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Medicare Could Have Saved $301.5 Million if Bundled Payment Rates for Opioid Use Disorder Treatment Services Had Reflected Services Provided to Enrollees

REPORT HIGHLIGHTS

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Medicare Could Have Saved $301.5 Million if Bundled Payment Rates for Opioid-Use-Disorder Treatment Services Had Reflected Services Provided to Enrollees

Why OIG Did This Audit

- To address the impact of the opioid crisis on Medicare enrollees, a Federal law authorized CMS to make bundled payments to opioid treatment programs (OTPs) for opioid-use-disorder (OUD) treatment services. CMS developed bundled payment rates for OUD treatment services with a requirement that at least one OUD treatment service be provided to an enrollee during a 7-day episode of care.
- As part of OIG's oversight of the stewardship of Federal funds used to combat the opioid crisis, we performed this audit to identify whether vulnerabilities existed related to payments for OUD treatment services and to provide information to CMS to use for future rulemaking and policy development.
- This audit compared the bundled payments for OUD treatment services with payment amounts that we calculated for individual OUD treatment services provided to enrollees during the corresponding episode of care.

What OIG Found

- For 100 sample items, bundled payments for 89 sample items were higher than the OIG-calculated payment amounts based on the OUD services actually provided by OTPs to enrollees.
- Bundled payments generally exceeded OIG-calculated payment amounts because CMS's methodology to determine bundled payment rates did not reflect the combination of specific OUD treatment services and the frequency of treatment services that OTPs provided to enrollees during an episode of care.
- On the basis of our sample results, we estimated that Medicare could have saved $301.5 million (53 percent of $564.6 million in total payments) if the bundled payments developed by CMS had reflected the types and frequency of OUD treatment services provided to enrollees.

What OIG Recommends

We made three recommendations to CMS, including that it use the results of our audit or gather additional information on the combination of OUD treatment services and the frequency of each type of treatment service provided to Medicare enrollees, and consider revising its methodology for determining the nondrug component of weekly bundled payment rates. The full recommendations are in the report.

CMS concurred with one recommendation and described actions it had taken and planned to take to address that recommendation. However, CMS did not concur with our remaining two recommendations.

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INTRODUCTION

WHY WE DID THIS AUDIT

The United States faces a nationwide public health emergency due to the opioid crisis. The high potential for misuse of opioids has led to alarming trends across the country, including record numbers of people developing opioid use disorder (OUD).[1] According to a survey conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2023, of people aged 12 or older, an estimated 8.9 million people misused opioids, and an estimated 5.7 million people had an OUD.[2]

To address the impact of the opioid crisis on individuals enrolled in Medicare Part B (enrollees), the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) amendments provided enrollees with Medicare coverage for OUD treatment services furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020.[3] The SUPPORT Act also authorized the Centers for Medicare & Medicaid Services (CMS) to make bundled payments to OTPs for OUD treatment services during an episode of care as defined by the Secretary of Health and Human Services (the Secretary).[4] An episode of care is 1 week long (i.e., 7 days in a row).[5] To implement the SUPPORT Act, CMS established Medicare requirements for OUD treatment services furnished by OTPs, including the requirement that an OTP furnish at least one service in order to bill for a bundled payment.[6]

As part of the Office of Inspector General's (OIG's) oversight of the stewardship of Federal funds used to combat the opioid crisis and the quality of care provided to individuals diagnosed with an OUD, we performed this audit to identify whether vulnerabilities existed related to

[1] An OUD is defined as "a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opioids despite significant opioid-induced problems" (42 CFR § 8.2). Following our audit period, a final Federal rule modified certain provisions of 42 CFR § 8.2 (89 Fed. Reg. 7528 (Feb. 2, 2024)). Any references to definitions codified in 42 CFR § 8.2 reflect references that were in effect during our audit period.

[2] SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2023 National Survey on Drug Use and Health*. Accessed on Feb. 20, 2025. The survey was based on interviews conducted from January through December 2023 and asked interviewees about their substance use in the 12 months before the interview.

[3] P.L. No. 115-271, § 2005, enacted on Oct. 24, 2018. Section 2005(c)(2) of the SUPPORT Act amended section 1834 of the Social Security Act by adding a new subsection (w).

[4] Social Security Act § 1834(w)(1). CMS makes a bundled payment to cover multiple services provided to an enrollee during a specific period rather than paying for each service separately. CMS refers to the multiple services included in the bundled payment as a "weekly bundle."

[5] 42 CFR § 410.67(b).

[6] 42 CFR § 410.67.

Medicare Part B payments for OUD treatment services and to provide information to CMS that it could use for future rulemaking and policy development.[7]

OBJECTIVES

Our objectives were to: (1) compare the bundled payments for OUD treatment services with payment amounts that we calculated for individual OUD treatment services that were provided to Medicare enrollees during the corresponding episode of care by determining the types and frequency of OUD treatment services and (2) determine whether OUD treatment services provided to enrollees complied with certain Medicare requirements.

BACKGROUND

Medicare Program

The Medicare program provides health insurance coverage to people aged 65 and over, people with certain disabilities, and people with end-stage renal disease. Medicare Part B provides medical insurance for medical and other health services, including OUD treatment services furnished by OTPs. CMS administers the Medicare program.

Opioids and Treatment for Opioid Use Disorder (OUD)

Opioids reduce the intensity of pain signals and feelings of pain. (Examples of opioids are morphine and fentanyl.) Prescription opioids are generally safe when taken for a short period and as directed by a doctor. Because opioids produce euphoria in addition to pain relief, they can be misused and lead to development of an OUD. An effective treatment of OUD is the use of medication in combination with behavioral health services.

The Food and Drug Administration (FDA) has approved three medications to treat OUD: buprenorphine, naltrexone, and methadone.[8] These medications relieve the withdrawal symptoms and psychological cravings that cause chemical imbalances in the body. Behavioral health services are intended to help individuals with an OUD achieve and sustain remission and recovery. The services may include structured, professionally administered clinical interventions (e.g., psychotherapy, counseling, and peer support services) and can be delivered in person, or remotely via telehealth or telemedicine.

[7] For a list of OIG's reports and information related to the opioid crisis, see OIG's Featured Topic "Combating the Opioid Epidemic."

[8] According to SAMHSA, buprenorphine reduces the effects of physical dependency on opioids, such as withdrawal symptoms. Naltrexone blocks the effects of opioids. Methadone reduces opioid cravings and withdrawals, blocking the effects of opioids.

Opioid Treatment Programs' Furnishing of OUD Treatment Services

Federal regulations define an OTP as a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.[9, 10] OTPs must be certified by SAMHSA, be accredited by a SAMHSA-approved accrediting body, comply with all pertinent State laws and regulations, and register with the Drug Enforcement Agency.[11] OTPs must provide treatment for OUD in accordance with Federal opioid treatment standards and comply with these standards as a condition of certification.[12]

An individual may be admitted to an OTP for maintenance or detoxification treatment.[13] OTPs are required to provide counseling, vocational, educational, and other treatment services.[14] For each individual admitted for treatment, an OTP must conduct initial and periodic assessments and prepare a treatment plan.[15] In addition, an OTP must conduct at least eight random drug tests per year per individual.[16]

An OTP must ensure that medications are administered or dispensed only by a physician licensed under the appropriate State law and registered under the appropriate State and

[9] 42 CFR § 8.2.

[10] An opioid agonist is a drug that activates opioid receptors in the brain, resulting in a similar opioid effect, such as reducing feelings of pain.

[11] Social Security Act § 1861(jjj)(2) and 42 CFR § 8.11. Following our audit period, a final Federal rule modified certain provisions of 42 CFR § 8.11 (89 Fed. Reg. 7528 (Feb. 2, 2024)). This report refers to Federal requirements that were in effect during our audit period.

[12] Federal opioid treatment standards are codified at 42 CFR § 8.12. SAMHSA published a final rule, which went into effect after our audit period on Apr. 2, 2024, that modified certain provisions of 42 CFR § 8.12 (89 Fed. Reg. 7528 (Feb. 2, 2024)). This report refers to Federal opioid treatment standards that were in effect during our audit period.

