

U.S. Department of Health and Human Services  
**Office of Inspector General**



# The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D

**Ann Maxwell**  
Deputy Inspector General  
for Evaluation and Inspections  
May 2023, OEI-02-22-00160





## The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D

### Key Results

Almost all Medicare Part D enrollees who received buprenorphine for the treatment of opioid use disorder received the recommended amounts.

Only a small number of enrollees either received very high amounts of buprenorphine or received buprenorphine at the same time as they received high amounts of other opioids.

Most prescribers ordered buprenorphine for a limited number of Part D enrollees; very few had patterns that raise concern.

These findings further support the recent repeal of the waiver—which was in place, in part, to limit diversion of buprenorphine.

This report also provides baseline information and recommendations that can assist the Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services (the Department) as they work to continue to improve access to buprenorphine, while also ensuring that the risk of diversion and misuse remains low.

### Why OIG Did This Review

Opioid-related overdose deaths in the United States remain a concern, with an estimated 82,310 deaths in 2021.<sup>1</sup> As the country continues to struggle with the opioid crisis, it is essential to ensure access to buprenorphine to treat individuals with opioid use disorder.<sup>2</sup>

Buprenorphine has been shown to decrease illicit opioid use and opioid-related overdose deaths.<sup>3</sup> However, there are concerns about access to this potentially life-saving medication. Previous Office of Inspector General (OIG) work has shown a need to increase the number of Medicare enrollees receiving treatment for opioid use disorder. OIG has found that just 18 percent of Medicare enrollees with a diagnosis of opioid use disorder received medication to treat their opioid use disorder.<sup>4</sup> Furthermore, Black, Hispanic, and Asian/Pacific Islander Medicare enrollees are less likely to receive medication to treat their opioid use disorder than are White enrollees.<sup>5</sup>

At the same time, buprenorphine for the treatment of opioid use disorder—hereafter referred to as buprenorphine—has the potential for misuse and is at risk for diversion. To address this risk, providers were required to obtain a waiver through the Substance Abuse and Mental Health Services Administration (SAMHSA) to prescribe or administer buprenorphine in office-based settings and were limited in the number of patients they could treat. This waiver is commonly referred to as the “DATA waiver” after the Drug Addiction Treatment Act (DATA) of 2000 that established the waiver program.

In December 2022, the Consolidated Appropriations Act, 2023, repealed the waiver requirement and the corresponding patient limits.<sup>6</sup> This change comes alongside a wider effort by the Administration to expand access to treatment, in part, by eliminating barriers.<sup>7</sup>

This data brief provides information related to the risk of misuse and diversion of buprenorphine in Medicare Part D in 2021—prior to the repeal of the DATA waiver. Prescribing of buprenorphine has been limited, in part, due to concerns related to misuse and diversion. Yet, up until now, there has been little information available on the extent to which buprenorphine may

be misused or diverted in Medicare. This data brief describes the use of buprenorphine and looks at several measures to assess the risk of misuse and diversion of buprenorphine in Medicare.

### **How OIG Did This Review**

We focused this review on Medicare Part D claims for buprenorphine indicated for the treatment of opioid use disorder in 2021—prior to the repeal of the DATA waiver. We did not include claims for buprenorphine indicated for pain. Buprenorphine covered by Medicare Part D is generally prescribed in office-based settings and filled at retail pharmacies.

### **What OIG Found**

Almost all Medicare Part D enrollees who received buprenorphine to treat their opioid use disorder received the recommended amounts. Most enrollees received buprenorphine-naloxone combination products, which have a reduced risk of misuse or diversion; however, 16 percent of enrollees received buprenorphine monoproductions. Only a small number of enrollees received very high amounts of buprenorphine or received buprenorphine at the same time as they received high amounts of opioids indicated for pain.

Most prescribers ordered buprenorphine for only a limited number of enrollees, which could provide an opportunity to increase access. Further, very few prescribers had patterns that raise concern. Only 35 prescribers ordered buprenorphine for multiple Part D enrollees who either received very high levels of buprenorphine or received buprenorphine at the same time as they received high amounts of opioids.

### **What OIG Recommends**

Together, these findings suggest that the risk of misuse and diversion of buprenorphine in Medicare Part D is low. These findings further support the recent repeal of the DATA waiver—which was in place, in part, to limit diversion of buprenorphine. The repeal of the waiver is a significant step towards increasing access to treatment.

Further, the data in this report provide baseline information about buprenorphine utilization and prescribing that can assist CMS, the Department, and others as they implement changes related to the repeal and take other steps to improve access to buprenorphine, while also ensuring that the risk of misuse and diversion remains low.

Accordingly, we recommend that CMS (1) monitor the use of buprenorphine and share information, as appropriate, with Departmental partners; (2) inform providers about buprenorphine use and the low risk of diversion to encourage providers to treat more Part D enrollees who have opioid use disorder; (3) take steps to inform providers about the availability of buprenorphine combination products in Part D, which can minimize the risk of misuse and diversion; and (4) follow up on the prescribers with concerning patterns identified in this report. CMS concurred with three of our recommendations. While it did not indicate whether it concurred with the other recommendation, it did indicate ongoing activity it felt was responsive.

