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

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Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased

Why OIG Did This Review

The Nation has been grappling with an opioid crisis for several years. In 2017 alone, there were 47,600 opioid-related overdose deaths in the United States. It continues to be a public health emergency. The Office of Inspector General (OIG) has been tracking opioid use in Medicare during this crisis, particularly since 2016.[1] OIG has identified beneficiaries at serious risk of misuse or overdose and has identified prescribers with questionable prescribing for these beneficiaries. These types of analyses are crucial to understanding and addressing the national opioid crisis. Building on past OIG work, this data brief details opioid use in Medicare Part D in 2018 and trends in drugs used to treat opioid use disorder.

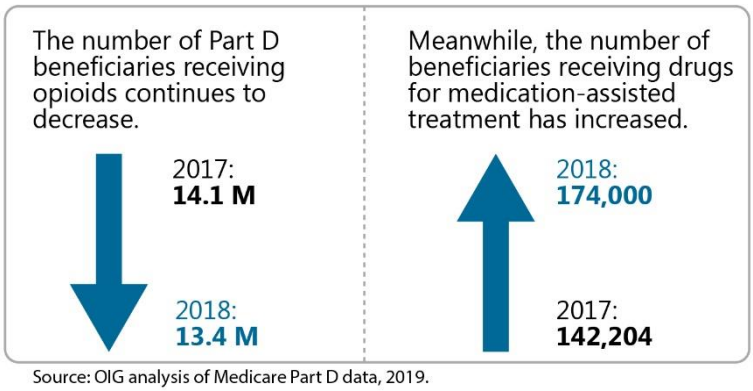
What OIG Found

Nearly 3 in 10 Medicare Part D beneficiaries (29 percent) received opioids in 2018, a significant decrease from the previous 2 years. At the same time, the number of beneficiaries receiving drugs for medication-assisted treatment (MAT) for opioid use disorder has steadily increased and reached 174,000 in 2018. In addition, the number of beneficiaries receiving prescriptions through Part D for naloxone—a drug that can reverse the effects of an opioid overdose—more than doubled from 2017 to 2018.

Key Takeaways

- ✓ In 2018, the use of opioids in Medicare Part D decreased from the previous 2 years.
- ✓ At the same time, more Medicare beneficiaries received drugs for medication-assisted treatment for opioid use disorder.
- ✓ The number of beneficiaries at serious risk decreased.
- ✓ The number of prescribers with questionable opioid prescribing for beneficiaries at serious risk also decreased.
- ✓ While concerns remain, the decreases in use attest to the value of awareness, drug treatment, and law enforcement efforts in addressing the crisis.

Nearly 354,000 beneficiaries received high amounts of opioids in 2018, with about 49,000 of them at serious risk of opioid misuse or overdose. About 200 prescribers ordered opioids for large numbers of beneficiaries at serious risk.



Source: OIG analysis of Medicare Part D data, 2019.

What OIG Concludes

Progress has been made in decreasing opioid use in Part D and increasing the use of MAT drugs and the availability of naloxone. It is imperative for the Department of Health and Human Services—including the Centers for Medicare & Medicaid Services (CMS) and OIG—to continue to implement effective strategies and develop new ones to address this epidemic.

