



HHS OIG Data Brief • May 2020 • OEI-02-19-00130

Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look

Why OIG Did This Review

As the Nation continues to struggle with the opioid crisis, it is vital to gain a deeper understanding of those who are at risk of misuse or overdose. The 2020 COVID-19 pandemic makes the need to look at this population even more pressing. The National Institutes of Health recently issued a warning that individuals with opioid use disorder could be particularly hard hit by COVID-19, as it is a disease that attacks the lungs. Respiratory disease is known to increase the mortality risk among people taking opioids.¹

The Office of Inspector General (OIG) has been tracking opioid use in Medicare Part D throughout the opioid crisis.² OIG identified 71,260 Part D beneficiaries at serious risk of misuse or overdose in 2017; each of these beneficiaries received extreme amounts of opioids or appeared to be doctor shopping. This data brief provides a deeper understanding of these beneficiaries by examining their Medicare claims from 2017 and 2018 and determining the following: their opioid amounts; the extent to which they had opioid overdoses; the extent to which they received naloxone through Medicare Part D; and the extent to which they have a diagnosis of opioid use disorder and received drugs for medication-assisted treatment (MAT drugs) through Part D. This information is critical to helping the Department of Health and Human Services (HHS) target its efforts to combat the opioid crisis.

What OIG Found

- Most Part D beneficiaries at serious risk of opioid misuse or overdose in 2017 received high amounts of opioids the following year.
- Fewer beneficiaries at serious risk in 2017 received extreme amounts of opioids or appeared to be doctor shopping the following year.
- Eleven percent of beneficiaries at serious risk in 2017 had an overdose or adverse effect from an opioid in 2017 or 2018.
- About one-quarter of beneficiaries at serious risk in 2017 received a prescription through Part D for naloxone, a drug that reverses opioid overdoses.
- About half of beneficiaries at serious risk in 2017 have been diagnosed with opioid use disorder or other conditions related to the misuse of opioids.
- Only 7 percent of beneficiaries at serious risk in 2017 who were diagnosed with opioid use disorder received MAT drugs through Part D, possibly because of challenges that beneficiaries have in accessing prescribers.

See primer on page 3 for definitions of “extreme amounts,” “high amounts,” and “doctor shopping.”

What OIG Recommends

Although opioids can be appropriate under certain circumstances, steps should be taken to mitigate the risk of misuse and overdose, especially when beneficiaries receive high amounts of opioids for long periods of time. This data brief also demonstrates that opportunities exist for the Centers for Medicare & Medicaid Services (CMS) to expand its role in ensuring that beneficiaries receive treatment for opioid use disorder. Although CMS is taking some significant steps, we recommend that CMS educate Part D beneficiaries and providers about access to MAT drugs and naloxone. CMS concurred with our recommendation.



Primer: Beneficiaries at Serious Risk of Opioid Misuse or Overdose

Which beneficiaries were at serious risk of opioid misuse or overdose in 2017?

- Those who:
 - received **extreme amounts** of opioids—i.e., an average daily morphine equivalent dose* greater than 240 mg for 12 months during the year, or
 - **appeared to be doctor shopping**—i.e., received **high amounts** of opioids (an average daily morphine equivalent dose greater than 120 mg for 3 months) and had four or more prescribers and four or more pharmacies during the year.

How many beneficiaries were at serious risk in 2017?

- 71,260 beneficiaries were at serious risk in 2017. They included:
 - 57,611 beneficiaries who received **extreme amounts** of opioids, and
 - 14,814 beneficiaries who **appeared to be doctor shopping**.^{**}

What are the characteristics of beneficiaries at serious risk in 2017?

- Almost three-quarters of these beneficiaries were **under the age of 65** years; many qualified for Medicare because they were disabled.
- The vast majority of these beneficiaries were diagnosed with **chronic pain or back pain**.
- Most also had one or more common **chronic diseases or conditions**, such as hypertension, high cholesterol, or gastroesophageal reflux disease.^{***}
- About two-thirds have a diagnosis related to **anxiety or depression**.
- These beneficiaries are located throughout the Nation.

* For an explanation of morphine equivalent dose (MED), see page 4 of this data brief.

** In total, 1,165 beneficiaries were identified as being in both serious-risk groups in 2017. Other Part D beneficiaries may also be at serious risk but do not fall into either of these groups.

*** See Appendix A for more information about the most common diagnoses among beneficiaries at serious risk.

RESULTS

Most Part D beneficiaries at serious risk in 2017 received high amounts of opioids the following year

Four out of every five Part D beneficiaries who were at serious risk of opioid misuse or overdose in 2017 received high amounts of opioids the following year. A total of 71,260 beneficiaries were at serious risk of opioid misuse or overdose in 2017 because they received extreme amounts of opioids or appeared to be doctor shopping (i.e., receiving high amounts of opioids in addition to having four or more prescribers and four or more pharmacies). Most of these beneficiaries—57,604 of 71,260—also received high amounts of opioids in 2018. None of these 57,604 beneficiaries had a diagnosis of cancer or were in hospice care.