## Primer – Buprenorphine for the Treatment of Opioid Use Disorder

- Opioid use disorder is a problematic pattern of opioid use that leads to clinically significant impairment or distress. Over 1.1 million people enrolled in Part D had a diagnosis of opioid use disorder in 2021.<sup>8</sup>
- Buprenorphine is a medication used to treat opioid use disorder.<sup>9</sup> It suppresses withdrawal symptoms and relieves cravings.
- Buprenorphine and other medications used to treat opioid use disorder are commonly referred to as medications for opioid use disorder (MOUD).<sup>10</sup> These medications have been shown to decrease illicit opioid use and opioid-related overdose deaths.<sup>11</sup>
- Buprenorphine is designated as a Schedule III controlled substance—meaning that it has the potential for abuse and is at risk for diversion, but has a lower risk than Schedule II controlled substances, such as oxycodone.<sup>12</sup>
- Until recently, to prescribe or administer buprenorphine in an office-based setting, a provider had to obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA). This waiver is commonly referred to as the “DATA waiver” after the Drug Addiction Treatment Act (DATA) of 2000 that established the waiver program.<sup>13</sup> It is also commonly referred to as the “X-waiver.”
- To qualify for this waiver, providers were generally required to complete approved training and have the capacity to refer patients to counseling and other ancillary services.<sup>14</sup> Providers were limited in the number of patients whom they were allowed to treat.<sup>15</sup>
- In late December 2022, the waiver requirement was repealed.<sup>16</sup> In its place, all providers who apply for or renew their Drug Enforcement Administration (DEA) registration to prescribe controlled substances must take a one-time training on treating and managing patients with substance use disorders.<sup>17</sup>

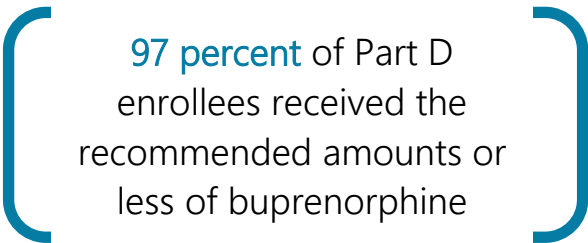
# FINDINGS

Ensuring access to treatment for opioid use disorder—including buprenorphine—is critical to helping address the Nation’s opioid crisis. At the same time, it is also important to ensure that diversion risks are limited.

This data brief describes Medicare Part D enrollees’ use of buprenorphine. It also looks at several measures to assess the risk of diversion, including the extent to which Part D enrollees received buprenorphine-naloxone combination products—which have a reduced risk of misuse or diversion; the extent to which enrollees receive very high amounts of buprenorphine; and the extent to which enrollees receive buprenorphine at the same time as they receive high amounts of opioids indicated for pain.<sup>18</sup> The data brief also looks at buprenorphine prescribing and the extent to which prescribers have concerning patterns.

## Almost all Medicare Part D enrollees who received buprenorphine for the treatment of opioid use disorder received the recommended amounts

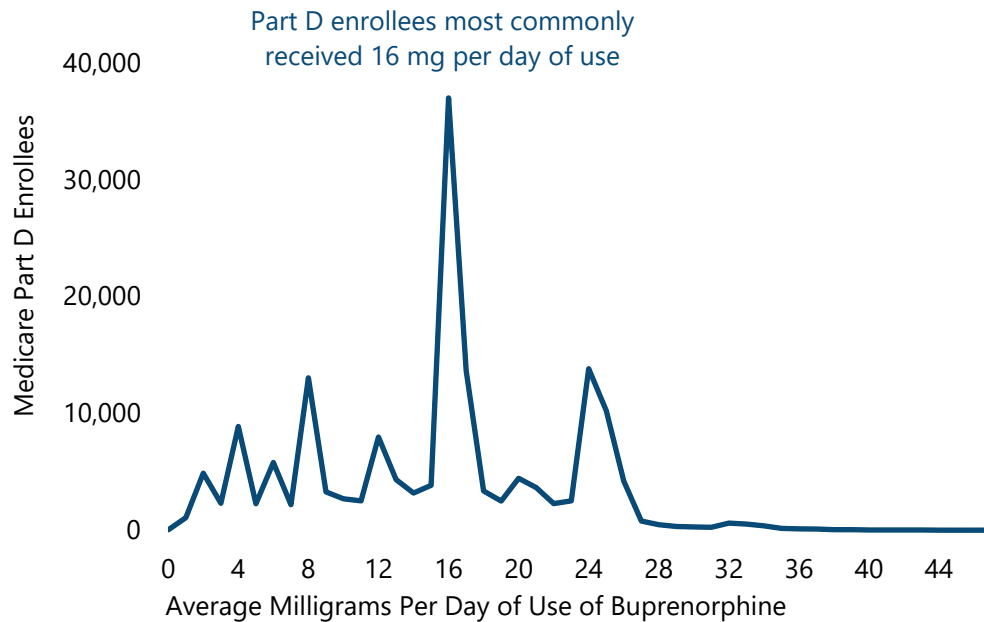
A total of 170,408 people enrolled in Medicare Part D received buprenorphine in 2021. Almost all of these enrollees—97 percent—received the recommended amounts or less of buprenorphine. In general, buprenorphine products have a recommended daily dose range of 4 mg to 24 mg.<sup>19</sup>



**97 percent** of Part D enrollees received the recommended amounts or less of buprenorphine

Enrollees most commonly received an average daily dosage of buprenorphine of around 16 mg per day. Enrollees also commonly received dosages of around 24 mg per day, followed by 8 mg per day and then 4 mg per day. A small number of enrollees received around 32 mg a day or more. See Exhibit 1.

## Exhibit 1: Most Part D enrollees received dosages of buprenorphine at or below the recommended range of 4 mg to 24 mg per day



Source: OIG analysis of Prescription Drug Event data, 2023.

On average, enrollees received a total of 7 months of buprenorphine in the year. About a quarter of enrollees received buprenorphine for the entire year.

In addition, the majority of enrollees received buprenorphine from a few prescribers and pharmacies. Over half of enrollees—57 percent—received buprenorphine from one prescriber and almost three quarters—73 percent—filled their prescriptions at one pharmacy.