RESULTS

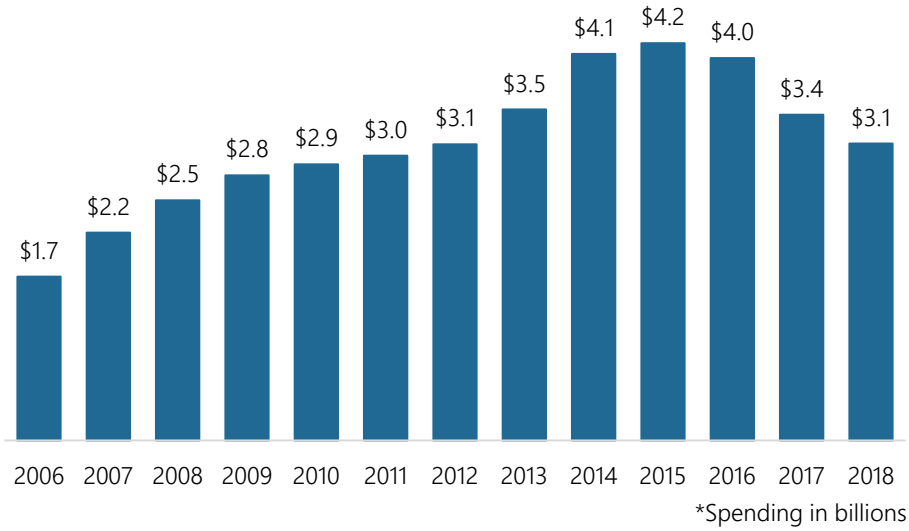
Nearly 3 in 10 Medicare Part D beneficiaries received opioids in 2018, a decrease from the previous 2 years

In 2018, nearly 3 in 10 beneficiaries received at least one prescription opioid through Medicare Part D. Twenty-nine percent of beneficiaries—13.4 million of the total of 46.8 million beneficiaries enrolled in Medicare Part D—received opioids. This is a significant decrease from 2017, when 31 percent of beneficiaries received opioids through Part D, and from 2016, when 33 percent did. (See Appendix A for information about opioid use in each State.)

Part D paid for 71 million opioid prescriptions—an average of 5.3 prescriptions per beneficiary receiving opioids in 2018.[2] This too was a decrease from 2017 and 2016, when Part D paid for 76 million and 79 million opioid prescriptions, respectively. Tramadol was the most commonly dispensed opioid in each of the 3 years.[3]

Overall Part D spending for opioids also went down; Part D paid $3.1 billion for opioids in 2018, compared to $3.4 billion in 2017 and $4.0 billion in 2016. See Exhibit 1.

Exhibit 1: Spending for opioids in Part D has continued to decrease, but remained at over $3 billion in 2018



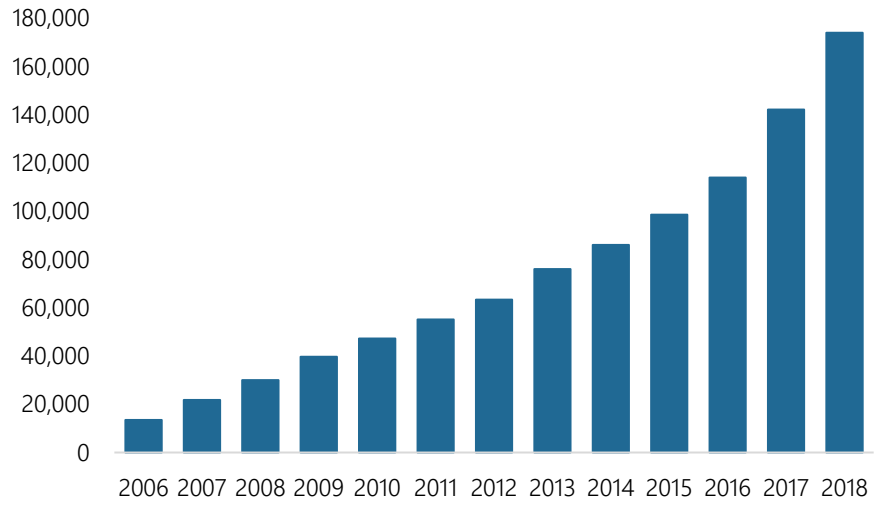
Source: OIG analysis of Medicare Part D data, 2019.

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

Beneficiaries' use of drugs for medication-assisted treatment (MAT) has steadily increased in Part D. These drugs help treat opioid use disorder (OUD)—a problematic pattern of opioid use that leads to clinically significant impairment or distress.[4] 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.[5] Part D covers two drugs indicated for the treatment of OUD: buprenorphine and naltrexone.[6] We refer to these drugs as "MAT drugs."

In 2018, the number of Medicare beneficiaries receiving MAT drugs through Part D reached 174,000, an increase of 22 percent from 2017. 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, 2019.

