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Office of Inspector General
Data Brief
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Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder

Key Takeaways

Opioid use disorder is a chronic disease that can be treated with medication.

Yet less than 16 percent of beneficiaries received medication to treat their opioid use disorder.

Even fewer beneficiaries received both medication and behavioral therapy to treat their opioid use disorder.

Beneficiaries in Florida, Texas, Nevada, and Kansas were less likely to receive medication for their opioid use disorder than those nationwide.

Furthermore, Asian/Pacific Islander, Hispanic, and Black beneficiaries were less likely to receive medication than White beneficiaries.

Why OIG Did This Review

Opioid-related overdose deaths in the United States are at an all-time high, reaching an estimated 70,000 in 2020.[1] As the country continues to struggle with the opioid crisis, it is critical that people with opioid use disorder have access to treatment. The coronavirus disease 2019 (COVID-19) pandemic has made this need even more urgent, particularly because the toll it has taken on beneficiaries' mental health and the extent to which it has increased the number of beneficiaries with opioid use disorder are not yet known.

Opioid use disorder—a problematic pattern of opioid use that leads to clinically significant impairment or distress—is a chronic disease that can be treated with certain medications. These medications have been shown to decrease illicit opioid use and opioid-related overdose deaths. The combination of these medications with behavioral therapy is referred to as medication-assisted treatment.

Medicare plays an important role in ensuring that beneficiaries with opioid use disorder have access to treatment. Three medications are approved for the treatment of opioid use disorder: buprenorphine, methadone, and naltrexone. Beneficiaries can receive these drugs in office-based settings or from opioid treatment programs. To prescribe or administer buprenorphine in office-based settings, providers must receive a waiver through the Substance Abuse and Mental Health Services Administration (SAMHSA). In addition, opioid treatment programs are the only outpatient settings allowed to administer and dispense methadone.

How OIG Did This Review

We analyzed claims from Medicare Parts B, C, and D to determine the extent to which beneficiaries diagnosed with opioid use disorder received medication and behavioral therapy to treat their opioid use disorder through Medicare in 2020.

What OIG Found

About 1 million Medicare beneficiaries were diagnosed with opioid use disorder in 2020. Yet less than 16 percent of these beneficiaries received medication to treat their opioid use disorder, raising concerns that beneficiaries face challenges accessing treatment. Furthermore, less than half of the beneficiaries who received medication to treat their opioid use disorder also received behavioral therapy. These services may be provided in-person or via telehealth; however, the full extent to which beneficiaries use

telehealth for behavioral therapy is unknown, as Medicare does not require opioid treatment programs to report this information.

In addition, beneficiaries in Florida, Texas, Nevada, and Kansas were less likely to receive medication to treat their opioid use disorder than beneficiaries nationwide. Furthermore, Asian/Pacific Islander, Hispanic, and Black beneficiaries were less likely to receive medication than White beneficiaries. Older beneficiaries and those who did not receive the Part D low-income subsidy were also less likely to receive medication to treat their opioid use disorder.

What OIG Recommends

These findings show a need to increase the number of Medicare beneficiaries receiving treatment for opioid use disorder. Accordingly, we recommend that the Centers for Medicare & Medicaid Services (CMS) take these steps: (1) conduct additional outreach to beneficiaries to increase awareness about Medicare coverage for the treatment of opioid use disorder; (2) take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder; (3) assist SAMHSA by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings and the geographic areas where Medicare beneficiaries remain underserved; (4) take steps to increase the utilization of behavioral therapy among beneficiaries receiving medication to treat opioid use disorder; (5) create an action plan and take steps to address disparities in the treatment of opioid use disorder; and (6) collect data on the use of telehealth in opioid treatment programs. CMS concurred with four of our recommendations and did not explicitly indicate whether it concurred with the other two recommendations.

Primer: Treatment of Opioid Use Disorder

Medications to Treat Opioid Use Disorder

Opioid use disorder is a chronic disease that can be treated with certain medications. These medications have been proven to decrease the risk of overdose mortality and improve quality of life.[2] The combination of these medications with behavioral therapy is referred to as medication-assisted treatment (MAT). Throughout this report, we refer to these medications as MAT drugs.[3]

Three drugs are currently approved for the treatment of opioid use disorder.

- **Buprenorphine** is a Schedule III controlled substance that suppresses opioid withdrawal symptoms by relieving cravings.[4] To prescribe or administer buprenorphine in office-based settings, providers must obtain a waiver through the Substance Abuse and Mental Health Services Administration (SAMHSA).[5]
- **Methadone** is a Schedule II controlled substance that reduces opioid cravings by blunting or blocking the effects of opioids. Methadone is highly regulated; only opioid treatment programs are allowed to administer or dispense methadone for treatment of opioid use disorder in outpatient settings.[6] Patients typically go in-person each day to receive their dose of methadone.[7] Medicare began covering methadone for MAT at opioid treatment programs in 2020.[8]
- **Naltrexone** works by blocking the opioid receptors in the brain, which is reported to reduce opioid cravings.[9] Unlike buprenorphine and methadone, naltrexone is not a controlled substance and can be prescribed or administered by any qualified health care provider. Patients must go through full detoxification before beginning naltrexone.

Behavioral Therapy to Treat Opioid Use Disorder

Behavioral therapy—such as individual or group therapy—is recommended for patients receiving medication to treat opioid use disorder. Opioid treatment programs are required to offer behavioral therapy.[10] Behavioral therapy is not required when medication is provided in an office-based setting.

Medicare Coverage of Treatment for Opioid Use Disorder in Outpatient Settings

Beneficiaries can receive MAT drugs in office-based settings or from opioid treatment programs. In office-based settings, beneficiaries either receive prescriptions for medications that they fill at pharmacies or their healthcare providers directly administer the MAT drugs. Medicare pays for these medications differently depending on where beneficiaries receive them. Beneficiaries may also receive these medications through other sources, such as by paying out-of-pocket.

Behavioral therapy that beneficiaries receive in office-based settings or at opioid treatment programs is covered by Medicare Part B or Part C. Providers in office-based settings can bill for these services individually or use a bundled payment code that covers behavioral therapy and care coordination. Opioid treatment programs are paid through bundled payments.

RESULTS

Just over 1 million Medicare beneficiaries had a diagnosis of opioid use disorder in 2020

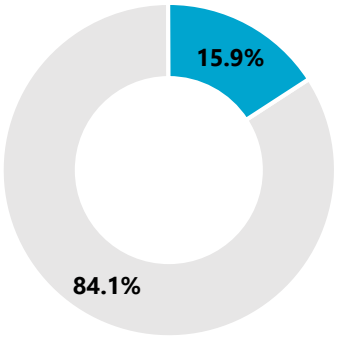
In 2020, just over 1 million Medicare beneficiaries—1,055,809 in total—had a diagnosis of opioid use disorder.[11] Opioid use disorder is a problematic pattern of opioid use that leads to clinically significant impairment or distress and is sometimes referred to as opioid addiction. It is a chronic disease that may cause people to seek opioids compulsively or in ways that they find difficult to control despite harmful consequences.

Diagnosing opioid use disorder requires a thorough evaluation that may include checking a patient's history of opioid prescriptions or testing a patient's urine for drugs.[12] To receive a diagnosis, a patient must meet two or more diagnostic criteria, such as craving opioids or often taking opioids in larger amounts or over a longer period than intended.[13] See Appendix A for a complete list of diagnostic criteria.

Yet less than 16 percent of these beneficiaries received medication to treat their opioid use disorder

Medications to treat opioid use disorder—sometimes called medication-assisted treatment (MAT) drugs—can decrease illicit opioid use and opioid-related overdose deaths.[14] Only 167,734 of the more than 1 million beneficiaries with opioid use disorder—less than 16 percent—received medication to treat their opioid use disorder in 2020 through Medicare.[15] See Exhibit 1. They accounted for fewer than 1 in 6 of all Medicare beneficiaries with opioid use disorder.

Exhibit 1: Less than 16 percent of beneficiaries with opioid use disorder received medication to treat this condition through Medicare.



Source: OIG analysis of Medicare claims data, 2021.

Each of these 167,734 beneficiaries received at least one of the three approved drugs to treat opioid use disorder: buprenorphine, methadone, and naltrexone. The Food and Drug Administration (FDA) recommends that all three of these drugs be available to all patients because certain medications may be more

appropriate for some patients than others.[16] See Appendix B for the percentage of beneficiaries who received each type of medication.

The low proportion of beneficiaries with opioid use disorder receiving MAT drugs through Medicare raises concern. MAT drugs may not be medically necessary for all of these beneficiaries. However, this low proportion may indicate that beneficiaries have challenges accessing treatment for opioid use disorder despite Medicare's new coverage of opioid treatment programs in 2020.

These challenges may be due to a variety of reasons. Researchers have found that there are gaps between the number of providers who are authorized to treat patients with opioid use disorder with medication and the number of patients who need care.[17] Furthermore, individuals may also avoid seeking treatment due to stigma associated with opioid use disorder.[18] Lastly, beneficiaries may have delayed or avoided seeking health care during the COVID-19 pandemic.[19]

Beneficiaries most commonly received medication to treat their opioid use disorder that was prescribed or administered in health care providers' offices

About 12 percent of the beneficiaries with opioid use disorder received MAT drugs that were prescribed or administered in their health care providers' offices—i.e., in office-based settings. This represents a total of 130,502 Medicare beneficiaries and includes both beneficiaries whose providers ordered prescriptions that were filled at pharmacies and beneficiaries whose providers directly administered their medications (e.g., long-acting injectable MAT drugs).