## Most enrollees received buprenorphine-naloxone combination products—these products are generally recommended for the treatment of opioid use disorder to minimize the risk of misuse or diversion

Medications that contain both buprenorphine and naloxone—i.e., buprenorphine combination products—are recommended for most individuals receiving buprenorphine for opioid use disorder. The addition of naloxone to the medication helps minimize the risk of misuse and diversion.<sup>20</sup> It acts as a deterrent. If the medication is crushed or dissolved for misuse, the naloxone blunts the effects of the buprenorphine.<sup>21</sup> In total, 84 percent—or 142,321 enrollees—received a combination product in 2021 through Part D.<sup>22</sup>

The remaining 16 percent—or 28,087 enrollees—received medications that contain only buprenorphine—i.e., buprenorphine monoproducts. According to SAMHSA, buprenorphine monoproducts should be reserved for patients such as pregnant patients, patients who are allergic to naloxone, and patients who cannot afford treatment if the combination product is required.<sup>23</sup>

While SAMHSA recommends that buprenorphine monoproducts be used for patients who cannot afford treatment with combination products, it is important to note that the Part D enrollee copayment for the most common monoproduct was, on average, similar to the copayment for the equivalent combination product. Specifically, for enrollees who are not in the Part D Extra Help program (also known as the Part D Low-Income Subsidy), the average copayment for a generic sublingual tablet containing 8 mg of buprenorphine was 24 cents, while the average copayment for an equivalent tablet with naloxone was 25 cents. People receiving Extra Help also had similar copayments for sublingual tablets formulated with and without naloxone. However, other combination products—namely, generic and brand-name sublingual films—had higher copayments than tablets. See Appendix A for more information.

## **A small number of people enrolled in Medicare Part D received very high amounts of buprenorphine or received buprenorphine at the same time as they received high amounts of other opioids**

A total of 1,245 enrollees either received very high average daily dosages of buprenorphine or received buprenorphine at the same time as they received high amounts of opioids indicated for pain in 2021.<sup>24</sup> These patterns may indicate that enrollees are experiencing care coordination issues. It could also mean that buprenorphine is being misused or diverted.<sup>25</sup> These enrollees represent just 0.7 percent of all enrollees who received buprenorphine in 2021.

### **Few enrollees received very high amounts of buprenorphine**

In total, 323 Part D enrollees received more than 36 mg per day of buprenorphine, which is more than 50 percent higher than the maximum recommended daily dose. These enrollees received very high average daily dosages for more than 90 days.<sup>26</sup> Further, some of these enrollees received a very high number of days supply during the year. For example, 41 enrollees received more than 14 months supply of buprenorphine in a 12-month period.

The low number of enrollees who received very high amounts of buprenorphine suggests that misuse and diversion of buprenorphine is not widespread in Medicare Part D.<sup>27</sup>

## Fewer than a thousand enrollees received buprenorphine and high amounts of opioids indicated for pain

The majority of Part D enrollees who received buprenorphine for opioid use disorder did not receive any opioids indicated for pain.<sup>28</sup> However, a total of 927 enrollees received buprenorphine at the same time as they received high amounts of opioids indicated for pain.<sup>29</sup> Each of these enrollees received opioids with an average morphine milligram equivalent (MME) of greater than 50 mg while they received buprenorphine for more than 90 days during the year. Receiving buprenorphine for opioid use disorder at the same time as opioids indicated for pain may indicate coordination-of-care issues or diversion.

Nonetheless, the small number of enrollees receiving buprenorphine and high amounts of opioids further suggests that misuse and diversion of buprenorphine is limited in Medicare Part D.

## Most prescribers ordered buprenorphine for a limited number of Part D enrollees; very few had patterns that raise concern

Most prescribers ordered buprenorphine for only a few people enrolled in Medicare Part D. In total, 39,199 prescribers ordered buprenorphine for Medicare Part D enrollees in 2021. A third of these prescribers ordered buprenorphine for only one enrollee during the year. Another third of these prescribers ordered buprenorphine for two to five enrollees. Just 5 percent of prescribers ordered buprenorphine for more than 30 enrollees during the year.

The low number of enrollees each prescriber treated may have been related to the patient limits set by the DATA waiver, which was eliminated at the end of 2022.<sup>30</sup> Also, providers may be hesitant to treat enrollees due to stigma around opioid use disorder or concerns about misuse and diversion.<sup>31</sup> Given the large number of prescribers who ordered buprenorphine for just a few enrollees, additional steps may be necessary to meet the goal of increasing access to treatment.

## Just 35 prescribers had patterns that raise concern

Just 35 prescribers had patterns that stood out from the norm and raise concern. They each ordered buprenorphine for multiple enrollees who either received very high levels of buprenorphine or received buprenorphine at the same time as they received high amounts of opioids indicated for pain. Of these, only two prescribers ordered buprenorphine for more than five enrollees who received very high amounts of buprenorphine. The remaining 33 prescribers ordered buprenorphine for more than 5 enrollees at the same time as these enrollees received high amounts of opioids.



These 35 prescribers may warrant further scrutiny. However, the low number of prescribers with concerning prescribing patterns suggests that diversion of buprenorphine in Medicare Part D is low.

# RECOMMENDATIONS

Buprenorphine is an important medication for the treatment of opioid use disorder. It reduces opioid cravings and has been shown to decrease illicit opioid use and overdose deaths. Ensuring that patients who need buprenorphine have access to it is critical to addressing the Nation's opioid crisis.