The number of prescriptions for MAT drugs also has increased steadily in Part D. From 2017 to 2018, this number rose from 1.3 million to 1.6 million prescriptions, an increase of 24 percent. Previously, from 2016 to 2017, the number of prescriptions for these drugs also had increased by 24 percent. Congress and the Department have taken steps to increase access to MAT drugs, which may have contributed to these increases.[7] (See Appendix B for more information on the use of MAT drugs in Part D.)

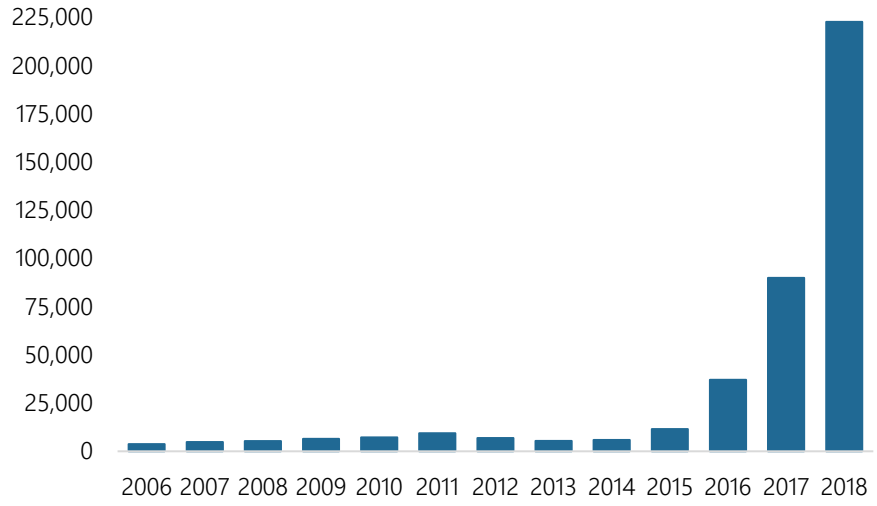
Many more beneficiaries are receiving opioid overdose reversal drugs through Part D

The number of beneficiaries receiving naloxone prescriptions through Part D more than doubled from 2017 to 2018. Naloxone is a drug that can reverse the effects of an opioid overdose and prevent death. 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 administered in a timely fashion, naloxone can save lives by blocking the effects of opioids and restoring normal breathing.

The Department has made increasing the availability of naloxone a priority in its efforts to combat the opioid crisis.[8]

Almost a quarter of a million beneficiaries (222,655) received a naloxone prescription in 2018, about two and a half times the number of beneficiaries in 2017.[9] See Exhibit 3.

Exhibit 3: The number of beneficiaries receiving prescriptions for naloxone—a drug that can reverse an opioid overdose—more than doubled from 2017 to 2018



Source: OIG analysis of Medicare Part D data, 2019.

The total number of prescriptions for naloxone also more than doubled from 2016 to 2017 in Part D and more than doubled again the next year, reaching 239,210 prescriptions in 2018. Congress and the Department have taken steps to increase the availability of naloxone—as they have done with MAT drugs— which may be contributing to these increases.[10] (See Appendix B for more information on the use of naloxone in Part D.)

More than 350,000 Part D beneficiaries received high amounts of opioids in 2018

In 2018, a total of 353,751 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 23 percent from 2017, when 458,935 beneficiaries received high amounts of opioids. In 2016, a total of 501,008 beneficiaries received high amounts of opioids.[11]

Each of the 353,751 beneficiaries who received high amounts of opioids in 2018 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. 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.[12]

Opioids also carry health risks, including respiratory depression, constipation, drowsiness, and confusion.[13] 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.[14]

Almost 49,000 beneficiaries are at serious risk of opioid misuse or overdose, fewer than in the previous 2 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 48,558 beneficiaries were in these two groups in 2018.[15] This does not include beneficiaries who have cancer or were in hospice care. Specifically, 40,374 beneficiaries received extreme amounts of opioids (i.e., an average daily MED greater than 240 mg for 12 months) and 8,796 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 612 beneficiaries were in both groups.