[13] 42 CFR § 8.12(e). Maintenance treatment "means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid use disorder" (42 CFR § 8.2). Detoxification treatment "means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical and psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within [the detoxification treatment] period" (42 CFR § 8.2). Regulations effective after our audit period use the term "continuous medication treatment" to describe maintenance treatment and the term "withdrawal management" to describe detoxification treatment.

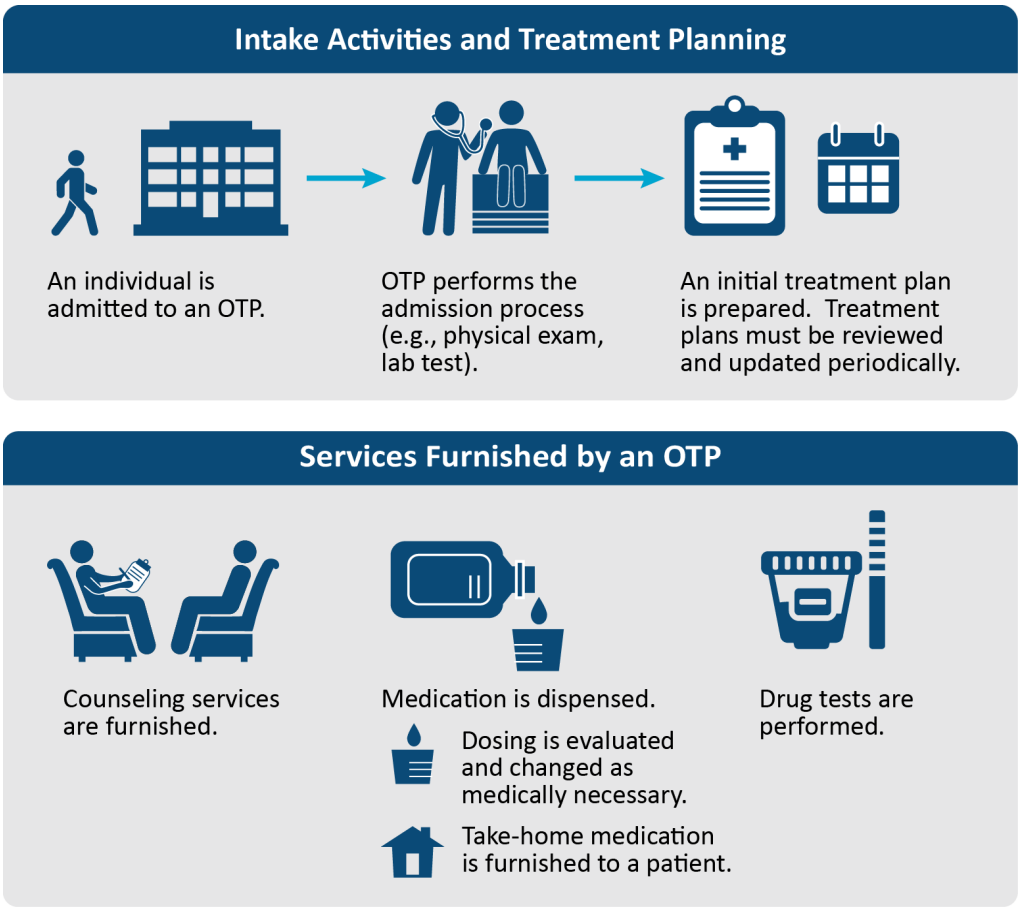
[14] 42 CFR § 8.12(f)(1).

[15] 42 CFR § 8.12(f)(4). SAMHSA published a final rule, which went into effect after our audit period on Apr. 2, 2024, that modified certain provisions of 42 CFR § 8.12 (89 Fed. Reg. 7528 (Feb. 2, 2024)). Regulations effective after our audit period use the term "care plan." This report uses the term "treatment plan" to be consistent with 42 CFR § 410.67 and the regulations that were in effect during our audit period.

[16] 42 CFR § 8.12(f)(6).

Federal laws or by an agent of such physician (supervised by and under the order of the physician).[17] A patient admitted to an OTP takes medications for OUD under the supervision of a physician. After a physician determines that the enrollee can handle opioid drugs without supervision, the enrollee may be allowed to take medications at home between OTP visits. Federal opioid treatment standards refer to such use of medication as "unsupervised or take-home use."[18] Figure 1 shows an OTP's general process for furnishing OUD treatment services.

Figure 1: An Opioid Treatment Program's General Process for Furnishing OUD Treatment Services



Medicare Part B Bundled Payments for OUD Treatment Services

Section 2005 of the SUPPORT Act established the Medicare Part B benefit for OUD treatment services furnished by OTPs and required that one or more bundled payments be used to pay for

[17] 42 CFR § 8.12(h)(1).

[18] 42 CFR § 8.12(i).

these services.[19] CMS implemented section 2005 of the SUPPORT Act by establishing Federal regulations on Medicare coverage and payment of OUD treatment services furnished by OTPs on or after January 1, 2020.[20] Specifically, these regulations set the requirements for OTPs, the scope of OUD treatment services, and the methodology for determining the bundled payments (discussed in the next section).[21]

Generally, a bundled payment combines the payments for two separate components of OUD treatment services covered under Medicare Part B: a drug component covering the FDA-approved medications for OUD and a nondrug component covering the other OUD treatment services reflected in an enrollee's treatment plan.[22, 23] The nondrug component includes the following services: (1) the dispensing and administration of OUD medications, (2) substance use counseling, (3) individual and group therapy, and (4) toxicology testing (i.e., drug testing).[24]

CMS established nine Healthcare Common Procedure Coding System (HCPCS) codes (G2067 through G2075) for an OTP to use to bill for bundled payments.[25] For example, HCPCS code G2067 covers methadone and the services included in the nondrug component, while G2068 covers buprenorphine and the services included in the nondrug component. See Appendix B for a description of these HCPCS codes and the associated national Medicare bundled payment rates for calendar years (CYs) 2020, 2021, and 2022.[26]

[19] See footnote 3.

[20] 84 Fed. Reg. 62568 (Nov. 15, 2019); 42 CFR § 410.67.

[21] To participate in the Medicare program and receive payment, an OTP must be enrolled in Medicare, have in effect a certification by SAMHSA, be accredited by a SAMHSA-approved accrediting body, and have in effect a Medicare provider agreement with CMS (42 CFR § 410.67(c)).

[22] 42 CFR § 410.67(d).

[23] The bundled payment for an episode of care (i.e., treatment 7 days in a row) in which no medication is provided consists of a single payment for the nondrug component for all OUD treatment services reflected in an enrollee's treatment plan (42 CFR § 410.67(d)(2)).

[24] Medicare Part B also covers medication for the emergency treatment of opioid overdose and covers other nondrug services, including intake activities and assessments and overdose education furnished in conjunction with the medication for opioid overdose.

[25] HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

[26] Payments to OTPs vary based on geographic location. CMS also established eight HCPCS codes (G2076 through G2080, G1028, G2215, and G2216) for add-on services, such as take-home medication. Medicare reimburses OTPs separately for these services.

To bill for a bundled payment for an episode of care, an OTP must provide at least one OUD treatment service.[27] For example, if an OTP provides at least one service to an enrollee during an episode of care, e.g., dispensing of methadone, the OTP may receive the full bundled payment as reimbursement for the services covered by HCPCS code G2067.[28] CMS established the threshold of at least one service "in the interest of combating the opioid crisis and in the best interest of [enrollees]" and "to minimize barriers to OTPs enrolling in Medicare and beginning to furnish services to Medicare [enrollees]."[29]

CMS's Development of Bundled Payment Rates

CMS developed a methodology to determine the bundled payment rates for OUD treatment services provided to an enrollee during a weekly episode of care. To determine the bundled payment for each HCPCS code, CMS combined the separate payments for the drug component and the nondrug component into a single payment.[30]

Drug Component of a Bundled Payment

To calculate the payment for the drug component of a bundled payment, CMS generally used the average sales price (ASP) or the national average drug acquisition cost (NADAC) of the typical daily treatment dosage.[31, 32] For example, CMS used a typical 100-milligram daily dose for OUD treatment with methadone and a typical 16-milligram daily dose for OUD treatment with oral buprenorphine.[33]

[27] 42 CFR § 410.67(d)(3).

[28] HCPCS code G2067 is described as "medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled OTP)."