However, there are concerns about access to these medications, including buprenorphine. OIG has found that very few Medicare enrollees with opioid use disorder—just 18 percent—received medication.<sup>32</sup> Furthermore, Black, Hispanic, and Asian/Pacific Islander enrollees are less likely to receive medication to treat their opioid use disorder than are White enrollees.<sup>33</sup>

At the same time, it is important to ensure that diversion risks of buprenorphine are limited. The findings of this report suggest that the risk of misuse and diversion of buprenorphine in Part D is low. Notably, almost all of the people enrolled in Medicare Part D who received buprenorphine received the recommended amounts. Most enrollees received combination products which have a reduced risk of misuse or diversion. In addition, only a small number of enrollees received very high amounts of buprenorphine or received buprenorphine at the same time as they received high amounts of opioids indicated for pain. Further, just 35 prescribers had buprenorphine prescribing patterns that raise concern.

Together, these findings further support the recent repeal of the waiver—which was in place, in part, to limit the diversion of buprenorphine. The repeal of the waiver is a significant step towards increasing access to treatment coming at a time when opioid-related overdose deaths remain near all-time highs, with an estimated 82,310 deaths in 2021. Considering the magnitude of the opioid epidemic, it is critical that CMS and the Department use all of the tools at their disposal to address the crisis.

Further, the data in this report provide baseline information about buprenorphine utilization and prescribing that can assist CMS, the Department, and others as they implement changes related to the repeal and take other steps to improve access to buprenorphine, while also ensuring that the risk of misuse and diversion remains low.

## We recommend that CMS:

### **Monitor the use of buprenorphine and share information, as appropriate, with Departmental partners**

With the repeal of the DATA waiver, CMS can play a unique role in monitoring the impact changes in buprenorphine utilization and prescribing due to its access to timely claims data. For example, using Medicare claims data, CMS can provide early insight into any improvements in access that follow the repeal. CMS could also

provide early warnings to the Department and its partners if there are any changes in utilization or prescribing patterns that raise concern related to misuse or diversion.

As such, CMS should use its existing analytic capabilities along with the results in this report as baseline data and a roadmap to conduct monitoring of the use of buprenorphine. CMS should pay particular attention to any changes in these patterns and share this information with the Department and its partners, as appropriate. For example, CMS could provide information to members of its existing cross-agency committees, such as the overdose prevention committee. This analysis can provide CMS and its partners with early, timely information about changes in utilization and prescribing patterns and can help to identify continued barriers to access or concerns about misuse or diversion.

### **Inform providers about buprenorphine use and the low risk of diversion to encourage providers to treat more Part D enrollees who have opioid use disorder**

This report found that the risk of diversion of buprenorphine in Part D appears to be low. It also found that most prescribers ordered buprenorphine for just a small number of Part D enrollees. As noted, providers may be hesitant to treat patients due to stigma around opioid use disorder or concerns about misuse or diversion.

Accordingly, CMS should inform providers about buprenorphine use in Medicare. It should aim to dispel stigma and share the results of the report—especially the results indicating a low risk of diversion and misuse in Medicare Part D—and other information to encourage providers to treat more enrollees who have opioid use disorder, as appropriate.

To do this, CMS could conduct outreach to prescribers that explains that prescribers with a license from the DEA to prescribe controlled substances are no longer required to separately register to prescribe buprenorphine. It could also share information about the low risk of misuse and diversion of buprenorphine in Medicare Part D. CMS could consider conducting this outreach through a Medicare Learning Network publication or its annual letter to Medicare providers.

### **Take steps to inform providers about the availability of buprenorphine combination products in Part D, which can minimize the risk of misuse and diversion**

Buprenorphine combination products—i.e., medications that contain both buprenorphine and naloxone—are recommended for most patients with opioid use disorder over buprenorphine monoproducts to minimize the risk of misuse and diversion. However, 16 percent of Part D enrollees who received buprenorphine in 2021 received only buprenorphine monoproducts.

CMS should take steps to inform providers about the availability of buprenorphine combination products in Part D and remind prescribers that the use of these products, rather than monoproducts, can decrease the risk of misuse and diversion. As a part of its efforts, CMS should ensure that providers are aware of the availability

of buprenorphine combination products with relatively low copays, such as generic buprenorphine-naloxone sublingual tablets. Providing this information to providers is particularly important in light of the repeal of the DATA waiver, as an increased number of providers are newly able to order buprenorphine for patients.

**Follow up on the prescribers with concerning patterns identified in this report**

Although very few prescribers had patterns that raise concern, these prescribers may warrant further scrutiny. In a separate memorandum, we will refer to CMS the providers who had buprenorphine prescribing patterns that raise concern. CMS should review this information in conjunction with its ongoing efforts and take action, as appropriate.

# AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with three of our recommendations. While it did not indicate whether it concurred with the other recommendation, it did indicate ongoing activity it felt was responsive.

CMS did not explicitly indicate whether it concurred with our recommendation to monitor the use of buprenorphine and share information, as appropriate, with Departmental partners. Rather, it provided reasons why this recommendation was not necessary. CMS stated that it already has monitoring and information sharing processes in place which will continue. These include quarterly Drug Trend Analysis and a national proactive data analysis project that is shared with Part D plan sponsors when unusual changes in utilization or spending are detected. CMS also stated that, as OIG found buprenorphine misuse and diversion has been quite low, it has not risen to a level of investigative concern at this time.

While OIG is supportive of CMS's existing monitoring and information sharing processes, OIG recommends that CMS build on these existing efforts and conduct additional targeted monitoring of buprenorphine. Doing so is of particular importance as the Department and its partners work to assess the impact of the repeal of the DATA waiver and take additional actions to address the continued opioid crisis. As part of these efforts, CMS could, for example, provide information to members of its existing cross-agency committees, such as the overdose prevention committee. These actions could help to identify and address continued barriers to access to buprenorphine or concerns about misuse or diversion in the wake of the repeal of the DATA waiver.

