

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE MADE \$17.8 MILLION IN  
POTENTIALLY IMPROPER PAYMENTS FOR  
OPIOID-USE-DISORDER TREATMENT  
SERVICES FURNISHED BY  
OPIOID TREATMENT PROGRAMS**

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**August 2023  
A-09-22-03005**

# *Office of Inspector General*

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## Report in Brief

Date: August 2023

Report No. A-09-22-03005

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

To address the United States' opioid epidemic, section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act established a new Medicare Part B benefit category for opioid use disorder (OUD) treatment services furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020. As part of OIG's oversight of the integrity and proper stewardship of Federal funds used to combat the opioid crisis, we performed this audit to identify vulnerabilities, such as the potential for improper payments, for services covered in this new benefit category.

Our objective was to determine whether payments made to OTPs for OUD treatment services complied with Medicare requirements.

### How OIG Did This Audit

Our audit covered 2.1 million Medicare Part B claims for OUD treatment services provided to 40,067 Medicare enrollees from January 1, 2020, through September 30, 2021, for which Medicare paid \$364.1 million. A claim contained OUD treatment services for one or more weekly episodes of care or one or more add-on services.

We analyzed the claims data for OTPs' billing patterns for OUD treatment services. We obtained information from Medicare Administrative Contractors (MACs) about their claims adjudication systems and claims processing edits. We did not obtain or review documentation from OTPs, e.g., medical records.

## Medicare Made \$17.8 Million in Potentially Improper Payments for Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs

### What OIG Found

Payments made to OTPs for OUD treatment services may not have complied with Medicare requirements. Specifically, Medicare made up to \$17.8 million in potentially improper payments to OTPs, consisting of the following payments: \$10.4 million for claims for which a bundled payment was made for a weekly episode of care (i.e., a weekly bundle) that was covered by a payment for another weekly bundle for the same enrollee at the same OTP; \$5.1 million for take-home supplies of medication (i.e., methadone or buprenorphine) that were covered by other payments for take-home supplies of medication or by payments for weekly bundles that included medication; \$1.3 million for OUD treatment services that were claimed without an OUD diagnosis; and \$1 million in payments for intake activities that occurred a total of 14 or more times for the same enrollee during our audit period.

These potentially improper payments occurred because, among other causes, CMS did not instruct MACs to implement system edits to prevent OTPs from being paid for OUD treatment services covered by other Medicare payments for the same enrollee at the same OTP.

### What OIG Recommends and CMS Comments

We made six recommendations to CMS, including that CMS: (1) work with MACs and other Medicare contractors to determine whether claims billed by OTPs for OUD treatment services complied with Medicare requirements; (2) instruct MACs, based upon the results of this audit, to notify appropriate providers so that the providers can exercise reasonable diligence to identify, report, and return any overpayments, up to \$17.8 million, in accordance with the 60-day rule; and (3) instruct MACs to implement edits in their claims processing systems to prevent an OTP from being paid for two weekly bundles with the same service date for the same enrollee at the same OTP. The full text of our recommendations is shown in the report.

CMS concurred with four of six recommendations and provided information on actions that it planned to take to address these recommendations. CMS did not explicitly state whether it concurred with one recommendation. CMS did not concur with another recommendation and stated that our audit alone is not sufficient basis upon which CMS can support a 60-day-rule notice of overpayments to identified providers. We maintain that our recommendations are valid because we believe that this audit report constitutes credible information of potential overpayments.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

The United States currently 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).<sup>1</sup> According to a report issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2020, of people aged 12 or older, an estimated 10.1 million people misused opioids in the prior year, and an estimated 1.6 million people had an OUD in 2019.<sup>2</sup> Furthermore, from 2020 to 2021, the number of opioid-related overdose deaths in the United States increased from an estimated 70,029 to an estimated 80,816.<sup>3</sup> The Medicare population, including individuals who are eligible for both Medicare and Medicaid, has the fastest growing prevalence of OUD compared with the general adult population.<sup>4</sup>

To address the Nation's opioid epidemic, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) established a new Medicare Part B benefit category for OUD treatment services furnished by opioid treatment programs (OTPs) beginning on or after January 1, 2020.<sup>5</sup> As part of the Office of Inspector General's (OIG's) oversight of the integrity and proper stewardship of Federal funds used to combat the opioid crisis, we performed this audit to identify vulnerabilities, such as the potential for improper payments, for services covered in this new benefit category.

### OBJECTIVE

Our objective was to determine whether payments made to OTPs for OUD treatment services complied with Medicare requirements.

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<sup>1</sup> Federal regulations (42 CFR § 8.2) define OUD as “a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opioids despite significant opioid-induced problems.”

<sup>2</sup> SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health*. Available online at <https://www.samhsa.gov>. Accessed on Feb. 8, 2023.

<sup>3</sup> Centers for Disease Control and Prevention, National Center for Health Statistics, press release dated May 11, 2022.

<sup>4</sup> 84 Fed. Reg. 62568, 62630 (Nov. 15, 2019).

<sup>5</sup> P.L. No. 115-271, § 2005, enacted Oct. 24, 2018.

## **BACKGROUND**

### **The Medicare Program**

The Medicare program provides health insurance to people aged 65 and over, people with certain disabilities, and people with end-stage renal disease. Medicare Part B provides insurance for preventative and medical services, including OUD treatment services furnished by OTPs, that are not covered under Medicare Part A. (Part A generally covers care in a hospital, skilled nursing facility, or hospice, and covers certain home health services.)

The Centers for Medicare & Medicaid Services (CMS) administers Medicare. CMS contracts with Medicare Administrative Contractors (MACs) for 12 defined geographic areas (i.e., jurisdictions) to, among other things, process and pay Medicare Part B claims, conduct reviews and audits, safeguard against improper payments, and educate providers on Medicare billing requirements. Claims processing includes receiving claims from providers, performing claims edits, and adjudicating claims.<sup>6</sup>

### **Opioids and Treatment for Opioid Use Disorder**

Opioids are natural (e.g., morphine), synthetic (e.g., fentanyl), or semisynthetic (e.g., oxycodone and heroin) chemicals that interact with opioid receptors on nerve cells in the body or brain and reduce the intensity of pain signals and feelings of pain. Prescription opioids are generally safe when taken for a short time and as directed by a doctor, but because they produce euphoria in addition to pain relief, they can be misused and have addiction potential. OUD, sometimes called opioid abuse or dependence (or opioid addiction), is a problematic pattern of opioid use that causes significant impairment or distress.

According to SAMHSA, an effective treatment of OUD is the use of medication in combination with counseling and behavioral therapies. OUD can be treated in a hospital or office setting or in a nonresidential OTP facility.

The Food and Drug Administration (FDA) has approved three medications to treat OUD: buprenorphine, naltrexone, and methadone.<sup>7</sup> These medications relieve the withdrawal symptoms and psychological cravings that cause chemical imbalances in the body. Buprenorphine can be prescribed by any practitioner who has a current Drug Enforcement Administration (DEA) registration that includes the authority to prescribe Schedule-III

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<sup>6</sup> An edit is programming within the standard claims processing system that selects certain claims; evaluates or compares information on the selected claims or other accessible sources; and depending on the evaluation, takes action on the claims, such as paying them in full, paying them in part, or suspending them for manual review.

<sup>7</sup> Buprenorphine and methadone are opioid agonist treatment medications, and naltrexone is an opioid antagonist treatment medication. An agonist is a drug that activates opioid receptors in the brain, resulting in a similar opioid effect, such as reducing feelings of pain. An antagonist is a drug that blocks the effects of opioids by attaching to the opioid receptors without activating them. Antagonists cause no opioid effect and block full agonist opioids.

controlled substances as permitted by applicable State law.<sup>8</sup> Naltrexone can be prescribed and administered by any practitioner licensed to prescribe medications. However, methadone can be dispensed and administered only by SAMHSA-certified OTPs because it is a Schedule-II controlled substance, which is highly regulated.<sup>9</sup>

## **Opioid Treatment Programs**

Federal regulations define an OTP as “a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication” (42 CFR §§ 8.2 and 410.67). OTPs must be certified by SAMHSA and accredited by a SAMHSA-approved accrediting body, comply with all pertinent State laws and regulations, and register with DEA (Social Security Act (the Act) § 1861(jjj)(2); 42 CFR § 8.11). OTPs must provide treatment for OUD in accordance with Federal opioid treatment standards (42 CFR § 8.12) and must comply with these standards as a condition of certification.

A patient may be admitted to an OTP for short- or long-term detoxification treatment or maintenance treatment.<sup>10</sup> An OTP must ensure that a patient is admitted to maintenance treatment by qualified personnel, e.g., a physician, who have determined, based on accepted medical criteria, that the patient is currently addicted to an opioid drug. In addition, an OTP must provide at least eight random drug tests per year per patient.<sup>11</sup>

OTPs are required to provide patients with services such as initial and periodic assessment services and counseling, vocational, educational, and other treatment services. To determine the most appropriate combination of services and treatments, each patient accepted for treatment at an OTP must be assessed initially and periodically by qualified personnel.<sup>12</sup>

OTPs 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 Federal laws or

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<sup>8</sup> DEA or Congress classifies a drug into one of five schedules depending on the drug’s acceptable medical use and the drug’s abuse or dependency potential. Schedule III drugs have a moderate to low potential for physical and psychological dependence.