[29] 84 Fed. Reg. 62568, 62642 (Nov. 15, 2019).

[30] *Medicare Benefit Policy Manual,* chapter 17, § 40.1.1(F)(1).

[31] The ASP is a market-based price that reflects the weighted average of all manufacturer sales prices for a drug and includes all rebates and discounts that are privately negotiated between manufacturers and purchasers. The NADAC reflects the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs. For our audit period, the payment for methadone was calculated using the ASP, and the payment for oral buprenorphine was calculated using the NADAC.

[32] CMS identified the typical daily treatment dosage for each medication using the FDA-approved prescribing information or through a review of the published peer-reviewed literature (84 Fed. Reg. 62568, 62651 (Nov. 15, 2019)).

[33] 84 Fed. Reg. 62568, 62651 (Nov. 15, 2019).

Nondrug Component of a Bundled Payment

To calculate the payment for the nondrug component of a bundled payment, CMS identified OUD treatment services typically provided to enrollees. Specifically, CMS used:

- the reimbursement rates from the CY 2019 Medicare Physician Fee Schedule (PFS) for one psychotherapy service (30 minutes), one group psychotherapy service, and one substance use counseling service;[34]

- prorated reimbursement rates from the CY 2019 Clinical Laboratory Fee Schedule (CLFS) for presumptive and definitive drug testing services;[35] and

- an approximation of the average dispensing fees for oral medications used by State Medicaid programs.[36]

Table 1 on the following page shows how CMS calculated the nondrug component of the bundled payment for CY 2020 for weekly bundles with oral medication (e.g., HCPCS code G2067 (methadone, weekly bundle)) based on the sum of the reimbursement rates for the individual OUD treatment services (shown with their Current Procedural Terminology (CPT®)[37] and HCPCS codes) and an approximated dispensing fee.[38]

[34] For substance use counseling services, CMS used the nonphysician practitioner reimbursement rate for HCPCS code G0396 (Alcohol and/or substance (other than tobacco) abuse structured assessment and brief intervention 15 to 30 minutes) (84 Fed. Reg. 62568, 62658–62659 (Nov. 15, 2019)).

[35] Presumptive drug testing is used to determine the presence or absence of drugs in a urine sample. Definitive drug testing is used to identify specific medications, illicit substances, and metabolites.

[36] CMS stated there was no comparable Medicare Part B oral dispensing fee for medication for OUD treatment. CMS calculated the dispensing fee for oral medications using an approximation of the average of State Medicaid dispensing fees. The dispensing fee was not applicable to injectable or implantable drugs (84 Fed. Reg. 62568, 62659 (Nov. 15, 2019)). We did not review bundled payments for injectable or implantable drugs.

[37] CPT codes are developed by the American Medical Association for reporting medical services and procedures.

[38] 84 Fed. Reg. 62568, 62658–62659 (Nov. 15, 2019).

Table 1: CMS's Calculation of the CY 2020 Payment for the Nondrug Component of the Bundled Payment for Weekly Bundles With Oral Medication

CPT or HCPCS Code	Brief Description of CPT or HCPCS Code	Medicare Payment Rate or Fee
90832[39, 40]	Psychotherapy, 30 minutes with patient	$68.47
90853	Group psychotherapy	27.39
G0396	Counseling service	30.94
80305	Drug test, presumptive*	6.30
G0480	Drug test, definitive†	28.61
NA	Dispensing fee	10.50
Total Nondrug Payment Rate		**$172.21**

* The CLFS rate for a presumptive drug test for CY 2019 was $12.60. CMS prorated this rate by dividing it by 2 ($12.60/2 = $6.30) to reflect CMS's presumption that a presumptive test would be provided twice a month.

† The CLFS rate for a definitive drug test for CY 2019 was $114.43. CMS prorated this rate by dividing it by 4 ($114.43/4 = $28.61) to reflect CMS's presumption that a definitive drug test would be provided once a month.

CMS adjusted the nondrug component of the bundled payment by applying a geographic adjustment factor and the annually updated Medicare Economic Index.[41]

HOW WE CONDUCTED THIS AUDIT

Our audit covered 2.7 million Medicare Part B paid claim lines representing bundled payments totaling $564.6 million for OUD treatment services billed with HCPCS codes G2067 (weekly bundle with methadone), G2068 (weekly bundle with buprenorphine), and G2074 (weekly bundle without a drug) with dates of service from January 1, 2020, through September 30, 2022

[39] *CPT copyright 2019 American Medical Association. All rights reserved.*

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

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[41] A geographic adjustment factor is used to account for cost differences in furnishing services in differing localities (42 CFR § 414.26). The Medicare Economic Index is a measure of inflation associated with physician practice costs and general wage levels (42 CFR § 405.504(d)).

(audit period).[42] We decided to review these three HCPCS codes because they represented more than 99 percent of the total Medicare Part B bundled payments for our audit period.

We reviewed a random sample of 100 claim lines, which we refer to as "sample items." These sample items were associated with 79 different OTPs. For each sample item, we requested that the respective OTP identify all OUD treatment services (e.g., counseling services and drug testing services) that it provided to the enrollee during the episode of care and provide documentation related to those services, including the enrollee's treatment plan and medication orders.[43] We also requested that the OTPs complete a questionnaire to obtain information about how they provided OUD treatment services, including the methods they used to provide services (e.g., in person and via telehealth) and the types of medication they used to treat OUD (e.g., buprenorphine and methadone).

To address our first objective, for each sample item, we determined the type of drug, types of OUD treatment services, and frequency (i.e., number of services during an episode of care) of individual OUD treatment services that the OTP provided to the enrollee. After determining the individual OUD treatment services that the OTP provided to the enrollee, we calculated a revised payment amount for these services, which we refer to as the "OIG-calculated payment amount." We then computed the difference between CMS's bundled payment and the OIG-calculated payment amount to determine the differences between the types and frequency of OUD treatment services that OTPs actually provided during the episodes of care and the services included in CMS's bundled payment rate.[44]

To address our second objective, for each sample item, we reviewed whether the supporting documentation included a treatment plan and whether the treatment plan listed the frequency of services provided to the enrollee, e.g., counseling and psychotherapy services.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[42] The Medicare Part B claims data included a claim line for each bundled payment. We used the "Claim Line Allowed Charge Amount" field in these claims data to arrive at the total amount of $564,591,264. The "Claim Line Allowed Charge Amount" is the lesser of the submitted charge by a provider or the locality-adjusted rate published on the CMS website. The data we used were the most recent data available when we started our audit.

[43] Of the 100 sample items, 98 were for HCPCS code G2067 (OUD treatment with methadone) and 2 were for HCPCS code G2068 (OUD treatment with buprenorphine). None of the sample items were for HCPCS code G2074 (weekly bundle without a drug).

[44] Our calculation accounted for the OUD treatment services that the OTPs actually provided to the enrollees associated with our sample items. CMS's bundled payment included OUD treatment services that CMS considered were typically provided to enrollees during an episode of care.

Appendix A describes our audit scope and methodology, Appendix C describes our statistical sampling methodology, and Appendix D contains our sample results and estimates.

FINDINGS

Our comparison of the bundled payments for OUD treatment services and the types and frequency of individual OUD treatment services that were provided to Medicare enrollees showed that the bundled payments generally were higher than the OIG-calculated payment amounts for individual treatment services that OTPs provided to Medicare enrollees during the corresponding episode of care. In addition, some OUD treatment services provided to the enrollees did not comply with certain Medicare requirements.