Each of these 57,604 beneficiaries received a high amount of opioids through Part D in 2018, i.e., they had an average daily morphine equivalent dose (MED) that exceeded 120 mg for at least 3 months during the year. MED—which is also known as morphine milligram equivalent (MME)—is a measure that converts all the various opioids and strengths into one standard value. A daily MED of 120 mg is equivalent to taking 12 tablets a day of Vicodin 10 mg or 16 tablets a day of Percocet 5 mg.

Most of these beneficiaries (46,472) had opioid amounts that were twice that high. These beneficiaries had an average daily MED that exceeded 240 mg for at least 3 months during 2018. This is equivalent to receiving 32 tablets of Percocet 5 mg every day for 3 months.

Although beneficiaries may receive opioids for legitimate purposes, receiving high amounts of opioids in multiple years raises concerns. The Centers for Disease Control and Prevention (CDC) has published a guideline on prescribing opioids to patients with chronic pain. This guideline 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.³ For patients who are already taking high dosages of opioids, prescribers should offer the patients the opportunity to re-evaluate their continued use of these dosages, and prescribers should offer to work with them to taper their opioids to safer dosages.⁴ HHS recently issued a guide for clinicians on how to appropriately reduce or discontinue long-term use of opioids.⁵ The guide emphasizes that prescribers should decide based on the patient's individual circumstances whether tapering is appropriate.

Fewer beneficiaries at serious risk in 2017 received extreme amounts of opioids or appeared to be doctor shopping the following year

Of the 71,260 beneficiaries at serious risk in 2017, a total of 57,611 received extreme amounts of opioids for the entire year of 2017. This number decreased the following year, with 27,137 of the beneficiaries at serious risk in 2017 receiving extreme amounts of opioids for the entire year of 2018. These beneficiaries each had an average daily MED of greater than 240 mg for all of 2018. None of them had a diagnosis of cancer or were in hospice care.

The number of beneficiaries who appeared to be doctor shopping decreased to a greater extent. A total of 14,814 beneficiaries at serious risk in 2017 appeared to be doctor shopping that year, meaning that in 2017 they each received a high amount of opioids in addition to having four or more prescribers and four or more pharmacies. The number of these beneficiaries meeting these strict criteria significantly decreased the following year, with 2,452 of the beneficiaries at serious risk in 2017 receiving high amounts of opioids and having four or more prescribers and four or more pharmacies again in 2018.

For beneficiaries at serious risk in 2017, these decreases show apparent progress from the efforts of HHS—including CMS and OIG—and the efforts of others to address the opioid crisis. While we recognize the apparent progress for this group of beneficiaries, it is important to note that most of them continued to receive high amounts of opioids in 2018 and continued to face considerable risk.

Eleven percent of beneficiaries at serious risk in 2017 had an overdose or an adverse effect from opioids

Eleven percent of the beneficiaries at serious risk in 2017 (8,153 of 71,260 beneficiaries) had an overdose or an adverse effect from opioids in 2017 or the following year.

A total of 3,320 beneficiaries at serious risk in 2017 had an overdose in 2017 or 2018. This is about 5 percent of the beneficiaries at serious risk in 2017. Overdoses occur when high doses of opioids, alone or in combination with other substances, cause breathing to slow to dangerous levels or stop altogether.

Beneficiaries who appeared to be doctor shopping in 2017 were more likely to have an overdose than those who received extreme amounts of opioids. Nine percent of beneficiaries who appeared to be doctor shopping in 2017 had an overdose in 2017 or 2018, while 4 percent of beneficiaries who received extreme amounts of opioids had an overdose during the same time.⁶



Beneficiaries who appeared to be doctor shopping were even more likely to have an overdose.

Notably, there may have been more beneficiaries who had an overdose but did not receive care billed to Medicare.

An additional 4,833 beneficiaries at serious risk in 2017 had an adverse effect caused by an opioid during the year or 2018. Most of these beneficiaries—3,100 of 4,833—received emergency care for these adverse effects.

About one-quarter of beneficiaries at serious risk in 2017 received a prescription for naloxone—a drug that reverses opioid overdoses—through Part D

A total of 16,036—23 percent—of the beneficiaries at serious risk in 2017 received naloxone prescriptions through Medicare Part D in 2017 or 2018. Naloxone is a medication that can reverse the effects of an opioid overdose. 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.



Naloxone is a safe antidote to an opioid overdose. When given in time, naloxone can save lives.

Ensuring that at-risk individuals have naloxone on hand in the event of an overdose is critical for reducing the number of overdose deaths. Accordingly, in December 2018, HHS recommended that providers strongly consider prescribing naloxone to patients with an increased risk of opioid overdose, such as those who receive higher opioid amounts and those with a history of overdose.⁷

Beneficiaries may receive naloxone from sources other than Part D. Notably, most States allow for third-party prescriptions, which means that family members or friends of an at-risk patient can get a prescription for naloxone in their own names.⁸ In addition, a number of recent initiatives have increased community-based distribution of naloxone.⁹

About half of the beneficiaries at serious risk in 2017 have been diagnosed with opioid use disorder or other conditions related to the misuse of opioids

About 48 percent (34,365) of the beneficiaries at serious risk in 2017 had a diagnosis of opioid use disorder or a diagnosis related to the misuse of opioids in 2017 or 2018.

