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The Consistently Low Percentage of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder Remains a Concern

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Data Brief
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The Consistently Low Percentage of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder Remains a Concern

Key Results

Medicare enrollees continue to face challenges accessing medication to treat their opioid use disorder, with certain groups of enrollees facing even greater challenges than others.

Yet, for the first time, more than 600,000 enrollees received naloxone—the opioid overdose-reversal drug—through Medicare Part D, an important step toward reducing overdose-related deaths.

Why OIG Did This Review

Opioid-related overdose deaths remain near all-time highs. In 2022, there were an estimated 83,827 opioid-related overdose deaths in the United States.[1] Most of these deaths involved synthetic opioids, such as illicit fentanyl.[2] As such, the Office of Inspector General (OIG) continues to monitor access to treatment for opioid use disorder and the opioid overdose-reversal drug naloxone—both of which can save lives.

This data brief is a part of a series, released annually by OIG since 2017, that monitors indicators of the opioid epidemic in Medicare. It provides the most updated information on the number of enrollees experiencing opioid overdoses and the number receiving medication for opioid use disorder and overdose-reversal medications. It also monitors the use of prescription opioids and questionable prescribing in Part D.[3]

What OIG Found

About 52,000 people enrolled in Medicare experienced an opioid overdose during 2022. The exact number is likely higher, as additional enrollees may have overdosed who did not receive medical care billed to Medicare. Further, of the about 1.1 million enrollees who have opioid use disorder, just 18 percent received medication to treat their disorder.[4] This low percentage highlights that enrollees are continuing to face challenges accessing treatment. In some States, the percentage of enrollees receiving treatment for their opioid use disorder was far lower than that for the Nation, with just 6 percent receiving medication in Florida. In addition, certain groups of enrollees—including those without the low-income subsidy—were less likely than others to receive medication. There are also notable disparities by race and ethnicity in those receiving medication.

On the other hand, the number of Part D enrollees receiving the opioid overdose-reversal drug naloxone grew to more than 600,000—an all-time high. Although reaching this high number is an important step toward reducing overdose-related deaths, there is also new concern. In 2023, Narcan—a brand-name naloxone—became available over-the-counter. Because of Narcan's change from prescription to over-the-counter status, manufacturers of generic equivalents of Narcan—i.e., 4 mg naloxone nasal sprays—must also now change their products to over-the-counter status. As a result, Narcan and its generic equivalents will no longer be covered by Medicare Part D. Without Part D coverage, enrollees will likely face higher out-of-pocket costs, which may create access barriers.

In addition, we found that key indicators of misuse or diversion of prescription opioids in Part D continue to decline. The number of Medicare enrollees who received high amounts of prescription

opioids decreased from prior years, as did the number who received extreme amounts of opioids or who appear to be doctor shopping. Further, the number of prescribers with questionable prescribing remained about 100, similar to that for the prior 2 years.

What OIG Recommends

As the opioid epidemic continues to take tens of thousands of lives each year, it is essential that the Centers for Medicare & Medicaid Services (CMS) and the Department continue to work to ensure access to medication to treat opioid use disorder and opioid overdose-reversal drugs. CMS and the Department have taken a number of actions to increase access to medication for opioid use disorder. However, the low percentage of enrollees receiving medication to treat their opioid use disorder calls for additional action.

OIG has made several recommendations to CMS in previous studies related to treatment. Notably, to encourage providers to treat more Part D enrollees who have opioid use disorder, OIG recommended that CMS inform providers about the use of buprenorphine—a common medication to treat opioid use disorder—and the low risk of diversion of this medication in Medicare.[5] CMS should continue its efforts to implement these and other recommendations and to identify additional ways to improve access to medication to treat opioid use disorder for all Medicare enrollees who need it.

Further, as part of this data brief, OIG recommends that CMS educate enrollees and providers about options for access to overdose-reversal medications, as Narcan and its generic equivalents will no longer be covered by Part D. Depending on the enrollee's circumstances, these options may include receiving coverage of over-the-counter naloxone through certain States' Medicaid programs (if dually eligible). CMS concurred with our recommendation.

FINDINGS

Opioid overdoses remain a concern; about 52,000 people enrolled in Medicare Part D experienced an overdose in 2022

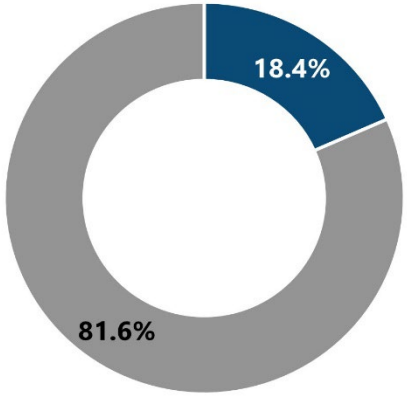
In 2022, at least 51,864 people enrolled in Medicare Part D had an opioid overdose. This is the number of Part D enrollees who received medical care for an opioid overdose, such as an emergency room visit, that was billed to Medicare.[6] These overdoses represent non-fatal and fatal events. As mentioned, most fatal opioid-related overdoses nationwide involve synthetic opioids, such as illicit fentanyl.[7]

The total number of enrollees who had an opioid overdose is likely higher, given that enrollees who had an overdose and did not receive medical care billed to Medicare are not captured in this analysis.[8]

Fewer than 1 in 5 Medicare enrollees with opioid use disorder received medication to treat their disorder

Opioid use disorder is a problematic pattern of opioid use that leads to clinically significant impairment or distress.[9] It is a chronic condition that can be treated with certain medications that have been shown to decrease illicit opioid use and opioid-related overdose deaths. In 2022, about 1.1 million people enrolled in Medicare had a diagnosis of opioid use disorder.[10] See Appendix A for information about this group of enrollees.

Exhibit 1: About 18 percent of enrollees with opioid use disorder received medication to treat this condition through Medicare.



Source: OIG analysis of Medicare claims data, 2023.

Overall, just 18 percent of Medicare enrollees received medication to treat their opioid use disorder in 2022

Medications to treat opioid use disorder have been shown to decrease illicit opioid use and opioid-related overdose deaths. Yet, just 210,771 of the about 1.1 million Medicare enrollees with opioid use disorder—slightly more than 18 percent—received medication for this disorder in 2022.[11] See Exhibit 1.

Each of these 210,771 enrollees received at least one of three approved drugs to treat opioid use disorder: buprenorphine, methadone, and naltrexone.[12] These medications are sometimes referred to as medications for opioid use disorder (MOUD).

The overall proportion of enrollees with opioid use disorder receiving medication remained about the same as in 2021.[13] This low proportion continues to raise concern. It may indicate that enrollees are facing ongoing challenges accessing treatment.

These challenges may be due to a variety of reasons, including difficulties accessing providers who can prescribe medication. They may also be, in part, due to stigma surrounding both opioid use disorder and its treatment.[14] This stigma may make it less likely for individuals to seek treatment and for providers to choose to provide treatment.

Enrollees most commonly received buprenorphine in office-based settings. In 2022, 13 percent (145,054) of the about 1.1 million Medicare enrollees with opioid use disorder received buprenorphine.[15] The vast majority of these enrollees received buprenorphine in office-based settings, while a small number received it in opioid treatment programs.[16] See Exhibit 2.

Until late 2022, prescribers were required to obtain a waiver from the Substance Abuse and Mental Health Administration (SAMHSA) to prescribe or administer buprenorphine in office-based settings and were limited in the number of patients they could treat.[17] As a result, enrollees may have had more limited access to providers.

Exhibit 2: Most Medicare enrollees receiving medication for opioid use disorder received buprenorphine in an office-based setting.

Proportion of the 1.1 Million Medicare Enrollees With Opioid Use Disorder by Medication and Setting			
	Office Based	Opioid Treatment Program	Total*
Buprenorphine	12%	<1%	**13%**
Methadone	-	5%	**5%**
Naltrexone	<1%	<1%	**<1%**
Total*	13%	6%	**18%**

* Percentages do not sum to totals because of rounding, some enrollees received multiple medications, and some enrollees received medication from both settings.
Source: OIG analysis of Medicare data, 2023.