Specifically, we found the following:

- For the 100 sample items, the bundled payments for 89 sample items were higher than the OIG-calculated payment amounts based on the OUD services actually provided by OTPs to enrollees; the bundled payments for 11 sample items were lower than the OIG-calculated payment amounts. In total, for the 100 sample items, the bundled payments were $21,216, and the OIG-calculated payment amounts were $9,901. The bundled payments generally exceeded the OIG-calculated payment amounts because CMS's methodology to determine the bundled payment rates did not reflect the combination of specific OUD treatment services and the frequency of treatment services that OTPs provided to enrollees during an episode of care. On the basis of our sample results, we estimated that Medicare could have saved $301.5 million (53 percent of $564.6 million in total payments) if the bundled payment rate methodology developed by CMS had reflected the types and frequency of OUD treatment services provided to Medicare enrollees.[45]

- Of the 100 sample items, 10 included OUD treatment services provided to enrollees that did not comply with certain Medicare requirements. Specifically, of these 10 sample items, 3 sample items did not have an associated treatment plan covering the episode of care and 7 sample items had an associated treatment plan that did not indicate the frequency at which an enrollee was to receive counseling or other behavioral health services. CMS's lack of monitoring activities to identify whether OUD treatment services were properly documented in enrollees' treatment plans contributed to these deficiencies. On the basis of our sample results, we estimated that Medicare made 266,446 bundled payments (10 percent of the total 2.7 million bundled payments) for episodes of care for which there was no associated treatment plan or for which the

[45] We estimated that Medicare could have saved $301,479,659. Our estimate accounted for the differences in payment amounts for the 100 sample items, including the payments for sample items that were higher and lower than the OIG-calculated payment amounts.

treatment plan did not comply with certain Medicare requirements.[46] Without properly documented treatment plans, enrollees may be at risk for poor treatment outcomes.

BUNDLED PAYMENTS FOR OUD TREATMENT SERVICES GENERALLY WERE HIGHER THAN OIG-CALCULATED PAYMENT AMOUNTS FOR SERVICES THAT OPIOID TREATMENT PROGRAMS PROVIDED TO ENROLLEES

CMS established nine HCPCS codes for OTPs to bill Medicare for OUD treatment services and assigned a bundled payment rate to each code by combining the payments for the drug (e.g., methadone) and nondrug (e.g., counseling service) components of OUD treatment services. To bill for one of the HCPCS codes, the OTP must have provided at least one service to the enrollee during the episode of care.[47]

For 89 sample items, the bundled payments were higher than the OIG-calculated payment amounts. For the remaining 11 sample items, the bundled payments were lower than the OIG-calculated payment amounts. The bundled payments for the 100 sample items totaled $21,216, and the OIG-calculated payment amounts for the 100 sample items totaled $9,901.

The following example describes the bundled payment that an OTP received when providing only medication services and the difference between the bundled payment and the OIG-calculated payment amount for the same services.

Example: Bundled Payment to an OTP for OUD Treatment Services Exceeded the OIG-Calculated Payment When the OTP Provided 7 Days of Medication and No Other Services

An OTP received a bundled payment of $208.54 for an enrollee's episode of care in CY 2022. During the episode of care, the OTP dispensed 7 daily doses of oral medication (methadone) to the enrollee, including 6 daily doses for take-home use. The OTP did not provide any other OUD treatment services to the enrollee. Based on the services that the OTP provided during the episode of care, we calculated the payment to be $47.82 ($37.38 for the drug component combined with $10.44 for the nondrug component (medication-dispensing fee)). We determined that the bundled payment the OTP received exceeded the OIG-calculated payment for the services by $160.72 (bundled payment of $208.54 less $47.82 for the drug component and dispensing fee).

[46] Because each of the 10 sample items had at least 1 OUD treatment service in the weekly bundle, we are not recommending recovery of the payments associated with the sample items or the estimated number of bundled payments for which there was no associated treatment plan or for which the treatment plan did not comply with certain Medicare requirements.

[47] 42 CFR § 410.67(d)(3); 84 Fed. Reg. 62568, 62642 (Nov. 15, 2019).

Although CMS had flexibility in determining the scope and frequency of treatment services provided by OTPs that were appropriate to include in the weekly bundled payment rates, the OUD treatment services that CMS factored into those rates did not reflect the combination of treatment services provided by OTPs during an episode of care. In addition, the nondrug component of the bundled payment did not reflect the frequency at which OUD treatment services were provided to enrollees. The following two sections detail these findings.

OUD Treatment Services That CMS Factored Into Bundled Payment Rates Did Not Reflect the Combination of Treatment Services That Were Provided by Opioid Treatment Programs During an Episode of Care

All 100 sample items had at least 1 OUD treatment service, e.g., dispensing of methadone, provided for the episode of care as required by CMS for the OTP to receive reimbursement for the full bundled payment. However, none of the sample items reflected all of the services that CMS factored into the bundled payment rates.[48] Table 2 on the following page shows the number of sample items for the different combinations of OUD treatment services provided to enrollees during the episodes of care.

[48] Table 1 shows all services included in the nondrug component of the weekly bundled payment.

Table 2: Combinations of OUD Treatment Services Provided to Enrollees for the 100 Sample Items

Combination of OUD Treatment Services	Number of Sample Items
Medication and Dispensing of Oral Medication (Dispensing)	**49**
Medication, Dispensing, and One Other OUD Treatment Service	
Medication, Dispensing, and Counseling Services	20
Medication, Dispensing, and Drug Testing Services (Definitive)	9
Medication, Dispensing, and Drug Testing Services (Presumptive)*	3
Medication, Dispensing, and Individual Psychotherapy Services†	2
Medication, Dispensing, and Group Psychotherapy	2
Subtotal	**36**
Medication, Dispensing, and Two or More OUD Treatment Services	
Medication, Dispensing, Counseling Services, and Drug Testing Services (Definitive)	7
Medication, Dispensing, Individual Psychotherapy Services, and Drug Testing Services (Definitive)	3
Medication, Dispensing, Group Psychotherapy or Counseling Services, and Drug Testing Services (Presumptive)	3
Medication, Dispensing, Group Psychotherapy or Counseling Services, Drug Testing Services (Presumptive), and Drug Testing Services (Definitive)	2
Subtotal	**15**
Total Number of Sample Items	**100**

* See footnote 35 for the definitions of definitive and presumptive drug testing.

† Our questionnaire for OTPs asked whether they provided counseling or psychotherapy services because some OTP documentation did not clearly indicate which services were provided. For example, if an OTP responded that it provided psychotherapy services, we categorized those services as psychotherapy.

Only 15 of 100 sample items had 2 or more OUD treatment services other than medication dispensing.

Of the 100 sample items, 49 sample items included only medication and medication dispensing, and 51 sample items included medication and at least 1 OUD treatment service other than medication dispensing. Of these 51 sample items, 36 had 1 OUD treatment service other than medication dispensing, and only 15 had 2 or more OUD treatment services other than medication dispensing.

The Nondrug Component of the Bundled Payment Did Not Reflect the Frequency at Which OUD Treatment Services Were Provided to Enrollees

For the 51 sample items that included a medication and at least 1 OUD treatment service other than medication dispensing, the nondrug component of the bundled payment did not reflect the frequency at which OTPs had provided OUD treatment services to enrollees during an episode of care. Figure 2 shows the types and frequency of OUD treatment services for the nondrug component that were provided during episodes of care and shows each payment rate as a percentage of the nondrug component payment for the 100 sample items.

Figure 2: Frequency of OUD Treatment Services in the Sample and the Percentage of the Nondrug Component Payment per Service Type

Type of OUD Treatment Service	Frequency of Services in the Sample* (100 Sample Items)	CY 2020 Payment Rate	Percentage of Nondrug Component Payment
Counseling service	31	$30.94	17.97%
Drug test, definitive†	21	28.61	16.61%
Drug test, presumptive†	8	6.30	3.66%
Psychotherapy with patient (individual psychotherapy)	5	68.47	39.76%
Group psychotherapy	4	27.39	15.90%
Dispensing fee††	96	10.50	6.10%
Total		**$172.21**	**100%**

Counseling and definitive drug testing services made up 34.58 (17.97 + 16.61) percent and were provided more often than other services.

Individual and group psychotherapy services made up 55.66 (39.76 + 15.90) percent but were rarely provided.

* Some OTPs provided more than one nonmedication service during an episode of care. See Table 2.

† Payment rates for drug tests were prorated as part of the nondrug component. See Table 1.

†† Of the 100 sample items, 4 were for take-home medication doses that were not dispensed during the episode of care.