<sup>9</sup> Schedule II drugs are classified as having a high potential for abuse, which may lead to severe psychological or physical dependence.

<sup>10</sup> Detoxification treatment is “the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or 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 such period” (42 CFR § 8.2). Maintenance treatment is “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).

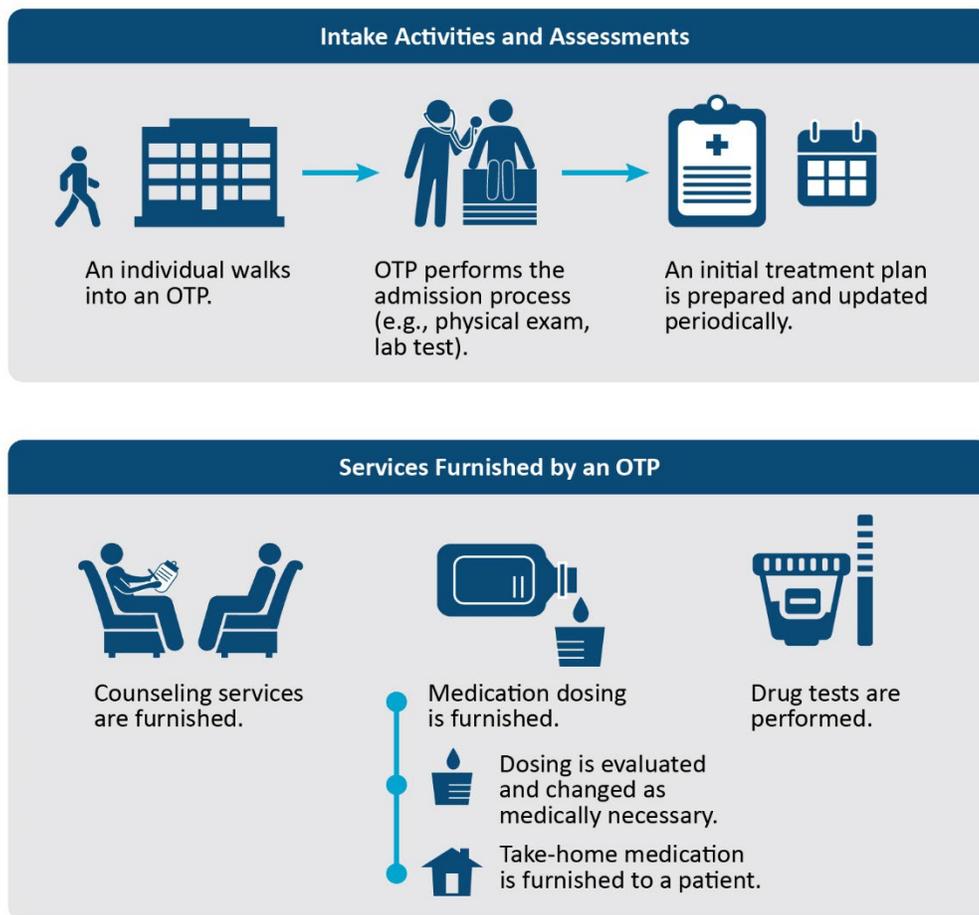
<sup>11</sup> 42 CFR § 8.12(f)(6).

<sup>12</sup> The initial assessment must include preparation of a treatment plan that includes the patient’s short-term goals and tasks that the patient must perform to complete those goals (42 CFR § 8.12(f)(4)).

by an agent of such physician (supervised by and under the order of the physician).<sup>13</sup> A patient admitted to an OTP takes medications for OUD under the supervision of a physician. After a period of stability, the patient 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.”<sup>14</sup>

Figure 1 shows an OTP’s general process for furnishing OUD maintenance treatment services.

**Figure 1: An Opioid Treatment Program’s General Process for Furnishing Maintenance Treatment Services**



<sup>13</sup> 42 CFR § 8.12(h)(1). A physician must be appropriately licensed by the State to dispense covered medications and possess a waiver under 21 U.S.C. section 823(g)(2) (42 CFR § 8.2).

<sup>14</sup> 42 CFR § 8.12(i). To limit the potential for diversion of buprenorphine and methadone to the illicit market, generally, take-home medication may be furnished to a patient if the medical director (i.e., a physician who assumes responsibility for administering all medical services performed by an OTP) has determined that the patient is responsible in handling opioid medications and has documented in the patient’s medical record the physician’s rationale for permitting the patient’s use of take-home medication (e.g., absence of recent abuse of drugs and length of time in maintenance treatment).

## **Medicare Part B Coverage of Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs**

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)). Historically, OTPs could not enroll as providers in Medicare or be paid for services furnished to Medicare enrollees. Section 2005 of the SUPPORT Act established the Medicare Part B benefit for OUD treatment services furnished by OTPs.<sup>15, 16</sup> CMS implemented section 2005 of the SUPPORT Act, effective January 1, 2020, by establishing Federal regulations on Medicare coverage and payment of OUD treatment services furnished by OTPs (42 CFR § 410.67).<sup>17</sup> Specifically, these regulations set forth the requirements for OTPs, the scope of OUD treatment services, and the methodology for determining bundled payments to OTPs for furnishing OUD treatment services (discussed in the next section).

Under the OTP benefit, Medicare covers: (1) FDA-approved medications for OUD, (2) dispensing and administration of OUD medications, if applicable; (3) substance use counseling; (4) individual and group therapy; (5) toxicology testing; (6) intake activities, including initial assessments; and (7) periodic assessments (42 CFR § 410.67).<sup>18</sup> To be payable by Medicare, OUD treatment services furnished by OTPs must be medically reasonable and necessary (the Act § 1862(a)(1)(A)). An OTP must submit claims to its assigned MAC, which is based on the location of its practice.

### **Types of Payments for Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs**

Section 1834(w)(2) of the Act, as added by the SUPPORT Act, directed CMS to implement the Medicare OUD treatment benefit using one or more bundled payments. A bundled payment generally is a single, comprehensive payment that covers all of the services involved in a patient's episode of care.

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<sup>15</sup> Before the enactment of the SUPPORT Act, Medicare Part D covered opioid treatment with buprenorphine and naltrexone but not with methadone.

<sup>16</sup> Medicare Part B covers OUD treatment services furnished by both nonresidential OTPs (effective Jan. 1, 2020) and hospital-based outpatient OTPs (effective Jan. 1, 2021) (42 CFR § 410.67 and *Medicare Claims Processing Manual* (Claims Processing Manual), chapter 39, § 40). An example of a nonresidential OTP is a clinic operated by a private organization that provides counseling and methadone medication on an outpatient basis.

<sup>17</sup> 84 Fed. Reg. 62568 (Nov. 15, 2019).

<sup>18</sup> Effective Jan. 1, 2021, Federal regulations (42 CFR § 410.67(b)) added to the definition of OUD treatment services opioid antagonist medications (i.e., naloxone) that are approved by the FDA for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication. Naloxone rapidly reverses an opioid overdose.

CMS established bundled payments for OUD treatment services for weekly episodes of care, including FDA-approved medications for treatment of OUD, dispensing and administration of the medications (if applicable), substance use counseling, individual and group therapy, and toxicology testing. An episode of care is 1 week long, referred to as a “contiguous 7-day period” (i.e., 7 days in a row).<sup>19</sup>

There are two types of bundled payments for an episode of care: a bundled payment for an episode of care in which medication is dispensed or administered and a bundled payment for an episode of care in which no medication is dispensed or administered. Specifically:

- The bundled payment for an episode of care in which medication is dispensed or administered consists of a drug component and a nondrug component. The drug component covers the applicable medication in the patient’s treatment plan. The nondrug component covers all other OUD treatment services shown in the patient’s treatment plan (i.e., substance use counseling, individual and group therapy, toxicology testing if performed, and dispensing and administration of medication).
- The bundled payment for an episode of care in which no medication is dispensed or administered covers all OUD treatment services shown in the patient’s treatment plan (i.e., substance use counseling, individual and group therapy, and toxicology testing if performed).

CMS also established individual payments for intake activities, periodic assessments, additional counseling and therapy, and take-home supplies of medication. These services are referred to as “add-on” services.

### **Reimbursement of Opioid Treatment Programs’ Claims for Opioid-Use-Disorder Treatment Services**

CMS established 17 Healthcare Common Procedure Coding System (HCPCS) codes that OTPs include on claims to be reimbursed for OUD treatment services: 9 HCPCS codes (G2067 through G2075) that are used for the bundled payments for a weekly episode of care and 8 HCPCS codes for add-on services (G2076 through G2080, G1028, G2215, and G2216).<sup>20, 21</sup> We refer to the claim for which a bundled payment is made for a weekly episode of care as a “weekly bundle.”