Less commonly, enrollees received methadone from opioid treatment programs. In 2022, about 5 percent (62,020) of the about 1.1 million Medicare enrollees with opioid use disorder received methadone. All of these enrollees received methadone through opioid treatment programs. Under Federal law, only opioid treatment

programs are allowed to administer or dispense methadone for the treatment of opioid use disorder.[18]

The lower proportion of enrollees receiving methadone may indicate that enrollees are facing barriers to accessing opioid treatment programs. Patients typically go in person each day to opioid treatment programs to receive their dose of methadone.[19] The need to travel to opioid treatment programs, which can be burdensome, may hinder access.[20] Furthermore, more stigma is attached to opioid treatment programs and the use of methadone than to the use of buprenorphine, and this stigma may impact the likelihood that patients will seek treatment.[21]

A small number of enrollees received naltrexone. Among the about 1.1 million Medicare enrollees with opioid use disorder, less than one percent (9,038) of enrollees received naltrexone in 2022. Naltrexone is a third medication indicated for the treatment of opioid use disorder and requires abstinence from opioids for 7 to 14 days before initiation.[22]

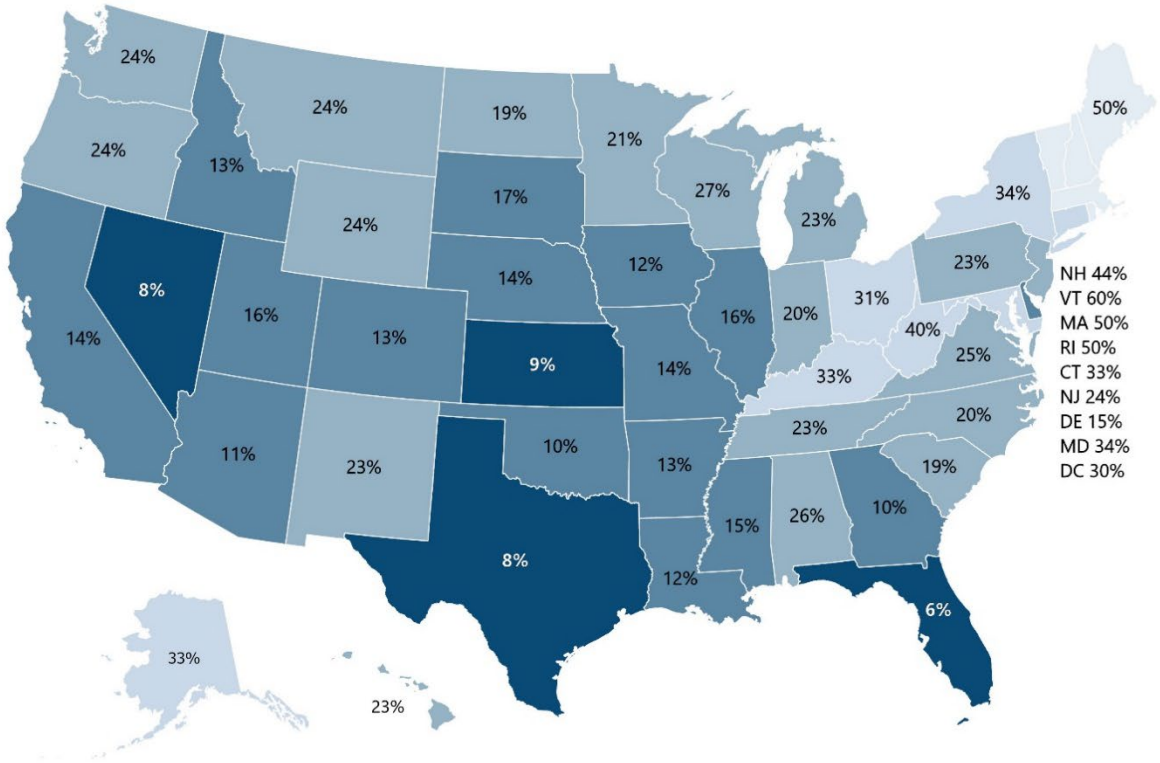
In some States, the percentage of enrollees who received medication for their opioid use disorder was far lower than that for the Nation, with just 6 percent receiving medication in Florida

In Florida, Texas, Kansas, and Nevada, fewer than 10 percent of enrollees received medication to treat their opioid use disorder, compared to 18 percent of enrollees nationwide. See Exhibit 3.

Among the States, Florida had the lowest percentage of enrollees receiving medication to treat their opioid use disorder, with just 6 percent of enrollees receiving medication. The low percentage in Florida is particularly concerning, as Florida has the highest number of enrollees with opioid use disorder in the Nation. A total of 160,586 Medicare enrollees (14 percent of the about 1.1 million) with opioid use disorder live in Florida.

Texas and Nevada had the second and third lowest percentages of enrollees receiving medication, at 8 percent each. Kansas also had a low percentage (9 percent). See Exhibit 3 and Appendix B.

Exhibit 3: Less than 10 percent of Medicare enrollees in Florida, Texas, Nevada, and Kansas received medication for their opioid use disorder.



Source: OIG analysis of Medicare claims data, 2023.

Certain groups of Medicare enrollees were less likely than others to receive medication to treat their opioid use disorder

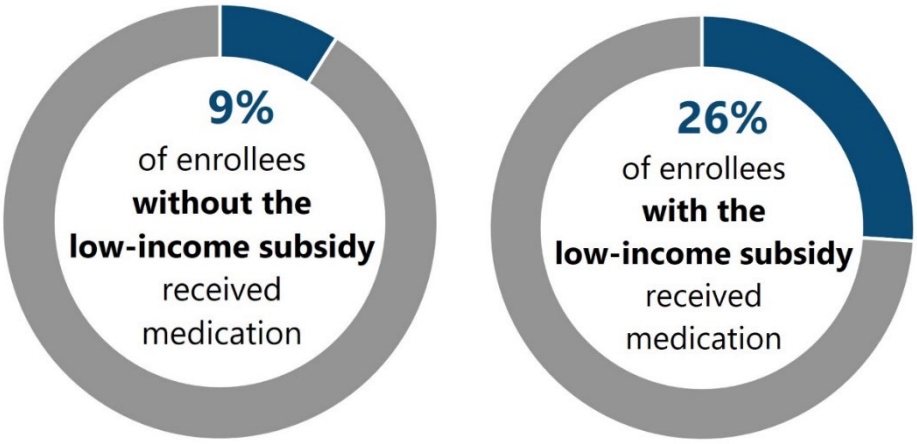
Certain groups of enrollees—including those who did not receive the low-income subsidy, those over the age of 65, and female enrollees—were less likely than other groups to receive treatment.

Enrollees without the Part D low-income subsidy were far less likely than those with the subsidy to receive medication to treat their opioid use disorder

The Part D low-income subsidy—also known as Extra Help—is available to some enrollees who have limited income and assets.[23] It provides assistance with paying for Part D premiums and cost-sharing.

In 2022, 9 percent of enrollees without the subsidy received medication for opioid use disorder, compared to 26 percent of enrollees with the subsidy. This represents a nearly 3-fold difference. See Exhibit 4.

Exhibit 4: Medicare enrollees without the Part D low-income subsidy were almost 3 times less likely to receive medication for their opioid use disorder than were those with the subsidy.



Source: OIG analysis of Medicare claims data, 2023.

Of note, enrollees without the subsidy were less likely to receive medication to treat their opioid use disorder than enrollees with the subsidy regardless of their race and ethnicity; age group; or sex.

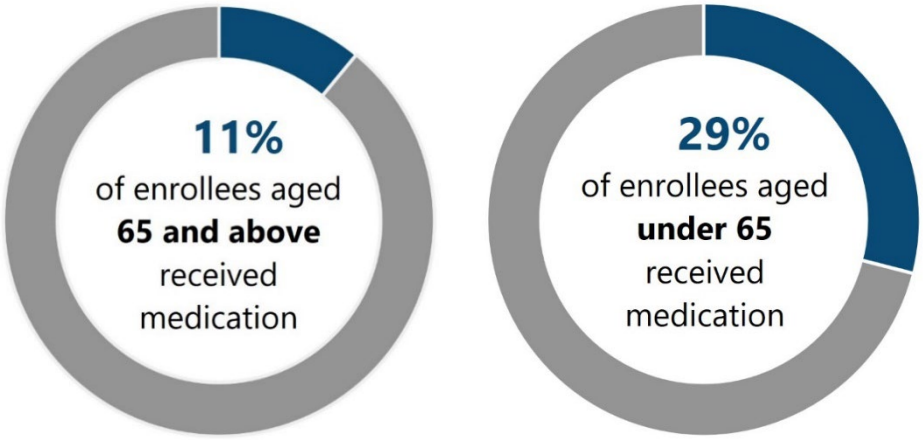
Enrollees without the low-income subsidy generally pay higher cost-sharing for medication than those with the subsidy. On average, enrollees without the subsidy paid $268 annually for Part D cost-sharing for medications for opioid use disorder in 2022. In contrast, enrollees with the subsidy paid an average of $19 annually in cost-sharing for these medications in 2022.[24]

Older enrollees were much less likely than younger enrollees to receive medication to treat their opioid use disorder

Older enrollees—i.e., those aged 65 and above—were less likely to receive medication to treat their opioid use disorder than were those under the age of 65. Of note, enrollees under 65—who often qualify for Medicare due to disability—account for 40 percent of enrollees with opioid use disorder.[25]

In 2022, 11 percent of older enrollees received medication to treat their opioid use disorder, compared to 29 percent of those under 65—about a 2.5-fold difference. See Exhibit 5.