CMS concurred with our recommendation to inform providers about buprenorphine use and the low risk of diversion to encourage providers to treat more Part D enrollees who have opioid use disorder. CMS stated that it will seek to include this information in upcoming provider outreach.

CMS also concurred with our recommendation to take steps to inform providers about the availability of buprenorphine combination products in Part D, which can minimize the risk of misuse and diversion. CMS stated that it will seek to include this information in upcoming provider outreach.

Lastly, CMS concurred with our recommendation to follow up on the prescribers with concerning patterns identified in this report. CMS stated that it was pleased that only 35 providers out of 39,199 were identified as having concerning prescribing patterns and that it will follow up on these 35 providers.

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

# 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 used U.S. Food and Drug Administration (FDA) drug labels and the Center for Disease Control and Prevention's (CDC's) Morphine Milligram Equivalent (MME) conversion file.

PDE records are for prescriptions that enrollees received through Part D. They do not include prescriptions paid for through other programs, prescriptions paid for in cash, or illicitly purchased drugs. Part D sponsors submit a PDE record to CMS each time a drug is dispensed to a person enrolled 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, FDA drug labels, 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., medication for opioid use disorder). The National Claims History File contains claims data from Medicare Parts A and B, including diagnosis codes. Part C Encounter Data contain medical claims data, including diagnosis codes, for Medicare Advantage plan enrollees. FDA drug labels indicate dosing equivalents between buprenorphine products. CDC's MME conversion file contains information about each opioid drug's morphine milligram equivalence.

## Identifying Medicare Part D Enrollees with Buprenorphine

Using the PDE records, we first identified people enrolled in Medicare Part D with at least one prescription for buprenorphine indicated for the treatment of opioid use disorder with a date of service in 2021.<sup>34</sup> We did not include prescriptions for buprenorphine indicated for pain in this study. For the purposes of this study, we use the term "buprenorphine" to mean buprenorphine indicated for the treatment of opioid use disorder.

## Average Daily Dosage of Buprenorphine Analysis

Next, we determined the amount of buprenorphine that each Part D enrollee received in 2021 by calculating each enrollee's average daily dosage of buprenorphine.<sup>35</sup>

To do this, we first calculated the total number of milligrams of buprenorphine in each prescription.<sup>36</sup> We standardized buprenorphine products with higher

bioavailability in order to sum dosages across different buprenorphine products.<sup>37</sup> We then determined the milligrams per day of buprenorphine for each prescription by dividing the total number of milligrams by the total days supply.

Next, we summed each enrollee's milligrams of buprenorphine for each day of the year on the basis of the dates of service and days supply on each PDE record.

We then calculated the days of use of buprenorphine for each enrollee. Each calendar date in 2021 with a day supply of buprenorphine is considered a day of use. For example, an enrollee who received a day supply for each date in 2021 had 365 days of use.

We then divided the total milligrams of buprenorphine over the year by the total number of days of use to get the average daily dosage of buprenorphine per day of use in 2021.

Next, we identified the recommended range of buprenorphine. To do this, we reviewed FDA-approved drug labels of buprenorphine and buprenorphine-naloxone products indicated for the treatment of opioid use disorder.

We also calculated the number of prescribers and pharmacies associated with each enrollee's buprenorphine prescriptions in 2021.

## Buprenorphine Combination Product and Monoproduct Analysis

Next, we identified which buprenorphine prescriptions were buprenorphine-naloxone combination products and which were buprenorphine-only monoproducts in 2021.

Using this information, we determined the percentage of Part D enrollees who received at least one buprenorphine combination product in 2021 and the percentage who only received monoproducts.

In addition, using the PDE records, we determined the number of PDE for each buprenorphine combination product and each buprenorphine monoproduct. We then calculated the average Part D copayment per unit of the most common buprenorphine monoproduct and the equivalent buprenorphine combination products for enrollees in 2021.<sup>38</sup> The copayment per unit of these medications was calculated for enrollees with and without Extra Help.<sup>39</sup>

## Identifying Part D Enrollees Who Received Very High Amounts of Buprenorphine

We considered enrollees to have received very high amounts of buprenorphine if their average daily dosage of buprenorphine was more than 36 mg for more than 90 days in 2021. This analysis excluded enrollees who had a diagnosis of cancer or sickle cell disease; had a hospice stay; or received palliative care at any point in 2021.

## Identifying Part D Enrollees Who Received Buprenorphine and High Amounts of Opioids Indicated for Pain

We identified enrollees who received buprenorphine indicated for the treatment of opioid use disorder at the same time as they received opioids indicated for pain in 2021.<sup>40</sup>

Next, we determined the amount of opioids that each of these enrollees received in 2021. To do this, we calculated each enrollee's average daily morphine milligram equivalent (MME) dose.<sup>41</sup> The MME converts opioids of different ingredients, strengths, and forms into equivalent milligrams of morphine. It allows us to sum dosages of different opioids to determine an enrollee's daily opioid level.

To calculate each enrollee's average daily MME, we first calculated the MME for each prescription.<sup>42</sup> We used the following equation:

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

Next, we summed each enrollee's MME for each day of the year based on the dates of service and days supply on each prescription.

For each enrollee, we then calculated the number of days on which they had both buprenorphine and other opioids.

We then calculated each enrollee's average MME over these days of overlap. We divided the total MME for the days of overlap by the total days of overlap for each enrollee.