For all 100 sample items, OTPs provided certain OUD treatment services more frequently than other services. Specifically, counseling and drug testing services were more frequently provided than individual and group psychotherapy services. Counseling and definitive drug testing services made up approximately 35 percent of the nondrug component of the weekly bundled payment rate. The least frequently provided services—individual psychotherapy and

group psychotherapy—represented approximately 56 percent of the payment for the nondrug component, even though the services were seldom provided during an episode of care.[49]

CMS's Methodology To Determine Bundled Payment Rates Did Not Reflect the Frequency at Which Opioid Treatment Programs Provided OUD Treatment Services to Enrollees

Bundled payments generally were higher than the OIG-calculated payment amounts for the corresponding episodes of care because CMS's methodology to determine the bundled payment rates did not reflect the frequency at which OTPs provided OUD treatment services to enrollees during an episode of care.

In its comments on a 2019 final rule, CMS stated that "for the purposes of valuation [of the weekly bundled payment], [CMS] assumed one substance use counseling service, one individual [psychotherapy] therapy session, one group [psychotherapy] therapy session per week and one toxicology test per month."[50] Also, in the final rule, CMS included in its weekly bundled payment rates two presumptive drug tests and one definitive test per month, which were included at prorated amounts; however, it did not prorate other services.[51] Furthermore, during its rulemaking process, CMS noted that the frequency of OUD treatment services would vary over time.

In response to our questions about CMS's review of the specific OUD treatment services provided during an episode of care, CMS officials stated that CMS monitored OTPs' billing of bundled payments but did not review the specific services that OTPs provided during an episode of care. In addition, according to the officials, section 1834(w) of the Social Security Act required CMS to create weekly bundles. CMS stated that it believed that developing additional codes, such as coding for medication-only services, would be a departure from the statutorily mandated bundled payment methodology and might require OTPs to implement burdensome administrative processes to determine when to bill the appropriate HCPCS codes. CMS stated that its goal "is to minimize barriers to OTPs enrolling in Medicare and beginning to furnish services to Medicare [enrollees]."

Medicare Could Have Saved an Estimated $301.5 Million

On the basis of our sample results, we estimated that Medicare could have saved $301,479,659 (53 percent of $564,591,264 in total payments) if the bundled payment rate methodology

[49] For CY 2023 and subsequent years, CMS adjusted the nondrug component of the bundled payment by including the CY 2019 Medicare PFS nonfacility rate for psychotherapy, 45 minutes with patient, instead of the rate for psychotherapy, 30 minutes with patient (87 Fed. Reg. 69404, 69774 (Nov. 18, 2022)). This adjustment increased the reimbursement rate of the nondrug bundle after our audit period.

[50] 84 Fed. Reg. 62568, 62641 (Nov. 15, 2019).

[51] 84 Fed. Reg. 62568, 62659 (Nov. 15, 2019). Also, see the notes to Table 1 for details on the prorated amounts for the presumptive and definitive tests.

developed by CMS had reflected the types and frequency of OUD treatment services provided to Medicare enrollees.

SOME SAMPLE ITEMS INCLUDED OUD TREATMENT SERVICES THAT DID NOT COMPLY WITH CERTAIN MEDICARE REQUIREMENTS

The bundled payment for an episode of care in which a medication is provided reflects payment for the applicable opioid medication (such as methadone or buprenorphine) and all other OUD treatment services in an enrollee's treatment plan.[52] An enrollee's treatment plan identifies the OUD treatment services and the frequency at which these services are to be provided.[53, 54] During the rulemaking process, CMS stated that "we expect [that] OTPs will ensure that treatment plans reflect the full scope of services expected to be furnished during an episode of care and will update treatment plans regularly to reflect changes."[55] In addition, OTPs are required to maintain a recordkeeping system that is adequate to document and monitor patient care.[56]

Of the 100 sample items, 10 included OUD treatment services provided to enrollees that did not comply with certain Medicare requirements. Specifically, of these 10 sample items, 3 sample items did not have an associated treatment plan covering the episode of care, and 7 sample items had an associated treatment plan that did not indicate the frequency at which the enrollee was to receive counseling or other behavioral health services. CMS's lack of monitoring activities to identify whether OUD treatment services were properly documented in enrollees' treatment plans contributed to these deficiencies. According to CMS officials, CMS relied on the existence of an OTP's certification to ensure that the OTP complied with treatment plan requirements.[57]

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[52] 42 CFR § 410.67(d)(2).

[53] 42 CFR § 8.12(f)(4). The regulation at 42 CFR § 8.12(f)(4) is incorporated under numbers (6) and (7) of the definition of "opioid use disorder treatment service" at 42 CFR § 410.67(b). The numbers under this definition were changed to Roman numerals (vi) and (vii) at 87 Fed. Reg. 69404, 70224 (Nov. 18, 2022), effective Jan. 1, 2023 (i.e., after our audit period). SAMHSA is responsible for issuing and modifying regulations related to OTP accreditation and standards for the treatment of OUD with medications for OUD at 42 CFR § 8.12. CMS issued regulations for Medicare coverage and payment of OUD treatment services furnished by OTPs at 42 CFR § 410.67.

[54] Treatment planning is a collaborative process in which professionals and a patient develop a written document that identifies important treatment goals; describes measurable, time-sensitive action steps toward achieving those goals with expected outcomes; and reflects a verbal agreement between a counselor and a client.

[55] 84 Fed. Reg. 62568, 62645 (Nov. 15, 2019).

[56] 42 CFR § 8.12(g)(1).

[57] OTP certification requires OTPs to comply with SAMHSA's Federal opioid treatment standards at 42 CFR § 8.12 (42 CFR § 8.11(a)(2)).

On the basis of our sample results, we estimated that Medicare made 266,446 bundled payments (approximately 10 percent of the total 2,664,461 bundled payments) for episodes of care for which there were no associated treatment plans or for which the treatment plans did not comply with certain Medicare requirements.[58] Enrollees may be at risk for poor treatment outcomes if they do not have properly documented treatment plans.

CONCLUSION

Although CMS developed the bundled payment rates based on OUD treatment services that CMS determined were typically provided by OTPs during an episode of care, the results of our audit showed that the services that CMS decided to include when developing those rates did not reflect the frequency of services that OTPs provided to enrollees. As a result, the bundled payments to OTPs generally were higher than the OIG-calculated payment amounts for the episodes of care associated with our sample. For 49 of 100 sample items, OTPs provided only medication and medication-dispensing services, and Medicare made the full bundled payments to the OTPs when enrollees did not receive other services that were covered by the bundled payments. According to CMS officials, creating additional bundled payment rates (i.e., rates for medication-only services) would be a departure from the statutorily mandated bundled payment methodology.[59]

CMS recognized that the frequency of OUD treatment services varies depending on an enrollee's treatment needs. CMS stated that it would monitor OTPs' billing for bundled payments given the low threshold of requiring at least one OUD treatment service to be provided to the enrollee during the episode of care. However, according to CMS, it had not reviewed the types and frequency of OUD treatment services that OTPs provided to Medicare enrollees during an episode of care.[60] Section 1834(w)(2) of the Social Security Act provides CMS with the authority to adjust its weekly bundles based on the type of medication provided, the frequency of services, the scope of services furnished, or other factors as CMS determines appropriate. CMS can use the results of our audit in evaluating its bundled payment methodology and consider revising that methodology to reflect the types and frequency of OUD treatment services that OTPs provided to enrollees during an episode of care.

In addition, the results of our audit showed that some OTPs could not provide documentation of treatment plans, or the treatment plans did not include the frequency of services to be

[58] Some OTPs provided various reasons for not properly documenting treatment plan services, while other OTPs did not explain why they did not have properly documented treatment plans. For example, one OTP official stated that the staff member who was responsible for developing an enrollee's treatment plan did not follow the OTP's procedures and was no longer employed by the OTP.

[59] Section 2005 of the SUPPORT Act required that one or more bundled payments be used to pay for OUD treatment services and stated that the Secretary may implement bundles based on the type of medication, the frequency of services, the scope of services, and other factors as the Secretary determines appropriate. Therefore, CMS has flexibility to design weekly bundled payment rates within the parameters of the SUPPORT Act.

[60] CMS provided this information to us on Apr. 12, 2024.

provided to enrollees. CMS did not perform any monitoring activities to identify whether it made bundled payments for OUD treatment services that were included in enrollees' treatment plans. Enrollees may be at risk for poor treatment outcomes if they do not have properly documented treatment plans.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services take the following actions to align its bundled payment rates with OUD treatment services provided to enrollees during an episode of care, which could have saved Medicare an estimated $301,479,659 during our audit period:

- Use the results of our audit or gather additional information on the combination of OUD treatment services and the frequency of each type of treatment service provided to Medicare enrollees, and consider revising its methodology for determining the nondrug component of the weekly bundled payment rates.