Exhibit 5: Medicare enrollees aged 65 and above were about 2.5 times less likely to receive medication for their opioid use disorder than were those under 65.



Source: OIG analysis of Medicare claims data, 2023.

Older enrollees were less likely to receive medication for opioid use disorder than were enrollees under 65, regardless of their race and ethnicity; low-income subsidy status; or sex.

Female enrollees were less likely than male enrollees to receive medication to treat their opioid use disorder

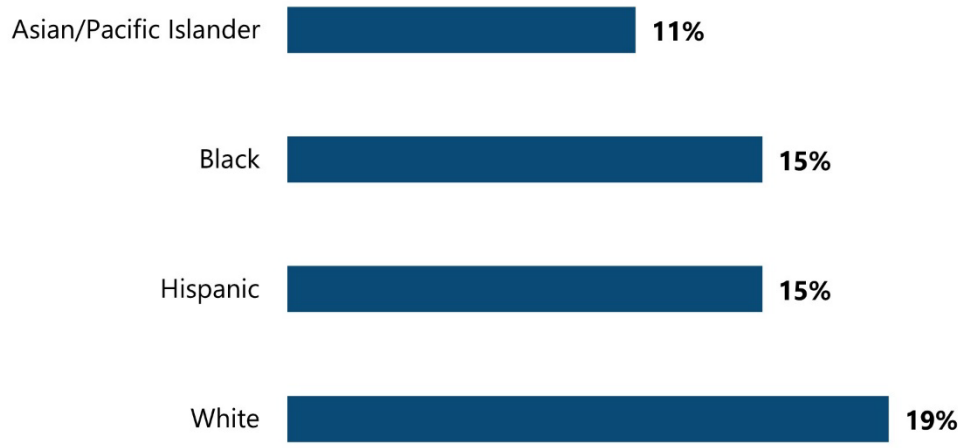
In 2022, 15 percent of female and 23 percent of male enrollees received medication to treat their opioid use disorder.

Female enrollees were less likely to receive medication regardless of their race and ethnicity; low-income subsidy status; or age group.

There also are notable disparities by race and ethnicity in those who received medication for opioid use disorder through Medicare

There are differences by race and ethnicity in the percentage of Medicare enrollees who received medication to treat their opioid use disorder.[26] Eleven percent of Asian/Pacific Islander, 15 percent of Black, 15 percent of Hispanic, and 19 percent of White enrollees received medication to treat their opioid use disorder in 2022. See Exhibit 6.

Exhibit 6: About 15 percent or less of Asian/Pacific Islander, Black, and Hispanic Medicare enrollees received medication to treat their opioid use disorder.



Source: OIG analysis of Medicare claims data, 2023.

Asian/Pacific Islander, Black, and Hispanic enrollees were less likely than White enrollees to receive medication to treat their opioid use disorder, regardless of their low-income subsidy status or sex.[27]

Of note, Hispanic and Asian/Pacific Islander enrollees without the Part D low-income subsidy had particularly low likelihoods of receiving medication, with just 6 percent of each group receiving medication.

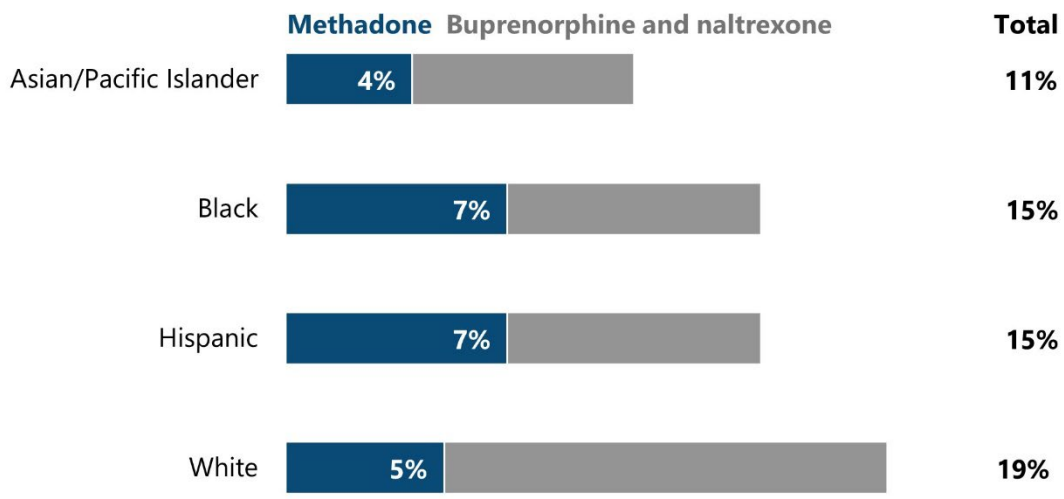
There were also differences in the settings in which enrollees received medication to treat their opioid use disorder

While Black and Hispanic enrollees were less likely overall to receive medication to treat their opioid use disorder, they were more likely than other enrollees to receive methadone at opioid treatment programs.

About 7 percent of Hispanic and of Black enrollees received methadone to treat their opioid use disorder. These enrollees account for about half of all Hispanic and half of all Black enrollees who received medication. See Exhibit 7.

Typically, patients who receive methadone must travel each day to opioid treatment programs to receive their doses.[28] In contrast, buprenorphine and naltrexone can be prescribed in office-based settings and dispensed by pharmacies, making them more convenient than methadone.[29] In addition, as previously mentioned, methadone generally has more stigma attached to it than does buprenorphine or naltrexone.[30]

Exhibit 7: Black and Hispanic enrollees were more likely to receive methadone—which is only available at opioid treatment programs—than were Asian/Pacific Islander and White enrollees.



Source: OIG analysis of Medicare claims data, 2023.

The number of enrollees who received prescriptions for the overdose-reversal drug naloxone increased substantially, to an all-time high of more than 600,000 enrollees

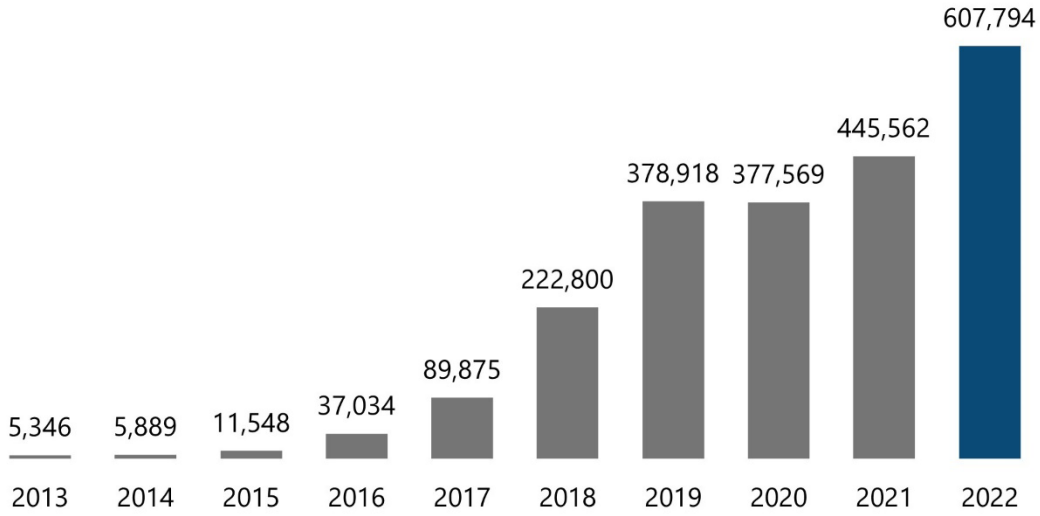
The number of enrollees who received naloxone prescriptions through Part D grew in 2022, continuing an upward trend that has occurred in every recent year other than 2020.

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.[31]

A total of 607,794 enrollees received naloxone through Part D in 2022, compared to 445,562 enrollees in 2021.[32] See Exhibit 8. This represents a 36-percent increase in the number of enrollees receiving naloxone.[33] The growth in the number of Medicare enrollees receiving naloxone is an important step forward in addressing the opioid crisis.

The most commonly dispensed versions of naloxone were the brand-name drug Narcan and its generic equivalents (i.e., 4 mg naloxone nasal sprays). About 96 percent of the naloxone dispensed through Part D in 2022 was Narcan or a generic equivalent.[34]

Exhibit 8: The number of enrollees receiving naloxone through Part D increased significantly in 2022.



Source: OIG analysis of Medicare data, 2023.