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<sup>19</sup> Enrollees do not have a copayment for OUD treatment services but are responsible for the Medicare Part B deductible.

<sup>20</sup> HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies. For an episode of OUD treatment, physicians and other practitioners in the office setting may bill Medicare using HCPCS codes G2086, G2087, and G2088. Because OTPs do not bill these HCPCS codes, we did not include claims with these codes in our audit.

<sup>21</sup> An OTP may submit a claim with an HCPCS code for an add-on service with or without submitting a claim for the bundled payment for a weekly episode of care.

Appendix B lists the 17 HCPCS codes with descriptions and the national Medicare payment rates for calendar years (CYs) 2020 and 2021 for each code.

An example of an HCPCS code for a weekly bundle is G2067, which 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 . . . .” If an OTP furnished at least one service described in this HCPCS code to a patient during the week that corresponds to the episode of care, the OTP may submit a claim using HCPCS code G2067. An example of an HCPCS code for an add-on service is G2078, which is described as “take-home supply of methadone, up to 7 additional day supply . . . .”

CMS provided specific instructions to nonresidential OTPs on completing a claim form (Form CMS-1500, Health Insurance Claim Form) for service dates for weekly bundles and add-on services.<sup>22</sup> The claim form must include the diagnosis or nature of illness or injury.<sup>23</sup>

For weekly bundles, an OTP determines the service dates based on whether the OTP adopts the standard or weekly billing cycle:

- *Standard billing cycle:* a particular day of the week is set to begin episodes of care for all enrollees, in which the service date for all enrollees is the first day of the OTP’s billing cycle.
- *Weekly billing cycle:* episodes of care vary among enrollees, in which the first service date depends on the day of the week when an enrollee was first admitted to the OTP or when Medicare billing began for the enrollee.

Figures 2 and 3 on the next page illustrate the differences between the standard and weekly billing cycles.

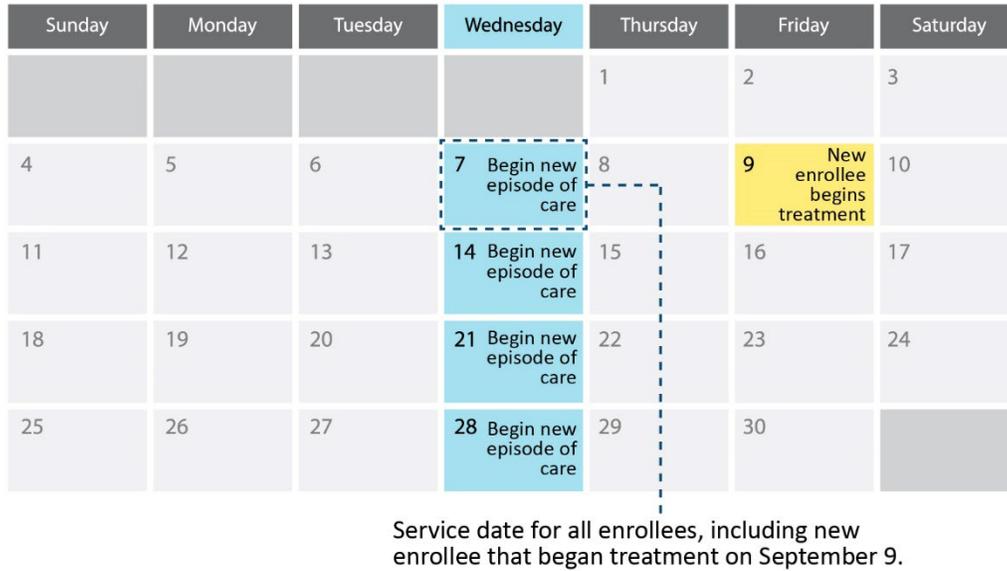
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<sup>22</sup> Medicare Learning Network (MLN), Opioid Treatment Programs (OTPs) Medicare Billing and Payment Fact Sheet, MLN 8296732 (May 2020). Available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MLN8296732-print-friendly.pdf>. Accessed on Apr. 12, 2023.

<sup>23</sup> Opioid treatment services are for the treatment of OUD. For the Medicare Part B benefit, CMS did not specify the exact diagnosis codes to be used for OUD; however, CMS’s *Identifying Beneficiaries with a Treated Substance Use Disorder (SUD): Technical Specifications* (September 2021) and CMS’s initiative, Value in Opioid Use Disorder Treatment demonstration program, implemented on Apr. 1, 2021, list OUD diagnosis codes.

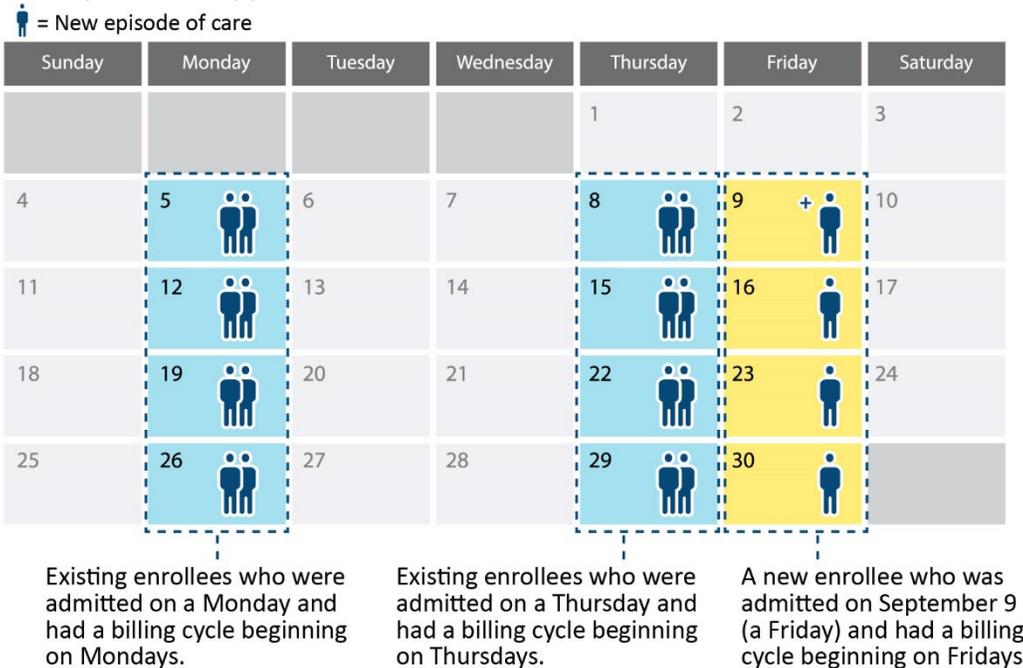
**Figure 2: Example of an OTP That Adopts a Standard Billing Cycle**

The **standard billing cycle** sets a particular day of the week to begin all episodes of care, in which the service date for all Medicare enrollees is the first day of the OTP’s billing cycle.



**Figure 3: Example of an OTP That Adopts a Weekly Billing Cycle**

The **weekly billing cycle** varies across patients, in which the first service date depends on the day of the week when a patient was first admitted to an OTP or when Medicare billing began for the enrollee. With this approach, when an enrollee is beginning treatment or restarting treatment after a break in treatment, the service date is the first day when the patient was admitted, and the service date for subsequent consecutive episodes of care is the first day after the previous 7-day period ended.



For add-on services, the service date is the date that the service was furnished. However, if an OTP has chosen to adopt a standard billing cycle, the service date may be the same as the first day of the billing cycle.

### **Medicare Requirements for Providers To Identify and Return Overpayments**

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>24</sup>

The 6-year lookback period is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>25</sup>

### **HOW WE CONDUCTED THIS AUDIT**

Our audit covered approximately 2.1 million Medicare Part B claims for OUD treatment services furnished to 40,067 Medicare enrollees from January 1, 2020, through September 30, 2021 (audit period), for which Medicare paid \$364.1 million to 1,040 nonresidential OTPs.<sup>26</sup> A claim contained OUD treatment services for one or more weekly episodes of care or one or more add-on services.

Table 1 on the next page shows the total number of claims and paid amounts by HCPCS code for OUD treatment services that we audited. Of the 17 HCPCS codes, we did not review claims for 5 codes (i.e., G1028, G2070, G2072, G2075, and G2216) because the Medicare claims data for our audit period did not include payments for these codes.

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<sup>24</sup> The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>25</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual—Part 1*, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

<sup>26</sup> We refer to the nonresidential OTPs that we reviewed as “OTPs” in this report.

