordered opioids for at least 39 beneficiaries who received extreme amounts of opioids or 16 beneficiaries who appeared to be doctor shopping. See OIG, Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased, OEI-02-19-00390, July 2019. OIG identified 282 prescribers with questionable opioid prescribing in 2017. These prescribers each ordered opioids for at least 45 beneficiaries who received extreme amounts of opioids or 18 beneficiaries who appeared to be doctor shopping. See OIG, Opioid Use in Medicare Part D Remains Concerning, OEI-02-18-00220, June 2018. 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. We are working with our law enforcement partners and with CMS to follow up on the prescribers we identified in our reviews as having questionable opioid prescribing.
- ²⁹ Examples of key initiatives—taken by HHS and others—to address the opioid crisis include the development and implementation of the following: the Comprehensive Addiction and Recovery Act of 2016 (CARA), P.L. No. 114-198; the Substance Use—Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act), P.L. No. 115-271; HHS's *Strategy to Combat Opioid Abuse, Misuse, and Overdose;* CDC's "Guideline for Prescribing Opioids for Chronic Pain: United States"; and CMS's Overutilization Monitoring System. For more information on CMS's Overutilization Monitoring System and its other efforts to address opioid overutilization in Part D see CMS, *Improving Drug Utilization Review Controls in Part D*, undated webpage. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization on May 15, 2020.
- ³⁰ OIG, Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look, OEI-02-19-00130, May 2020.
- ³¹ Dr. Nora Volkow, Director, National Institute on Drug Abuse, National Institutes of Health, *COVID-19: Potential Implications for Individuals with Substance Abuse Disorders*, April 6, 2020. Accessed at https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders on April 9, 2020.
- ³² For instance, during the pandemic, Medicare will pay for services delivered via telehealth in a beneficiary's home. Pharmacies can also fill prescriptions for Schedule II controlled substances—including many powerful opioids—with a prescription provided over the telephone, rather than a written prescription, as long as certain condition are met. For more information about telehealth, see CMS, *Expansion of Telehealth With 1135 Waiver*. Accessed at https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet on May 26, 2020. For more information about prescribing controlled substances, see the Drug Enforcement Administration's letter to Practitioner Registrants and Pharmacists dated March 28, 2020. Accessed at https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-021)(DEA073)%20Oral%20CII%20for%20regular%20CII%20scirpt%20(Final)%20+Esign%20a.pdf on May 26, 2020.
- ³³ See OIG, *Utilization of Medication-Assisted Treatment in Medicare*, OEI-02-20-00390, forthcoming, and OIG, *Opioid Use in Medicare Part D in 2020*, OEI-02-20-00400, forthcoming.

- ³⁴ These files contain MME conversion factors for each National Drug Code. MED and MME are interchangeable terms.
- ³⁵ Using CMS's Integrated Data Repository, we reviewed 66,501,797 PDE records for opioids with dates of service in 2019. 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.
- ³⁶ Part D covers two MAT drugs indicated for OUD: buprenorphine and naltrexone. Some buprenorphine products indicated for OUD also contain naloxone, e.g., Suboxone. To identify PDE records for MAT drugs containing buprenorphine or naltrexone, we matched the NDCs to First Databank. We reviewed each drug and included all formulations indicated for the treatment of OUD. Note that some of these formulations are also indicated for alcohol use disorder. We based this on PDE records from CMS's Integrated Data Repository.
- ³⁷ To identify PDE records for naloxone, we matched the NDCs to First Databank. We included formulations indicated for the emergency treatment of a known or suspected opioid overdose in this analysis. We based this on PDE records from CMS's Integrated Data Repository.
- ³⁸ See ICD-10 CM 2018: The Complete Official Codebook (American Medical Association).
- ³⁹ 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 May 8, 2020.
- ⁴⁰ We included opioids dispensed in 2018 with days of use in 2019. This analysis excludes PDE records for injection, intravenous, and intrathecal opioids, as well as opioids indicated for medication-assisted treatment.
- ⁴¹ We identified beneficiaries with a cancer diagnosis or hospice stay by using CMS's National Claims History File and Part C Encounter data. In total, we identified 2,925,801 beneficiaries with cancer or in hospice care who received at least 1 opioid.
- ⁴² We selected these criteria because they closely align with the criteria that CMS used in 2016 and 2017 for its Overutilization Monitoring System. Through 2017, CMS's Overutilization Monitoring System identified beneficiaries who had a daily MED of 120 mg for 90 days plus four or more prescribers and four or more pharmacies. Note that the guidance uses the term "more than 3 prescribers and more than 3 pharmacies," which is the equivalent of "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 3, 2017. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf on May 8, 2020.

⁴³ For our analysis, we counted prescribers in group practices separately.