Enrollees will likely face higher out-of-pocket costs for Narcan, as it is now available over-the-counter

Narcan became available over-the-counter in September 2023. As a result, Narcan will no longer be considered a prescription medication and, therefore, will no longer be covered by Medicare Part D.[35] Federal law prohibits Medicare Part D from covering over-the-counter medications under most circumstances.[36]

Narcan's change to over-the-counter status will also impact generic equivalents of Narcan—i.e., other 4 mg naloxone nasal spray products. Manufacturers of these products will now be required to submit a supplement to their applications to the Food and Drug Administration (FDA) to effectively change their products to over-the-counter status.[37] This means that, after a period of transition, generic 4 mg naloxone nasal spray will also no longer be covered by Part D.[38]

Without Part D coverage, enrollees will likely face higher out-of-pocket costs for Narcan because they will pay the full cost of the medication rather than a portion of the cost (e.g., cost-sharing). Higher out-of-pocket cost may create access barriers for some enrollees, particularly those who receive the low-income subsidy. Enrollees with the low-income subsidy paid an average of about $2 in cost-sharing for Narcan and its generic equivalents in 2022, while other enrollees paid an average of $29. In contrast, Narcan's manufacturer stated that its suggested price for over-the-counter Narcan is $44.99.[39]

For enrollees facing higher out-of-pocket costs and potential access barriers for over-the-counter Narcan or its generic equivalents, there may be alternatives depending

on the enrollees' circumstances. For example, some enrollees may have coverage of over-the-counter naloxone through their Medicare Advantage plan. CMS has encouraged Medicare Advantage plans to cover over-the-counter naloxone under their Medicare Advantage supplemental benefits.[40] However, taking this action is optional for plans and would only impact those enrolled in Medicare Advantage plans that opt to offer this benefit. In addition, dually eligible Medicare enrollees (i.e., those who are enrolled in Medicaid and Medicare) may have the cost of over-the-counter naloxone covered by Medicaid, depending on their State.[41] Alternatively, other—less common—formulations and dosages of naloxone, such as injectable naloxone, will remain prescription drugs and continue to be covered by Part D. In addition, a different opioid overdose-reversal medication—a nalmefene nasal spray—was recently approved by FDA as a prescription drug.[42] Ensuring that Medicare enrollees and their providers know about covered and over-the-counter options is critical, given the extent of the opioid crisis.

Indicators of misuse and diversion of prescription opioids in Part D continue to decline

OIG has been monitoring opioid prescribing in Medicare Part D since 2017, looking for patterns that may indicate misuse or diversion that warrant further scrutiny. The number of concerning patterns has declined over time with new lows in key areas in 2022.

About 176,000 people enrolled in Part D received high amounts of prescription opioids in 2022, fewer than in prior years

In 2022, a total of 176,021 enrollees received high amounts of opioids through Part D—i.e., each enrollee 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. These enrollees did not have cancer and were not in hospice care. Although enrollees may receive opioids for legitimate purposes, these amounts raise concern as opioids carry a number of health risks.[43]

The number of enrollees receiving high amounts of opioids is a decrease from 2021, when 199,169 enrollees received high amounts. It is also a decline from previous years. In 2016, when OIG first began measuring this number, a total of 501,008 enrollees received these high amounts. (See Appendix C for more information about previous years.)

Just under 20,000 people enrolled in Part D received extreme amounts of prescription opioids or appeared to be doctor shopping, also a decline from prior years

Two subgroups of enrollees in particular are at serious risk from prescription opioids: (1) enrollees who receive extreme amounts of opioids and (2) enrollees who appear to be doctor shopping. This does not include enrollees who had cancer or were in hospice care. Other Part D enrollees may also be at serious risk but do not fall into either group.

A total of 19,936 enrollees were in these two subgroups. Specifically, 18,426 enrollees received extreme amounts of opioids (i.e., had an average daily MED greater than 240 mg for 12 months) and 1,626 enrollees 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 116 enrollees were in both groups.

The number of enrollees at serious risk in 2022 (19,936 enrollees) represents a 14-percent decline from 2021 and a 78-percent decline from 2016.[44]

While the number of enrollees at serious risk from prescription opioids has declined substantially, these patterns still raise concern when they are observed. They may signal that an enrollee's care is not being monitored or coordinated properly or that an enrollee's care needs to be reassessed. Alternatively, they may indicate that the prescribers and pharmacies are not checking an enrollee's opioid history before prescribing.[45] They may also indicate that an enrollee is seeking medically unnecessary drugs—perhaps to use them recreationally or to divert them—or that an enrollee has an opioid use disorder and is at risk of overdose.

About 100 prescribers had questionable opioid prescribing for Part D enrollees at serious risk, similar to the number in 2021

A total of 23,925 prescribers ordered opioids for at least 1 enrollee at serious risk of opioid misuse or overdose (i.e., an enrollee who received extreme amounts of opioids or appeared to be doctor shopping) in 2022. The vast majority of these prescribers ordered opioids for only one or two of these enrollees. However, some prescribers ordered for many more.

A total of 101 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 enrollees at serious risk.[46] In total, these 101 prescribers ordered 43,871 opioid prescriptions—totaling almost $15 million of Part D costs—for enrollees at serious risk in 2022.

The number of prescribers with questionable prescribing for enrollees at serious risk is similar to that for 2021, when 98 prescribers had questionable prescribing. It also represents a decline of 75 percent since 2016.[47]

Although opioids may be necessary for some patients, prescribing to an unusually high number of enrollees at serious risk raises concerns. It may indicate that enrollees 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. It may 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 has been sold or stolen and is being used for illegal purposes.

While concerns about opioid prescribing have declined, it remains important that opioids be prescribed only when medically necessary and that, when identified, questionable prescribing patterns be addressed.

RECOMMENDATION

As the opioid epidemic continues to take tens of thousands of lives each year, it is essential that CMS and the Department continue to work to ensure access to medication for opioid use disorder and to opioid overdose-reversal drugs.

This data brief finds that Medicare enrollees continue to face challenges accessing medication to treat their opioid use disorder, with some groups of enrollees facing even greater challenges than other groups. Yet, for the first time, more than 600,000 enrollees received naloxone—the opioid overdose-reversal drug—through Medicare Part D, an important step in addressing the opioid crisis. The findings also demonstrate that concerns about misuse and diversion of prescription opioids continue to lessen.

CMS, the Department, and Congress have taken a number of actions to increase access to medication for opioid use disorder. In late December 2022, legislation lifted certain Federal restrictions on the prescribing of buprenorphine, the most common medication to treat opioid use disorder.[48] In addition, CMS took steps to increase the number of enrollees receiving treatment and to address disparities. For example, CMS released its Behavioral Health Strategy in 2022. Goals listed in the Behavioral Health Strategy include strengthening equity and quality in behavioral health care and improving access to substance use disorder prevention, treatment, and recovery services.[49]

However, the low percentage of enrollees receiving medication to treat their opioid use disorder calls for additional action. OIG has previously made several recommendations to CMS to increase access to treatment. Notably, to encourage providers to treat more Part D enrollees who have opioid use disorder, OIG recommended that CMS inform providers about the use of buprenorphine—a common medication to treat opioid use disorder—and the low risk of diversion of this medication in Medicare.[50] OIG has also recommended that CMS create an action plan and take steps to address disparities in the treatment of opioid use disorder.[51] Further, from a report examining access to treatment for opioid use disorder in Medicaid, OIG has recently recommended that CMS encourage and support States' efforts to reduce barriers to medication for opioid use disorder, especially among groups who may be underserved.[52]

OIG urges CMS to continue its efforts to implement these and other recommendations and to identify additional ways to improve access to medication to treat opioid use disorder for all Medicare enrollees who need it. OIG will also refer prescribers with questionable opioid prescribing identified in this report to CMS for follow-up, as appropriate.

In addition, we recommend that CMS:

Educate enrollees and providers about options for access to overdose-reversal medications, as Narcan and its generic equivalents will no longer be covered by Part D

Overdose-reversal medications save lives. It is critical that individuals at risk of overdose have them on hand in the event of an emergency. Ensuring continued access to these medications for Medicare enrollees is particularly important in the coming months when Medicare Part D will no longer cover Narcan or its generic equivalents.

As noted, Medicare Part D does not cover over-the-counter medications under most circumstances. As a result, enrollees will lose Part D coverage of Narcan and its generic equivalents after they become available over-the-counter.[53] Without coverage, enrollees will likely have increased out-of-pocket costs which may create access barriers.

For enrollees facing higher out-of-pocket costs, there may be alternatives to purchasing Narcan or its generic equivalents over-the-counter. Ensuring that enrollees and providers know about these alternatives is critical, given the extent of the opioid crisis and the high number of enrollees—almost 600,000—who received Narcan or a generic equivalent through Part D.

To help ensure that Medicare Part D enrollees continue to have uninterrupted access to opioid overdose-reversal medications, CMS should educate enrollees and providers about Narcan and its generic equivalents' switch to over-the-counter status and the alternative options enrollees may have for receiving overdose-reversal medications. Depending on the enrollee's circumstances, these options may include, for example, receiving coverage of over-the-counter naloxone through certain Medicare Advantage plans that offer it as a supplemental benefit or through certain States' Medicaid programs (if dually eligible). Alternatively, enrollees could talk to their providers about whether other formulations or dosages of naloxone—that will remain prescription drugs—or a different overdose-reversal medication would be appropriate.