**Table 1: Total Number of Claims and Paid Amounts by HCPCS Code for Our Audit Period**

HCPCS Code	Description	Number of Claims	Payment Amount
Codes for Weekly Bundles			
G2067	Methadone weekly bundle	1,556,676	\$321,915,432
G2068	Buprenorphine weekly bundle	40,930	10,212,071
G2069	Buprenorphine (injectable) weekly bundle	70	43,936
G2071	Buprenorphine (implant removal) weekly bundle	1	162
G2073	Naltrexone weekly bundle	37	49,110
G2074	Weekly bundle not including a drug	49,321	8,058,070
	<b>Subtotal for Weekly Bundles</b>	<b>1,647,035</b>	<b>\$340,278,781</b>
Codes for Add-on Services			
G2076	Intake activities*	13,589	\$2,392,365
G2077	Periodic assessment	30,106	3,375,724
G2078	Methadone, take-home supply up to 7 days	382,629	16,595,463
G2079	Buprenorphine, take-home supply up to 7 days	12,505	1,253,644
G2080	Additional 30 minutes of counseling	5,489	237,127
G2215	Nasal naloxone, take-home supply	94	9,024
	<b>Subtotal for Add-on Services</b>	<b>444,412</b>	<b>\$23,863,347</b>
	<b>GRAND TOTAL (Weekly Bundles and Add-on Services)</b>	<b>2,091,447</b>	<b>\$364,142,128</b>

\* Intake activities include an initial medical examination, physical evaluation, and initial assessment of the enrollee.

We analyzed the claims data for OTPs' billing patterns for OUD treatment services. We interviewed CMS officials and obtained written responses from the MACs regarding their claims adjudication systems and claims processing edits within those systems. We did not obtain or review documentation from OTPs, e.g., medical records.

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 A describes our audit scope and methodology, and Appendix C lists related OIG reports on OTPs and medications used to treat OUD.

## FINDINGS

Payments made to OTPs for OUD treatment services may not have complied with Medicare requirements.<sup>27</sup> Specifically, Medicare made up to \$17,817,121 in potentially improper payments to OTPs, consisting of payments for:

- weekly bundles that were covered by payments for another weekly bundle for the same enrollee at the same OTP (\$10,418,939),
- take-home supplies of medication (i.e., methadone or buprenorphine) that were covered by other payments for take-home supplies of medication or by payments for weekly bundles that included medication (\$5,085,208),
- OUD treatment services that were claimed without an OUD diagnosis (\$1,354,148), and
- an excessive number of intake activities, i.e., which occurred a total of 14 or more times for the same enrollee during our audit period (\$958,826).

These potentially improper payments occurred because CMS did not instruct MACs to implement system edits to prevent OTPs from being paid for OUD treatment services that were covered by other Medicare payments for the same enrollee at the same OTP. In addition, CMS's billing guidance did not explicitly state that an OTP should not bill add-on HCPCS codes for take-home supplies of medication when it had already billed for a weekly bundle that included medication for the same episode of care. Furthermore, CMS did not require OTPs to include on claims for OUD treatment services an OUD diagnosis code to indicate that an enrollee had an OUD.

### **MEDICARE PAID FOR WEEKLY BUNDLES THAT WERE COVERED BY PAYMENTS FOR ANOTHER WEEKLY BUNDLE FOR THE SAME ENROLLEE AT THE SAME OPIOID TREATMENT PROGRAM**

HCPCS codes G2067 through G2075 (i.e., the codes for weekly bundles) cover episodes of care for a contiguous 7-day period and cannot be billed for the same enrollee more than once in a 7-day period. When an enrollee is switching from one drug to another, an OTP should bill for only one HCPCS code describing a weekly bundle payment for that week and use the code for the drug dispensed for most of the week. OUD treatment services may be furnished at more than one OTP within 7 days in certain, limited clinical situations, such as when an enrollee temporarily receives medication at a different OTP to accommodate a personal situation (i.e., guest dosing) or when an enrollee's care is transferred to a different OTP.<sup>28</sup>

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<sup>27</sup> To be conservative, we considered these payments potentially improper because some of the OUD treatment services, such as claims that did not include an OUD diagnosis code, may have been allowable if medical review had been performed.

<sup>28</sup> 84 Fed. Reg. 62568, 62649 (Nov. 15, 2019); CMS, Claims Processing Manual, chapter 39, § 40.

Of the \$340,278,781 paid for weekly bundles, Medicare made potentially improper payments of up to \$10,418,939 (3 percent). In each instance, Medicare paid for a weekly bundle that was covered by a payment for another weekly bundle for the same enrollee at the same OTP.<sup>29</sup> We identified two scenarios with potentially improper payments:

- a weekly bundle with a service date that was within 7 days of another weekly bundle’s service date for the same enrollee at the same OTP (\$9,613,731) and
- two weekly bundles with the same service date for the same enrollee at the same OTP (\$805,208).

Figure 4 shows an example of a weekly bundle with methadone with a service date that was within 7 days of a service date for a weekly bundle without medication for the same enrollee at one OTP.

**Figure 4: A Weekly Bundle With Methadone That Was Billed Within 7 Days of a Weekly Bundle Without Medication**

		Potentially Improper Claim
Claim Date of Service	2/8/2020	2/11/2020 (3 days later)
HCPCS Code and Weekly Bundle Type	G2067 Methadone Drug Bundle 	G2074 Nondrug Bundle 
OTP Reimbursement Amount	\$196.93	\$158.48

In this example, the OTP submitted a claim for a weekly bundle with methadone (HCPCS code G2067) with the service date February 8, 2020. This weekly bundle was for counseling, toxicology testing (if performed), and dispensing and administration of drugs. The OTP submitted another claim for a weekly bundle without medication (HCPCS code G2074) with the service date February 11, 2020, which was within 7 days of February 8, 2020. This weekly bundle covered the same services except for dispensing and administration of medication. Therefore, the claim for HCPCS code G2074 did not comply with the requirement that codes for weekly bundles generally cannot be billed for the same enrollee more than once in a 7-day period.<sup>30</sup>

<sup>29</sup> According to CMS, it identified a similar issue that resulted in about \$12 million in potential overpayments when it conducted claims data analysis for the period January 2020 to June 2021. CMS stated that it would not recover the \$12 million at this time because CMS policy allows for certain exceptions and therefore it is not necessarily the case that all of the \$12 million was an overpayment. However, CMS did not explain the exceptions to CMS policy that would allow Medicare to pay for a weekly bundle that was covered by a payment for another weekly bundle for the same enrollee at the same OTP.

<sup>30</sup> 84 Fed. Reg. 62568, 62649 (Nov. 15, 2019); CMS, Claims Processing Manual, chapter 39, § 30.6.

Figure 5 shows an example of an OTP that billed two weekly bundles with the same service date for the same enrollee.

In this example, the OTP was reimbursed for two weekly bundles (one for methadone and another for buprenorphine) with the same service date (November 2, 2020) for the same enrollee.<sup>31</sup> This OTP should have been paid for only one of the weekly bundles.

According to CMS, in November 2019, it instructed MACs to implement edits in their claims processing systems to prevent a weekly bundle from being paid when the service date was within 7 days of another weekly bundle’s service date. However, in April 2020, to provide flexibilities to OTPs, CMS instructed MACs not to turn on those edits.<sup>32</sup> According to CMS, OTPs that have a standard billing cycle expressed concern about having the service date fall on a day that they were closed, such as a holiday. Although CMS cited the need to provide these flexibilities, a holiday should not affect the service date on a claim because that date should be the beginning of either the standard or weekly billing cycle that an OTP established.

In addition, in the physician fee schedule Final Rule for CY 2020, CMS stated that it allowed more than one OTP to be paid for the same episode of care when an enrollee received guest dosing, i.e., when an enrollee received medications at another OTP, such as when the enrollee was traveling or was transferring from one OTP to another.<sup>33</sup> The \$10,418,939 of potentially improper payments that we identified were for weekly bundles covered by payments for another weekly bundle for the same enrollee at the same OTP, not for an enrollee receiving guest dosing.

**Figure 5: Example of an OTP That Billed Weekly Bundles With the Same Service Date for the Same Enrollee**

	Potentially Improper Claim	
<b>Claim Date of Service</b>	11/2/2020	11/2/2020 (same day)
<b>HCPCS Code and Weekly Bundle Type</b>	G20 <sup>67</sup> Methadone Drug Bundle 	G20 <sup>68</sup> Buprenorphine Drug Bundle 
<b>Provider Reimbursement Amount</b>	\$219.37	\$270.35

<sup>31</sup> To be conservative, when an OTP billed weekly bundles with the same service date, we determined that the claim with the lower payment was potentially improper. For example, in Figure 5, we determined that the claim with HCPCS code G2067, which had a lower Medicare payment amount than the claim with HCPCS code G2068, was potentially improper.

<sup>32</sup> CMS did not attribute the reason for instructing the MACs not to turn on the edits to the COVID-19 public health emergency. CMS did not state when it would instruct the MACs to turn on the weekly bundle edit.

<sup>33</sup> 84 Fed. Reg. 62568, 62649 (Nov. 15, 2019).