In total, 44 percent (31,468) of beneficiaries at serious risk in 2017 had a diagnosis of opioid use disorder. This diagnosis indicates that an individual has a problematic pattern of opioid use that leads to clinically significant impairment or distress. Opioid use disorder is sometimes referred to as opioid addiction. Patients with a diagnosis of opioid use disorder may require medication-assisted treatment (MAT), which combines medication with counseling and behavioral therapy. Diagnosing opioid use disorder requires

a thorough evaluation, which may include, for example, checking the patient's history of opioid prescriptions or testing the patient's urine for drugs.¹⁰ To receive a diagnosis, a patient must have two or more signs of the disorder, such as those listed in Exhibit 1. For more information about the signs of opioid use disorder, see Appendix B.

Opioid use disorder can range from mild to severe. A diagnosis of moderate-to-severe opioid use disorder—also known as opioid dependence—was among the most common diagnoses for beneficiaries at serious risk in 2017.

An additional 4 percent of beneficiaries at serious risk in 2017 (2,897 beneficiaries) had diagnoses related to the misuse of opioids. These beneficiaries did not have a diagnosis of opioid use disorder, but they had other concerning opioid use. For example, a number of beneficiaries were diagnosed with opioid intoxication or opioid withdrawal (in the absence of opioid use disorder).



Exhibit 1. Signs of opioid use disorder can include:*

- often taking opioids in larger amounts or over a longer period than was intended;
- having a persistent desire (or making unsuccessful efforts) to cut down or control opioid use;
- spending a great deal of time obtaining opioids, using opioids, or recovering from their effects;
- craving opioids; and
- failing to fulfill major obligations at work, school, or home because of recurrent opioid use.

*For a complete list of signs, see Appendix B.
Source: *Diagnostic and Statistical Manual of Mental Disorders: DSM-5*, 2013.

Only 7 percent of beneficiaries with opioid use disorder received MAT drugs through Part D, possibly because of challenges that beneficiaries have in accessing prescribers

Seven percent of beneficiaries at serious risk in 2017 who were diagnosed with opioid use disorder received a drug for MAT through Part D.¹¹ MAT is a proven method of treating opioid use disorder and can prevent relapse.¹² It combines medication—referred to as “MAT drugs”—with counseling and behavioral therapies to treat substance use disorders, including opioid use disorder.

In total, 2,123 of the 31,468 beneficiaries at serious risk in 2017 who had opioid use disorder received MAT drugs through Part D in 2017 or 2018.

Part D covers two medications approved for treating opioid use disorder: buprenorphine and naltrexone. Buprenorphine is the MAT drug that is most commonly received by serious-risk beneficiaries with opioid use disorder. Buprenorphine suppresses opioid withdrawal symptoms and relieves cravings. In total, 2,069 of the beneficiaries at serious risk with opioid use disorder received buprenorphine through Part D in 2017 or 2018.¹³ Only certain healthcare practitioners may prescribe buprenorphine for MAT; see Exhibit 3 for information about the waiver program that allows providers to prescribe buprenorphine.

Naltrexone was less commonly used among beneficiaries at serious risk in 2017 with opioid use disorder.¹⁴ This drug is reported to reduce opioid cravings; however, a patient must go through full detoxification before beginning naltrexone for MAT. In total, 84 of the beneficiaries at serious risk with opioid use disorder received naltrexone through Part D in 2017 or 2018.¹⁵

Exhibit 2. Medication-Assisted Treatment

- MAT is a proven method of treating opioid use disorder that combines medication with counseling and behavioral therapy.
- Part D covers two MAT drugs for opioid use disorder when they are appropriately prescribed: buprenorphine and naltrexone.



Exhibit 3. Buprenorphine Waiver Program

- Health care providers who have received a buprenorphine waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) are allowed to prescribe buprenorphine in an office-based setting.
- The waiver program is intended to increase access to quality buprenorphine treatment from trained providers while also preventing drug diversion.
- To qualify for a waiver, providers must have completed approved addiction training.
- Waivered providers are limited in the number of patients they may treat.

The limited number of beneficiaries with opioid use disorder who received MAT drugs through Part D may result, in part, from beneficiaries having challenges in accessing providers who can prescribe buprenorphine. Although Part D is not the only source for MAT drugs, it is an important source.

About one-quarter of beneficiaries at serious risk in 2017 who had opioid use disorder—8,305 of the 31,468—live in counties with limited to no access to providers who can prescribe buprenorphine for MAT.¹⁶

Of the 8,305 beneficiaries with limited access, 1,620 live in counties with no healthcare providers who can prescribe buprenorphine for MAT. The remaining 6,685 live in counties that have limited capacity to treat patients, meaning that the total number of patients that providers in these counties are permitted to treat is low.

It is important to note that some beneficiaries may be receiving MAT drugs from other sources, such as opioid treatment programs (sometimes referred to as methadone clinics). Methadone is not covered by Part D when it is used for MAT.¹⁷ On January 1, 2020, Medicare Part B began covering methadone that is provided by opioid treatment programs.