To educate enrollees and providers, CMS could add information to its website and the Medicare & You Handbook. It could also use its annual letter to providers to communicate with them about this topic. If appropriate, CMS could also work with Medicare Advantage plans and State Medicaid agencies to ensure that their enrollees are aware of coverage options.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with our recommendation to educate enrollees and providers about options for access to overdose-reversal medications, as Narcan and its generic equivalents will no longer be covered by Part D. CMS stated that it will seek to include this information in upcoming enrollee and provider outreach to help make both aware of other coverage options for overdose-reversal medications that will continue to be available after Narcan and its generic equivalents fully transition to over-the-counter status and remaining inventory of products labeled as prescription only have been exhausted.

The full text of CMS's comments can be found in Appendix E.

METHODOLOGY

We based this study primarily on five data sources: Medicare Part D Prescription Drug Event (PDE) records, the First Databank, the Medicare Enrollment Database, the National Claims History File, and Part C Encounter Data. We also use the Center for Disease Control and Prevention's (CDC's) Morphine Milligram Equivalent (MME) conversion file.

PDE records are for prescriptions that people enrolled in Medicare 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 an enrollee in their plans. Each record contains information about the drug and enrollee, as well as the identification numbers for the pharmacy and the prescriber. For the purposes of this study, we use the term "prescription" to mean one PDE record.

To obtain descriptive information about the drugs, enrollees, and prescribers, we matched PDE records to data from the First Databank, the National Claims History File, Part C Encounter Data, and CDC's MME conversion file. The 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 and prescribed medications. Part C Encounter Data contain medical claims data, including diagnosis codes and prescribed medications, for Medicare Advantage plan enrollees. CDC's MME conversion file contains information about each opioid drug's morphine milligram equivalence.[54]

Analysis of Opioid Overdoses

To determine the number of people enrolled in Part D who had an opioid overdose in 2022, we used inpatient and outpatient (including professional) claims data from the National Claims History File and Part C Encounter Data. We considered an enrollee to have had an overdose if the enrollee had at least one claim from Medicare Part A, B, or C with a diagnosis of an opioid poisoning from prescription or illicit opioids in 2022.

Analysis of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder

We used Medicare Parts A and B Claims Data and Part C Encounter Data to determine which Medicare enrollees had a diagnosis of opioid use disorder in their 2022 claims. We considered enrollees to have opioid use disorder if they had a diagnosis code

categorized as "opioid abuse" (F11.1) or "opioid dependence" (F11.2) on any claim during 2022.

We then determined the extent to which these enrollees received medication to treat their opioid use disorder in outpatient settings through Medicare in 2022.

Prescription Drug Event Records. We first used the PDE records to identify the number of enrollees who filled prescriptions for medications for opioid use disorder at pharmacies in 2022. Drugs filled at pharmacies are covered by Part D. They may be covered by standalone prescription drug plans (PDPs) or prescription drug plans that are part of Medicare Advantage plans (MA-PDs).

Medicare Claims and Part C Encounter Data. We then used Medicare Part B Claims Data and Part C Encounter Data to identify the number of enrollees who were prescribed medications for opioid use disorder through opioid treatment programs or in a provider's office.

Characteristics of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder

We determined key characteristics of the Medicare enrollees who were less likely to receive medication to treat their opioid use disorder. To do this, we used the Medicare Enrollment Database file.

We first determined the percentage of enrollees in each State who received medication to treat their opioid use disorder. Next, we determined each enrollee's Part D low-income subsidy status, age, sex, and race and ethnicity. Note that Medicare data combine race and ethnicity and allow for only one response. The data are limited to seven options: American Indian/Alaska Native, Asian/Pacific Islander, Black (or African-American), Hispanic, Non-Hispanic White, Other, and Unknown. The data are not further disaggregated. Race and ethnicity information is based on data collected from the Social Security Administration and an algorithm developed by the Research Triangle Institute. This algorithm attempts to improve the quality of the Social Security Administration's data by amending the race data for certain groups on the basis of name and geography, as well as requests made by individuals for certain government materials to be provided in Spanish. Although this information is currently the best available for the entire Medicare enrollee population, comparisons to self-reported data (available in certain, limited circumstances) show that race and ethnicity is still misclassified for some enrollees. Because of these limitations and small enrollee populations in the data, we did not provide specific data for American Indian/Alaska Native enrollees or enrollees with other or unknown race and ethnicity.

Next, we determined the extent to which enrollees received medication to treat their opioid use disorder by these characteristics. We also calculated the average annual enrollee cost-sharing for medication to treat their opioid use disorder for enrollees with and without the low-income subsidy.

Analysis of Trends in Part D for Naloxone

Next, we identified all Part D prescriptions for naloxone—a drug that reverses opioid overdoses. We calculated the total number of Part D enrollees who received naloxone and the number of prescriptions for naloxone from 2013 to 2022. We also calculated the average enrollee cost-sharing per prescription by naloxone labels (i.e., Narcan brand and generic equivalent versions).

Analysis of Part D Enrollees Receiving Prescription Opioids

We determined the amount of prescription opioids that each Part D enrollee received in 2022. To do this, we calculated each enrollee's average daily morphine equivalent dose (MED).[55] The MED converts opioids of different ingredients, strengths, and forms into morphine milligram equivalents. It allows us to sum dosages of different opioids to determine an enrollee's daily opioid level.

To calculate each enrollee's average daily MED, we first calculated the MED for each prescription (i.e., for each PDE record).[56] To do this, we used the following equation:

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

Next, we summed each enrollee's MED for each day of the year based on the dates of service and days supply on each prescription. We refer to this as the daily MED. We excluded from this analysis enrollees who had a diagnosis of cancer or a hospice stay at any point in 2022.[57]

We analyzed the MED data using the same criteria that we used in our previous annual analyses of the 2016 to 2021 data.[58] We began by determining the extent to which enrollees received high amounts of opioids. To do this, we calculated each enrollee's average daily MED over each 90-day period in 2022. We considered enrollees to have high amounts of opioids if they exceeded an average daily MED of 120 mg for any 90-day period and received opioids for 90 or more days in the year.

We then determined the extent to which these enrollees received extreme amounts of opioids. We calculated each enrollee's average daily MED over the entire year. We considered an enrollee 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 enrollees appeared to be doctor shopping. To do this, we calculated the total number of prescribers and pharmacies from which each enrollee received opioids in 2022. We considered enrollees 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 enrollees who received high amounts of opioids and the number at serious risk—i.e., the number who received extreme amounts of opioids or appeared to be doctor shopping—to the numbers of enrollees whom we had previously identified in our annual analyses of the 2016 to 2021 data.

Identification of Prescribers With Questionable Prescribing

For this analysis, we identified prescribers who ordered opioids for a high number of Part D enrollees at serious risk—i.e., enrollees who received extreme amounts of opioids and enrollees 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.[59]

In total, 17,753 prescribers ordered opioids for enrollees who received extreme amounts of opioids and 8,261 prescribers ordered opioids for enrollees who appeared to be doctor shopping. For each of these prescribers, we calculated the number of enrollees in each group for whom the prescriber ordered opioids. We then identified the prescribers who ordered opioids for the highest number of enrollees in each group. All of these prescribers are extreme outliers in terms of the number of enrollees to whom they prescribed opioids in one of the groups at serious risk. These prescribers were more than 3 standard deviations above the mean and in the top 0.3 percent.

Limitations

This analysis is based on Medicare claims data. It is not based on a review of medical records. The analysis does not include data on opioids, medications for opioid use disorder, or naloxone that enrollees may have received from sources other than Medicare. Analysis related to race and ethnicity is based on the best available information; however, there are limitations to these data. For a fuller discussion, see OIG, *Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability To Assess Health Disparities*, OEI-02-21-00100, June 2022.

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

Characteristics of Medicare Enrollees With Opioid Use Disorder in 2022

	People Enrolled in Medicare With Opioid Use Disorder	Proportion of All People Enrolled in Medicare With Opioid Use Disorder
All	1,147,768	100%
Part D Low-Income Subsidy		
With	635,373	55%
Without	512,395	45%
Age Group		
<65	453,787	40%
65+	693,981	60%
Sex		
Female	642,145	56%
Male	505,623	44%
Race and Ethnicity*		
Asian/Pacific Islander	10,837	0.9%
Black	172,691	15%
Hispanic	113,775	10%
White	823,992	72%

* Because of previously identified limitations and small enrollee populations in the data, we did not provide specific data for American Indian/Alaska Native enrollees or enrollees with other or unknown race and ethnicity. As a result, race and ethnicity data do not sum to 100 percent.