- Consider developing, within its statutory authority, additional HCPCS codes for the weekly bundles (e.g., codes reflecting services provided at lower frequencies).

We also recommend that the Centers for Medicare & Medicaid Services work with SAMHSA (or a designated agency) to perform monitoring activities to ensure OTPs have properly documented OUD treatment services in enrollees' treatment plans.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS concurred with our first recommendation and described actions it had taken and planned to take to address that recommendation. However, CMS did not concur with our second and third recommendations. After reviewing CMS's comments, we revised our second and third recommendations to address CMS's concerns regarding its statutory authority. We maintain that our recommendations, as revised, are valid.

CMS's comments are included in their entirety as Appendix E.

The following sections summarize CMS's comments and our responses.

CMS COMMENTS

CMS concurred with our first recommendation (that it consider revising its methodology for determining the nondrug component of the weekly bundled payment rates) and stated that it has monitored and collected data on the use of OTP services since the start of the benefit. CMS also stated that it will continue to monitor and collect data and may consider changes as appropriate in the future.

CMS did not concur with our second recommendation (that it consider developing additional HCPCS codes for the weekly bundles). CMS stated that the Social Security Act "requires the Secretary to make a bundled payment for the services that are furnished by an OTP to an individual during an episode of care" and that further stratification of payment and coding for these bundles appears inconsistent with that statutory direction.[61] CMS also noted that the potential savings identified in our report are predicated on an approximately 50-percent reduction in the Medicare payment amount for the base level of care provided by OTPs, making it less likely to improve Medicare enrollees' access to this kind of care. In addition, CMS stated that the payment rates for the component services addressed in our analysis correspond with Medicare payment amounts in other settings, and that these amounts may not correspond with typical costs involved in maintaining care at OTPs. CMS stated that, therefore, it does not believe it is appropriate to develop additional HCPCS codes for the weekly bundles at this time but will continue to consider the accuracy of the rates for future rulemaking.

CMS did not concur with our third recommendation (that it perform monitoring activities to ensure that Medicare makes bundled payments only when OTPs have properly documented OUD treatment services in enrollees' treatment plans). CMS stated that treatment plans are a SAMHSA requirement—not a CMS payment requirement.

OFFICE OF INSPECTOR GENERAL RESPONSE

We acknowledge the actions that CMS has taken and plans to take to address our first recommendation.

Regarding our second recommendation, we continue to recommend that CMS consider developing additional HCPCS codes for the weekly bundles. However, based on CMS's comments regarding its statutory authority, we revised the example in our recommendation and added that CMS consider developing additional HCPCS codes within its statutory authority. Further, with respect to CMS's statement that further stratification of payment and coding for bundles appears inconsistent with statutory direction, we maintain that, in considering the development of additional HCPCS codes, CMS may have other options to reflect the actual services being provided. For example, it could prorate psychotherapy services in a similar manner to toxicology services to reflect a frequency of treatment services that CMS expects OTPs would provide.[62] As described in the report, we found that OTPs provided only medication and medication-dispensing services for 49 of 100 sample items, while Medicare

[61] In the recommendation in our draft report, we included an example of CMS developing a HCPCS code for only medication and counseling service provided during an episode of care. In its comments, CMS noted that the Social Security Act defines OUD treatment services to include certain medications by an OTP as well as other services (e.g., counseling, therapy, and toxicology tests) and other items/services the Secretary deems appropriate.

[62] When calculating nondrug payment rates, CMS presumed that a presumptive drug test would be provided twice a month and a definitive drug test would be provided once a month. For the weekly bundled payment, CMS prorated the payment rate for these services based on the presumption that these types of drug testing would be furnished at these frequencies. (See Table 1 on page 8.)

made the full bundled payments to the OTPs even though enrollees did not receive other services covered by the bundled payments.

We acknowledge CMS's statement that the potential savings we identified are predicated on an approximately 50-percent reduction in the Medicare payment amount, making it less likely to improve Medicare enrollees' access; however, our audit was intended to provide an independent assessment of CMS's program as it related to bundled payments for OUD treatment services. Our methodology used statistically valid means to determine the potential cost savings amount based on the actual services provided to Medicare enrollees and the payment rates that CMS assigned to services included in the weekly bundled payment. Based on our findings and estimates, we maintain our recommendation that CMS consider developing additional HCPCS codes for the weekly bundles. Further, with respect to CMS's statement that the payment rates for the component services addressed in our analysis correspond with Medicare payment amounts in other settings, and that these amounts may not correspond with typical costs involved in maintaining care at OTPs, our analysis used the payment rates that CMS assigned to the services and used to develop the weekly bundle payment.

Regarding our third recommendation, CMS stated that treatment plans are a SAMHSA requirement, not a CMS payment requirement. If enrollees do not have properly documented treatment plans, enrollees may be at risk for poor treatment outcomes. Based on CMS's comments, we revised our recommendation to reflect that CMS should work with SAMHSA (or a designated agency) to ensure that OTPs have properly documented OUD treatment services in enrollees' treatment plans.

OTHER MATTERS

For CMS's use and future policy development, we collected information on: (1) the Medicare Part B payments for OUD treatment services with methadone and buprenorphine provided during our audit period and (2) the delivery methods of medication dispensing (in person or for take-home use) and counseling and psychotherapy services (in person or via two-way interactive audio or audio-video communication technology).

NINETY-SEVEN PERCENT OF MEDICARE PART B BUNDLED PAYMENTS FOR OUD TREATMENT SERVICES WITH MEDICATION INCLUDED PAYMENT FOR METHADONE TREATMENT

CMS established nine HCPCS codes (G2067 through G2075) for an OTP to use to bill for bundled payments. See Appendix B for a description of these HCPCS codes and the associated national Medicare bundled payment rates for CYs 2020, 2021, and 2022.

About 97 percent of Medicare Part B bundled payments for OUD treatment services with medication included payment for dispensing of methadone during an episode of care.[63] The remaining 3 percent of the bundled payments included payment for dispensing of buprenorphine.

Table 3 shows the breakdown of bundled payments during our audit period for OUD treatment services that included payments for dispensing of methadone and buprenorphine.

Table 3: Breakdown of Bundled Payments During Our Audit Period for OUD Treatment Services With Methadone and Buprenorphine

Calendar Year	No. of Bundled Payments for G2067 (Methadone)	No. of Bundled Payments for G2068 (Buprenorphine, oral)	Total No. of Bundled Payments
2020	821,598	21,114	842,712
2021	1,014,508	27,251	1,041,759
2022 (January–September)	689,153	17,362	706,515
Total	**2,525,259**	**65,727**	**2,590,986**
Percentage of No. of Payments	**97%**	**3%**	**100%**

In the questionnaire that we sent to 79 OTPs associated with the 100 sample items, we asked each OTP which medication options (i.e., methadone and buprenorphine) it provided to enrollees for OUD treatment services. Of the 79 OTPs, 14 provided methadone and stated that they did not provide buprenorphine. Of the 14 OTPs that did not provide buprenorphine, 13 OTPs provided the following reasons why they did not provide it:[64]

- Buprenorphine is offered through other means, e.g., in physician offices (five OTPs).
- The OTP plans to provide buprenorphine in the future (three OTPs).
- The OTP is strictly a methadone clinic (two OTPs).
- It is difficult for the OTP to ensure compliance with OTP standards when an enrollee can obtain a buprenorphine prescription from a non-OTP provider (one OTP).

[63] Only one of the nine HCPCS codes that CMS established is for methadone provided by OTPs. In office-based settings, OIG found that most Medicare enrollees with opioid use disorder received buprenorphine in 2022. OIG, *The Consistently Low Percentage of Medicare Enrollees Receiving Medication to Treat Their Opioid Use Disorder Remains a Concern* (OEI-02-23-00250), Dec. 11, 2023.

[64] The remaining OTP did not state a reason for not providing buprenorphine as a medication option.

- The OTP does not have a medical professional who is authorized to prescribe buprenorphine (one OTP).