CONCLUSION AND RECOMMENDATION

Gaining a deeper understanding of beneficiaries who are at serious risk of opioid misuse or overdose is vital to addressing the Nation's opioid epidemic. The need for this information has become even more critical given the additional danger that the respiratory illness COVID-19 presents to beneficiaries with opioid use disorder. This data brief takes an in-depth look at 71,260 beneficiaries whom OIG identified as being at serious risk in 2017, determining the following: their opioid amounts; the extent to which they had opioid overdoses; the extent to which they received naloxone through Medicare Part D; and the extent to which they have opioid use disorder and received MAT drugs through Part D.

Most beneficiaries at serious risk in 2017 received high amounts of opioids in the following year. Raising even more concern, 11 percent of beneficiaries at serious risk in 2017 had an overdose or an adverse effect from an opioid. About one-quarter of beneficiaries at serious risk in 2017 received a prescription for naloxone—an opioid-overdose reversal drug—through Part D. About half of the beneficiaries at serious risk in 2017 have been diagnosed with opioid use disorder or other condition related to the misuse of opioids. However, only 7 percent of beneficiaries at serious risk in 2017 who were diagnosed with opioid use disorder received MAT drugs through Part D, possibly because of challenges that beneficiaries have in accessing prescribers. Note that beneficiaries may receive MAT drugs or naloxone from sources other than Medicare.

This data brief indicates that many beneficiaries at serious risk of misuse or overdose may need their care to be reassessed. CDC recommends that for patients who are already taking high dosages of opioids, prescribers should offer the patients the opportunity to re-evaluate their continued use of these dosages, and prescribers should offer to work with these patients to taper their opioids to safer dosages. HHS recently issued a guide for clinicians on how to appropriately reduce or discontinue long-term use of opioids. In addition, CMS is implementing a number of new initiatives to address opioid overutilization and encourage coordination of care in Part D.¹⁸

This data brief also demonstrates that opportunities exist for CMS to expand its role in ensuring that beneficiaries receive treatment for opioid use disorder. CMS is taking some significant steps by implementing the SUPPORT for Patients and Communities Act. In addition, CMS has taken a number of steps to improve access to MAT drugs and naloxone through Part D.¹⁹ Yet, other opportunities exist for CMS to ensure that beneficiaries receive treatment. Specifically, we recommend that CMS:

Educate Part D beneficiaries and providers about access to MAT drugs and naloxone

CMS plays an important role in education and awareness among beneficiaries and healthcare providers about treatment and coverage under Medicare. CMS should determine the best strategies to increase awareness among beneficiaries and healthcare providers about access to MAT drugs under Part D and under the new changes to Medicare Part B, which covers opioid use disorder treatment and MAT drugs.²⁰ For example, CMS could expand its outreach by enhancing its webpage for beneficiaries to comprehensively explain this information, including coverage of MAT drugs under Part B and Part D, and how to find outpatient treatment programs and providers who can prescribe buprenorphine. This outreach should also include information about access to naloxone. In addition, CMS could partner with Part D sponsors to increase awareness among Part D beneficiaries about access to MAT drugs and naloxone.

Further, we encourage CMS to partner with the Substance Abuse and Mental Health Services Administration (SAMHSA) when developing strategies to educate beneficiaries and providers. For example, CMS could partner with SAMHSA to provide Part D beneficiaries with information about the specific providers in their area who can prescribe MAT drugs. CMS could also partner with SAMHSA to send letters to providers who serve Part D beneficiaries in areas with limited or no providers who can prescribe buprenorphine for MAT. These letters could inform providers about the need for SAMHSA-waivered providers in their area and include instructions about how to become a waivered provider.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with our recommendation to educate Part D beneficiaries and providers about access to MAT drugs and naloxone. CMS stated that it currently partners with Part D plan sponsors to promote awareness of opioid treatment and coverage options and that it will consider additional ways to increase awareness among beneficiaries and health care providers about opioid treatment and coverage options under Medicare, including providing additional information about coverage of MAT drugs and naloxone on its websites and in the *Medicare & You* handbook. CMS stated that it will also continue to work with its partners within HHS as it develops strategies for educating beneficiaries and providers.

OIG appreciates CMS's efforts to promote awareness of opioid treatment and coverage options. OIG urges CMS to specifically partner with SAMHSA when developing additional strategies to educate beneficiaries and providers.

For the full text of CMS's response, see Appendix C.

METHODOLOGY

We based this data brief on an analysis of prescription drug event (PDE) records, Medicare Claims Data, and Part C Encounter data. 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 the beneficiary. The National Claims History File contains claims data—including diagnosis codes—from Medicare Parts A and B. Part C Encounter Data contain medical claims data—including diagnosis codes—for beneficiaries enrolled in Medicare Advantage plans.

This review focuses on 71,260 beneficiaries whom OIG identified as being at serious risk of opioid misuse or overdose in 2017. These include 57,611 beneficiaries who received extreme amounts of opioids and 14,814 beneficiaries who appeared to be doctor shopping.²¹ We conducted the analyses described below for beneficiaries at serious risk.