The majority of these beneficiaries received buprenorphine. About 95 percent of these beneficiaries—a total of 123,745—who received MAT drugs in office-based settings received buprenorphine.[20] As noted earlier, methadone for the treatment of opioid use disorder is not available in office-based settings.

Providers are required to obtain waivers to prescribe or administer

Exhibit 2: SAMHSA's Buprenorphine Waiver Program

- Only health care providers who have received a buprenorphine waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) are authorized to prescribe buprenorphine in office-based settings.
- 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 training.*
- Providers are limited in the number of patients they may treat.

* Since April 2021, providers who plan to treat up to 30 patients have been exempt from some of the requirements related to training, counseling, and other services.

buprenorphine in office-based settings, and they are limited in the number of patients they may treat. See Exhibit 2. As a result, beneficiaries may have had limited access to these providers.[21] OIG has previously raised concerns about the lack of access to providers with a buprenorphine waiver. In 2018, 40 percent of all counties in the United States did not have a single provider with a buprenorphine waiver.[22] Furthermore, areas where access to MAT drugs was considered most critical did not always have providers.

In most instances, beneficiaries who received buprenorphine in office-based settings had this medication covered by Part D.[23] In rare instances, it was covered by Part B or Part C.[24]

A smaller proportion of beneficiaries who received MAT drugs in office-based settings received naltrexone. About 6 percent of beneficiaries—a total of 8,257—who received MAT drugs in office-based settings received naltrexone. In most instances, beneficiaries' naltrexone was covered by Part D.[25] Rarely, it was covered by Part B or Part C.[26]

Less commonly, beneficiaries received medication to treat their opioid use disorder from opioid treatment programs

In 2020, less than 4 percent of the beneficiaries with opioid use disorder received MAT drugs from opioid treatment programs. This represents 39,602 beneficiaries with opioid use disorder. See Exhibit 3.

A low number of beneficiaries may have received MAT drugs from opioid treatment programs because Medicare only began covering services provided at opioid treatment programs in 2020.[27] In addition, beneficiaries may be experiencing difficulties accessing opioid treatment programs for other reasons such as geographic limitations or patient admission requirements.[28] The need to travel to opioid treatment programs may hinder access, as patients often must make daily trips, which can be burdensome.[29] Furthermore, more stigma is attached to opioid treatment programs and the use of methadone than the use of

Exhibit 3: Opioid Treatment Programs

- Opioid treatment programs can provide all three MAT drugs—buprenorphine, methadone, and naltrexone—to treat patients with opioid use disorder. Importantly, they are the only entities that can provide methadone in outpatient settings.
- These programs are required to provide adequate medical, counseling, vocational, educational, and other assessment and treatment services.
- A patient receiving methadone typically must visit an opioid treatment program each day to receive a dose. Over time, the patient may be able to receive unsupervised take-home doses.
- Medicare began covering opioid treatment programs in 2020. It provides reimbursements through weekly bundled payments.

buprenorphine, and this stigma may impact the likelihood that beneficiaries will seek treatment.[30]

The vast majority of these beneficiaries received methadone. A total of 96 percent of beneficiaries who received MAT drugs from opioid treatment programs—38,170 in all—received methadone.[31] Importantly, opioid treatment programs are the only entities that can provide methadone for the treatment of opioid use disorder in outpatient settings. Fewer beneficiaries received buprenorphine. Rarely, beneficiaries received long-acting injectable naltrexone. See Exhibit 4.

Exhibit 4: Beneficiaries who received treatment from opioid treatment programs most commonly received methadone.

MAT Drug	Beneficiaries
Methadone	38,170
Buprenorphine	2,164
Injectable Naltrexone	26
Total	**39,602***

* Of these beneficiaries, 758 beneficiaries received more than 1 type of MAT drug.
Source: OIG analysis of Medicare claims data, 2021.

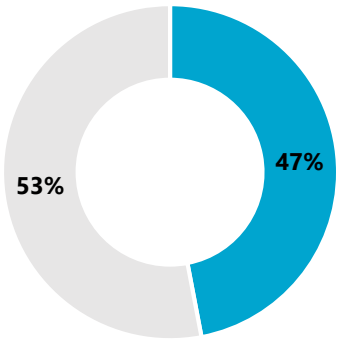
Almost all of the beneficiaries who received buprenorphine at opioid treatment programs received buprenorphine tablets.[32] Rarely, they received long-acting injectable buprenorphine. See Appendix B for more information.

Less than half of the beneficiaries who received medication to treat their opioid use disorder also received behavioral therapy

Forty-seven percent of all beneficiaries who received medication to treat their opioid use disorder also received behavioral therapy through Medicare. See Exhibit 5. This amounted to a total of 78,760 beneficiaries.

Behavioral therapy can be beneficial for people with opioid use disorder, as these services can increase patient engagement, modify patient behavior, and address any co-occurring mental health disorders.[33] Examples of behavioral therapy include individual and group therapy. SAMHSA recommends

Exhibit 5: Only 47 percent of beneficiaries who received MAT drugs also received behavioral therapy.



Source: OIG analysis of Medicare claims data, 2021.

including behavioral therapy in treatment as needed.[34]

Less than one-third of the beneficiaries who received medication in an office-based setting also received behavioral therapy.

Less than one-third of the 130,502 beneficiaries who received MAT drugs in office-based settings also received behavioral therapy. This represents 39,957 beneficiaries. Most of these beneficiaries—37,151—received individual psychotherapy and 7,275 received group psychotherapy.[35]

Although recommended by SAMHSA, providers who prescribe or administer MAT drugs in office-based settings are not required by SAMHSA to provide behavioral therapy to beneficiaries.[36] This is because the benefits of medication such as reducing the risk of overdose and death are far greater than the risks associated with not receiving behavioral therapy.[37]

The low proportion of beneficiaries receiving behavioral therapy raises additional concern as beneficiaries with opioid use disorder often have co-occurring mental health disorders.[38]

About half of these beneficiaries used telehealth to receive behavioral therapy. Telehealth is seen as an important tool in the treatment of opioid use disorder and other substance use disorders because it reduces barriers in access to treatment. Approximately half of the 39,957 beneficiaries—a total of 21,390—used telehealth for at least 1 behavioral therapy service.

In 2019, Medicare began allowing the use of telehealth for the treatment of substance use disorders and co-occurring mental health disorders with fewer restrictions than most other services.[39] In most instances, real time and two-way audio visual communication is required. During the COVID-19 pandemic, further expansions of telehealth occurred that allowed behavioral therapy to be delivered using audio-only communication.[40]

A small number of beneficiaries received behavioral therapy billed to Medicare through newly established office-based bundled payments for opioid use disorder. Medicare established bundled payments that combine behavioral health therapy and care coordination for the treatment of opioid use disorder in office-based settings in 2020.[41] However, only 1,823 beneficiaries received behavioral therapy that was billed to Medicare using these newly established bundled payments.

The relatively low utilization of these bundled payment codes may be because these codes are new. These codes only became available to bill beginning in January 2020. It may also indicate that the bundled payments need to be reassessed.

Beneficiaries who received MAT drugs from opioid treatment programs also received behavioral therapy, as required

Medicare beneficiaries who received MAT drugs from an opioid treatment program in 2020 also received behavioral therapy to address their opioid use disorder. Opioid treatment programs are required to provide behavioral therapy to all patients.[42]

These services may be provided in-person or via telehealth. During the COVID-19 pandemic, Medicare also allowed for audio-only calls for behavioral health and certain other services from opioid treatment programs.

However, the extent to which beneficiaries received behavioral health and other services via telehealth from opioid treatment programs cannot be determined, as CMS does not require opioid treatment programs to report this information on Medicare claims.[43] In contrast, CMS does require other types of providers such as physicians to report when services are delivered via telehealth on Medicare claims.[44]

Beneficiaries in Florida, Texas, Nevada, and Kansas were two to three times less likely to receive medication to treat their opioid use disorder than beneficiaries nationwide

Beneficiaries in Florida, Texas, Kansas, and Nevada were two to three times less likely to receive medication to treat their opioid use disorder. In each of these States, fewer than 8 percent of the beneficiaries with opioid use disorder received MAT drugs, compared to about 16 percent nationwide. See Exhibit 6.

Florida and Texas had the lowest percentage of beneficiaries. In Florida, just 5 percent of beneficiaries with opioid use disorder received MAT drugs through Medicare. In Texas, only 6 percent did so. Nevada (7 percent) and Kansas (7 percent) also had low percentages. See Exhibit 6 and Appendix C.