## **MEDICARE PAID FOR TAKE-HOME SUPPLIES OF MEDICATION THAT WERE COVERED BY OTHER PAYMENTS FOR TAKE-HOME SUPPLIES OF MEDICATION OR BY PAYMENTS FOR WEEKLY BUNDLES THAT INCLUDED MEDICATION**

HCPCS codes G2067 through G2075 (i.e., the codes for weekly bundles) cover episodes of care for a contiguous 7-day period and cannot be billed for the same enrollee more than once in a 7-day period.<sup>34</sup> The add-on HCPCS codes G2078 (take-home supply of methadone) and G2079 (take-home supply of buprenorphine, oral) may be billed for up to 7 additional days of take-home supplies with the primary HCPCS code for the respective weekly bundles (i.e., G2067 for the methadone weekly bundle and G2068 for the buprenorphine weekly bundle).<sup>35</sup> These add-on codes may be billed along with the respective HCPCS codes for weekly bundles in units of up to 3 for a total of up to a 1-month supply.<sup>36</sup> SAMHSA allows a maximum take-home supply of 1 month of medication; therefore, CMS does not expect the add-on codes for take-home supplies to be billed any more than three times in 1 month in addition to the weekly bundles.<sup>37</sup>

Of the \$17,849,107 paid for take-home supplies of medication (i.e., methadone and buprenorphine), Medicare made potentially improper payments of up to \$5,085,208 (28 percent). In each instance, Medicare paid for a take-home supply of medication that was covered by another payment for a take-home supply of medication or by a payment for a weekly bundle that included medication for the same enrollee at the same OTP.

For example, Medicare paid an OTP for a weekly bundle of methadone (1 unit of HCPCS code G2067) on July 31, 2021, and an add-on service for a take-home supply of methadone (1 unit of HCPCS code G2078) each day from August 1 through August 30, 2021 (a total of 30 units for the month) for the same enrollee. Because the OTP was allowed to bill up to only 3 units of take-home medication along with the weekly bundle of methadone to cover take-home medication for a given month, Medicare should not have allowed payment for 27 units of take-home medication.

In another example, Medicare paid an OTP for weekly bundles of methadone and take-home supplies of methadone covering the same episodes of care for the same enrollee. (See Table 2 on the next page.)

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<sup>34</sup> 84 Fed. Reg. 62568, 62649 (Nov. 15, 2019); CMS, Claims Processing Manual, chapter 39, § 40.

<sup>35</sup> 42 CFR § 410.67(d)(4)(i)(D); CMS, Claims Processing Manual, chapter 39, § 30.6.1.

<sup>36</sup> One unit of the add-on HCPCS codes G2078 or G2079 represents up to a 1-week supply of medication.

<sup>37</sup> 84 Fed. Reg. 62568, 62648 (Nov. 15, 2019).

**Table 2: Weekly Bundles of Methadone and Take-Home Supplies of Methadone Were Paid for the Same Episodes of Care**

Service Date	HCPCS Code G2067 Methadone Weekly Drug Bundle Payment Amount*	HCPCS Code G2078 Methadone Take-Home Supply Payment Amount†
7/10/2021	\$198.21	\$37.38
7/17/2021	198.21	37.38
7/24/2021	198.21	37.38

\* Includes 7 days of medication.

† Includes up to an additional 7 days of medication.

The OTP received reimbursement for HCPCS code G2067 (a weekly bundle of methadone) and HCPCS code G2078 (a take-home supply of methadone up to 7 days) for episodes of care with the service dates July 10, July 17, and July 24, 2021. HCPCS code G2067 included medication for the episode of care. Although an OTP may bill 3 units of take-home medication along with the weekly bundle of methadone to cover take-home medication for a given month, Medicare should not have paid for the take-home supplies of methadone because the payment for each weekly bundle of methadone included payment for up to 7 days of medication covering the same episode of care.<sup>38</sup>

Medicare’s billing guidance (e.g., the *Medicare Claims Processing Manual* (Claims Processing Manual) and Medicare Learning Network (MLN) Fact Sheet) did not explicitly state that an OTP should not bill an add-on HCPCS code for a take-home supply of medication when it had already billed for a weekly bundle that included medication for the same episode of care.<sup>39</sup> According to CMS, “an OTP could bill 3 [units] of the add-on code for take-home doses on the same day as the weekly bundle, as long as they don’t bill the weekly bundle that includes payment for the drug again during those 4 weeks.”

In addition, CMS did not instruct MACs to implement system edits to prevent an OTP from being paid when it had submitted a claim for a take-home supply of medication (i.e., methadone and buprenorphine) that was covered by another payment for a take-home supply of medication or by a payment for a weekly bundle that included medication.

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<sup>38</sup> CMS confirmed our understanding that the OTP should not have billed for these take-home supplies of methadone.

<sup>39</sup> CMS, Claims Processing Manual, chapter 39, § 30.6.1. MLN’s [Opioid Treatment Programs \(OTPs\) Medicare Billing and Payment Fact Sheet](#), MLN 8296732 (May 2020). Accessed on Apr. 12, 2023.

## MEDICARE PAID FOR OPIOID-USE-DISORDER TREATMENT SERVICES THAT WERE CLAIMED WITHOUT A DIAGNOSIS OF OPIOID USE DISORDER

No payment may be made for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Act § 1862(a)(1)(A)). Federal regulations define an OUD treatment service as an item or a service for the treatment of OUD that is furnished by an OTP (42 CFR § 410.67).

Medicare made potentially improper payments of up to \$1,354,148 to 70 OTPs for OUD treatment services that were claimed without an OUD diagnosis. Specifically, 7,570 claims were submitted without an OUD diagnosis code.<sup>40</sup> Of the 70 OTPs, 4 accounted for \$766,552 of the total amount paid (57 percent). Furthermore, of the total amount paid, \$521,621 (39 percent) was paid to OTPs that submitted 2,518 claims (33 percent) containing the diagnosis code F1020, which was for “alcohol dependence, uncomplicated.”

Table 3 shows the top three diagnosis codes that OTPs included on claims for OUD treatment services without an OUD diagnosis code.<sup>41</sup> The diagnosis codes are ranked by the total amount paid for the claims.

**Table 3: Top Three Diagnosis Codes That Opioid Treatment Programs Included on Claims Without an OUD Diagnosis Code**

Rank	Diagnosis Code and Description	Paid Amount	Percentage of Total Amount Paid
1	F1020: Alcohol dependence, uncomplicated	\$521,621	39%
2	F1420: Cocaine dependence, uncomplicated	94,248	7%
3	F411: Generalized anxiety disorder	71,168	5%

CMS did not require OTPs to submit claims with an OUD diagnosis code to indicate that an enrollee had an OUD. CMS stated that it monitors claims for OUD treatment services without an OUD diagnosis and that the lack of an OUD diagnosis code on a claim is not conclusive evidence of an improper claim because an OUD diagnosis is not required for payment when an OTP submits a claim for OUD treatment services. CMS also stated that it does not typically review diagnosis codes when performing audits of OTP claims.

<sup>40</sup> We analyzed all data fields for diagnosis codes in the Medicare claims data.

<sup>41</sup> See footnote 23.

The claims data did not show that OUD treatment services were furnished to enrollees who had OUD diagnoses. Requiring OTPs to include OUD diagnosis codes on claims could be a way for CMS to monitor whether OTPs furnished OUD treatment services to enrollees who had an OUD.

### MEDICARE PAID FOR AN EXCESSIVE NUMBER OF INTAKE ACTIVITIES

HCPCS code G2076 covers intake activities and should be billed only for a new enrollee starting treatment at an OTP. Intake activities include the initial medical examination, a fully documented physical evaluation, and an initial assessment of the enrollee conducted by a physician.<sup>42</sup>

Of the \$2,392,365 paid for intake activities for 6,344 enrollees, Medicare made potentially improper payments of up to \$958,826 (40 percent) for an excessive number of intake activities furnished to 100 enrollees (less than 2 percent).<sup>43</sup> For example, for 1 enrollee, an OTP billed 91 intake activities from January 6, 2020, through September 27, 2021, totaling \$15,615. The OTP billed for an intake activity every 7 days from the preceding claim for an intake service (i.e., one intake activity per week). It is unlikely that the enrollee would have been discharged from and readmitted to the OTP every week during the 90-week period.<sup>44</sup>

Table 4 shows ranges for the number of claims for intake activities per enrollee, the number and percentage of enrollees for each range, the paid amount for those enrollees, and the percentage of the total amount paid for all those enrollees who had intake activities.