Opioid Amounts

First, we determined the extent to which these beneficiaries at serious risk received high amounts of opioids in 2018 using CDC’s MME conversion file and the PDE records. CDC’s MME conversion file contains information about each opioid’s drug morphine milligram equivalence. To determine each beneficiary’s average daily MED, we first calculated the MED for each opioid prescription (i.e., PDE record).²² We did this using the following equation:

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

We then summed each beneficiary’s MED for each day of the year using the dates of service and days supply on each PDE record. We refer to this as the daily MED.

Next, we calculated each beneficiary’s average daily MED over each 90-day period in 2018 and for the entire year. We excluded beneficiaries with a diagnosis of cancer or a hospice stay at any point in 2018 from the analysis of opioid amounts.²³

We then determined the proportion of the 71,260 beneficiaries who received a high amount of opioids in 2018, i.e., they had an average daily MED of greater than 120 mg for any 90-day period in 2018 and they received opioids for 90 days or more in 2018. We also determined the proportion of 71,260 beneficiaries who had an average daily MED of greater

than 240 mg for any 90-day period in 2018 and the proportion who had an average daily MED of greater than 240 mg for the entire year of 2018. We also determined the proportion of the 71,260 beneficiaries who received high amounts of opioids and had 4 or more prescribers and 4 or more pharmacies for opioids in 2018.

Opioid Overdoses

Next, using inpatient and outpatient claims data from the National Claims History File and Part C Encounter Data, we determined the extent to which the 71,260 beneficiaries had an opioid-related overdose in 2017 or 2018. We considered a beneficiary to have had an overdose if he or she had at least one claim from Medicare Parts A, B, or C with a diagnosis of an opioid poisoning from prescription or illicit opioids.

For the remaining beneficiaries, we determined the extent to which they had an adverse effect caused by opioid use in 2017 or 2018 and the extent to which these adverse effects were treated during an emergency care visit—i.e., an emergency room, urgent care, or trauma care visit.

The ICD-10 diagnosis codes contain specific codes for adverse effect(s) from opioids. We included the codes for adverse effects related to both prescription and illicit opioids.

Naloxone

We determined the number of beneficiaries at serious risk who received naloxone—a drug used to reverse opioid overdoses—through Part D in 2017 or 2018. We based this analysis on the PDE records.

Opioid Use Disorder or Conditions Related to Opioid Misuse

We then analyzed the data from National Claims History File and Part C Encounter Data to determine the extent to which the 71,260 beneficiaries had a diagnosis of opioid use disorder or other conditions related to opioid misuse in 2017 or 2018.

Specifically, we calculated the number of beneficiaries with a diagnosis of opioid use disorder. We considered a beneficiary to have opioid use disorder if he or she had a diagnosis code categorized as “opioid abuse” (F11.1) or “opioid dependence” (F11.2).²⁴

For the beneficiaries who did not have a diagnosis of opioid use disorder, we determined the number who had a diagnosis related to the misuse of opioids, such as opioid intoxication, or other opioid related disorders.²⁵

Lastly, we identified the most common diagnoses overall for these beneficiaries.²⁶

Drugs for Medication-Assisted Treatment

Using the PDE records, we determined the extent to which the 31,468 beneficiaries who had a diagnosis of opioid use disorder received

MAT drugs through Part D for opioid use disorder in 2017 or 2018. Specifically, we determined the number and proportion of beneficiaries who received buprenorphine indicated for the treatment of opioid use disorder or naltrexone indicated for the treatment of opioid use disorder.²⁷

Next, using data from the OIG data brief *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder* (OEI-12-17-00240), we determined the proportion of beneficiaries with opioid use disorder who lived in counties with no or low capacity to provide buprenorphine for MAT.²⁸

Limitations

This study is based on an analysis of Medicare claims data, Part C Encounter data, and PDE records. Beneficiaries in this analysis may have received additional services or drugs through other payers, such as Medicaid. For example, beneficiaries may have received methadone in an opioid treatment program that is not included in this analysis.

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: COMMON DIAGNOSES

Exhibit A-1: Most Beneficiaries at Serious Risk in 2017 Had Diagnoses of Chronic Pain or Back Pain; Many Also Had One or More Common Chronic Diseases or Conditions.

| ICD-10-CM Code | Description | Number of Serious-Risk Beneficiaries With Diagnosis | Percentage |
|----------------|--|---|------------|
| I10 | Essential (primary) hypertension | 52,587 | 74% |
| G89.29 | Other chronic pain | 51,841 | 73% |
| M54.5 | Low back pain | 51,031 | 72% |
| G89.4 | Chronic pain syndrome | 47,160 | 66% |
| F41.9 | Anxiety disorder, unspecified | 35,404 | 50% |
| E78.5 | Hyperlipidemia, unspecified (high cholesterol) | 34,953 | 49% |
| K21.9 | Gastroesophageal reflux disease without esophagitis (GERD) | 33,029 | 46% |
| F32.9 | Major depressive disorder, single episode, unspecified | 30,864 | 43% |
| M54.2 | Cervicalgia (neck pain) | 29,712 | 42% |

Note: Beneficiaries may have more than one diagnosis.

Source: OIG analysis of 2017 and 2018 Medicare claims data, 2019.