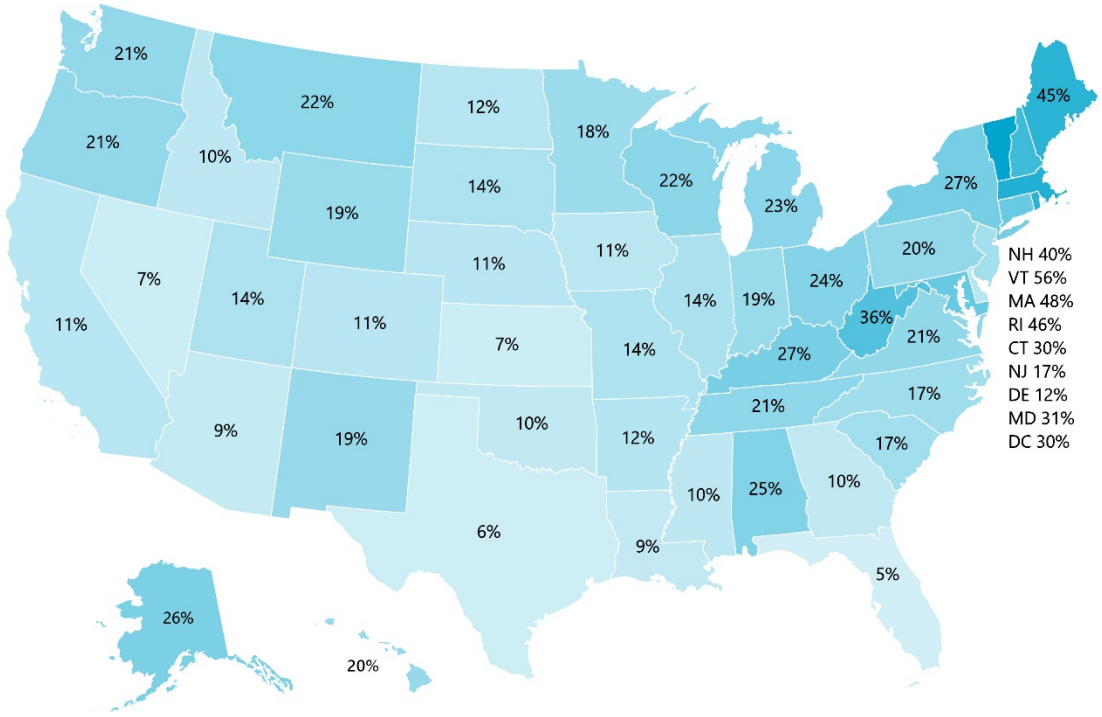
Notably, Florida, Texas, and Nevada also had very low numbers of providers who have buprenorphine waivers and are authorized to prescribe buprenorphine to treat opioid use disorder. Each of these States had fewer than 45 providers with a buprenorphine waiver per 1,000 Medicare beneficiaries with opioid use disorder. These States, along with Mississippi, Oklahoma, Louisiana, and Alabama were the seven States with the lowest numbers of providers in the country.[45] OIG has previously raised concerns that many areas of the country have limited access to providers who are authorized to prescribe buprenorphine.[46]

Furthermore, beneficiaries in Texas and Florida rarely received treatment from opioid treatment programs. Less than 1 percent of the beneficiaries with opioid use disorder in these States received MAT drugs from an opioid treatment program, compared to 4 percent nationwide. The percentage was equally low in South Dakota, Idaho, Wyoming, Nebraska, and North Dakota. These States tended to have low numbers of opioid treatment programs enrolled in Medicare relative to the number of

beneficiaries with opioid use disorder. There are no opioid treatment programs enrolled in Medicare in South Dakota and Wyoming.[47]

It is important that beneficiaries have access to opioid treatment programs because they are the only source of methadone for MAT in outpatient settings.

Exhibit 6: Beneficiaries in Florida, Texas, Nevada, and Kansas were the least likely to receive medication for their opioid use disorder.



Source: OIG analysis of Medicare claims data, 2021.

Asian/Pacific Islander, Hispanic, and Black beneficiaries were less likely to receive medication to treat their opioid use disorder than White beneficiaries

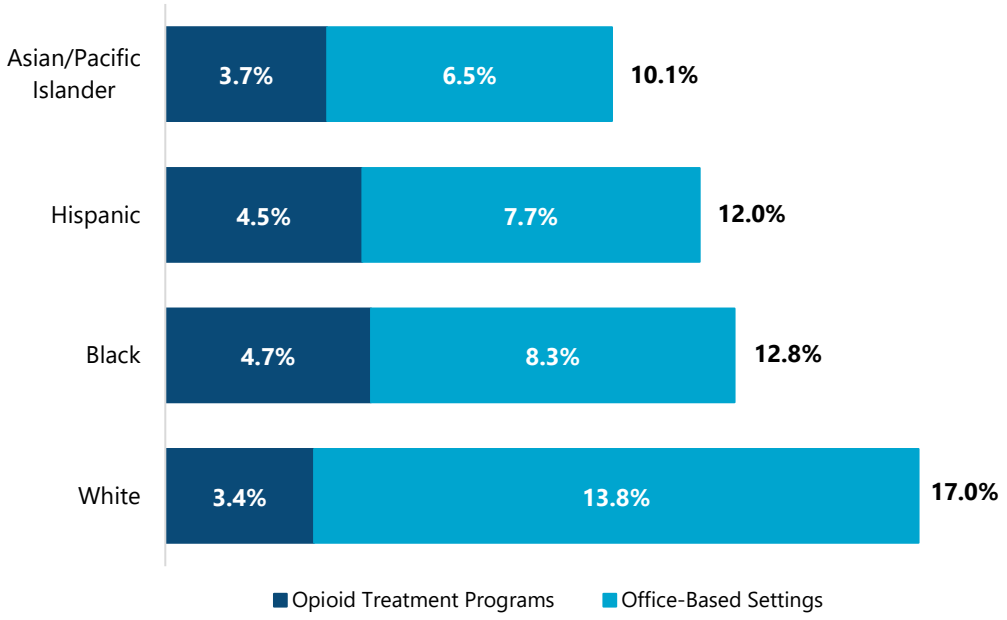
There are notable racial and ethnic disparities in medication for opioid use disorder. Lower percentages of Asian/Pacific Islander, Black, and Hispanic beneficiaries received MAT drugs to treat their opioid use disorder than White beneficiaries.[48] About 10 percent of Asian/Pacific Islander, 12 percent of Hispanic, and 13 percent of Black beneficiaries received medication compared to 17 percent of White beneficiaries. See Exhibit 7.

In addition, differences exist in the settings from which beneficiaries received MAT drugs to treat their opioid use disorder. Asian/Pacific Islander, Hispanic, and Black beneficiaries were less likely to receive MAT drugs in office-based settings than White beneficiaries. Receiving medication in an office-based setting can be less

burdensome than receiving it from an opioid treatment program.[49] Beneficiaries who are prescribed buprenorphine in office-based settings can fill these prescriptions at pharmacies.

Furthermore, Asian/Pacific Islander, Hispanic, and Black beneficiaries were more likely to receive MAT drugs from opioid treatment programs than White beneficiaries. Patients who receive methadone from opioid treatment programs typically must travel each day to programs to receive their doses.[50] In addition to being less convenient, more stigma is generally attached to methadone than buprenorphine.[51]

Exhibit 7: Asian/Pacific Islander, Hispanic, and Black beneficiaries were less likely than White beneficiaries to receive medication to treat their opioid use disorder.*



* The totals are less than the sum because some beneficiaries received drugs in both settings.
Source: OIG analysis of Medicare claims data, 2021.

Older beneficiaries and those not receiving the Part D low-income subsidy were also less likely to receive medication to treat their opioid use disorder

Older beneficiaries were less likely to receive medication than younger beneficiaries to treat their opioid use disorder. Older beneficiaries—i.e., those aged 65 and older—were far less likely to receive MAT drugs than those under the age of 65. Younger beneficiaries often qualify for Medicare because of disability and account for almost half of beneficiaries with opioid use disorder.

Just 8 percent of beneficiaries with opioid use disorder over the age of 65 received MAT drugs, compared to 25 percent of those under 65—a 3-fold difference. See Exhibit 8.

Exhibit 8: Older beneficiaries were 3 times less likely to receive medication to treat their opioid use disorder than younger beneficiaries.

Source: OIG analysis of Medicare claims data, 2021.

Older beneficiaries were less likely to receive MAT drugs than younger beneficiaries, regardless of the State they lived in. In every State, a lower percentage of older beneficiaries received MAT drugs than younger beneficiaries.

Beneficiaries not receiving the Part D low-income subsidy were less likely to receive medication to treat their opioid use disorder than those receiving the subsidy. Some beneficiaries who have limited income and assets receive assistance with paying for Part D premiums and cost-sharing. This assistance is called the Part D low-income subsidy.[52] Beneficiaries who did not receive this subsidy were less likely to receive MAT drugs.

Beneficiaries who did not receive the low-income subsidy were three times less likely to receive MAT drugs through Medicare than beneficiaries who did receive it. In total, just 8 percent of beneficiaries who did not receive the subsidy received MAT drugs, compared to 23 percent of beneficiaries who did receive the subsidy. See Exhibit 9.

Exhibit 9: Beneficiaries not receiving the Part D low-income subsidy were almost 3 times less likely to receive medication to treat their opioid use disorder than those receiving the subsidy.

Source: OIG analysis of Medicare claims data, 2021.