**Table 4: Enrollees Who Had at Least 14 Intake Activities (Representing Less Than 2 Percent of All Enrollees) Accounted for 40 Percent of the Total Amount Paid for Intake Activities**

Number of Claims for Intake Services per Enrollee	Number of Enrollees	Percentage of Enrollees	Number of Claims	Paid Amount	Percentage of Total Paid Amount for All Enrollees
1 to 4	6,116	96.4%	7,049	\$1,258,532	53%
5 to 13	128	2.0%	968	175,007	7%
14 to 21	12	0.2%	188	33,044	1%
Greater than 21	88	1.4%	5,384	925,782	39%
<b>Total</b>	<b>6,344</b>	<b>100%</b>	<b>13,589</b>	<b>\$2,392,365</b>	<b>100%</b>

<sup>42</sup> 42 CFR § 410.67(b)(6); CMS, Claims Processing Manual, chapter 39, § 30.6.1.

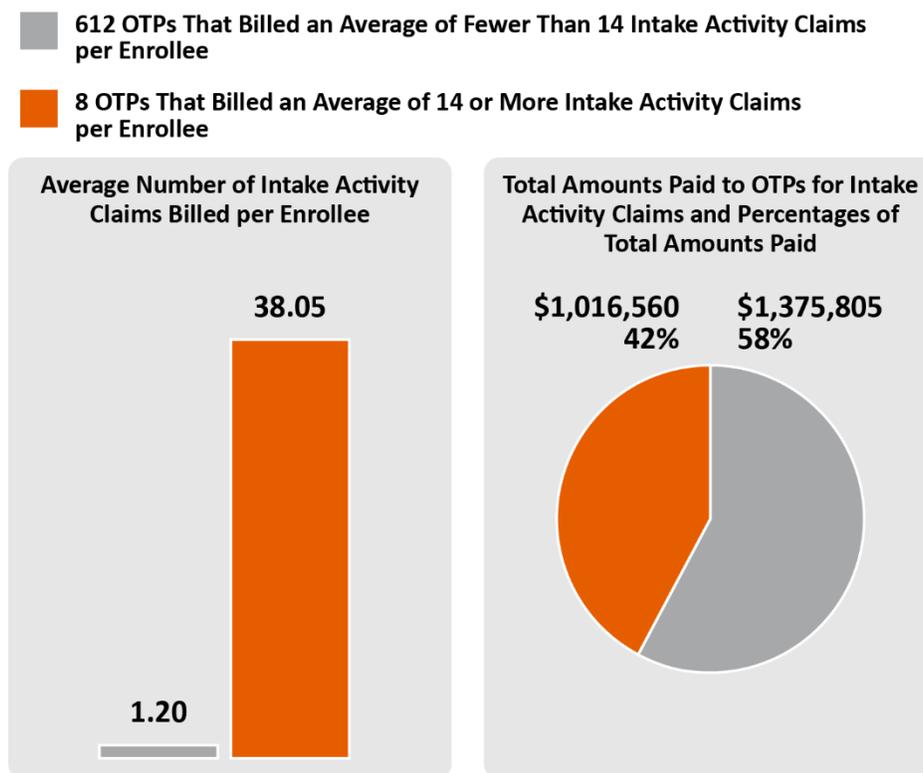
<sup>43</sup> We considered intake activities excessive if they were claimed a total of 14 or more times for the same enrollee during our 21-month audit period.

<sup>44</sup> CMS did not require an OTP to indicate on the claim form the date of discharge from the OTP (if a discharge had occurred).

In addition, of the 620 OTPs that billed for intake activities, only 8 OTPs billed 14 or more intake activities per enrollee during our audit period.<sup>45</sup> The remaining 612 OTPs billed fewer than 14 intake activities per enrollee.

Figure 6 compares the average number of intake activity claims billed per enrollee and the total amount paid for 8 OTPs that billed 14 or more intake activity claims per enrollee with the other 612 OTPs.

**Figure 6: Comparison of the 8 Opioid Treatment Programs That Billed 14 or More Intake Activity Claims per Enrollee With the Other 612 Opioid Treatment Programs**



The 8 OTPs billed claims for an average of 38 intake activities per enrollee, whereas the 612 OTPs billed claims for an average of 1 intake activity per enrollee. Furthermore, Medicare paid \$1,016,560 (42 percent of the total payment for intake activities) to these 8 OTPs.

CMS stated that it did not limit the number of times per year that OTPs could bill for intake activities and it did not have plans to establish any limits on intake activities.

Because 42 percent of the total payment for intake activities was made to 8 OTPs that billed 14 or more intake activity claims per enrollee during our audit period, additional education to these 8 OTPs on proper billing of intake activities may be necessary.

<sup>45</sup> The 8 OTPs billed fewer than 14 intake activities for some enrollees.

## CONCLUSION

After Medicare Part B began to cover OUD treatment services in January 2020, CMS established certain program safeguards to prevent improper payments, such as issuing Medicare billing guidance (e.g., the Claims Processing Manual and MLN Fact Sheet). However, based on our audit, we concluded that CMS could take additional steps to ensure that Medicare pays only for OUD treatment services that complied with Medicare requirements.

For our audit period, Medicare made up to \$17,817,121 in potentially improper payments to OTPs, including payments for weekly bundles that were covered by payments for another weekly bundle for the same enrollee at the same OTP and payments for OUD treatment services that were claimed without an OUD diagnosis.

These potentially improper payments occurred because CMS did not instruct MACs to implement system edits to prevent OTPs from being paid for OUD treatment services that were covered by other Medicare payments for the same enrollee at the same OTP. CMS initially instructed MACs to implement edits in their claims processing systems to prevent a weekly bundle from being paid when the service date was within 7 days of another weekly bundle's service date. However, to provide flexibilities to OTPs, CMS later instructed MACs not to turn on those edits. In addition, CMS did not instruct MACs to implement system edits to prevent an OTP from being paid when it had submitted a claim for a take-home supply of medication (i.e., methadone and buprenorphine) that was covered by another payment for a take-home supply of medication or by a payment for a weekly bundle that included medication.

Furthermore, Medicare's billing guidance (e.g., the Claims Processing Manual and MLN Fact Sheet) did not explicitly state that an OTP should not bill an add-on HCPCS code for a take-home supply of medication when it had already billed for a weekly bundle that included medication for the same episode of care. In addition, CMS did not require OTPs to include on claims for OUD treatment services an OUD diagnosis code to indicate that an enrollee had an OUD.

Finally, because 8 of the 620 OTPs billed intake activities that occurred 14 or more times per enrollee during our audit period, additional education to these 8 OTPs on proper billing of intake activities may be necessary.

## RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- work with MACs and other Medicare contractors as appropriate to determine whether claims billed by OTPs for OUD treatment services complied with Medicare requirements;
- instruct MACs, based upon the results of this audit, to notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential

overpayments) so that the providers can exercise reasonable diligence to identify, report, and return any overpayments, up to \$17,817,121, in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation;

- instruct MACs to implement edits in their claims processing systems to prevent an OTP from being paid for: (1) a weekly bundle with a service date that was within a contiguous 7-day period of another weekly bundle's service date for the same enrollee at the same OTP or (2) two weekly bundles with the same service date for the same enrollee at the same OTP;
- revise its billing guidance to specify that OTPs should not bill add-on HCPCS codes for take-home supplies of medication for the same episode of care that was already covered by a weekly bundle that included medication, and instruct MACs to implement edits in their claims processing systems to identify improperly billed claims for take-home medication;
- develop billing requirements for OTPs to include OUD diagnosis codes on claims for OUD treatment services to indicate that enrollees have OUD diagnoses, and consider working with MACs to implement a system edit to ensure that OTP payments are made for enrollees only when OUD diagnosis codes are included on claims; and
- work with MACs to provide education on billing of intake activities to the 8 OTPs that billed 14 or more intake activity claims per enrollee during our audit period.

#### **CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, CMS concurred with our first, third, fourth, and sixth recommendations and provided information on actions that it planned to take to address these recommendations. However, CMS did not concur with our second recommendation. CMS did not explicitly state whether it concurred with our fifth recommendation but stated that it concurs to explore ways to educate providers about including an OUD diagnosis code on claims. CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, are included as Appendix D.

After reviewing CMS's comments, we maintain that our second and fifth recommendations are valid, but we refined the wording of our first recommendation. Our summaries of CMS's specific comments on the recommendations and our responses are in the following sections.

## **CMS COMMENTS**

CMS had the following comments on our recommendations:

- Regarding our first recommendation, CMS concurred and stated that it will work with Medicare contractors and review a sample of claims.
- Regarding our second recommendation, CMS did not concur and stated that medical record review would be needed to identify actual overpayments and that OIG did not perform this review. CMS stated that, therefore, the audit alone is not sufficient basis upon which CMS can support a 60-day-rule notice of overpayments to identified providers. CMS also stated that it will review medical records for a sample of claims to ensure that OTP services are billed appropriately to Medicare.
- Regarding our third recommendation, CMS concurred and stated that it will explore the possibility of developing new edits while maintaining flexibility for OTPs.
- Regarding our fourth recommendation, CMS concurred and stated that it will issue billing guidance and explore ways to prevent improper overlap between claims for weekly bundles that include medication and claims for take-home supplies of the same medication for the same period.
- Regarding our fifth recommendation, CMS stated that it concurs to explore ways to educate providers about including an OUD diagnosis code on claims and reiterated that a diagnosis code for an OUD on the claim itself is not necessary to meet Medicare medical necessity requirements because it could be found in the patient's records.
- Regarding our sixth recommendation, CMS concurred and stated that it will educate Medicare-enrolled OTPs to reinforce requirements for billing intake activities.