APPENDIX B: OPIOID USE DISORDER

Exhibit B-1: Diagnostic Criteria for Opioid Use Disorder*

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
10. Tolerance, as defined by either of the following:
 - A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
 - A markedly diminished effect with continued use of the same amount of opioid.
11. Withdrawal, as manifested by either of the following:
 - The characteristic of opioid withdrawal syndrome.
 - Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

* For a diagnosis of opioid use disorder, at least 2 of the 12 criteria should be observed within a 12-month period. The presence of 2 or 3 symptoms is considered mild opioid use disorder. The presence of 4 or 5 symptoms is considered moderate opioid use disorder. Six or more symptoms is considered severe opioid use disorder. There are some exceptions for considering tolerance and withdrawal as critical for opioid use disorder if the beneficiary is under appropriate medical supervision.

Source: *Diagnostic and Statistical Manual of Mental Disorders: DSM-5*, 2013.

APPENDIX C: AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

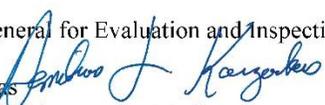
Centers for Medicare & Medicaid Services

Administrator

Washington, DC 20201

DATE: April 7, 2020

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections

FROM: Demetrios Kouzoukas 
Principal Deputy Administrator for Medicare

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look (OEI-02-19-00130)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS is committed to using our full expertise and resources to combat the opioid epidemic, and is taking steps to help prevent opioid misuse in Medicare Part D while balancing the need for appropriate, individualized pain management. Our actions to date have helped decrease drug overdose deaths by 4.1 percent in 2017-2018 and from January 2017 to September 2019, there has been a 32 percent reduction in total morphine milligram equivalents dispensed monthly by retail and mail order pharmacies. We recognize that more work is needed, and we are continuing to take action.

The SUPPORT for Patients and Communities Act (SUPPORT Act) has given Medicare new authority to pay for opioid use disorder (OUD) treatment services provided at opioid treatment programs (OTP) under Part B and Part C. Since January 1, 2020, Medicare has covered OUD treatment services in a bundled payment, including dispensing and administration of medication to treat OUD, individual and group therapy, toxicology testing, and periodic assessments. For the first time, Medicare is covering methadone for the treatment of OUD, which can only be furnished by OTPs. The coverage also includes in-person and virtual delivery of counseling and therapy services furnished by OTPs, broadening access to these critical services.

Plan sponsors (including Medicare Advantage plans offering Part D coverage (MA-PDs) and standalone Prescription Drug Plans (PDPs)) have an important role in detecting and preventing potential misuse of opioids. As a payer, CMS oversees Medicare Part D plan sponsors to ensure that they are in compliance with CMS requirements that protect beneficiaries and can help prevent and address opioid overutilization. All Medicare Part D plan sponsors are expected to have a documented, written strategy for addressing overutilization of prescription opioids. Medicare Part D plan sponsors are expected to use multiple tools, including formulary management, case management that includes beneficiaries' clinicians aimed at coordinated care, and safety edits at the point of dispensing.

CMS has implemented a series of additional changes to further the goal of preventing opioid misuse. To reduce the potential for chronic opioid use or misuse, CMS expects all Part D plan sponsors to limit initial opioid prescription fills for the treatment of acute pain to no more than a seven days' supply. This policy change is consistent with the Centers for Disease Control and

Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain. CMS also expects all Part D plan sponsors to implement a new opioid care coordination safety edit. This edit creates an alert for pharmacists when a beneficiary's daily opioid usage reaches high levels. To help identify and prevent opioid users from taking duplicate or key "potentiator" drugs, CMS also expects Part D plan sponsors to implement additional safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines.

CMS has also implemented section 704 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) in a final rule published in 2018. This effort established the framework under which Part D sponsors may implement drug management programs beginning in 2019. CMS incorporated many aspects of the previous retrospective opioid overutilization policies, including CMS's Overutilization Monitoring System (OMS), and added new aspects to comply with CARA.

Under the drug management programs, Part D sponsors engage in case management of potential at-risk beneficiaries reported by OMS who meet the minimum OMS criteria, through contact with their opioid prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a beneficiary is determined to be at-risk, after written notice to the beneficiary, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or selected network pharmacy(ies) that the beneficiary may generally choose, and/or through a beneficiary-specific point-of-sale claim edit. Thus, drug management programs provide Part D plan sponsors an additional tool to promote better coordination between providers and beneficiaries with respect to opioid use by their patients.

In 2019, CMS finalized additional enhancements to the OMS including revised metrics to track high opioid overuse and to provide additional information to Part D plan sponsors about high risk beneficiaries who take opioids and "potentiator" drugs, such as benzodiazepines or high dose gabapentin, which when taken with an opioid increase the risk of an adverse event.

Under section 2004 of the SUPPORT Act, enacted on October 24, 2018, all Part D sponsors are required to have a drug management program for plan years beginning on or after January 1, 2022. Another provision under section 2006 expands drug management programs to include Part D beneficiaries with a history of opioid-related overdose effective, January 1, 2021. CMS proposed a rule on February 18, 2020 (CMS-4190-P) to implement these provisions.