Part D copayments may be a barrier for some beneficiaries receiving MAT drugs in office-based settings. Beneficiaries who did not receive the low-income subsidy paid an average of $324 in 2020 for Part D copayments for MAT drugs. A small number of beneficiaries paid much higher amounts. About 1,500 beneficiaries paid more than $1,300 in 2020 for Part D copayments for MAT drugs. Copayments are not a barrier for treatment from opioid treatment programs. Currently, there are no copayments for drugs and services from opioid treatment programs.[53]

Beneficiaries who did not receive the Part D low-income subsidy are also less likely than beneficiaries who did receive the subsidy to receive MAT drugs, regardless of their age or State.

Female beneficiaries were also less likely to receive medication to treat their opioid use disorder than male beneficiaries. A lower percentage of female beneficiaries with opioid use disorder received MAT drugs than male beneficiaries. In total, 13 percent of female and 19 percent of male beneficiaries received medication to treat their opioid use disorder in 2020.

RECOMMENDATIONS

Access to treatment for opioid use disorder is increasingly important as concerns about the opioid epidemic and the increase in overdose deaths heighten. Medicare plays a key role in ensuring that beneficiaries have access to treatment.

Yet less than 16 percent of beneficiaries are receiving medication through Medicare to treat their opioid use disorder that has been shown to decrease illicit opioid use and opioid-related overdose deaths. Even fewer beneficiaries are receiving both medication and behavioral therapy through Medicare.

In addition, despite Medicare being a national program, there is significant variation among States in the percentages of beneficiaries receiving medication to treat their opioid use disorder. This may be due in part to low numbers of providers with a buprenorphine waiver and opioid treatment programs available to treat patients with opioid use disorder in some States.

There are also notable racial and ethnic disparities reflected in the use of medication for opioid use disorder. Asian/Pacific Islander, Hispanic, and Black beneficiaries are less likely to receive medication to treat their opioid use disorder than White beneficiaries. These groups are also less likely to receive medication in office-based settings which have less stigma attached and are more convenient than opioid treatment programs.

Together, these findings show a need to increase the number of Medicare beneficiaries receiving treatment for opioid use disorder. The Department of Health and Human Services (HHS) and CMS have recently taken several steps to expand access to treatment. For example, in April 2021 HHS released new practice guidelines that exempt eligible providers seeking a buprenorphine waiver from certain training requirements as long as they are treating 30 or fewer patients with buprenorphine.[54] Furthermore, CMS improved the information available to beneficiaries about Medicare coverage for the treatment of opioid use disorder. In addition, CMS now requires that providers screen Medicare beneficiaries for potential opioid use disorder during annual wellness visits and initial preventative physical exams.[55] CMS also established an additional payment when medication for the treatment of opioid use disorder is initiated in an emergency department.[56] CMS should build on these efforts, address the continuing gap in treatment, and ensure that Medicare beneficiaries with opioid use disorder receive needed treatment.

We recommend that CMS:

Conduct additional outreach to beneficiaries to increase awareness about Medicare coverage for the treatment of opioid use disorder

CMS plays an important role in increasing awareness among beneficiaries about Medicare coverage for the treatment of opioid use disorder. CMS should take additional steps to increase awareness about medication to treat opioid use disorder among beneficiaries and individuals who help beneficiaries make health care decisions. For example, through its National Training Program, CMS could create a training for its partners, not-for-profit professionals, and volunteers who work with older adults and people with disabilities. The training could educate these individuals about Medicare coverage for opioid use disorder treatment including office-based treatment and opioid treatment programs, and how they can help beneficiaries find care.

CMS should also more clearly state on its Medicare.gov website that beneficiaries can receive treatment for opioid use disorder at opioid treatment programs or in office-based settings. The website should provide a link for beneficiaries to find providers who offer treatment in office-based settings. Currently, the website only provides a link that helps beneficiaries find treatment at opioid treatment programs.

CMS should also target its outreach efforts to certain groups of beneficiaries who are less likely to receive medication to treat their opioid use disorder. These should include beneficiaries in certain States and those who are older, Asian/Pacific Islander, Black, Hispanic, and female.

Take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder

CMS should take several steps to increase the number of providers who can treat beneficiaries for opioid use disorder in office-based settings. CMS is in a unique position to conduct outreach to providers to encourage them to treat Medicare beneficiaries with opioid use disorder. CMS has a number of mechanisms such as Medicare Learning Network alerts that can be used to communicate important information to providers. CMS should use its outreach mechanisms to educate providers about Medicare coverage for opioid use disorder treatment. The outreach could also provide information about which States or areas of the country have the greatest need for additional providers.

CMS could also assess whether making changes to Medicare payment mechanisms could help increase the number of providers treating beneficiaries for opioid use disorder in office-based settings. Specifically, it could assess whether its current payment mechanisms and reimbursement rates reflect the level of care necessary to treat beneficiaries for opioid use disorder, given the complex needs of this population. As part of this effort, CMS could determine why so few providers used the office-based bundled payment codes when billing for opioid use disorder treatment in 2020.

If necessary, based on the results of these assessments, CMS could adjust its payment mechanisms and reimbursement rates to better align them with the level of care required for treating beneficiaries with opioid use disorder in office-based settings. CMS could also consider developing an add-on code for the initiation of medication for the treatment of opioid use disorder in office-based settings similar to the new add-on code for the initiation of medication for the treatment of opioid use disorder in emergency department settings.[57]

CMS should also continue its outreach efforts to increase the number of opioid treatment programs available to Medicare beneficiaries. CMS has taken steps to increase the number of opioid treatment programs enrolled in Medicare, including working with SAMHSA to reach unenrolled opioid treatment programs. CMS should continue these efforts. In addition, CMS could provide information to States to help them determine whether the number of opioid treatment programs available to Medicare beneficiaries in certain States or areas is adequate. CMS could also assess whether opioid treatment programs are facing any barriers to treating Medicare beneficiaries. For example, CMS could determine whether the structure of the weekly bundled payments reflects the level of care required to treat a beneficiary.

Assist SAMHSA by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings and the geographic areas where Medicare beneficiaries remain underserved

Monitoring access to providers who are authorized to prescribe buprenorphine and determining which areas of the country need additional providers are important to ensuring access to treatment. As the agency responsible for administering the Buprenorphine Waiver Program, SAMHSA is central to monitoring access to these providers. However, SAMHSA lacks comprehensive data on the number of patients served under the program.

To address this issue, SAMHSA recently concurred with an OIG recommendation to develop comprehensive methods and measures to assess access to buprenorphine prescribed or administered by waivered providers.[58] To do this, SAMHSA is considering ways to increase its own capacity to collect and analyze existing administrative data, such as data from CMS, to monitor access to buprenorphine.

To assist SAMHSA in its efforts, CMS should provide SAMHSA with data on the number of patients receiving buprenorphine and the geographic areas where patients with opioid use disorder remain underserved. Because of its national scope and size, Medicare data may provide SAMHSA with important insights and help ensure access to treatment more widely.

Take steps to increase the utilization of behavioral therapy among beneficiaries receiving medication to treat opioid use disorder

Patients receiving medication to treat opioid use disorder may also benefit from behavioral therapy. This therapy can increase patient engagement, modify patient behavior, and address co-occurring mental health disorders. CMS should take steps

to increase the number of beneficiaries who receive behavioral therapy as a part of the treatment for opioid use disorder. Taking into account shortages of behavioral health providers, CMS should conduct outreach to providers and beneficiaries that reinforces the benefits of behavioral therapy. It could provide information to primary care providers about how they can help their Medicare patients connect with behavioral health providers by, for example, using the Medicare Find & Compare website to identify providers in their areas who treat opioid use disorder.[59] The outreach could also remind behavioral health care providers of the new bundle payment for opioid treatment.

Create an action plan and take steps to address disparities in the treatment of opioid use disorder

CMS should create an action plan and take steps to address disparities among Asian/Pacific Islander, Black, Hispanic, and other underserved communities in the treatment of opioid use disorder for Medicare beneficiaries.

This standalone action plan should align with the overarching CMS Equity Plan developed by CMS's Office of Minority Health and use the CMS Health Equity Framework and the priorities within the plan as a foundation for establishing measurable, actionable goals to achieve health equity. This action plan should identify ways to promote increased understanding and awareness of disparities in opioid use disorder, and develop promising approaches to reduce disparities in the treatment of opioid use disorder as well as steps to disseminate this information to providers and other stakeholders in order to reduce and eliminate disparities and achieve health equity.

Furthermore, the actions outlined in this plan should include targeted outreach to providers who serve and beneficiaries who are members of these communities. This outreach could ensure that there is more culturally sensitive and respectful care available for patients with opioid use disorder. To conduct this outreach, it may be important to identify and collaborate with local leaders and groups within Asian/Pacific Islander, Black, and Hispanic communities where disparities are prevalent.

CMS should use the data it is currently collecting on disparities and the data in this report to develop this plan. It should also collaborate with the HHS Office of Minority Health and SAMHSA, as appropriate.

Collect data on the use of telehealth in opioid treatment programs

The use of telehealth to treat opioid use disorder is considered an important tool in ensuring access to care. CMS currently does not monitor beneficiaries' utilization of telehealth in opioid treatment programs or assess its impact on access to care. This is because opioid treatment programs do not submit information about telehealth on Medicare claims. CMS should require opioid treatment programs to indicate on Medicare claims when telehealth is used to provide care. This information will allow CMS to monitor the use of telehealth at opioid treatment programs.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with four of our recommendations and did not explicitly indicate whether it concurred with the other two recommendations.