## **OFFICE OF INSPECTOR GENERAL RESPONSE**

Our responses to CMS's comments on the first, second, and fifth recommendations are as follows:

- Regarding our first recommendation, we refined the wording to recommend that CMS work with not only MACs but other Medicare contractors as appropriate to determine whether claims billed by OTPs for OUD treatment services complied with Medicare requirements.
- Regarding our second recommendation, we believe that this audit report constitutes credible information of potential overpayments. The 60-day rule does not require identification of actual overpayments to trigger a provider's obligation to exercise

reasonable diligence to identify, report, and return overpayments. Instead, the 60-day rule requirements are triggered when a provider receives credible information of potential overpayments. These potential overpayments included OTP claims for the same enrollee at the same OTP that did not meet Medicare requirements. For example, as our report states, Medicare paid an OTP for two weekly bundles (one for methadone and another for buprenorphine) with the same service date (November 2, 2020) for the same enrollee. In addition, by not including diagnosis codes on claims, OTPs did not show that they furnished OUD treatment services to enrollees who had OUD diagnoses. Finally, the 8 OTPs that billed 14 or more intake activity claims per enrollee had a significantly higher average of intake activities per enrollee than the remaining 612 OTPs. If CMS does not provide notice of potential overpayments to OTPs, OTPs may not exercise reasonable diligence to determine receipt of and quantify any overpayments. Therefore, we maintain that our recommendation is valid.

- Regarding our fifth recommendation, we maintain that requiring OTPs to include OUD diagnosis codes on claims could be a way for CMS to monitor whether OTPs furnished OUD treatment services to enrollees who had an OUD.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered Medicare Part B claims with 2,091,447 claims for OUD treatment services furnished to 40,067 Medicare enrollees from January 1, 2020, through September 30, 2021, for which Medicare paid \$364,142,128 to 1,040 nonresidential OTPs.

We analyzed the claims data for OTPs' billing patterns for OUD treatment services. We did not obtain or review documentation from OTPs, e.g., enrollees' medical records.

We did not assess the overall internal control structure of CMS. Rather, we limited our review to CMS's internal controls for the control activities and monitoring activities related to the findings in this report. Specifically, we interviewed CMS officials and obtained written responses from MACs regarding their claims adjudication systems and claim edits within their systems. We also reviewed CMS Technical Direction Letters for information on system edits and monitoring activities and reviewed Medicare billing guidance, including related sections of the Claims Processing Manual.

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 2022 to May 2023.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- interviewed CMS officials and obtained written responses from MACs to gain an understanding of how claims for OUD treatment services are billed and processed and the program safeguards (e.g., using system edits and performing claims audits) in place to prevent improper payments to OTPs and promote OTP compliance with Medicare requirements;
- obtained nationwide claims data for OUD treatment services from CMS's IDR;
- analyzed the claims data for OUD treatment services to identify: (1) HCPCS codes for weekly bundles for medication with dates of service that overlapped dates of service for other codes for weekly bundles and HCPCS codes for take-home supplies of medication, (2) the frequency of the add-on HCPCS code G2076 (intake activities) for enrollees,

(3) the frequency of the add-on HCPCS code G2077 (periodic assessment) for enrollees, and (4) claims associated with diagnosis codes other than OUD diagnosis codes;

- identified the amount that Medicare paid OTPs for OUD treatment services that may not have complied with Medicare requirements; 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 OPIOID-USE-DISORDER  
TREATMENT SERVICES**

<b>HCPCS Code</b>	<b>Description</b>	<b>National Medicare Payment Rate for CY 2020*</b>	<b>National Medicare Payment Rate for CY 2021*</b>
Codes for Weekly Bundles			
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
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
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
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
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

<b>HCPCS Code</b>	<b>Description</b>	<b>National Medicare Payment Rate for CY 2020</b>	<b>National Medicare Payment Rate for CY 2021</b>
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
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
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
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 <sup>†</sup>	NA <sup>†</sup>
<b>Codes for Add-On Services</b>			
G2076	Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment that includes preparation of a treatment plan	\$179.46	\$181.97
G2077	Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment	\$110.28	\$111.82
G2078	Take-home supply of methadone; up to 7 additional day supply	\$35.28	\$37.38
G2079	Take-home supply of buprenorphine (oral); up to 7 additional day supply	\$86.26	\$81.08
G2080	Each additional 30 minutes of counseling in a week of medication assisted treatment	\$30.94	\$31.37

HCPCS Code	Description	National Medicare Payment Rate for CY 2020	National Medicare Payment Rate for CY 2021
G2215	Take-home supply of nasal naloxone	NA <sup>†</sup>	\$92.13 <sup>‡</sup>
G2216	Take-home supply of injectable naloxone	NA <sup>†</sup>	MAC-priced <sup>‡</sup>
G1028	Take-home supply of nasal naloxone	NA <sup>†</sup>	NA <sup>†</sup>

\* The national Medicare payment rates for CY 2020 were available online at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program/Downloads/CY2020-OTP-Payment-Rates.pdf>. The national Medicare payment rates for CY 2021 were available online at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cy2021-otp-payment-rates.pdf>. Accessed on March 16, 2022, and May 3, 2023, respectively.

<sup>†</sup> 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 a G code and priced it during the rulemaking cycle.

<sup>‡</sup> There were no CY 2020 National Medicare payment rates for HCPCS codes G2215 and G2216. HCPCS code G2215 and G2216 were added in the physician fee schedule Final Rule for CY 2021. The CY 2021 National Medicare payment rates for HCPCS codes G2215 and G2216 were included in the physician fee schedule Final Rule for CY 2021. HCPCS code G1028 was added in the physician fee schedule Final Rule for CY 2022; therefore, HCPCS code G1028 did not have a payment rate in either CY 2020 or CY 2021.

**APPENDIX C: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>The Risk of Misuse and Diversion of Buprenorphine for Opioid Use Disorder Appears to Be Low in Medicare Part D</i>	<a href="#"><u>OEI-02-22-00160</u></a>	5/16/2023
<i>Opioid Overdoses and the Limited Treatment of Opioid Use Disorder Continue To Be Concerns for Medicare Beneficiaries</i>	<a href="#"><u>OEI-02-22-00390</u></a>	9/13/2022
<i>More Than 90 Percent of the New Hampshire Managed Care Organization and Fee-for-Service Claims for Opioid Treatment Program Services Did Not Comply With Medicaid Requirements</i>	<a href="#"><u>A-01-20-00006</u></a>	6/23/2022
<i>California Improperly Claimed at Least \$23 Million of \$260 Million in Total Medicaid Reimbursement for Opioid Treatment Program Services</i>	<a href="#"><u>A-09-20-02009</u></a>	4/20/2022
<i>Many Medicare Beneficiaries Are Not Receiving Medication To Treat Their Opioid Use Disorder</i>	<a href="#"><u>OEI-02-20-00390</u></a>	12/15/2021
<i>SAMHSA’s Oversight Generally Ensured That the Commission on Accreditation of Rehabilitation Facilities Verified That Opioid Treatment Programs Met Federal Opioid Treatment Standards</i>	<a href="#"><u>A-09-20-01002</u></a>	10/1/2021
<i>About Seventy-Nine Percent of Opioid Treatment Program Services Provided to Medicaid Beneficiaries in Colorado Did Not Meet Federal and State Requirements</i>	<a href="#"><u>A-07-20-04118</u></a>	9/21/2021
<i>Concerns Persist About Opioid Overdoses and Medicare Beneficiaries’ Access to Treatment and Overdose-Reversal Drugs</i>	<a href="#"><u>OEI-02-20-00401</u></a>	8/10/2021
<i>SAMHSA Is Missing Opportunities To Better Monitor Access to Medication-Assisted Treatment Through the Buprenorphine Waiver Program</i>	<a href="#"><u>OEI-BL-20-00260</u></a>	6/14/2021
<i>California Claimed at Least \$2 Million in Unallowable Medicaid Reimbursement for a Selected Provider’s Opioid Treatment Program Services</i>	<a href="#"><u>A-09-20-02001</u></a>	1/25/2021
<i>Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken To Address Them</i>	<a href="#"><u>A-09-20-01001</u></a>	11/18/2020
<i>CMS Should Pursue Strategies To Increase the Number of At-Risk Beneficiaries Acquiring Naloxone Through Medicaid</i>	<a href="#"><u>OEI-BL-18-00360</u></a>	9/18/2020
<i>SAMHSA’s Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements</i>	<a href="#"><u>A-09-18-01007</u></a>	3/6/2020

Report Title	Report Number	Date Issued
<i>New York Claimed Tens of Millions of Dollars for Opioid Treatment Program Services That Did Not Comply With Medicaid Requirements Intended To Ensure the Quality of Care Provided to Beneficiaries</i>	<a href="#">A-02-17-01021</a>	2/4/2020
<i>Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder</i>	<a href="#">OEI-12-17-00240</a>	1/29/2020
<i>Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased</i>	<a href="#">OEI-02-19-00390</a>	7/8/2019

## APPENDIX D: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

*Administrator*  
Washington, DC 20201

**DATE:** July 11<sup>th</sup>, 2023

**TO:** Amy Frontz  
Deputy Inspector General for Audit Services

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

**SUBJECT:** Office of Inspector General (OIG) Draft Report: *Medicare Made \$17.8 Million in Potentially Improper Payments for Opioid-Use-Disorder Treatment Services Furnished by Opioid Treatment Programs, A-09-22-03005*

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 and high-quality treatment, including services provided by Opioid Treatment Programs (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.