In addition, CMS utilizes the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) to conduct data analysis that is shared with plan sponsors to help them identify outlier prescribers and high risk pharmacies. For example, plans receive Quarterly Outlier Prescriber Schedule II Controlled Substances Reports, which provide a peer comparison of prescribers of Schedule II controlled substances. These reports now provide a separate analysis of just opioids. Part D plan sponsors also receive quarterly reports, which contain a list of pharmacies identified by CMS as high risk and provide Part D plan sponsors with information to investigate potential fraud, waste and abuse. CMS has also sent letters to prescribers whose opioid prescribing patterns were elevated as compared with their peers. CMS also utilizes the Investigative MEDIC to detect, prevent, and proactively deter fraud, waste, and abuse for high-risk prescribers and pharmacies in Medicare Parts C and D by focusing primarily on complaint intake and response, data analysis, investigative activities, referrals to law enforcement partners, and law enforcement support.

To assist clinicians, nurses, and other health care providers to assess opioid-prescribing habits while continuing to ensure patients have access to the most effective pain treatment, CMS

released an interactive online mapping tool. The mapping tool allows the user to see both the number and percentage of Medicare opioid claims at the local level and offers spatial analyses to identify “hot spots” or clusters in order to better understand how this critical issue impacts communities nationwide.

To help ensure access to medication-assisted treatment (MAT) and naloxone, CMS requires that Medicare Part D formularies include covered Medicare Part D drugs used for MAT and mandates Medicare Part C coverage of the behavioral health element of MAT services. CMS has begun reviewing formulary and benefit designs related to MAT drugs to ensure that Part D plan sponsors are not discouraging beneficiaries with opioid use disorder from enrolling. CMS also encourages Part D plan sponsors to include at least one overdose reversal drug naloxone product on their generic or low cost-sharing tier of their formularies.

CMS recognizes that it is important for Medicare beneficiaries and those who care for them to understand that these options are available to them under Medicare, so CMS is also working to educate clinicians, health plans, pharmacy benefit managers, and other providers and suppliers on services covered by Medicare to treat beneficiaries with OUD. In the February 2020 proposed rule, CMS proposed to implement Section 6102 of the SUPPORT Act that requires that, starting in plan year 2021, Part D plan sponsors must disclose to each enrollee information about the risks of prolonged opioid use related to the treatment of pain and coverage of non-opioid medications and alternate treatments.

CMS and HHS are also conducting outreach and education through their websites. The HHS website includes a page where visitors can learn about OUD treatment options and search for treatment facilities. CMS also maintains a webpage on OUD treatment that provides information on MAT coverage and includes a link to find opioid treatment programs. In addition, CMS has implemented updates to the Medicare & You handbook required by the SUPPORT Act, which include educational resources regarding opioid use and pain management, as well as descriptions of covered alternative (non-opioid) pain-management treatments.

OIG’s recommendations and CMS’ responses are below.

OIG Recommendation

CMS should educate Part D beneficiaries and providers about access to MAT drugs and naloxone.

CMS Response

CMS concurs with this recommendation. CMS already partners with Part D plan sponsors to promote awareness of opioid treatment and coverage options. For example, in the CY 2020 Call Letter, CMS recommended that Part D sponsors do targeted education of prescribers and enrollees on co-prescribing of naloxone to prevent accidental overdoses and to sensitively address the needs of persons with opioid use disorders. CMS will consider additional ways to increase awareness among beneficiaries and health care providers about opioid treatment and coverage options under Medicare, including providing additional information about coverage of MAT drugs and naloxone on its websites and in the Medicare & You handbook. In addition, CMS will continue to work with our partners within HHS when developing strategies to educate beneficiaries and providers.

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

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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 National Institutes of Health, National Institute on Drug Abuse, *COVID-19: Potential Implications for Individuals with Substance Abuse Disorders*, April 6, 2020. Accessed at <https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders> on April 9, 2020.

² OIG, *Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased*, OEI-02-19-00390, July 2019. OIG, *Opioid Use in Medicare Part D Remains Concerning*, OEI-02-18-00220, June 2018. OIG, *Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing*, OEI-02-17-00250, July 2017.

³ The Centers for Disease Control and Prevention (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. See CDC, "CDC Guideline for Prescribing Opioids for Chronic Pain: United States, 2016." *MMWR* 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.

⁴ *Ibid.*

⁵ The guide provides insights for clinicians on when and how to work with patients to taper opioids. It also reiterates that under most circumstances, HHS does not recommend abrupt opioid dose reduction or discontinuation. See Department of Health and Human Services, *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, September 2019. Accessed at https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version_HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf on October 21, 2019.

⁶ In total, 1,284 of the 14,814 beneficiaries who appeared to be doctor shopping in 2017 had an overdose in 2017 or 2018. A total of 2,097 of the 57,611 beneficiaries who received extreme amounts of opioids in 2017 had an overdose during the same time.

⁷ HHS, *HHS Recommends Prescribing or Co-Prescribing Naloxone to Patients At High Risk for an Opioid Overdose* (December 2018). Accessed at <https://www.hhs.gov/about/news/2018/12/19/hhs-recommends-prescribing-or-co-prescribing-naloxone-to-patients-at-high-risk-for-an-opioid-overdose.html> on October 3, 2019. Also see HHS, *Naloxone: The Opioid Reversal Drug that Saves Lives*. Accessed at <https://www.hhs.gov/opioids/sites/default/files/2018-12/naloxone-coprescribing-guidance.pdf> on October 3, 2019.