Lastly, we identified the enrollees who received buprenorphine and high amounts of opioids. We considered enrollees to have received buprenorphine and high amounts of opioids if their opioids had an average daily MME of greater than 50 mg over the days of overlap and had more than 90 days of overlap. This analysis excluded enrollees who had a diagnosis for cancer or sickle cell disease; had a hospice stay; or received palliative care at any point in 2021.

## Prescriber Analysis

We identified all prescribers who ordered at least one buprenorphine prescription in 2021. We used the prescriber National Provider Identifier (NPI) on the PDE records to identify prescribers. We considered each NPI to indicate a unique prescriber.<sup>43</sup> For each prescriber, we counted the number of Part D enrollees for whom they ordered buprenorphine.

Next, we identified prescribers who had prescribing patterns that stood out from the norm and raised concern. To do this, we identified prescribers who either ordered



buprenorphine for more than five enrollees who received very high amounts of buprenorphine or ordered buprenorphine for more than five enrollees who received buprenorphine at the same time that they received high amounts of opioids.

## Limitations

This analysis is based on Medicare claims data. We did not review medical records or independently verify the accuracy of the Medicare claims data for this study. The analysis does not include data on buprenorphine or opioids that enrollees may have received from sources other than Medicare Part D.

## Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

# APPENDIX A

**Sublingual tablet buprenorphine combination products and monoproducs had similar copayments among Part D enrollees; however, for enrollees without Extra Help sublingual films have higher copayments than tablets**

Drug Label	Average Copayment Per Unit	
	Enrollees with Extra Help*	Enrollees without Extra Help
Buprenorphine 8 mg sublingual tablet	\$0.03	\$0.24
Buprenorphine-naloxone 8-2 mg sublingual tablet	\$0.03	\$0.25
Buprenorphine-naloxone 8-2 mg sublingual film	\$0.04	\$0.77
Suboxone 8-2 mg sublingual film**	\$0.06	\$2.15

\* Extra Help is also known as the Part D Low-Income Subsidy.

\*\* Suboxone is a brand-name version of buprenorphine-naloxone.

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

# APPENDIX B

## Agency Comments

Following this page are the official comments from CMS.

# AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*

Washington, DC 20201

**DATE:** April 24, 2023

**TO:** Ann Maxwell  
Deputy Inspector General for Evaluation and Inspections

**FROM:** Chiquita Brooks-LaSure *Chiquita LaS*  
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Report: *The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D* (OEI-02-22-00160)

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 ensuring that Medicare beneficiaries who have an opioid use disorder (OUD) have access to appropriate treatment, including medication-assisted treatment such as buprenorphine. Ensuring access to these benefits, while guarding against improper use and prescribing, 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.

To that end, CMS was pleased that OIG found that almost all Medicare Part D enrollees who received buprenorphine for the treatment of an OUD received the recommended amounts, and that very few prescribers of buprenorphine (.089%) had patterns that raised concern.

While CMS appreciates the positive findings in this report, there are additional monitoring and coordination efforts that CMS has taken that are not referenced in the report, which CMS believes are integral to the successful outcomes described in the report. For example, CMS monitors prescription drug use in Part D (including over-utilization and/or under-utilization of opioids, buprenorphine, and medication-assisted treatment (MAT)) 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 that are outliers, or share information with Departmental partners, as appropriate. Other efforts include the quarterly Drug Trend Analysis, a national proactive data analysis project conducted by CMS in collaboration with the Plan Program Integrity Medicare Drug Integrity Contractor (PPI MEDIC), which detects unusual changes in specific drug utilization and total Medicare Part D drug spending for prescription drug event (PDE) records. The quarterly Drug Trend Analysis would identify any changes in buprenorphine use or prescribing. Any unusual changes would be reviewed for further action and included in the quarterly report sent to Part D plan sponsors.

In addition, CMS has relationships with Departmental partners through which we share information on cases and strategies, when appropriate. CMS convenes ad hoc meetings with our law enforcement partners to discuss emerging and ongoing fraud schemes. As OIG found in this report, buprenorphine misuse and diversion has been quite low, and therefore has not risen to a level of investigative concern at this time. However, these ongoing monitoring efforts will ensure that any changes can be identified and addressed proactively.

Combatting the opioid epidemic is a priority for the agency, and we appreciate that the OIG recognizes the success of CMS' many ongoing efforts, which will be key in moving this effort forward.

OIG's recommendations and CMS' responses are below.

### **OIG Recommendation**

CMS should monitor the use of buprenorphine and share information, as appropriate, with Departmental partners.

### **CMS Response**

CMS has in place comprehensive monitoring and information sharing processes, and these have continued after the repeal of the Drug Addiction Treatment Act (DATA) waiver. As described above, these efforts include the quarterly Drug Trend Analysis, a national proactive data analysis project shared with Part D plan sponsors that detects unusual changes in specific drug utilization and total Medicare Part D drug spending for prescription drug event (PDE) records, including changes in utilization or prescribing patterns that raise concern related to misuse or diversion, ad hoc meetings with our law enforcement partners to discuss emerging and ongoing fraud schemes, and monitoring over-utilization and/or under-utilization of opioids, buprenorphine, and medication-assisted treatment (MAT), and tracking access issues. CMS will continue to monitor this area for any changes. As OIG found in this report, buprenorphine misuse and diversion has been quite low, and therefore has not risen to a level of investigative concern at this time. Due to the current efforts by CMS, we continue to recommend that OIG remove this recommendation.

### **OIG Recommendation**

CMS should inform providers about buprenorphine use and the low risk of diversion to encourage providers to treat more Part D enrollees who have opioid use disorder.

### **CMS Response**

CMS concurs with this recommendation and will seek to include this information in upcoming provider outreach.