The number of beneficiaries at serious risk (48,558) was lower in 2018 than in previous years. OIG identified 71,260 beneficiaries at serious risk of opioid misuse or overdose in 2017 and 89,843 in 2016.[16] The numbers of beneficiaries in each of the two groups has decreased, with the larger drop occurring with beneficiaries who appear to be doctor shopping. (See Appendix C for more detailed information.) Despite the decrease, tens of thousands of beneficiaries in these two groups 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.[17] 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.[18] Prescribers can check these databases before ordering opioids to determine whether a beneficiary is already receiving opioids ordered by other prescribers.[19]

Examples of Beneficiaries at Serious Risk of Misuse or Overdose

A Pennsylvania beneficiary received 10,728 oxycodone tablets and 570 fentanyl patches in 2018. Her average daily MED was nearly 2,900 mg for the year—32 times the level that CDC recommends avoiding. She received all of her opioid prescriptions from a single physician.

A New York beneficiary received 38 opioid prescriptions during the year, including 14 1-month supplies of one strength of extended release morphine tablets and an additional 13 1-month supplies of another strength of morphine. In total, this beneficiary's average daily MED for the year was 2,173 mg. All of her prescriptions were ordered by a single physician.

Over the course of a year, an Alabama beneficiary received 56 opioid prescriptions ordered by 25 prescribers and filled at 5 pharmacies. These included prescriptions for morphine, oxycodone, and oxycodone-acetaminophen. In 1 month alone, this beneficiary received seven prescriptions from five different prescribers.

Almost 200 prescribers had questionable opioid prescribing for beneficiaries at serious risk

About 58,000 prescribers ordered opioids for at least 1 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 2018.[20] 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 198 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, 106 prescribers each ordered opioids for at least 39 beneficiaries who received extreme amounts of opioids in 2018. Further, 98 prescribers each ordered opioids for at least 16 beneficiaries who appeared to be doctor shopping.[21]

The number of prescribers with questionable prescribing for beneficiaries at serious risk decreased in 2018. There were 198 of these prescribers in 2018, down from 282 in 2017 and 401 in 2016.[22]

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 198 prescribers with questionable prescribing ordered 112,028 opioid prescriptions in 2018 for beneficiaries at serious risk, costing Part D a total of $32.4 million. As in previous years, a little more than one-third of these prescribers were nurse practitioners or physician assistants. In total, 41 were nurse practitioners and 34 were physician assistants.

Examples of Prescribers with Questionable Prescribing Patterns

One physician in Florida ordered opioids for 104 beneficiaries who received extreme amounts of opioids during 2018. In total, this physician ordered 2,619 opioids for these beneficiaries, costing Part D almost $1.2 million. In one instance, this physician ordered 37 opioid prescriptions for a single beneficiary, all of which were for oxycodone. The beneficiary had an average daily MED that was over 10 times the level that CDC recommends avoiding.

A physician in West Virginia ordered 1,419 opioids in 2018 for 99 beneficiaries who received extreme amounts of opioids. Part D paid nearly $303,000 for these opioids, the majority of which were oxycodone, morphine, and oxymorphone.

A physician in South Carolina ordered 237 opioids in 2018 for 46 beneficiaries who appeared to be doctor shopping. About half of these opioid prescriptions were for oxycodone.

CONCLUSION

Opioid use in Medicare Part D has decreased in 2018, while the use of drugs for medication-assisted treatment has increased. The number of beneficiaries receiving prescriptions through Part D for naloxone—a drug that can reverse the effects of an opioid overdose—has also increased. In addition, in 2018 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 2 years. The number of prescribers with questionable opioid prescribing for beneficiaries at serious risk has also decreased. Despite this apparent progress, concerns remain.

Almost 3 in 10 Part D beneficiaries received an opioid in 2018. About 354,000 beneficiaries received high amounts of opioids during the year, with about 49,000 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 a beneficiary is receiving poorly coordinated care or that the beneficiary's care may need to be reassessed. They also may indicate that opioids are being prescribed for medically unnecessary purposes and could be diverted for resale or recreational use.