CMS concurred with our recommendation to conduct additional outreach to beneficiaries to increase awareness about coverage for the treatment of opioid use disorder. CMS noted that it has previously conducted extensive outreach to beneficiaries regarding Medicare coverage for the treatment of opioid use disorder and will continue to conduct outreach as appropriate. CMS also stated that it has revised the Medicare & You Handbook and updated its website. In addition, CMS stated that it is currently analyzing drivers of disparities in the use of medication to treat opioid use disorder and will target future outreach to specific populations as appropriate.

CMS concurred with our recommendation to take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder. CMS stated that it has previously conducted extensive outreach to providers and opioid treatment programs about opportunities to treat Medicare beneficiaries with opioid use disorder. CMS also stated that it will continue to monitor payment mechanisms and rates for office-based treatment to assess their efficacy.

CMS did not explicitly indicate whether it concurred with our recommendation to assist SAMHSA by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings and the geographic areas where Medicare beneficiaries remain underserved. However, CMS stated that it regularly works with SAMHSA and will provide data when requested to do so.

CMS also did not explicitly indicate whether it concurred with our recommendation to take steps to increase the utilization of behavioral therapy among beneficiaries receiving medication to treat opioid use disorder. CMS noted that it has previously undertaken extensive outreach to beneficiaries to describe the benefits available to them for the treatment of opioid use disorder. It also stated that it will continue outreach to both providers and beneficiaries to ensure awareness of all Medicare-covered services and options.

CMS concurred with our recommendation to create an action plan and take steps to address disparities in the treatment of opioid use disorder. CMS stated that it has been working to identify and track drivers of disparities in the treatment of opioid use disorder. CMS also stated that it will use its existing equity framework, as described in the Equity Plan for Medicare, to further analyze and develop existing opioid use disorder plans to address, and amend as needed, disparities in the treatment of opioid use disorder.

Lastly, CMS also concurred with our recommendation to collect data on the use of telehealth in opioid treatment programs. CMS stated that it has finalized coding changes in the CY 2022 Physician Fee Schedule necessary to collect data to monitor the use of telehealth in opioid treatment programs. These changes will include a requirement to use a service-level modifier for audio-only services billed using the counseling and therapy add-on code. CMS also finalized that when two-way audio/video communication is used to furnish services billed under the counseling and therapy add-on code, opioid treatment programs will be required to append a modifier to the claim. In addition to these steps, OIG encourages CMS to also collect information on counseling and therapy services delivered via telehealth included in the weekly bundled payments.

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

METHODOLOGY

This data brief is based on the analysis of Medicare data from January 1, 2020, to December 31, 2020, including National Claims History File data, Part C Encounter Data, Part D prescription drug event (PDE) records, and the Medicare Enrollment Database.[60] 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 from Medicare Parts A and B. Part C Encounter Data contain medical claims data for beneficiaries enrolled in Medicare Advantage plans.

Identifying Beneficiaries with Opioid Use Disorder

We determined the extent to which Medicare beneficiaries had diagnoses of opioid use disorder in 2020 using Medicare Parts A and B Claims Data and Part C Encounter Data. We considered a beneficiary to have opioid use disorder if the beneficiary had a diagnosis code categorized as "opioid abuse" (F11.1) or "opioid dependence" (F11.2) on any claim during 2020, or if the beneficiary received service at an opioid treatment program in 2020.

Analysis of MAT Drugs

Using Medicare Part B Claims Data, Part C Encounter Data, and Part D PDE records, we determined the extent to which beneficiaries with opioid use disorder (as defined above) received MAT drugs through Medicare in 2020. Throughout the report, we use the term "beneficiaries who received medication to treat opioid use disorder" to refer to these beneficiaries.

First, we determined the number of beneficiaries with opioid use disorder who were prescribed or administered MAT drugs in office-based settings. We considered MAT drugs to be prescribed or administered in office-based settings if they were prescribed by a health care provider and filled at a pharmacy (and covered under Part D), or if they were administered directly to a patient by a health care provider (and covered under Part B and Part C). To identify these beneficiaries, we first used PDE records to identify the number of beneficiaries who filled prescriptions for MAT drugs at pharmacies in 2020. We then used Medicare Part B Claims Data and Part C Encounter Data to identify the number of beneficiaries who were administered MAT drugs in a health care provider's office. We also determined the number of beneficiaries who received each type of MAT drug (i.e., buprenorphine or naltrexone) prescribed or administered in an office-based setting.

Next, we determined the number of beneficiaries with opioid use disorder who received MAT drugs through opioid treatment programs. To do this, we used

Medicare Part B Claims Data and Part C Encounter Data to identify all beneficiaries for whom an opioid treatment program had billed at least one bundled payment code that included a MAT drug component. We also determined the total number of beneficiaries who received each type of MAT drug (i.e., methadone, buprenorphine, or naltrexone). Lastly, we determined how many beneficiaries received take-home doses of methadone and buprenorphine from opioid treatment programs.

Analysis of Behavioral Therapy

Using Medicare Part B Claims and Part C Encounter Data, we determined the extent to which beneficiaries with opioid use disorder who received MAT drugs also received behavioral therapy. These services can be provided through individual providers in office-based settings or through opioid treatment programs.

We first determined the extent to which beneficiaries who received MAT drugs in office-based settings also received behavioral therapy that was billed to Medicare. To do this, we identified beneficiaries who received MAT drugs in office-based settings and received individual psychotherapy or group psychotherapy. We also determined the number of these beneficiaries who received behavioral therapy through monthly office-based bundled payments. In addition, we determined the extent to which any of these services were delivered via telehealth. We considered a service to be delivered via telehealth when one of these codes had a modifier or Place of Service code indicating the service had been delivered via telehealth.

We then determined the number of beneficiaries who received both MAT drugs and behavioral health services through opioid treatment programs. We did this by identifying which beneficiaries received the opioid treatment programs bundled payment billing codes that include individual and group therapy components.

Characteristics of Beneficiaries

We also determined key characteristics of the beneficiaries who were less likely to receive MAT drugs. To do this, we used the Medicare Enrollment Database file. We first determined the percentage of beneficiaries in each State who received MAT drugs. For each State, we determined the total number of opioid treatment programs enrolled in the Medicare program and the total number of health care providers who have a buprenorphine waiver from SAMHSA.[61] We then calculated the number of each of these providers per 1,000 Medicare beneficiaries with opioid use disorder.

We also determined each beneficiary's race and ethnicity, age, Part D low-income subsidy status, and sex. In addition, we also determined the extent to which beneficiaries received MAT drugs in office-based settings and from opioid treatment programs by race and ethnicity. Race and ethnicity information is based on data collected from the Social Security Administration and an algorithm developed by the Research Triangle Institute. This algorithm attempts to improve the quality of the Social Security Administration's data by amending the race data for certain groups

based on name and geography, as well as requests made by individuals for certain government materials to be provided in Spanish.[62]

Limitations

This study determines the extent to which beneficiaries received MAT drugs and therapy through Medicare. Beneficiaries in this analysis may have received drugs or services through other payers, such as other insurance (e.g., plans covered by the Retiree Drug Subsidy), or self-pay. We did not review the medical records or independently verify the accuracy of the Medicare claims data for this study.

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

Diagnostic Criteria of Opioid Use Disorder

Exhibit A1: Diagnostic Criteria for Opioid Use Disorder*

1. Opioids are often taken in larger amounts or over longer periods than 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 an opioid, use an opioid, or recover from its effects
4. Craving or strong desire or urge to use opioids
5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school, or home
6. Continued opioid use despite persistent or recurrent social or interpersonal problems caused or exacerbated by 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 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:
    - a need for markedly increased amounts of opioids to achieve intoxication or desired effect, or
    - a markedly diminished effect with continued use of the same amount of opioids
11. Withdrawal as manifested by either:
    - the characteristic of opioid withdrawal syndrome, or
    - 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 two or three symptoms is considered mild opioid use disorder. The presence of four or five 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 B

Medications Received by Medicare Beneficiaries to Treat Opioid Use Disorder

Exhibit B1: Beneficiaries most commonly received buprenorphine to treat their opioid use disorder in 2020.

	Beneficiaries	Percent
Buprenorphine	125,321	75%
Methadone	38,170	23%
Naltrexone	8,282	5%
Total	**165,734***	**100%****

* These data include the number of Medicare beneficiaries with opioid use disorder who received a MAT drug in office-based settings and opioid treatment programs. A total of 4,005 beneficiaries received more than 1 MAT drug.
** The sum of this column does not equal 100 percent because some beneficiaries received more than 1 MAT drug
Source: OIG analysis of Medicare claims data, 2021.

Exhibit B2: In office-based settings, beneficiaries most commonly received buprenorphine to treat their opioid use disorder.*

MAT Drug	Total Number of Beneficiaries
Buprenorphine	**123,745****
Oral (tablets, sublingual film, buccal film)	123,583
Long-Acting Injectable	1,013
Naltrexone	**8,257*****
Tablets	6,888
Long-Acting Injectable	2,622
Total	**130,502******

* Methadone for MAT is not available in office-based settings.
** A total of 851 received more than 1 form of buprenorphine.
*** A total of 1,253 beneficiaries received more than 1 form of naltrexone.
**** A total of 1,500 received both buprenorphine and naltrexone prescribed or administered in a provider's office.
Source: OIG analysis of Medicare claims data, 2021.