Source: OIG analysis of Medicare data, 2023.

APPENDIX B

State Data about Medicare Enrollees Who Receive Medication to Treat Their Opioid Use Disorder, 2022

	Number of Enrollees With Opioid Use Disorder	Percentage of Enrollees Who Received Medication		Number of Enrollees With Opioid Use Disorder	Percentage of Enrollees Who Received Medication
Florida	160,586	6%	Pennsylvania	54,641	23%
Texas	84,566	8%	Michigan	37,611	23%
Nevada	15,417	8%	New Mexico	10,247	23%
Kansas	6,515	9%	Tennessee	33,386	23%
Georgia	34,601	10%	Hawaii	2,354	23%
Oklahoma	23,021	10%	Wyoming	795	24%
Arizona	32,686	11%	Washington	27,355	24%
Louisiana	25,914	12%	Montana	2,707	24%
Iowa	5,271	12%	Oregon	16,761	24%
Arkansas	11,430	13%	New Jersey	25,512	24%
Idaho	7,411	13%	Virginia	20,717	25%
Colorado	17,431	13%	Alabama	22,891	26%
Missouri	18,461	14%	Wisconsin	11,773	27%
California	113,984	14%	District Of Columbia	2,645	30%
Nebraska	3,164	14%	Ohio	31,207	31%
Delaware	6,840	15%	Connecticut	13,197	33%
Mississippi	12,414	15%	Alaska	1,380	33%
Utah	11,337	16%	Kentucky	22,615	33%
Illinois	24,686	16%	New York	43,823	34%
South Dakota	836	17%	Maryland	19,889	34%
Nation	**1,147,768**	**18%**	West Virginia	7,871	40%
South Carolina	15,584	19%	New Hampshire	5,476	44%
North Dakota	1,053	19%	Maine	5,832	50%
Indiana	24,165	20%	Rhode Island	4,025	50%
North Carolina	39,606	20%	Massachusetts	26,732	50%
Minnesota	13,529	21%	Vermont	2,431	60%

Source: OIG analysis of Medicare Part D data, 2023.

APPENDIX C

Prescription Opioid Use in Medicare Part D

Exhibit C-1: About 176,000 people enrolled in Part D received high amounts of opioids in 2022.

	Number of People Enrolled in Part D Who Received High Amounts of Opioids	Percentage Change from Previous Year
2016	501,008	-
2017	458,935	-8%
2018	353,751	-23%
2019	266,728	-25%
2020	225,463	-15%
2021	199,169	-12%
2022	176,021	-12%

Source: OIG analysis of Medicare Part D data, 2017-2023.

Exhibit C-2: Almost 20,000 people enrolled in Part D were at serious risk in 2022.

	Number of Enrollees Who Received Extreme Amounts of Opioids	Percentage Change from Previous Year	Number of Enrollees Who Appear To Be Doctor Shopping	Percentage Change from Previous Year	Total Number of Enrollees at Serious Risk*	Percentage Change from Previous Year
2016	69,563	-	22,308	-	**89,843**	-
2017	57,611	-17%	14,814	-34%	**71,260**	-21%
2018	40,374	-30%	8,796	-41%	**48,558**	-32%
2019	29,734	-26%	4,346	-51%	**33,809**	-30%
2020	27,325	-8%	2,131	-51%	**29,306**	-13%
2021	21,493	-21%	1,805	-15%	**23,186**	-21%
2022	18,426	-14%	1,626	-10%	**19,936**	-14%

* Numbers in the "total" column do not equal the sums of the numbers in the corresponding "extreme amount" and "doctor shopping" columns because enrollees can be in both groups.
Source: OIG analysis of Medicare Part D data, 2017-2023.

APPENDIX D

Prescribers With Questionable Opioid Prescribing for Enrollees at Serious Risk

Exhibit D: About 100 prescribers ordered opioids for a high number of Part D enrollees at serious risk in 2022.

	Number of Prescribers With Questionable Opioid Prescribing for Enrollees at Serious Risk	Percentage Change from Previous Year
2016	401	-
2017	282	-30%
2018	198	-30%
2019	142	-28%
2020	98	-31%
2021	98	0%
2022	101	3%

For more information on OIG's previous data briefs, see OIG's featured topics page, Combating the Opioid Epidemic, available at https://oig.hhs.gov/reports-and-publications/featured-topics/opioids/.
Source: OIG analysis of Medicare Part D data, 2017-2023.

APPENDIX E

Agency Comments

Following this page are the official comments from CMS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: November 22, 2023

TO: Ann Maxwell
Deputy Inspector General for Evaluations and Inspections

FROM: Chiquita Brooks-LaSure
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: The Consistently Low Percentage of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder Remains a Concern, OEI-02-23-00250

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. Substance use disorders (SUD), including opioid use disorder (OUD), impact the lives of millions of Americans, including individuals who are enrolled in the Medicare program. CMS is committed to ensuring that Medicare beneficiaries who have an OUD have access to appropriate treatment, including medications for opioid use disorder (MOUD). Ensuring access to these benefits and addressing equity concerns is an important part of combatting the nation's opioid epidemic, and CMS has been actively engaged in the work necessary to meet these goals.

CMS is pleased to note that OIG found a 36 percent increase in the number of enrollees receiving naloxone through Medicare from 2021 to 2022 and that indicators of misuse and diversion of prescription opioids in Part D continued to decline. However, CMS also recognizes there is more work to do in increasing access to SUD treatment and addressing health equity.

Several recent changes have expanded Medicare beneficiaries' access to MOUD. First, on January 1, 2020, Medicare began paying Medicare-enrolled Opioid Treatment Programs (OTPs) with a bundled payment to deliver OUD treatment services to Medicare beneficiaries as required by the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. Medicare Advantage plans must also include the OTP benefit and can contract with OTP providers in their service area or agree to pay an OTP on a non-contract basis. To further promote continuity of care, in addition to on-site treatment, OTPs may also provide beneficiaries with take-home doses of medication, in accordance with certain time in treatment standards, furthering beneficiaries' access to vital care.

Second, effective since December 2022, providers no longer need a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe MOUD, strengthening Medicare providers' ability to care for beneficiaries with OUDs.

In addition, to help ensure that people with a Medicare Advantage plan have access to behavioral health providers, CMS is proposing, through our Contract Year 2025 Medicare Advantage and Part D Proposed Rule (CMS-4205-P), to add a range of behavioral health providers under one category called "Outpatient Behavioral Health" as a facility-specialty for which CMS sets Medicare Advantage plan network adequacy standards. Specialists under this category will include Marriage and Family Therapists and Mental Health Counselors, Opioid Treatment Program providers, Community Mental Health Centers, addiction medicine physicians, and other providers who furnish addiction medicine and behavioral health counseling or therapy services in Medicare today.

CMS is also proposing to add this Outpatient Behavioral Health facility specialty to the list of the specialty types that will receive a 10% credit if the Medicare Advantage plan organization's contracted network of providers includes one or more telehealth providers of that specialty type who provide additional telehealth benefits for covered services.

Finally, in March 2023, the Food and Drug Administration (FDA) announced that Narcan, a brand-name formulation of the opioid overdose reversal drug naloxone, would be available without a prescription. While Medicare Part D generally does not cover over-the-counter medications, this change will remove barriers to access by allowing beneficiaries to purchase the medication without first meeting with a provider. Other options for Medicare-covered naloxone will remain available, such as other formulations or dosages of naloxone that remain prescription drugs, as well as other overdose reversal medications.

CMS will continue to monitor use of, and access to, these medications. CMS monitors prescription drug use in Part D (including over-utilization and/or under-utilization of opioids, buprenorphine, and other MOUD) through prescription drug event (PDE) data to oversee sponsors' compliance with drug utilization review (DUR) requirements as described in 42 CFR § 423.153. CMS also monitors complaints in the Complaint Tracking Module (CTM) in the Health Plan Management System to identify potential access issues. CMS may follow up with Part D plan sponsors or share information with Departmental partners, as appropriate.

Combatting the opioid epidemic is a top priority for CMS, and CMS remains committed to ongoing examination of its payment and coverage policies to ensure healthcare providers are enabled to execute best practices with respect to pain management and treatment of OUDs. OIG's recommendations and CMS' responses are below.

OIG Recommendation

CMS should educate enrollees and providers about options for coverage of overdose reversal medications, as Narcan and its generic equivalents will no longer be covered by Part D.

CMS Response

CMS concurs with this recommendation and will seek to include this information in upcoming beneficiary and provider outreach to help make beneficiaries and providers aware of other coverage options for overdose reversal medications that will continue to be available after Narcan and its generic equivalents fully transition to over-the-counter status and remaining inventory of products labeled as prescription-only have been exhausted.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Miriam Anderson served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Margaret Himmelright and Jason Kwong. Office of Evaluation and Inspections headquarters staff who provided support include Chris Galvin, Robert Gibbons, Althea Hosein, Michael Novello, and Sarah Swisher.