Although progress has been made in decreasing opioid use in Part D and increasing the use of MAT drugs and the availability of naloxone, it is imperative for the Department to continue to implement effective strategies and develop new ones to address this epidemic. While concerns remain, the decreases in use attest to the value of awareness, drug treatment, and law enforcement efforts in addressing the opioid crisis.

The Department has a five-point strategy to combat opioid misuse and overdose that emphasizes increasing access to treatment and better targeting the availability of opioid-reversal drugs.[23] The Department has also begun implementing the SUPPORT for Patients and Communities Act, which was signed into law in October 2018.[24] The law takes a multifaceted approach to addressing the opioid crisis and contains many provisions related to Medicare and Medicaid. It aims to expand access to prevention, treatment, and recovery services and, at the same time, to reduce access to the supply of inappropriate opioids. Key aspects include requiring CMS to notify "outlier prescribers of opioids" on an annual basis and requiring Part D plan sponsors to implement drug management programs beginning in 2022. Under these drug management programs—which are currently voluntary—sponsors may restrict certain at-risk beneficiaries to selected pharmacies or prescribers for their opioid prescriptions.

In addition, CMS implemented a number of changes in 2019.[25] For example, Part D sponsors are now 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 are now expected to limit initial opioid prescriptions to no more than 7 days for the treatment of acute pain.

OIG remains committed to fighting the opioid crisis. In June 2018, OIG released an opioid analysis toolkit that provides step-by-step instructions for using prescription drug data to identify patients who are at risk of opioid misuse or overdose.[26] We are also 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. This includes working closely with the Department of Justice's Appalachian Regional Prescription Opioid Strike Force.[27] In addition to continuing our enforcement efforts, we continue to identify other approaches to support prevention and treatment efforts and to improve the effectiveness of broader Department efforts. For example, OIG is conducting a series of reviews on key State and Departmental initiatives to address the opioid crisis, including access to MAT drugs.[28]

Looking forward, we encourage Part D sponsors to work with OIG and CMS to bolster their efforts to combat the opioid crisis in Medicare Part D on the front lines. As part of their efforts, we call on Part D sponsors to implement drug management programs for at-risk beneficiaries. We also support CMS and the Department as a whole in their efforts to fully implement the SUPPORT for Patients and Communities Act and to provide improved access to prevention, treatment, and recovery services.

Lastly, we 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. We also encourage States to provide greater access to these data, including sharing the data with entities such as State Medicaid agencies.

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.[29] 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 2018.[30] We calculated the total number of Part D beneficiaries who received opioids in 2018. We then calculated the total number of opioid prescriptions paid for by Part D in 2018 and the average number of opioid prescriptions per beneficiary. We compared the 2018 data to the data from 2016 and 2017 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 2018. 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 2018. 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 2018.[31] Next, we calculated the total number of beneficiaries who received naloxone and the number of prescriptions for naloxone from 2006 through 2018.[32]

Beneficiary Analysis

We determined the amount of opioids that each beneficiary received in 2018. To do this, we calculated each beneficiary's average daily morphine equivalent dose (MED).[33] 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).[34] 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 who had a diagnosis of cancer or a hospice stay at any point in 2018.[35]

We analyzed the MED data using the same criteria that we used in our previous analysis of the 2016 and 2017 data.[36] 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 2018. 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 2018. 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 and 2017 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.

In total, 34,930 prescribers ordered opioids for beneficiaries who received extreme amounts of opioids and 32,317 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.