Exhibit B3: In opioid treatment programs, beneficiaries most commonly received methadone.

MAT drug	Beneficiaries
Methadone	38,170
Take-home doses	*21,336*
Buprenorphine	2,164*
Oral Tablets	*2,161*
Take-home doses	*1,253*
Injection	*6*
Injectable Naltrexone	26
Total	**39,602****

* A total of three beneficiaries received more than one form of buprenorphine.
** A total of 758 beneficiaries received more than 1 type of MAT drug.
Source: OIG analysis of Medicare claims data, 2021.

APPENDIX C

Percentage of Medicare Beneficiaries Who Received Medication to Treat Their Opioid Use Disorder in Each State

Exhibit C1: Beneficiaries in Florida and Texas were the least likely to receive medication to treat their opioid use disorder in 2020.

	Percent of beneficiaries with an opioid use disorder who received medication			
State	**Prescribed or Administered in an Office-Based Setting**	**Opioid Treatment Program**	**Total***	**Total Number Who Received Medication**
Florida	5%	1%	5%	7,792
Texas	6%	1%	6%	4,973
Nevada	5%	2%	7%	988
Kansas	6%	1%	7%	413
Arizona	6%	3%	9%	2,735
Louisiana	8%	1%	9%	2,358
Oklahoma	8%	1%	10%	2,279
Georgia	8%	2%	10%	2,908
Idaho	10%	0%	10%	700
Mississippi	9%	1%	10%	1,586
Iowa	7%	5%	11%	474
Nebraska	10%	1%	11%	280
Colorado	9%	2%	11%	1,699
California	7%	4%	11%	12,695
Delaware	9%	3%	12%	770
North Dakota	11%	1%	12%	110
Arkansas	11%	1%	12%	1,063
Missouri	12%	2%	14%	2,339
Utah	13%	2%	14%	1,475
South Dakota	14%	0%	14%	107
Illinois	11%	3%	14%	2,971
New Jersey	13%	4%	17%	4,089
South Carolina	13%	4%	17%	2,201

Exhibit C1 (continued)

State	Prescribed or Administered in an Office-Based Setting	Opioid Treatment Program	Total*	Total Number Who Received Medication
	Percent of beneficiaries with an opioid use disorder who received medication			
North Carolina	15%	3%	17%	6,416
Minnesota	13%	5%	18%	2,049
Wyoming	18%	1%	19%	142
Indiana	16%	3%	19%	3,936
New Mexico	16%	4%	19%	1,751
Hawaii	13%	7%	20%	479
Pennsylvania	17%	3%	20%	9,394
Oregon	17%	4%	21%	3,112
Washington	17%	4%	21%	5,033
Virginia	16%	5%	21%	3,645
Tennessee	18%	3%	21%	6,068
Montana	18%	4%	22%	503
Wisconsin	16%	6%	22%	2,432
Michigan	17%	6%	23%	7,604
Ohio	21%	4%	24%	7,847
Alabama	21%	3%	25%	4,901
Alaska	23%	3%	26%	329
Kentucky	24%	3%	27%	5,926
New York	18%	9%	27%	11,229
District of Columbia	24%	7%	30%	655
Connecticut	18%	13%	30%	3,309
Maryland	15%	17%	31%	5,711
West Virginia	32%	5%	36%	2,554
New Hampshire	34%	7%	40%	2,079
Maine	37%	9%	45%	2,518
Rhode Island	33%	14%	46%	1,760
Massachusetts	35%	14%	48%	12,016
Vermont	38%	21%	56%	1,305

* The total percentages may be less than the sum of the office-based and opioid treatment program columns due to beneficiaries receiving MAT drugs in both settings.
Source: OIG analysis of Medicare claims data, 2021.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: November 15, 2021

TO: Christi A. Grimm
Principal Deputy Inspector General

FROM: Chiquita Brooks-LaSure
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder (OEI-02-20-00390)

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 Opioid Treatment Programs (OTPs) and office-based treatment. Ensuring access to these benefits and addressing equity concerns is an important part of combatting the nation's opioid epidemic, and CMS has been actively engaged in the work necessary to meet these goals.

Treatment through an OTP includes medication (such as methadone and buprenorphine), counseling, drug testing, and individual and group therapy. OTPs must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and enrolled in Medicare in order to be reimbursed for these services to Medicare beneficiaries. To implement Congress' establishment of Medicare payment for OTPs under the SUPPORT Act, on January 1, 2020, Medicare began paying Medicare-enrolled OTPs with a bundled payment to deliver OUD treatment services to Medicare beneficiaries. Medicare Advantage plans must also include the OTP benefit and can contract with OTP providers in their service area. CMS has also implemented office-based payment codes for treatment of OUD so that providers can offer care coordination, individual and group psychotherapy, and substance use counseling. These codes were expanded to be inclusive of all substance use disorders (SUDs), effective January 1, 2021. In addition, starting on January 1, 2021, Medicare Part B began covering hospital outpatient OTP services.

To support the availability of opioid treatment services and encourage their use by eligible beneficiaries, in 2019, CMS began conducting outreach encouraging OTPs to enroll in Medicare, resulting in more than 1,250 OTPs enrolling by October 2021. This outreach comprised more than 20 separate communications to OTPs, multiple calls and listening sessions, the creation of two new web pages,[1] and local engagement through the Medicare Administrative Contractors and CMS Regional Offices. Working with SAMHSA, CMS educated OTPs about becoming SAMHSA-certified; reached out to OTPs that were SAMHSA-certified but not yet enrolled in

[1] https://www.cms.gov/Center/Provider-Type/Opioid-Treatment-Program-Center and https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program

Medicare through language in SAMHSA's OTP certification letter; and examined and addressed barriers to enrollment, such as lack of familiarity with the Medicare program and payment, as OUD treatment services furnished by OTPs were not previously a Medicare benefit. CMS also reached out to Medicare Advantage Organizations during this time to educate them on the benefit. CMS has made many enrollment, billing, and education resources for office-based providers and OTPs available on the OTP webpage on CMS.gov.

Appropriate payment is an important part of ensuring provider participation and beneficiary access to care. CMS develops Medicare payment rates to meet statutory requirements including reflecting resource use for the care provided as appropriate. Prior to this audit, CMS has been monitoring the newly developed office-based bundled payment rates. This coding was new as of January 1, 2020, and was updated as of January 1, 2021 to include treatment for all substance use disorders, not just OUD. While OIG found that relatively few beneficiaries received behavioral therapy billed to Medicare through these office-based bundled payments, in addition to being new coding about which utilization data is still developing, the ongoing COVID-19 public health emergency may have also affected utilization. CMS is continuing to monitor this issue. In addition, to continue to facilitate access to the OTP benefit and improve our ability to collect data about use of telehealth, CMS finalized in the Calendar Year (CY) 2022 Physician Fee Schedule final rule a provision for OTPs to provide counseling and therapy services via audio-only technology, such as telephone calls, after the conclusion of the Public Health Emergency when audio/video communication is not available to the patient. To assess availability and uptake of treatment options, CMS also finalized a requirement that OTPs track use of audio-only technology with a billing modifier. CMS also finalized that after the conclusion of the PHE for COVID-19, when two-way interactive audio/video communication technology is used to furnish additional counseling and therapy services billed under the counseling and therapy add-on code, OTPs will be required to append a modifier to the claim. The use of these modifiers will allow CMS to track utilization of these flexibilities in the claims data and to evaluate that data as we consider future refinements to the OTP benefit. CMS already monitors use of telehealth for OUD treatment in general, as OTPs are not the only source of treatment for OUDs. Beneficiaries can receive OUD treatment in other outpatient settings from physicians and certain non-physician practitioners, which can include evaluation and management services, psychotherapy services, or a bundle of office-based substance use disorder treatment services; and analysis of the claim can indicate whether that treatment for an OUD was furnished via telehealth.

CMS takes seriously its role in ensuring beneficiaries understand the availability of these services, and as such, CMS has conducted outreach about the OTP benefit, including updating the Medicare & You Handbook to explain these benefits, as well as publishing blog posts and other information on Medicare.gov. CMS continues to update the Handbook, and has published changes in the 2022 Handbook that include information about coverage of office-based treatment. In addition, CMS updated the 2020 Medicare & You Handbook to highlight that behavioral health therapy is part of the OTP benefit and is covered both in-person and virtually, and expanded on this information in the 2021 Handbook. CMS also continues to promote behavioral health services to beneficiaries on the Medicare.gov website. CMS also initiated the Value in Opioid Use Disorder Treatment Demonstration Program in 2021, the goals of which include increasing access to opioid use disorder treatment services and improving physical and mental health outcomes for Medicare beneficiaries. The selected participants include providers located in three of the four states OIG cites in this report as having lower beneficiary use of medication for OUD treatment.[2]

[2] https://innovation.cms.gov/innovation-models/value-in-treatment-demonstration

Because addressing disparities is also an important part of increasing access, CMS has established an Equity Plan for Medicare. This publication provides a framework for measurable, actionable goals to achieve health equity. It is currently being updated and will reflect CMS' overall strategic plans as well as needs identified by stakeholders to expand an equity framework for the coming years. CMS has been working to identify and track drivers of disparities in the treatment of OUDs, and is following the framework established in the Equity Plan to analyze and develop a plan to address these disparities.