- There is little interest in buprenorphine in the region where the OTP provided OUD treatment services (one OTP).

Of 79 OTPs we asked why enrollees used methadone instead of buprenorphine, 45 OTPs responded and provided the following reasons:

- The OTP determined that methadone is more effective for individuals with an OUD (20 OTPs).

- The OTP or the enrollee, or both, determined that methadone was a more beneficial treatment option for the enrollee (15 OTPs).

- Buprenorphine has a long abstinence period and requires enrollees to be in moderate withdrawal before starting OUD treatment (seven OTPs).[65]

- Enrollees chose methadone because it was the more common medication, enrollees did not want to go into withdrawal, or previous treatment with buprenorphine had failed (four OTPs).[66]

ALMOST HALF OF THE MEDICATION DISPENSED TO ENROLLEES ASSOCIATED WITH OUR SAMPLE WAS FOR TAKE-HOME USE

CMS included in its weekly bundled payment with methadone a dispensing fee ($10.50) using an approximation of the average dispensing fees under State Medicaid programs for a week of daily dispensing of methadone.[67]

On the basis of our review of OTPs' medication dosing logs, we determined that the enrollees associated with our 100 sample items had a total of 657 days of medication dispensed to them. Of these 657 days of medication dispensed, 332 days of medication (50.5 percent) was dispensed for in-person dosing, and 325 days of medication (49.5 percent) was dispensed for take-home use.

[65] An enrollee should abstain from using opioids for at least 12 to 24 hours before taking buprenorphine.

[66] The number of OTPs associated with these reasons is more than 45 because 1 OTP provided multiple reasons.

[67] 84 Fed. Reg. 62568, 62658–62659 (Nov. 15, 2019).

OF 39 SAMPLE ITEMS, 21 HAD COUNSELING AND PSYCHOTHERAPY SERVICES PROVIDED TO ENROLLEES VIA TELEHEALTH

CMS allowed OTPs to use two-way interactive audio-video communication technology (sometimes referred to as "telehealth") for substance use counseling and individual and group therapy.[68] CMS did not require OTPs to identify whether a bundled payment was for an episode of care that included services provided via telehealth.

Of the 100 sample items, 39 sample items included counseling services or psychotherapy services, or both. More than half of these sample items (21) included counseling or psychotherapy services provided via telehealth (audio or video, or both). The remaining 18 sample items included services provided in person.

Table 4 shows the delivery methods that OTPs associated with our sample used to provide counseling and psychotherapy services.

Table 4: Delivery Methods That Opioid Treatment Programs Associated With Our Sample Used To Provide Counseling and Psychotherapy Services

Delivery Method	Number of Sample Items
In person	**18**
Telehealth	
Audio	16
Audio and video	1
Audio or video (OTP did not specify)	4
Telehealth Subtotal	**21**
Total	**39**

[68] 42 CFR § 410.67(b)(3)–(4).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 2,664,461 Medicare Part B paid claim lines representing bundled payments totaling $564,591,264 for OUD treatment services with HCPCS codes G2067, G2068, and G2074 with dates of service from January 1, 2020, through September 30, 2022.[69] We decided to review these three HCPCS codes because they represented more than 99 percent of the total Medicare Part B bundled payments for our audit period.

We reviewed a random sample of 100 claim lines, which we refer to as "sample items."[70] For each sample item, we requested that the OTP identify all OUD treatment services (e.g., counseling services and drug testing services) that it provided to the enrollee during the episode of care and provide documentation related to those services, including the enrollee's treatment plan and medication orders. We also requested that the OTPs complete a questionnaire with questions about how they provided OUD treatment services, including the methods they used to provide services (e.g., in person and via telehealth) and the types of medication they used to treat OUD (e.g., methadone and buprenorphine). The questionnaire also included general questions about services provided via telehealth, medication options, and reasons that the OTP did not offer buprenorphine if applicable.

Because our audit compared the bundled payments for OUD treatment services with payment amounts that we calculated and CMS deferred to SAMHSA for the oversight of OTP treatment planning requirements, we determined that internal controls were not significant to our audit objectives. Therefore, we did not perform an internal control assessment. Rather, we gained an understanding of how CMS established bundled payment rates by reviewing the Federal Register and regulations, interviewing CMS officials, and obtaining written responses to our questions from CMS.

We assessed the reliability of data obtained from CMS's Integrated Data Repository (IDR) by: (1) considering prior data reliability assessments on data from the IDR and (2) performing electronic testing on the data, such as testing for missing data and looking for duplicate values. We determined that the data were sufficiently reliable for the purposes of this audit.

We conducted our audit from January 2023 to April 2025.

[69] See footnote 42.

[70] See footnote 43.

METHODOLOGY

To accomplish our objectives, we:

- reviewed applicable Federal laws, regulations, and CMS policy manuals and guidance regarding OUD treatment services and bundled payment rates;

- interviewed CMS officials and obtained written responses to our questions to gain an understanding of how bundled payment rates were calculated and how claims for OUD treatment services were billed;

- obtained nationwide claims data for OUD treatment services from CMS's IDR;

- identified a sampling frame of 2,664,461 Medicare Part B paid claim lines totaling $564,591,264 for OUD treatment services billed with HCPCS codes G2067, G2068, and G2074 with dates of service during our audit period;

- selected a random sample of 100 claim lines (Appendix C);

- sent a questionnaire to 79 OTPs associated with the 100 sample items and reviewed the OTPs' written responses and supporting documentation for the services provided during the episodes of care;

- for each sample item:

    - determined the type of drug, the types of OUD treatment services, and the number of individual OUD treatment services that the OTP provided to the enrollee;

    - calculated the revised amount for the nondrug component services by: (1) multiplying the number of individual OUD treatment services that the OTP provided to the enrollee during the episode of care by the associated PFS or CLFS reimbursement rates, (2) adding the approximated medication-dispensing fee, and (3) applying the geographic adjustment factor and Medicare Economic Index applicable to the sample item;[71]

    - determined the OIG-calculated payment amount by adding CMS's reimbursement amount for the drug component and the revised amount that we calculated for the nondrug component services;

[71] We also adjusted the OIG-calculated payment for each sample item to align with the PFS and CLFS reimbursement rates for the individual services that the OTP provided to the enrollee.

- calculated the difference between CMS's bundled payment and the OIG-calculated payment amount to estimate the effect of the variations in the types and frequency of OUD treatment services that the OTP provided during the episode of care; and

- reviewed whether the supporting documentation included a treatment plan and whether the treatment plan indicated the frequency at which an enrollee was to receive behavioral health services, e.g., counseling and psychotherapy services;

- on the basis of our sample results, estimated the:

  - total amount of the difference between the allowed amount for the weekly bundled claim lines and the OIG-calculated payment amounts for the OUD treatment services (Appendix D), and

  - total number and percentage of weekly bundled claim lines that included OUD treatment services that did not have properly documented treatment plans (Appendix D); and

- discussed the results of our audit with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: NATIONAL MEDICARE PAYMENT RATES FOR OUD WEEKLY BUNDLED SERVICES

HCPCS Code	Description of OTP Services Included in Bundled Payment	National Medicare Payment Rate for CY 2020*	National Medicare Payment Rate for CY 2021*	National Medicare Payment Rate for CY 2022*
G2067	Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	$207.49	$212.00	$215.67
G2068	Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	258.47	255.70	257.08
G2069	Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	1,757.29	1,820.07	1,880.05
G2070	Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	5,326.84	4,960.70	5,372.26
G2071	Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	427.32	433.30	442.40
G2072	Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	5,545.95	5,182.88	5,599.10

HCPCS Code	Description of OTP Services Included in Bundled Payment	National Medicare Payment Rate for CY 2020*	National Medicare Payment Rate for CY 2021*	National Medicare Payment Rate for CY 2022*
G2073	Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	$1,342.67	$1,410.06	$1,449.22
G2074	Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing	161.71	163.97	167.42
G2075	Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing	NA†	NA†	NA†

* National Medicare payment rates for CY 2020. Accessed on Feb. 20, 2025. National Medicare payment rates for CY 2021. Accessed on Feb. 20, 2025. National Medicare payment rates for CY 2022. Accessed on Feb. 20, 2025.