Proportion of Beneficiaries in Each State Who Received Opioids Through Medicare Part D in 2018			
Alabama	42%	Nebraska	28%
Arkansas	40%	Virginia	28%
Mississippi	39%	Ohio	27%
Oklahoma	38%	Nevada	27%
Louisiana	37%	Iowa	27%
Tennessee	36%	New Mexico	27%
Georgia	36%	Illinois	27%
Kentucky	35%	Wisconsin	26%
South Carolina	34%	Maryland	26%
Missouri	33%	South Dakota	26%
Texas	33%	California	26%
North Carolina	33%	Delaware	25%
Indiana	32%	Pennsylvania	25%
Kansas	32%	North Dakota	25%
Utah	32%	Minnesota	24%
Idaho	31%	District of Columbia	24%
West Virginia	31%	Maine	22%
Michigan	30%	Connecticut	22%
Oregon	30%	New Jersey	21%
Wyoming	29%	Massachusetts	21%
Washington	29%	Rhode Island	21%
Alaska	29%	New Hampshire	21%
Colorado	29%	Vermont	19%
Florida	28%	New York	19%
Arizona	28%	Hawaii	18%
Montana	28%		

Source: OIG analysis of Medicare Part D data, 2019.

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 2018.

	2016	2017	2018	Percent Change from 2016 to 2017	Percent Change from 2017 to 2018
Beneficiaries who received a MAT drug through Part D	113,964	142,204	174,000	25%	22%
Part D prescriptions for drugs for MAT	1,030,730	1,278,161	1,591,112	24%	24%

Source: OIG analysis of Medicare Part D data, 2019.

Exhibit B-2: The number of beneficiaries and the number of prescriptions for naloxone more than doubled each year, between 2016 and 2018.

	2016	2017	2018	Percent Change from 2016 to 2017	Percent Change from 2017 to 2018
Beneficiaries who received naloxone through Part D	37,041	89,906	222,655	143%	148%
Part D prescriptions for naloxone	39,904	96,345	239,210	141%	148%

Source: OIG analysis of Medicare Part D data, 2019.

APPENDIX C: BENEFICIARIES RECEIVING OPIOIDS THROUGH PART D

Exhibit C-1: Almost 354,000 beneficiaries received high amounts of opioids through Part D in 2018, a decrease from the previous 2 years.

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

Source: OIG analyses of Medicare Part D data, 2017, 2018, and 2019.

Exhibit C-2: About 49,000 beneficiaries are at serious risk of opioid misuse or overdose in 2018, a decrease from the previous 2 years.

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

Source: OIG analyses of Medicare Part D data, 2017, 2018, and 2019.
* 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.

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.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

ENDNOTES

[1] OIG first began tracking opioid use in Part D in 2014. In 2016 and 2017, OIG conducted 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. 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.

[2] 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.

[3] In 2016, 2017, and 2018, the most commonly dispensed opioids included tramadol 50 mg, hydrocodone acetaminophen 10-325 mg, hydrocodone-acetaminophen 5-325 mg, and hydrocodone-acetaminophen 7.5-325 mg.

[4] *Diagnostic and Statistical Manual of Mental Disorders: DSM-5*. Arlington, VA: American Psychiatric Publishing, 2013.

[5] SAMHSA, *Medication and Counseling Treatment*. Accessed at https://www.samhsa.gov/medication-assisted-treatment/treatment on May 28, 2019.

[6] 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 28, 2019.

[7] 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 28, 2019.

[8] HHS, *Better Availability of Overdose-Reversing Drugs*. Accessed at https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/better-overdose-response/index.html on May 28, 2019.

[9] The total number of beneficiaries who received naloxone may be underestimated. This number includes only naloxone prescriptions that were paid for by Part D.

[10] 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 opioid-reversal drugs. See HHS, *Strategy to Combat Opioid Abuse, Misuse, and Overdose*. Accessed at https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf on May 28, 2019.

[11] In addition, a smaller percentage of beneficiaries who received an opioid received high amounts of opioids. In 2018, 2.6 percent of beneficiaries who received an opioid received high amounts, down from 3.3 percent in 2017 and 3.5 percent in 2016.

[12] 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." *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 28, 2019.

[13] 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. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546472/ on May 28, 2019. Also see CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016," details above in endnote 12.

[14] 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. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842546/ on May 28, 2019.

[15] This group of beneficiaries is a subset of the 353,751 beneficiaries who received high amounts of opioids.