Combatting the opioid epidemic is a priority for the agency, and we appreciate that the OIG recognizes that many ongoing efforts taken prior to the OIG's audit will be key in moving this effort forward.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

CMS should conduct additional outreach to beneficiaries to increase awareness about Medicare coverage for the treatment of opioid use disorder.

CMS Response

CMS concurs with this recommendation. Prior to this audit, CMS conducted extensive outreach to beneficiaries regarding Medicare coverage for the treatment of OUD, as detailed above, and will continue to conduct outreach as appropriate. Also prior to this audit, CMS finalized revisions and has now published the 2022 Medicare & You Handbook stating that beneficiaries can receive OUD treatment in office-based settings in addition to opioid treatment programs. The CMS website has also been updated to align messaging. To ensure that Medicare beneficiaries are connected with the provider who best fits their needs, CMS has detailed in the Handbook and website that beneficiaries should speak with their provider for information about where to go for these services. As stated above, CMS is currently analyzing drivers of disparities in use of medication to treat OUDs and will target future outreach to specific populations as appropriate. Regarding the availability of providers, we note that providers with a SAMHSA-issued buprenorphine waiver are limited in the number of patients they can treat, while some providers with waivers may not see the full panel of patients that a waiver would permit them to treat.

OIG Recommendation

CMS should take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder.

CMS Response

CMS concurs with this recommendation. Prior to this audit, CMS conducted extensive outreach to educate providers and Medicare-qualified SAMHSA-certified OTPs about opportunities to treat Medicare beneficiaries with OUDs. In order to provide treatment to Medicare beneficiaries, an OTP is required to have in effect a certification by SAMHSA and to be accredited by an accrediting body approved by SAMHSA. An office-based provider wishes to prescribe buprenorphine must also have a SAMHSA waiver, as described above. In addition, both office-based providers and OTPs must also be enrolled in Medicare to treat Medicare beneficiaries. After the initial outreach campaign and follow-up starting in 2019, more than 70 percent of SAMSHA-certified OTPs became enrolled in Medicare. As stated above, CMS worked with SAMHSA to include language in their certification letter to OTPs describing how to enroll in Medicare, and this language has been included since 2019. Regarding current payment mechanisms for office-based treatment, CMS develops Medicare payment rates to meet statutory

requirements including reflecting resource use for the care provided as appropriate. Prior to this audit, CMS has been monitoring these payment mechanisms and rates to assess their efficacy. This coding was new as of January 1, 2020, and was updated as of January 1, 2021 to include treatment for all substance use disorders, not just OUD. In addition to being new coding about which utilization data is still developing, the ongoing COVID-19 public health emergency may have also affected utilization. CMS is continuing to monitor this issue.

OIG Recommendation
CMS should assist SAMHSA by providing data about the number of Medicare beneficiaries receiving buprenorphine in office-based settings and the geographic areas where Medicare beneficiaries remain underserved.

CMS Response
CMS regularly works with, and will provide data when requested by, SAMHSA.

OIG Recommendation
CMS should take steps to increase the utilization of behavioral therapy among beneficiaries receiving medication to treat opioid use disorder.

CMS Response
Prior to this audit, as described above, CMS had undertaken extensive outreach to beneficiaries to describe benefits available to them for treatment of OUDs, including behavioral health therapy, and outreach to providers on how to enroll in Medicare and bill for these services. While treatment decisions and protocols are ultimately between the provider and beneficiary, CMS will continue outreach to both providers and beneficiaries to ensure awareness of all Medicare-covered services and options.

OIG Recommendation
CMS should create an action plan and take steps to address disparities in the treatment of opioid use disorder.

CMS Response
CMS concurs with this recommendation. Prior to this audit, CMS has been working to identify and track drivers of disparities in the treatment of OUDs. CMS will use our existing equity framework, as described in the Equity Plan for Medicare, to further analyze and develop existing OUD plans to address, and amend as needed, disparities in the treatment of OUDs.

OIG Recommendation
CMS should collect data on the use of telehealth in opioid treatment programs.

CMS Response
CMS concurs with this recommendation. As stated above, prior to this audit, CMS proposed the claims coding changes that would be necessary to collect data to monitor use of telehealth in opioid treatment programs, and has now finalized these requirements as proposed in the CY 2022 Physician Fee Schedule. Changes include a provision allowing OTPs to provide counseling and therapy services via audio-only technology, such as telephone calls, after the conclusion of the Public Health Emergency when audio/video communication is not available to the patient, and a requirement that OTPs use a service-level modifier for audio-only services billed using the counseling and therapy add-on code. CMS also finalized that after the conclusion of the PHE for COVID-19, when two-way interactive audio/video communication technology is used to furnish

additional counseling and therapy services billed under the counseling and therapy add-on code, OTPs will be required to append a modifier to the claim. The use of these modifiers will allow CMS to track utilization of these flexibilities in the claims data and to evaluate that data as we consider future refinements to the OTP benefit.

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

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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

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

Contact

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

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ENDNOTES

[1] These statistics are based on preliminary data. See Centers for Disease Control and Prevention (CDC), Vital Statistics Rapid Release, *Provisional Drug Overdose Death Counts*, *12 Month-ending Provisional Number of Drug Overdose Deaths*, August 1, 2021. Accessed at https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm on August 31, 2021.

[2] SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2020. Accessed at https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP21-02-01-002.pdf on May 25, 2021.

[3] These medications are also sometimes called medications for opioid use disorder or MOUD.

[4] Buprenorphine is also separately indicated for pain. Buprenorphine products indicated for pain are different than buprenorphine products indicated for the treatment of opioid use disorder.

[5] These waivers allowed certain practitioners to treat up to 100 patients with buprenorphine in the first year, although most qualified practitioners were limited to treating up to 30 patients in the first year. See 21 U.S.C. § 823(g)(2)(b)(III)(i). In subsequent years, a practitioner can treat up to 275 patients. See 42 CFR § 8.610.

[6] Methadone can be prescribed for pain in other outpatient settings.

[7] Over time, these patients can receive up to one month's worth of take-home doses. See 42 CFR § 8.12(h). Also see SAMHSA, *Federal Guidelines for Opioid Treatment Programs,* January 2015. Accessed at https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf on May 26, 2021. SAMHSA has also increased the flexibility in dispensing take-home doses of methadone and other MAT drugs during the COVID-19 pandemic. See SAMHSA, *Opioid Treatment Program (OTP) Guidance*, March 2020. Accessed at https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf on May 25, 2021.

[8] Prior to 2020, methadone for MAT was not covered by Part B because opioid treatment programs were not a recognized provider type in Medicare. Beneficiaries enrolled in Medicare Advantage plans may have had opioid treatment program services covered prior to 2020 as a supplemental benefit. CMS, *Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, April 2016.

[9] SAMHSA, *Naltrexone*. Accessed at https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone on May 25, 2021.

[10] 42 C.F.R. § 8.12(f).

[11] Each of these 1 million beneficiaries had a diagnosis of opioid use disorder on at least one Medicare claim in 2020 or received at least 1 service from an opioid treatment program in 2020. For the purposes of this report, we refer to these beneficiaries as "beneficiaries with opioid use disorder."

[12] For more information about assessing a patient for opioid use disorder, see CDC training document *Module 5: Assessing and Addressing Opioid Use Disorder*. Accessed at https://www.cdc.gov/drugoverdose/training/oud/ on May 25, 2021.

[13] *Diagnostic and Statistical Manual of Mental Disorders: DSM-5*, 2013.

[14] SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2020. Continued treatment with MAT drugs for opioid use disorder is linked with better retention and outcomes, compared to treatment without MAT drugs.

[15] This number represents the proportion of beneficiaries who received MAT drugs through Medicare. Additional beneficiaries may have received MAT drugs through other sources, such as by paying out-of-pocket.

[16] Food and Drug Administration, *Information about Medication-Assisted Treatment (MAT)*. Accessed at https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat on May 25, 2021.

[17] SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2020, p. ES-3. Also see A. Sharma, et al., "Update on Barriers to Pharmacotherapy for Opioid Use Disorders," Current Psychiatry Reports, 2017;19(6):35.

[18] National Institute of Drug Abuse, *Words Matter – Preferred Language for Talking About Addiction*. Accessed at https://www.drugabuse.gov/drug-topics/addiction-science/words-matter-preferred-language-talking-about-addiction on June 14, 2021.

[19] CDC estimates that 4 in 10 adults in the United States delayed or avoided medical care because of concerns related to COVID-19. See Mark E. Czeisler, Kristy Marynak, Kristie E.N. Clarke, et al., "Delay or Avoidance of Medical Care Because of COVID-19-Related Concerns—United States," June 2020, Morbidity and Mortality Weekly Report, 69:1250–1257. Accessed at https://www.cdc.gov/mmwr/volumes/69/wr/mm6936a4.htm#suggestedcitation on August 23, 2021. To help ensure access to care, several rules related to the provision of MAT drugs were relaxed during the COVID-19 pandemic. For more information, see Drug Enforcement Administration (DEA), *COVID-19 Information Page*. Accessed at https://www.deadiversion.usdoj.gov/coronavirus.html on September 9, 2021.