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.

Contact

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, *Provisional Drug Overdose Death Counts*, August 6, 2023. Accessed at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm on August 22, 2023.

[2] In 2022, an estimated 75,811 overdose deaths in 2022 involved synthetic opioids, other than methadone, including drugs such as fentanyl and tramadol. This accounted for approximately 90 percent of all opioid-related overdose deaths. CDC, *Provisional Drug Overdose Death Counts*, August 6, 2023. Accessed at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm on August 22, 2023.

[3] See OIG, *Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries* (OEI-02-22-00390) September 13, 2022. Also see OIG, *Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder* (OEI-02-20-00390) December 15, 2021; OIG, *Concerns Persist About Opioid Overdoses and Medicare Beneficiaries' Access to Treatment and Overdose-Reversal Drugs* (OEI-02-20-00401) August 10, 2021; OIG, *Opioid Use in Medicare Part D During the Onset of the COVID-19 Pandemic* (OEI-02-20-00400) February 2, 2021; OIG, *Opioid Use in Medicare Part D Continued To Decline in 2019, but Vigilance Is Needed as COVID-19 Raises New Concerns* (OEI-02-20-00320) August 13, 2020; OIG, *Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased* (OEI-02-19-00390) July 8, 2019; OIG, *Opioid Use in Medicare Part D Remains Concerning* (OEI-02-18-00220) June 17, 2018; and OIG, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing* (OEI-02-17-00250) July 11, 2017. Additionally, OIG looked at access to treatment for opioid use disorder in Medicaid. See OIG, *Many Medicaid Enrollees with Opioid Use Disorder Were Treated with Medication; However, Disparities Present Concerns* (OEI-BL-22-00260) September 26, 2023.

[4] This represents the number of Medicare enrollees who received medication to treat their opioid use disorder in outpatient settings.

[5] OIG, *The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D* (OEI-02-22-00160) April 16, 2023. Also see OIG, *The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder in Medicare Part D Continues to Appear Low: 2022* (OEI-02-24-00130) November 11, 2023.

[6] We considered an enrollee to have had an overdose if the enrollee had at least one claim from Medicare Part A, B, or C with a diagnosis of an opioid poisoning from prescription or illicit opioids.

[7] In 2022, an estimated 75,811 overdose deaths in 2022 involved synthetic opioids, other than methadone, including drugs such as fentanyl and tramadol. This accounted for approximately 90 percent of all opioid-related overdose deaths. CDC, *Provisional Drug Overdose Death Counts*, August 6, 2023. Accessed at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm on August 22, 2023.

[8] Further, if an enrollee's claim had yet to be submitted to Medicare at the time that claims data was analyzed for this report (July 2023), then their overdose would not be identified.

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

[10] Each of these 1.1 million Medicare enrollees had a diagnosis of opioid use disorder on at least 1 Medicare claim in 2022 or received at least 1 service from an opioid treatment program in 2022. We refer to these enrollees as "enrollees with opioid use disorder" throughout the report.

[11] This analysis includes medication for opioid use disorder that enrollees received through Medicare in outpatient settings, including medication prescribed in office-based settings and filled at pharmacies and medication received at opioid treatment programs.

[12] The Food and Drug Administration (FDA) recommends that all three of these medications be available to all patients because certain medications may be more appropriate for some patients than others. FDA, *Information about Medication-Assisted*

Treatment (MAT), May 23, 2023. Accessed at https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat on August 23, 2023.

[13] OIG, *Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries* (OEI-02-22-00390) September 13, 2022. By comparison, a recent study estimated that in 2021 just over 22 percent of adults who reported opioid use disorder in the past year received medication to treat their opioid use disorder. C.M. Jones, B. Han, G.T. Baldwin, E.B. Einstein, W.M. Compton, "Use of Medication for Opioid Use Disorder Among Adults With Past-Year Opioid Use Disorder in the US," 2021, *JAMA Netw Open*. 2023;6(8):e2327488. doi:10.1001/jamanetworkopen.2023.27488. Accessed at https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2807964?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=080723 on September 20, 2023.

[14] National Institute of Drug Abuse, *Words Matter – Preferred Language for Talking About Addiction*. Accessed at https://www.drugabuse.gov/drug-topics/addiction-science/words-matter-preferred-language-talking-about-addiction on June 14, 2023.

[15] Buprenorphine is a Schedule III controlled substance that suppresses opioid withdrawal symptoms by relieving cravings. Buprenorphine is also separately indicated for pain. Buprenorphine products indicated for pain are different from buprenorphine products indicated for the treatment of opioid use disorder and are not included in this review.

[16] Most enrollees receive buprenorphine in office-based settings that is dispensed by pharmacies and covered by Medicare Part D. Far less commonly, enrollees receive buprenorphine administered by a provider in an office-based setting covered under Medicare Part B or C.

[17] The Drug Addiction Treatment Act of 2000 (Title XXXV of the Children's Health Act of 2000, P.L. No. 106-310) allowed providers to obtain a waiver to prescribe Schedule III, IV, and V drugs—including buprenorphine—for substance use disorder treatment in office settings. Section 1262 of the Consolidated Appropriations Act, 2023 (P.L. No. 117-328), removed the waiver requirement.

[18] 21 U.S.C. § 823(g)(1). Also see 42 C.F.R. § 8.11 & § 8.12(h). Because methadone can only be provided through opioid treatment programs and cannot be dispensed by pharmacies, it is not covered by Part D. See also CMS, *Medicare Prescription Drug Benefit Manual,* Ch. 6, Sec. 10.8.

[19] Under certain circumstances, patients at opioid treatment programs are permitted to take home doses of both buprenorphine and methadone, thus alleviating the need to travel each day. See 42 CFR § 8.12(i). During the COVID-19 Public Health Emergency, SAMHSA increased the flexibility in dispensing take-home doses of methadone and other opioid agonist medications. See SAMHSA, *Opioid Treatment Program (OTP) Guidance*, March 2020. Accessed at https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf on June 6, 2023. In April 2023, SAMHSA temporarily extended flexibilities allowing unsupervised take-home medication under certain conditions until one year from the end of the public health emergency or until such time that the Department publishes final rules revising 42 C.F.R § 8, whichever occurs sooner. See SAMHSA, *Methadone Take-Home Flexibilities Extension Guidance*, August 2023. Accessed at https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance on August 24, 2023.

[20] Patients may experience difficulties accessing opioid treatment programs for other reasons, such as geographic limitations or patient admission requirements. There were approximately 1,400 opioid treatment programs enrolled in Medicare in the United States and its territories as of April 2023, but distribution of programs is not even across the States. See CMS, Opioid Treatment Program Providers, April 2023. Accessed at https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers on April 10, 2023. Notably, State laws related to opioid treatment programs differ. For instance, some States have laws and regulations related to where opioid treatment programs can be located. See J.R. Jackson, et al., "Characterizing variability in state-level regulations governing opioid treatment program," *Journal of Substance Abuse Treatment*, Vol. 115, August 2020.

[21] B. Andraka-Christou, "Addressing Racial and Ethnic Disparities in the Use of Medications for Opioid Use Disorder," *Health Affairs*, June 2021, Vol. 6, No. 40.

[22] The vast majority of enrollees who received naltrexone did so in office-based settings. These drugs were dispensed by pharmacies and covered by Part D.

[23] 42 C.F.R. § 423.315(d).

[24] Part D covered medications dispensed at pharmacies generally have cost-sharing. Medications dispensed or administered at opioid treatment programs do not have cost-sharing.

[25] People who qualify for Social Security Disability Insurance (SSDI) benefits are eligible for Medicare after a 24-month qualifying period. For more information, see Social Security Administration (SSA), *Disability Benefits | How You Qualify*. Accessed at https://www.ssa.gov/benefits/disability/qualify.html#anchor3 on June 2, 2023. Also see SSA, *Medicare Information*. Accessed at https://www.ssa.gov/disabilityresearch/wi/medicare.htm#general on September 1, 2023.

[26] This analysis uses the race and ethnicity information from Medicare's enrollment database, which is based on data collected from the Social Security Administration and an algorithm. Note that these data combine race and ethnicity and allow for only one response. Although these data are the best available information on race and ethnicity for Medicare enrollees, there are limitations to these data. See the methodology. For a fuller discussion, also see OIG, *Inaccuracies in Medicare's Race and Ethnicity Data Hinder the Ability To Assess Health Disparities* (OEI-02-21-00100) June 15, 2022.

[27] Asian/Pacific Islander and Hispanic enrollees were also less likely to receive medication regardless of their age group. However, older Black enrollees—i.e., those aged 65 and above—were more likely to receive medication than were older enrollees in other race/ethnicity groups.