⁸ Prescription Drug Abuse Policy System, *Good Samaritan Prevention Laws*. Accessed at <http://www.pdaps.org/datasets/good-samaritan-overdose-laws-1501695153> on September 24, 2019.

⁹ For example, see the Substance Abuse and Mental Health Services Administration (SAMHSA), *SAMHSA is Announcing the Availability of Up to \$4.7 Million for Improving Access to Overdose Treatment grants* (April 2018). Accessed at <https://www.samhsa.gov/newsroom/press-announcements/201804090200> on September 24, 2019.

¹⁰ For more information about assessing a patient for opioid use disorder, see the CDC training, *Module 5: Assessing and Addressing Opioid Use Disorder*. Accessed at <https://www.cdc.gov/drugoverdose/training/oud/> on January 9, 2020.

¹¹ Part D pays for outpatient prescription drugs—including MAT drugs. This analysis focuses on beneficiaries with opioid use disorder because MAT drugs are indicated for the treatment of opioid use disorder, not for other types of opioid misuse.

¹² SAMHSA, *Medication and Counseling Treatment*. Accessed at <https://www.samhsa.gov/medication-assisted-treatment/treatment> on September 19, 2019.

¹³ This includes beneficiaries who received buprenorphine indicated for MAT through Part D.

¹⁴ Naltrexone can be used for individuals with opioid use disorder or alcohol dependence. See SAMHSA, *Naltrexone*. Accessed at <https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone> on September 19, 2019.

¹⁵ Thirty of these beneficiaries received both buprenorphine and naltrexone.

¹⁶ We identified these counties on the basis of data from a recent OIG study, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020.

¹⁷ Methadone is not covered by Part D when used for the treatment of opioid use disorder because it cannot be dispensed for this purpose by a retail pharmacy. However, beneficiaries may have received methadone from sources other than Part D, such as Medicaid. Therefore, the total number of beneficiaries at serious risk receiving MAT drugs may be higher.

¹⁸ For example, since 2019, Part D sponsors have been expected to implement care-coordination alerts at the point of sale when a beneficiary's total daily MED reaches or exceeds 90 mg. Beginning in 2021, Part D sponsors will be required to provide a subset of beneficiaries with certain information about the treatment of pain, such as the risks of prolonged opioid use and coverage of nonopioid medications. Beginning in 2022, Part D sponsors will be required to have drug management programs for certain "at-risk beneficiaries," including those with a history of opioid overdose. See 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 January 8, 2020. Also see SUPPORT for Patients and Communities Act, P.L. No. 115-271. Also See CMS, *Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021* (CMS-4190-P), February 2020. Accessed at <https://www.regulations.gov/contentStreamer?documentId=CMS-2020-0010-0001&contentType=pdf> on February 12, 2020.

¹⁹ For instance, CMS began scrutinizing formulary and benefit designs related to MAT drugs to ensure that plans were not discouraging beneficiaries with opioid use disorder from enrolling. CMS also encourages plan sponsors to include at least one naloxone product on their generic or low cost-sharing tier of their formularies. For more information see, CMS, *Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2019. Accessed at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf> on January 8, 2020.

²⁰ Notably, beginning in 2020, Medicare Part B covers methadone provided by opioid treatment programs. See SUPPORT for Patients and Communities Act, P.L. No. 115-271, § 2005. Also see 84 Fed. Reg. 62568 (Nov. 15, 2019).

²¹ Beneficiaries who received extreme amounts of opioids each had an average daily MED of greater than 240 mg for the entire year and received opioids for 360 days or more in 2017. Beneficiaries who appeared to be doctor shopping each had an average daily MED greater than 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 in 2017. A total of 1,165 beneficiaries were identified as being in both groups. For more information see OIG, *Opioid Use in Medicare Part D Remains Concerning*, OEI-02-18-00220, June 2018.

²² To ensure that we included all the opioids each beneficiary used in 2018, we included opioids dispensed in 2017 with days of use in 2018. This analysis also excluded PDE records for injection, intravenous, and intrathecal opioids because CDC does not publish MME conversion factors for these opioids. Opioids indicated for MAT were also excluded from MED calculations.

²³ 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, 5,397 beneficiaries at serious risk of opioid misuse or overdose had a cancer diagnosis or hospice stay in 2018.

²⁴ See *ICD-10 CM 2018: The Complete Official Codebook* (American Medical Association).

²⁵ Diagnosis codes that indicate misuse are labeled "opioid use" (F11.9). Ibid.

²⁶ When identifying the most common diagnoses, we did not include diagnosis ICD-10 Z codes because they describe factors that influence a patient's health status—such as long-term use of the medication—or describe that a patient has received a health services, such as an immunization.

²⁷ Buprenorphine that is indicated for MAT can be formulated with or without naloxone. We included both formulations in this analysis.

²⁸ For more information about these counties, see OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020.