### **OIG Recommendation**

CMS should take steps to inform providers about the availability of buprenorphine combination products in Part D, which can minimize the risk of misuse and diversion.

**CMS Response**

CMS concurs with this recommendation and will seek to include this information in upcoming provider outreach. CMS appreciates OIG’s finding that most enrollees already received buprenorphine-naloxone combination products.

**OIG Recommendation**

CMS should follow up on the prescribers with concerning patterns identified in this report.

**CMS Response**

CMS concurs with this recommendation. CMS is pleased to note that OIG found that only 35 providers out of 39,199 had concerning prescribing patterns (.089%). While OIG’s findings underline that nearly all providers prescribing buprenorphine to Medicare Part D beneficiaries are doing so appropriately, we will follow up on the 35 providers that OIG identified.

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

Margaret Himmelright and Jason Kwong served as the team leaders for this study. Others in the Office of Evaluation and Inspections New York Regional Office who conducted the study include Miriam Anderson. Office of Evaluation and Inspections headquarters staff who provided support include Althea Hosein, Michael Novello, and Sara 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](mailto:Public.Affairs@oig.hhs.gov). OIG reports and other information can be found on the OIG website at [oig.hhs.gov](http://oig.hhs.gov).

Office of Inspector General  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC 20201

# ENDNOTES

<sup>1</sup> CDC, *Provisional Drug Overdose Death Counts*, January 1, 2023. Accessed at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm> on January 12, 2023.

<sup>2</sup> Increasing access to buprenorphine to treat opioid use disorder is a goal of the Administration. See Office of National Drug Control Policy, *The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One*, 2021. Accessed at [https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf?fbclid=IwAR2TBk34U\\_XRqLqK\\_pAYnUd\\_9f7zY3IbCQI9KxI6S5eYeRJdFzI9B09hZ84](https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf?fbclid=IwAR2TBk34U_XRqLqK_pAYnUd_9f7zY3IbCQI9KxI6S5eYeRJdFzI9B09hZ84) on December 21, 2022.

<sup>3</sup> 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.

<sup>4</sup> OIG, *Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries*, OEI-02-22-00390, September 2022.

<sup>5</sup> OIG, *Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder*, OEI-02-20-00390, December 2021.

<sup>6</sup> P.L. No. 117-328 § 1262. Also see SAMHSA, *Removal of DATA Waiver (X-Waiver) Requirement*, January 25, 2023. Accessed at <https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement> on March 9, 2023.

<sup>7</sup> Office of National Drug Control Policy, *National Drug Control Strategy*, April 2022. Accessed at <https://www.whitehouse.gov/wp-content/uploads/2022/04/National-Drug-Control-2022Strategy.pdf> on January 12, 2023.

<sup>8</sup> OIG, *Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries*, OEI-02-22-00390, September 2022.

<sup>9</sup> Buprenorphine products indicated for pain are different from buprenorphine products indicated for the treatment of opioid use disorder.

<sup>10</sup> Methadone and naltrexone are also approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorder.

<sup>11</sup> SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2021. Accessed at [https://store.samhsa.gov/sites/default/files/SAMHSA\\_Digital\\_Download/PEP21-02-01-002.pdf](https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf) on November 7, 2022.

<sup>12</sup> For more information about controlled substance scheduling, see DEA, *Drug Scheduling*. Accessed at <https://www.dea.gov/drug-information/drug-scheduling> on February 9, 2023.

<sup>13</sup> The Drug Addiction Treatment Act of 2000 was enacted under Title XXXV of the Children's Health Act of 2000, P.L. No. 106-310.

<sup>14</sup> Prior to April 2021, all providers were required to complete approved training and have the capacity to refer patients to counseling and other ancillary services. The Department of Health and Human Services (HHS) released new practice guidelines in 2021 that exempted eligible providers from these requirements if they are treating 30 or fewer patients. See 86 F.R. 22439. Congress has since repealed the need for a waiver. See 21 U.S.C. § 823(g)(2)(B)(iii)(I)-(II), repealed by Consolidated Appropriations Act, 2023, § 1262, P.L. No. 117-328 (Dec. 29, 2022).

<sup>15</sup> Before late December 2022, with a waiver, practitioners could treat up to 100 patients with buprenorphine in the first year, although most qualified practitioners were limited to treating up to 30. In subsequent years, a practitioner could treat up to



275 patients. See 42 CFR § 8.610. In December 2022, Congress repealed the need for a waiver. See 21 U.S.C. § 823(g)(2)(B)(iii)(I)-(II), repealed by Consolidated Appropriations Act, 2023, § 1262, P.L. No. 117-328 (Dec. 29, 2022).

<sup>16</sup> P.L. No. 117-328 § 1262.

<sup>17</sup> P.L. No. 117-328 § 1263.

<sup>18</sup> This analysis is based on Medicare claims data. We did not review medical records.

<sup>19</sup> Most buprenorphine products have recommended daily dosages ranging from 4 mg per day to 24 mg per day, based on their FDA-approved manufacturer labels. See SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2021. In addition, some buprenorphine products have higher bioavailability, meaning that they enter into the bloodstream more quickly, allowing for lower dosages. For this analysis, we standardized buprenorphine products with higher bioavailability to have the same recommended range as other buprenorphine products have. In addition, to accommodate early refills of prescriptions, we considered an enrollee's average daily dosage to be about 24 mg per day of use if it did not exceed 26 mg per day.