[28] After two years of continuous treatment and a determination that the patient is responsible in handling opioid drugs, patients may receive up to one month's worth of take-home doses. 42 CFR § 8.12(i)(3)(vi).

[29] Buprenorphine and naltrexone can also be administered or dispensed at opioid treatment programs, but it is far more common for an enrollee to receive these medications in office-based settings.

[30] B. Andraka-Christou, "Addressing Racial and Ethnic Disparities in the Use of Medications for Opioid Use Disorder," *Health Affairs*, June 2021, Vol. 6, No. 40. Also see SAMHSA, *The Opioid Crisis and The Black/African American Population: An Urgent Issue*, April 2020. Accessed at https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-05-02-001_508%20Final.pdf on June 21, 2021. Also see SAMHSA, *The Opioid Crisis and The Hispanic/Latino Population: An Urgent Issue*, July 2020. Accessed at https://store.samhsa.gov/sites/default/files/pep20-05-02-002.pdf on June 21, 2021.

[31] National Institute on Drug Abuse, *Naloxone for Opioid Overdose: Life-Saving Science*, June 2021. Accessed at https://nida.nih.gov/publications/naloxone-opioid-overdose-life-saving-science on August 10, 2022.

[32] The total number of prescriptions for naloxone also increased, reaching 703,625 prescriptions in 2022—a 40-percent increase from 2021.

[33] Additional enrollees may have received naloxone other than through 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. Also, enrollees who did not receive naloxone through Part D in 2022 may still have naloxone that they received through Part D from a prior year.

[34] In 2022, 14 percent of all naloxone dispensed through Part D was for brand-name Narcan and 83 percent was for generic equivalents of Narcan—i.e., 4 mg naloxone nasal spray products.

[35] The definition of a Part D drug does not include over-the-counter products. As such, they cannot be covered by Part D under the basic drug benefit or as a supplemental benefit. According to CMS, when a Part D covered drug switches to over-the-counter status, its existing inventory labeled as prescription only will continue to satisfy the definition of a Part D drug and will continue to be covered by Part D until its inventory runs out. See CMS, *Medicare Prescription Drug Benefit Manual*, Ch. 6,

Sec. 10.10 - Over-the-Counter Products (OTCs), January 15, 2016. Accessed at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf on August 1, 2023.

[36] There are some exceptions in which Medicare may provide over-the-counter drugs under a plan utilization management program or step therapy protocol, but the costs are treated as administrative costs and not Part D drug costs. For more information, see CMS, *Medicare Prescription Drug Benefit Manual*, Ch. 6 - Part D Drugs and Formulary Requirements, Sec. 10.10 - Over-the-Counter Products (OTCs), January 15, 2016. Accessed at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf on August 1, 2023. Also see CMS, *Medicare Prescription Drug Benefit Manual*, Ch. 7, Sec. 60.2 – Over-the-Counter Drugs as Part of Utilization Management Programs, February 19, 2010. Accessed at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/dwnlds/chapter7pdf on October 3, 2023.

[37] See FDA, *FDA Approves First Over-the-Counter Naloxone Nasal Spray*, March 29, 2023. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-first-over-counter-naloxone-nasal-spray on June 2, 2023.

[38] According to FDA, there will be a transition period when the switch of Narcan and its generic equivalents to over-the-counter status is being implemented. During this period, FDA will work with manufacturers seeking to switch their generic equivalent prescription naloxone products to nonprescription (i.e., over-the-counter) status. See FDA, *FDA takes steps to decrease barriers for overdose reversal agents with Dr. Marta Sokolowska Q&A With FDA Podcast Transcript*, July 10, 2023. Accessed at https://www.fda.gov/drugs/news-events-human-drugs/fda-takes-steps-decrease-barriers-overdose-reversal-agents-dr-marta-sokolowska on September 25, 2023.

[39] Emergent, *Emergent BioSolutions' NARCAN® Nasal Spray Launches Over the Counter Making it Possible for Everyone to Help Save a Life from an Opioid Overdose Emergency*, August 30, 2023. Accessed at https://investors.emergentbiosolutions.com/node/22286/pdf on September 1, 2023. Note that the cost-sharing amounts and price of Narcan are based on two doses.

[40] CMS, *Memo to All Medicare Advantage Organizations; Prescription Drug Plan Sponsors; Medicare-Medicaid Plans on Supplemental Benefit Coverage of Over-the-Counter Naloxone*, April 11, 2023. In addition, Part B will continue to cover naloxone that is provided by opioid treatment programs along with other treatment services.

[41] 42 U.S.C. § 1396r-8(k)(4).

[42] In May 2023, FDA approved Opvee, a nalmefene hydrochloride nasal spray. In addition, Medicare Part B will continue to cover naloxone provided by opioid treatment programs. For more information about Opvee, see FDA, *FDA Approves Prescription Nasal Spray to Reverse Opioid Overdose*, May 22, 2023. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-prescription-nasal-spray-reverse-opioid-overdose on June 23, 2023.

[43] 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 D.L. Chau, V. Walker, L. Pai, et al., "Opiates and Elderly: Use and Side Effects," *Clinical Interventions in Aging*, Vol. 3, No. 2, June 6, 2008, p. 276. D. Dowell, K.R. Ragan, C.M. Jones, G.T. Baldwin, R. Chou, "CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022," *MMWR Recomm Rep* 2022;71(No. RR-3):1–95. Accessed at https://www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7103a1-H.pdf on June 6, 2023. K.W. Saunders, K.M. Dunn, J.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, January 19, 2010, pp. 310–315.

[44] Between 2016 and 2020, the number of enrollees OIG identified as at serious risk of opioid misuse or overdose decreased between 14 percent and 32 percent annually.

[45] States maintain databases—called prescription drug monitoring programs—that track prescriptions for controlled substances. Prescribers can check these databases before ordering opioids to determine whether an enrollee is already receiving opioids ordered by other prescribers. 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 at http://www.pdmpassist.org/.

[46] Specifically, 56 prescribers each ordered opioids for at least 26 enrollees who received extreme amounts of opioids in 2022. Further, 53 prescribers each ordered opioids for at least 5 enrollees who appeared to be doctor shopping. Eight prescribers ordered opioids for high numbers of enrollees in both groups at serious risk.

[47] Of the 101 prescribers in 2022, 63 were also identified in at least one previous year (2016 through 2021) as having questionable prescribing.

[48] The Drug Addiction Treatment Act of 2000 (Title XXXV of the Children's Health Act of 2000, P.L. No. 106-310) allowed providers to obtain a waiver to prescribe Schedule III, IV, and V drugs—including buprenorphine—for substance use disorder treatment in office settings. Section 1262 of the Consolidated Appropriations Act, 2023 (P.L. No. 117-328), removed the waiver requirement.

[49] CMS, *CMS Behavioral Health Strategy*, May 2022. Accessed at https://www.cms.gov/cms-behavioral-health-strategy on July 31, 2023.

[50] OIG, *The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D* (OEI-02-22-00160) April 16, 2023.

[51] OIG, *Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder* (OEI-02-20-00390) December 15, 2021.

[52] OIG, *Many Medicaid Enrollees with Opioid Use Disorder Were Treated with Medication; However, Disparities Present Concerns* (OEI-BL-22-00260) September 26, 2023.

[53] According to CMS, when a Part D covered drug switches to over-the-counter status, any existing inventory of the drug labeled as prescription only will continue to satisfy the definition of a Part D drug and will continue to be covered by Part D until the inventory runs out. In addition, according to FDA, there will be a transition period during implementation of the switch of Narcan and its generic equivalents to over-the-counter status. During this period, the remaining stocks of prescription Narcan will remain available. FDA will also work with manufacturers seeking to switch their generic equivalent prescription naloxone products to nonprescription (i.e., over-the-counter) status. See CMS, *Medicare Prescription Drug Benefit Manual*, Ch. 6, Sec. 10.10 - Over-the-Counter Products (OTCs), January 15, 2016. Accessed at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf on August 1, 2023. Also see FDA, *FDA takes steps to decrease barriers for overdose reversal agents with Dr. Marta Sokolowska Q&A With FDA Podcast Transcript*, July 10, 2023. Accessed at https://www.fda.gov/drugs/news-events-human-drugs/fda-takes-steps-decrease-barriers-overdose-reversal-agents-dr-marta-sokolowska on September 25, 2023.

[54] MED and MME are interchangeable terms.

[55] 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 September 1, 2023.

[56] We included opioids dispensed in 2021 with days of use in 2022. This analysis excludes prescriptions for injection, intravenous, and intrathecal opioids, as well as opioids indicated for opioid use disorder.

[57] We identified enrollees with a cancer diagnosis or hospice stay by using CMS's National Claims History File and Part C Encounter data. In total, we identified 2,983,321 enrollees with cancer or in hospice care who received at least 1 opioid.

[58] 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 enrollees 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 September 1, 2023.

[59] For our analysis, we counted prescribers in group practices separately.