[20] This analysis includes buprenorphine formulations indicated for the treatment of opioid use disorder. It does not include formulations indicated for pain.

[21] To try to increase access during the COVID-19 pandemic, DEA allowed qualified providers to prescribe buprenorphine for MAT drugs via telephone without having first assessed patients in-person. See DEA, *Use of Telephone Evaluations to Initiate Buprenorphine Prescribing*. DEA also created exceptions for prescribing controlled substances across State lines during the COVID-19 Public Health Emergency. See DEA, *Exception to Separate Registration Requirements Across State Lines*, March 2020. These documents are available on DEA's COVID-19 Information Page. Accessed at https://www.deadiversion.usdoj.gov/coronavirus.html on September 22, 2021.

[22] OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020.

[23] In total, 123,617 beneficiaries with opioid use disorder received buprenorphine for MAT covered by Part D in 2020. This number includes drugs covered by Medicare Advantage prescription drug plans.

[24] In 2020, only 379 beneficiaries with opioid use disorder received buprenorphine for MAT administered in providers' offices that was billed to Part B or Part C.

[25] A total of 8,146 beneficiaries with opioid use disorder received naltrexone that was covered by Part D.

[26] A total of 355 beneficiaries with opioid use disorder received naltrexone administered in a health care provider's office that was covered by Part B or Part C.

[27] Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act, Pub. L. 115-271, enacted October 24, 2018) established a new benefit for opioid use disorder treatment services furnished by an opioid treatment program beginning on or after January 1, 2020. See 84 F.R. 62649. An opioid treatment program must be enrolled in Medicare to receive reimbursement for services provided to Medicare beneficiaries.

[28] There were approximately 1,170 opioid treatment programs enrolled in Medicare in the United States and its territories in 2020, but distribution of programs is not even across the States. Notably, State laws related to opioid treatment programs differ. For instance, some States have laws and regulations related to where opioid treatment programs can be located. See

J.R. Jackson, et al., "Characterizing Variability in State-Level Regulations Governing Opioid Treatment Programs," Journal of Substance Abuse Treatment 115, 2020.

[29] Under certain circumstances, patients are permitted to take home doses of both buprenorphine and methadone, thus alleviating the need to travel each day. See 42 CFR § 8.12(h). Also see SAMHSA, *Federal Guidelines for Opioid Treatment Programs*, January 2015. Accessed at https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf on May 26, 2021. SAMHSA has also increased the flexibility in dispensing take-home doses of methadone and other MAT drugs during the COVID-19 pandemic. See SAMHSA, *Opioid Treatment Program (OTP) Guidance*, March 2020. Accessed at https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf on May 25, 2021.

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

[31] In 2020, 21,336 beneficiaries received take-home doses of methadone.

[32] Beneficiaries who receive buprenorphine tablets are able to receive take-home doses. A total of 1,253 beneficiaries did so.

[33] ASPE, *Psychosocial Supports in Medication-Assisted Treatment: Recent Evidence and Current Practice,* 2019. Accessed at https://aspe.hhs.gov/system/files/pdf/262031/MATPsychLR.pdf on May 26, 2021.

[34] SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder,* 2020.

[35] A total of 5,296 beneficiaries with opioid use disorder received both individual and group psychotherapy.

[36] Instead, buprenorphine waivered providers must be able to provide beneficiaries with referrals to case-management services, which can include behavioral health services. Since April 2021, providers who plan to treat up to 30 patients have been exempt from this requirement. See 86 F.R. 22439.

[37] SAMHSA, *Treatment Improvement Protocol 63: Medications for Opioid Use Disorder*, 2020.

[38] In an analysis of beneficiaries enrolled in Medicare Fee-For-Service, CMS found that about 56 percent of the beneficiaries with an opioid use disorder also had anxiety and about 52 percent had depressive disorder. See CMS, *Medicare Fee-For-Service Beneficiaries with Opioid Use Disorder in 2018: Disparities in Prevalence by Beneficiary Characteristics*, December 2020. Accessed at https://www.cms.gov/files/document/oud-disparities-prevalence-2018-medicare-ffs-dh-002.pdf on September 2, 2021.

[39] Section 2001 of the SUPPORT Act removed geographic originating site requirements for telehealth for the treatment of substance use disorders and co-occurring mental health disorders effective July 1, 2019. It also made an individual's home a permissible originating site. P.L. No. 115-271 § 2001.

[40] CMS, *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, May 2021. Accessed at https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf on May 25, 2021.

[41] 84 F.R. 62674. Beginning in 2021, these bundled payments were expanded to include the treatment of all substance use disorders. See 85 F.R. 84643.

[42] 42 C.F.R. § 8.12(f).

[43] CMS requires opioid treatment programs to use a Place of Service code specific to opioid treatment programs (i.e., Place of Service code "58") instead of denoting a telehealth-specific Place of Service code (i.e., Place of Service code "02") on claims submitted to Medicare. CMS has continued to instruct opioid treatment programs to use this opioid treatment program-specific Place of Service code during the COVID-19 Public Health Emergency. See CMS, *Billing & Payment, COVID-19: CMS Allowing Audio-Only Calls for OTP Therapy, Counseling, and Periodic Assessments*, January 2021.

[44] During the COVID-19 Public Health Emergency, CMS instructed other health care providers delivering services via telehealth to use a modifier (modifier "95") specific to telehealth on their claims. CMS, *COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing*, March 2020. Accessed at https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf on May 25, 2021. Additional modifiers that indicate telehealth include GT and GQ.

[45] Kansas had slightly more providers with 64 per 1,000 Medicare beneficiaries with opioid use disorder, which was the 12th lowest rate in the country.

[46] OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020. Also see OIG, *Behavioral Health—Medication-Assisted Treatment Viewer*.

[47] Florida, Texas, Nebraska, and Idaho each had less than 0.8 opioid treatment programs per 1,000 Medicare beneficiaries with opioid use disorder. These States were in the lowest one-quarter of States in terms of the number of programs per beneficiary. No opioid treatment programs enrolled in the Medicare program are in either Wyoming or South Dakota. North Dakota had a higher number of opioid treatments programs, with 3.3 per 1,000 Medicare beneficiaries with opioid use disorder. These counts include Medicare-enrolled opioid treatment programs.

[48] Note that Medicare data combine race and ethnicity and allow for only one response. Furthermore, we did not include information on American Indian/Alaska Native beneficiaries because of limitation. This analysis uses the race and ethnicity information from Medicare's enrollment database, which is based on data collected from the Social Security Administration and an algorithm. Although this information is currently the best available for the entire Medicare beneficiary population, comparisons to self-reported data (available in certain, limited circumstances) show that race and ethnicity is still misclassified for some beneficiaries. In particular, Medicare beneficiaries with a race and ethnicity of American Indian/Alaska Native, Asian/Pacific Islander, or Hispanic are more likely to be misclassified. For a fuller discussion about the data, please see our forthcoming report *Medicare Data on Race and Ethnicity*, OEI-02-21-00100.

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

[50] Over time, patients can receive up to one month's worth of take-home doses.

[51] SAMHSA, *The Opioid Crisis and The Black/African American Population: An Urgent Issue*, April 2020. Accessed at https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-05-02-001_508%20Final.pdf on June 21, 2021. Also see SAMHSA, *The Opioid Crisis and The Hispanic/Latino Population: An Urgent Issue*, July 2020. Accessed at https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-05-02-002_0.pdf on June 21, 2021.

[52] 42 C.F.R. § 423.315(d).

[53] 84 F.R. 62665; 42 C.F.R. § 410.67(e).

[54] The new Practice Guidelines for Prescribing Buprenorphine exempt providers who plan to treat up to 30 patients from some of the requirements related to training, counseling, and other services. See 86 F.R. 22439. Also, in 2021 CMS's Center for Medicare and Medicaid Innovation implemented a demonstration program, Value in Opioid Use Disorder Treatment that is intended to increase access, improve outcomes, and reduce Medicare expenditure. CMS, *Value in Opioid Use Disorder Treatment Demonstration*. Accessed at https://innovation.cms.gov/innovation-models/value-in-treatment-demonstration on May 13, 2021.

[55] Section 2002 of the SUPPORT Act required that beginning January 1, 2020, annual wellness visits and initial preventative physical examinations include screening of potential substance use disorders—including opioid use disorder—and a review of any current prescriptions for opioids. CMS added this change to the Physician Fee Schedule for 2021. See 85 F.R. 85025.

[56] See 85 F.R. 84644.

[57] *Ibid*.

[58] OIG, *SAMHSA Is Missing Opportunities To Better Monitor Access to Medication-Assisted Treatment Through the Buprenorphine Waiver Program*, OEI-BL-20-00260, June 2021.

[59] The Medicare Find & Compare website is available at https://www.medicare.gov/care-compare/.

[60] We conducted this analysis based on Medicare data available as of July 21, 2021.

[61] To identify opioid treatment programs, we used CMS's Provider Enrollment, Chain, and Ownership System and CMS's Opioid Treatment Program Providers dataset which is available at https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers. We identified providers who had SAMHSA waivers to prescribe buprenorphine in an office-based setting using DEA data.

[62] Although this information is currently the best available for the entire Medicare beneficiary population, comparisons to self-reported data (available in certain, limited circumstances) show that race and ethnicity are still misclassified for some beneficiaries.