† There were no payment rates for HCPCS code G2075 because it was used for weekly bundles with new medication approved by the FDA but for which CMS had not finalized and priced a G code during the rulemaking cycle.

APPENDIX C: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

The sampling frame consisted of 2,664,461 paid Medicare Part B claim lines totaling $564,591,264 in Medicare-allowed amounts for OUD treatment services with HCPCS codes G2067, G2068, and G2074 with dates of service from January 1, 2020, through September 30, 2022.

SAMPLE UNIT

The sample unit was a claim line representing a bundled payment for a 7-day episode of care.

SAMPLE DESIGN AND SAMPLE SIZE

We selected a simple random sample of 100 claim lines (sample items).

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, Office of Audit Services (OAS) statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We sorted the items in the sampling frame by claim control number and claim line number and then consecutively numbered the items in the sampling frame. After generating the random numbers according to our sample design, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG-OAS statistical software to estimate the: (1) total amount of the difference between the allowed amount for the weekly bundled claim lines and the OIG-calculated payment amounts for the OUD treatment services and (2) total number and percentage of weekly bundled claim lines that included OUD treatment services that did not have properly documented treatment plans. We used this software to calculate the point estimate and the corresponding lower and upper limits of the two-sided 90-percent confidence interval.

APPENDIX D: SAMPLE RESULTS AND ESTIMATES

Table 5: Sample Details and Results for Differences Between Bundled Payment Amounts and OIG-Calculated Payment Amounts

Frame Size (Claim Lines)	Value of Total Bundled Payments in Sampling Frame	Sample Size	Value of Sample	No. of Sample Items That Had Differences Between Bundled Payment Amount and OIG-Calculated Payment Amount	Total Payment Difference Value in Sample
2,664,461	$564,591,264	100	$21,216	100	$11,315

Table 6: Estimated Total Difference Between Bundled Payment Amounts and OIG-Calculated Payment Amounts for OUD Treatment Services Provided to Enrollees During Episodes of Care in the Sampling Frame
(Limits Calculated at the 90-Percent Confidence Level)

Point estimate	$301,479,659
Lower limit	261,847,167
Upper limit	333,462,903

Table 7: Sample Details and Results for Claim Lines for OUD Treatment Services That Did Not Have an Associated Treatment Plan or Had an Associated Treatment Plan That Did Not List the Frequency of Services

Frame Size (Claim Lines)	Sample Size	No. of Sample Items That Did Not Have a Properly Documented Treatment Plan
2,664,461	100	10

Table 8: Estimated Number and Percentage of Claim Lines for OUD Treatment Services in the Sampling Frame That Did Not Have an Associated Treatment Plan That Was Properly Documented
(Limits Calculated at the 90-Percent Confidence Level)

	Estimated No. of Claim Lines	Percentage
Point estimate	266,446	10.0
Lower limit	147,249	5.5
Upper limit	436,216	16.4

APPENDIX E: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: May 27, 2025

TO: Amy J. Frontz
Deputy Inspector General for Audit Services

FROM: Dr. Mehmet Oz
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicare Could Have Saved $301.5 Million if Bundled Payment Rates for Opioid-Use-Disorder Treatment Services Had Reflected Services Provided to Enrollees*, A-09-23-03002

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report on Medicare bundled payments in Opioid Treatment Programs (OTPs). CMS is committed to ensuring that Medicare beneficiaries who have an opioid use disorder (OUD) have access to appropriate and high-quality treatment, including services provided by OTPs. Ensuring access to these benefits while also maintaining payment integrity 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.

Section 1834(w) of the Social Security Act (the Act) instructs the Secretary to make a bundled payment for the services that are furnished by an OTP to an individual during an episode of care. Section 1861(jjj) of the Act defines OUD treatment services to include certain opioid treatment medications furnished by an OTP, as well as other services such as substance use counseling, individual and group therapy, toxicology tests, and other items/services the Secretary determines are appropriate. OTPs must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), accredited by a SAMHSA-approved accrediting body, comply with all pertinent State laws and regulations, and register with the Drug Enforcement Agency. They must also be enrolled in Medicare to be paid for these services for Medicare beneficiaries.

As required by statute, in the CY 2020 Physician Fee Schedule (PFS) final rule, CMS set the requirements for OTPs, the scope of OUD treatment services, and the methodology for determining the bundled payments. The threshold to bill a full episode is that at least one service was furnished (from either the drug or non-drug component) to the patient during the week that corresponds to the episode of care. CMS stated in the final rule that while we identified a set of services for purposes of calculating the payment rate for the weekly bundle, it is not a requirement for billing the bundled payment that all of those services be furnished in a given episode of care. In calculating the bundled rate amount, CMS considered the rates paid to individual practitioners under the PFS or Clinical Lab Fee Schedule (CLFS) for the services. In the interest of combating the opioid crisis and in the best interest of beneficiaries, CMS' goal was to minimize barriers to OTPs enrolling in Medicare and beginning to furnish services to Medicare beneficiaries. Therefore, CMS finalized the rates associated with the bundle of services to be reflective of an average case and recognized that there is a range of service intensity depending on the severity of a beneficiary's stage of treatment.

As OIG has found in prior reports, Medicare beneficiaries with an OUD may face barriers in accessing MOUD treatment. OIG has reported extensively on this topic, and had recommended that CMS take steps to increase the number of providers and opioid treatment programs for Medicare beneficiaries with opioid use disorder[1]. Changes to billing rules could increase administrative burden and may discourage OTPs from enrolling, or maintaining enrollment in Medicare, which would reduce access to care for beneficiaries. Fighting the opioid epidemic is a priority for CMS, and CMS remains committed to ongoing examination of its payment and coverage policies to ensure healthcare providers are enabled to execute best practices with respect to pain management and treatment of OUDs.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

CMS should use the results of our audit or gather additional information on the combination of OUD treatment services and the frequency of each type of treatment service provided to Medicare enrollees, and consider revising its methodology for determining the nondrug component of the weekly bundled payment rates.

CMS Response

CMS concurs with this recommendation. CMS has monitored and collected data on use of OTP services since the start of the benefit. As a result, CMS has undertaken rulemaking each year to clarify the benefit and add services. CMS will continue to monitor, collect data, and may consider changes as appropriate in the future. Given this, CMS suggests OIG close the recommendation as implemented.

OIG Recommendation

CMS should consider developing additional HCPCS codes for the weekly bundles (e.g., a code only for medication and a counseling service provided during an episode of care).

CMS Response

CMS does not concur with this recommendation. CMS appreciates the recommendation, especially with regard to the Agency's stewardship responsibilities. In the case of these particular payment structures, the Act requires the Secretary to make a bundled payment for the services that are furnished by an OTP to an individual during an episode of care. The Act defines OUD treatment services to include certain opioid treatment medications furnished by an OTP, as well as other services such as substance use counseling, individual and group therapy, toxicology tests, and other items/services the Secretary determines are appropriate. Further stratification of payment and coding for these bundles appears inconsistent with that statutory direction. Additionally, CMS respectfully points out that the conclusions regarding potential savings are predicated on an approximately 50 percent reduction in Medicare payment amount for the base level of care provided by OTPs, making it less likely to improve Medicare beneficiaries' access to this kind of care. Also, CMS notes that the payment rates for the component services addressed in the analysis correspond with Medicare payment amounts in other settings, and that these amounts may not correspond with typical costs involved in maintaining care at OTPs. Therefore, CMS does not believe it is appropriate to develop additional HCPCS codes for the

[1] see *Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder*, OEI-02-20-00390, and *Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries*, OEI-02-22-00390).

weekly bundles at this time but will continue to consider the accuracy of the rates for future rulemaking.

OIG Recommendation

CMS should perform monitoring activities to ensure that Medicare makes bundled payments only when OTPs have properly documented OUD treatment services in enrollees' treatment plans.

CMS Response

CMS does not concur with this response. Treatment plans are a SAMHSA requirement, but not a CMS payment requirement.[2] Regarding payment requirements, CMS has published detailed billing and claims processing information to ensure OTPs understand how to bill Medicare.[3]

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

[2] 42 CFR 8.12 (f)(4)

[3] https://www.cms.gov/medicare/payment/opioid-treatment-program/billing-payment; https://www.cms.gov/files/document/chapter-39-opioid-treatment-programs-otps.pdf

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