Treatment through an OTP may include medication (such as methadone, buprenorphine, or naltrexone), substance use counseling, toxicology 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 paid 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.

Because treatment through an OTP was a new Medicare benefit starting in 2020, CMS determined that certain flexibilities were necessary to allow OTPs to transition into Medicare billing for the first time (e.g., the flexibility to adopt a standard weekly billing cycle vs. a weekly billing cycle that varies across patients), and to ease the transition for beneficiaries using these services. OIG's audit covered claims from January 1, 2020, through September 30, 2021, which was the beginning of the benefit and coincided with the start of the COVID-19 Public Health Emergency (PHE). Consequently, during this time, OTPs faced multiple challenges impacting their services, including workflow changes associated with the PHE, a rise in opioid-related mortality, an increase in demand for substance use services, and enrolling as new Medicare providers<sup>1</sup>. Throughout this time period, CMS continued to analyze usage and billing data to

<sup>1</sup> <https://www.cdc.gov/drugoverdose/databriefs/sudors-2.html>  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8585604/>

determine areas for additional attention and future program changes, including to minimize disruptions to care during the COVID-19 pandemic.

As described above, Medicare pays enrolled OTPs bundled payments based on weekly episodes of care. OTPs can apply a standard billing cycle by choosing a particular day of the week to begin all episodes of care, or they can adopt weekly billing cycles that vary depending on the patient. As OIG found, it is possible for one weekly bundled payment to overlap with another under certain circumstances due to these flexibilities. For example, overlaps in billing may be seen during weeks in which the OTP is closed for a holiday, when a beneficiary receives a “guest dose” of their prescribed medication at a different OTP, or if a beneficiary transfers care between OTPs. In all instances, CMS expects OTPs to provide sufficient documentation in the patient’s medical record to reflect the clinical situation and services provided. Because medical record review was not included in OIG’s analysis, we cannot definitively conclude that payments flagged were improper. CMS has analyzed overlapping billing and issued provider education to clarify these requirements to OTPs and continues to monitor this area.

When a beneficiary begins treatment at an OTP, the OTP may bill for intake activities, which include medical examination services, including a physical evaluation and an initial assessment of the beneficiary conducted by a physician. However, there may be instances when it is reasonable and necessary to have more than one intake assessment in a year. For example, a patient who leaves treatment for a period of time would need to be re-assessed upon their return. Therefore, to promote continuity of care and facilitate access to treatment, CMS did not finalize a limit on the number of times per year the intake code could be billed. CMS is monitoring utilization of OTP claims, including for the add-on code describing intake activities.

To further promote continuity of care, in addition to on-site treatment, OTPs may also provide beneficiaries with take-home doses of medication. As finalized in the CY 2020 PFS final rule (84 FR 62648), OTPs can bill Medicare for an adjustment for additional take-home supplies of methadone or oral buprenorphine of up to 21 days, in 7-day increments. We stated we do not expect the add-on codes for take-home supplies to be billed any more than 3 times in one month (in addition to the weekly bundled payment) consistent with SAMHSA rules at the time of study.<sup>2</sup> Data analysis at the Medicare Administrative Contractors (MAC) level has not found this area to be a high vulnerability at this time, but MACs will continue to monitor this area.

Treating patients with OUD is complex, and patients with OUD may also have other co-occurring substance use disorders (SUDs). While OIG correctly notes that Medicare rules allow payment only for expenses incurred for items or services that are reasonable and necessary for treatment of illness, CMS currently does not require OTPs to submit claims with an OUD diagnosis code to indicate that a beneficiary had an OUD. Chart review would have to be performed to determine whether a beneficiary had the requisite OUD diagnosis; lack of an OUD diagnosis on the claim is not conclusive evidence of an unallowable claim. Additionally, data analysis at the MAC level has indicated that the majority of services billed to Medicare by OTPs includes treatment furnished with methadone, a medication primarily indicated for the treatment of OUD and that can only be furnished at OTPs. As this benefit is relatively new, CMS continues to analyze usage and billing data to determine areas for additional attention.

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<sup>2</sup> <https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf>

The ongoing opioid PHE continues to be a priority for CMS' program integrity activities. In addition to the education and analyses described above, CMS' Investigations Medicare Drug Integrity Contractor (I-MEDIC) has conducted data analysis on Medication Assisted Treatment Program billing, and CMS's Unified Program Integrity Contractors (UPICs) have conducted medical record reviews to ensure that the OTP claims are supported by adequate documentation.

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

OIG's recommendations and CMS' responses are below.

**OIG Recommendation**

CMS should work with MACs to determine whether claims billed by OTPs for OUD treatment services complied with Medicare requirements.

**CMS Response**

CMS concurs with this recommendation and will work with Medicare contractors. Because making the determination requires a resource-intensive review of medical records, CMS will review a sample of claims, balancing available resources with ensuring that OTP services are billed appropriately to Medicare.

**OIG Recommendation**

CMS should instruct MACs, based upon the results of this audit, to notify appropriate providers (i.e., those for whom CMS determines this audit constitutes credible information of potential overpayments) so that the providers can exercise reasonable diligence to identify, report, and return any overpayments, up to \$17,817,121, in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation.

**CMS Response**

CMS does not concur with this recommendation. We appreciate OIG's review as to whether claims were billed appropriately by OTPs for OUD treatment services. However, medical record review would be needed to identify actual overpayments, and this review was not performed by OIG for purposes of this audit. Therefore, this audit alone is not sufficient basis upon which CMS can support a 60-day rule notice of overpayments to identified providers.

CMS will, however, review medical records for a sample of claims to ensure that OTP services are billed appropriately to Medicare, in accordance with the first OIG recommendation above.

**OIG Recommendation**

CMS should instruct MACs to implement edits in their claims processing systems to prevent an OTP from being paid for: (1) a weekly bundle with a service date that was within a contiguous 7-day period of another weekly bundle's service date for the same beneficiary at the same OTP or (2) two weekly bundles with the same service date for the same beneficiary at the same OTP.

**CMS Response**

CMS concurs with this recommendation and will explore the possibility of developing new edits while maintaining flexibility for OTPs to bill in scenarios where weekly billing cycles need to be synced.

**OIG Recommendation**

CMS should revise its billing guidance to specify that OTPs should not bill add-on HCPCS codes for take-home supplies of medication for the same episode of care that was already covered by a weekly bundle that included medication and instruct MACs to implement edits in their claims processing systems to identify improperly billed claims for take-home medication.

**CMS Response**

CMS concurs with this recommendation. CMS will issue billing guidance and explore ways to prevent improper overlap between claims for weekly bundles that include medication and claims for take-home supplies of the same medication for the same time period. We note that OTPs can bill Medicare for an adjustment for additional take home supplies of methadone or oral buprenorphine of up to 21 days, in 7-day increments, in addition to the weekly bundle that includes 7 days of medication. These can all be billed for one date of service for patients who the OTP does not expect to see for another 4 weeks. In cases where the patient is unexpectedly seen for non-drug services later in the month, the OTP can bill for the non-drug bundle when all applicable requirements are met.

**OIG Recommendation**

CMS should develop billing requirements for OTPs to include OUD diagnosis codes on claims for OUD treatment services to indicate that beneficiaries have OUD diagnoses, and consider working with MACs to implement a system edit to ensure that OTP payments are made for beneficiaries only when OUD diagnosis codes are included on claims.

**CMS Response**

CMS concurs to explore ways to educate providers about including an OUD diagnosis code on claims. As stated in our response, a diagnosis code for an OUD on the claim itself is not necessary to meet Medicare medical necessity requirements for OTP treatment. Rather, this diagnosis could be found in the patient's records.

**OIG Recommendation**

CMS should work with MACs to provide education on proper billing of intake activities to the 8 OTPs that billed 14 or more intake activity claims per beneficiary during our audit period.

**CMS Response**

CMS concurs with this recommendation and will educate Medicare-enrolled OTPs to reinforce requirements for billing intake activities.

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