<sup>20</sup> Daily buprenorphine monoproducs carry a higher risk of diversion than do buprenorphine combination products. SAMHSA, *Buprenorphine*, 2023. Accessed at <https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine> on February 1, 2023. Also see SAMHSA, *Buprenorphine Quick Start Guide*. Accessed at <https://www.samhsa.gov/sites/default/files/quick-start-guide.pdf> on November 8, 2022. Separately, naloxone is a medication used to reverse opioid overdoses. See SAMHSA, *Naloxone*, 2023. Accessed at <https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/naloxone> on February 1, 2023.

<sup>21</sup> SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2021.

<sup>22</sup> A total of 7,433 (4 percent) of Part D enrollees received both buprenorphine combination products and monoproducs.

<sup>23</sup> SAMHSA, *Buprenorphine Quick Start Guide*. SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2021.

<sup>24</sup> Five enrollees received very high average daily dosages of buprenorphine and also received buprenorphine at the same time as they received high amounts of opioids indicated for pain in 2021.

<sup>25</sup> According to SAMHSA, higher doses of buprenorphine may heighten diversion risk. SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2021.

<sup>26</sup> Enrollees with cancer or sickle cell disease; those receiving palliative care; and those in hospice care were not included in this analysis.

<sup>27</sup> It is also noteworthy that, according to the National Institute on Drug Abuse, data suggest that the bulk of buprenorphine misuse (use without a prescription) is for the purpose of controlling withdrawal and cravings for other opioids and not to get high. See National Institute on Drug Abuse, *Medications to Treat Opioid Use Disorder Research Report*, December 2021. Accessed at <https://nida.nih.gov/download/21349/medications-to-treat-opioid-use-disorder-research-report.pdf?v=99088f7584dac93ddcfa98648065bfbe> on October 25, 2022.

<sup>28</sup> This analysis excluded buprenorphine indicated for the treatment of pain.

<sup>29</sup> Enrollees with cancer or sickle disease; those receiving palliative care; and those who were in hospice care were not included in this analysis.

<sup>30</sup> Before late December 2022, with a waiver, practitioners could treat up to 100 patients with buprenorphine in the first year, although most qualified practitioners were limited to treating up to 30. In subsequent years, a practitioner could treat up to 275 patients. See 42 CFR § 8.610. In December 2022, Congress repealed the need for a waiver. See 21 U.S.C. § 823(g)(2)(B)(iii)(I)-(II), repealed by Consolidated Appropriations Act, 2023, § 1262, P.L. No. 117-328 (Dec. 29, 2022).

<sup>31</sup> SAMHSA, *Practical Tools for Prescribing and Promoting Buprenorphine in Primary Care Settings*, 2021. SAMHSA Publication No. PEP21-06-01-002. Accessed at <https://store.samhsa.gov/sites/default/files/pep21-06-01-002.pdf> on February 6, 2023. Also see National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Medication-Assisted Treatment for Opioid Use Disorder; Mancher, M., Leshner, Al, editors, *Medications for Opioid Use Disorder Save Lives. Ch.5*. Washington (DC): National Academies Press (US), March 30, 2019. Accessed at <https://www.ncbi.nlm.nih.gov/books/NBK541389/> on February 6, 2023.

<sup>32</sup> OIG, *Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries*, OEI-02-22-00390, September 2022.

<sup>33</sup> OIG, *Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder*, OEI-02-20-00390, December 2021.

<sup>34</sup> Additional Medicare Part D enrollees may have also received buprenorphine. For instance, some enrollees may have received buprenorphine covered by Medicare Part B, such as through opioid treatment programs. Others may have paid out of pocket for buprenorphine to treat their opioid use disorder. Buprenorphine indicated for pain was not included in this analysis.

<sup>35</sup> We limited this analysis to oral buprenorphine products.

<sup>36</sup> We included buprenorphine dispensed in 2020 with days supply in 2021. This analysis excluded prescriptions for implant and injection buprenorphine.

<sup>37</sup> To account for buprenorphine products with higher bioavailability, we standardized the milligrams across all products to be equivalent to Suboxone. For example, according to the FDA drug label one Zubsolv 5.7 mg buprenorphine/1.4 mg naloxone sublingual tablet provides equivalent buprenorphine exposure to that of one Suboxone 8 mg buprenorphine/2 mg naloxone sublingual tablet. Therefore, in our analysis we consider one of these Zubsolv tablets to have 8 mg of buprenorphine. For more information, see Orexo US, Inc., *Zubsolv: Highlights of Prescribing Information*, 2002. Accessed at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/204242s009lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204242s009lbl.pdf) on December 14, 2022.

<sup>38</sup> For each buprenorphine product, we divided the total copayments by the total quantity dispensed.

<sup>39</sup> We considered an enrollee to have receive Extra Help (also known as the Low-Income Subsidy) if they had at least 1 PDE in 2021 with more than \$0 of low-income subsidy.

<sup>40</sup> We did not include buprenorphine indicated for pain in this analysis. We considered enrollees to have received buprenorphine at the same time as they received other opioids if, after the first day supply of buprenorphine in 2021, buprenorphine PDE and other opioid PDEs had days supply that fell on the same calendar day.

<sup>41</sup> For more information on calculating opioid dosage, see CDC, *Calculating Total Daily Dose of Opioids for Safer Dosage*. Accessed at [https://stacks.cdc.gov/view/cdc/38481/cdc\\_38481\\_DS1.pdf](https://stacks.cdc.gov/view/cdc/38481/cdc_38481_DS1.pdf) on April 27, 2023.

<sup>42</sup> We included opioids dispensed in 2020 with days supply in 2021. This analysis excludes prescriptions for injection, intravenous, and intrathecal opioids, as well as opioids indicated as medications for opioid use disorder.

<sup>43</sup> For our analysis, we counted prescribers in group practices separately.