[16] A total of 19,192 of the beneficiaries identified as being at serious risk in 2018 were also identified as such in both 2016 and 2017. This represents 40 percent of the beneficiaries at serious risk in 2018.

[17] 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," details above in endnote 12.

[18] Missouri is the only State that lacks a Statewide prescription drug monitoring program. Currently, St. Louis County, Missouri, operates a program. For more information about prescription drug monitoring programs, see Prescription Drug Monitoring Program Training and Technical Assistance Center, Brandeis University, untitled webpage. Accessed at http://www.pdmpassist.org/ on May 28. 2019.

[19] State requirements for checking this information vary. For more information about these programs, see Prescription Drug Monitoring Program Training and Technical Assistance Center, Brandeis University, *Tracking PDMP Enhancement: The Best Practice Checklist*, 2017. Accessed at http://www.pdmpassist.org/pdf/2016_Best_Practice_Checklist_Report_20170228.pdf on March 29, 2018. See also 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 May 28, 2019.

[20] A total of 58,144 prescribers ordered opioids for at least 1 beneficiary at serious risk of opioid misuse or overdose in 2018.

[21] Six prescribers ordered opioids for high numbers of beneficiaries in both groups at serious risk.

[22] In total, we identified 73 prescribers as having questionable opioid prescribing in 2016, 2017, and 2018. 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.

[23] 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 28, 2019.

[24] SUPPORT for Patients and Communities Act, P.L. No. 115-271.

[25] 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.

[26] OIG, *Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose*, OEI-02-17-00560, June 2018.

[27] In October 2018, the Department of Justice (DOJ) announced the creation of the Appalachian Regional Prescription Opioid (ARPO) Strike Force to address illegal opioid prescriptions. The ARPO Strike Force originally consisted of jurisdictions in five States: Alabama, Kentucky, Ohio, Tennessee, and West Virginia. See DOJ, *Justice Department's Criminal Division Creates Appalachian Regional Prescription Opioid Strike Force to Focus on Illegal Opioid Prescriptions*. Accessed at https://www.justice.gov/opa/pr/justice-department-s-criminal-division-creates-appalachian-regional-prescription-opioid on June 10, 2019. To support the efforts of the ARPO Strike Force, OIG released the data brief *Concerns about Opioid Use in Medicare Part D in the Appalachian Region*, OEI-02-18-00224. The ARPO Strike Force has since expanded into Virginia. See DOJ, *Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedown Results in Charges Against 60 Individuals, Including 53 Medical Professionals*. Accessed at https://www.justice.gov/opa/pr/appalachian-regional-prescription-opioid-arpo-strike-force-takedown-results-charges-against on May 28, 2019.

[28] For example, OIG is releasing a series of factsheets on States' oversight opioid prescribing and monitoring. See OIG, *States' Oversight of Opioid Prescribing and Monitoring of Opioid Use*. Accessed at https://oig.hhs.gov/oas/opioid-oversight-map/oversight.asp on May 28, 2019. OIG is also assessing access to certain MAT drugs, see OIG, *Access to Buprenorphine-Waivered Providers for Treatment of Opioid Use Disorder*, OEI-12-17-00240, forthcoming. For more information about other planned opioid-related OIG work, see OIG, *Work Plan, 2019* at https://oig.hhs.gov/reports-and-publications/workplan/index.asp.

[29] These files contain MME conversion factors for each National Drug Code. MED and MME are interchangeable terms.

[30] Using CMS's Integrated Data Repository, we reviewed 70,587,887 PDE records for opioids with dates of service in 2018. 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.

[31] 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.

[32] 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.

[33] 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 23, 2019.

[34] We included opioids dispensed in 2017 with days of use in 2018. This analysis excludes PDE records for injection, intravenous, and intrathecal opioids, as well as opioids indicated for medication-assisted treatment.

[35] 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 2,982,945 beneficiaries with cancer or in hospice care who received at least 1 opioid.

[36] 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 2017. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf on May 23, 2019.