Opioid Treatment Programs: Enrolling in Medicare

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Learning Network®

Acronyms in this Presentation

- **ASP** – Average Sales Price
- **CAP** – Corrective Action Plan
- **CFR** – Code of Federal Regulations
- **CMS** – Centers for Medicare & Medicaid Services
- **CY** – Calendar Year
- **DEA** – Drug Enforcement Administration
- **EDI** – Electronic Data Interchange
- **FDA** – Food and Drug Administration
- **FFS** – Fee-For-Service
- **I&A** – Identity & Access Management System
- **MAC** – Medicare Administrative Contractor
- **MAT** – Medication-Assisted Treatment
- **MDM** – Medical Decision Making
- **MLN** – Medicare Learning Network
- **OTP** – Opioid Treatment Program
- **OUD** – Opioid Use Disorder
- **PECOS** – Provider Enrollment Chain and Ownership System
- **PFS** – Physician Fee Schedule
- **PTAN** – Provider Transaction Access Number
- **RVU** – Relative Value Unit
- **SAMHSA** – Substance Abuse and Mental Health Services Administration

Agenda

- **Overview & Background**
- **Final Opioid Treatment Program (OTP) Policies**
- **Enrolling in Medicare**
- **Question & Answer Session**

Overview

Expanding access to Opioid Use Disorder (OUD) treatment

- This is one of the Centers for Medicare & Medicaid Services' (CMS) key areas of focus in addressing the opioid epidemic

In this presentation

- Policies for implementing the new Medicare Part B benefit for OTPs
- Enrolling in Medicare

New Medicare Part B Benefit for OTPs

Dr. Pierre Yong
Lindsey Baldwin

The SUPPORT for Patients and Communities Act

- Section 2005 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act establishes a new Medicare Part B benefit for OUD treatment services furnished by OTPs on or after January 1, 2020.

- The statute allows implementation, “through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine[s] appropriate.”

Background

- Currently, the Substance Abuse and Mental Health Services Administration (SAMHSA) certifies about 1,700 OTPs nationwide.

- OTPs provide medication-assisted treatment for people diagnosed with an OUD. OTPs must be certified by the SAMHSA and accredited by an independent, SAMHSA-approved accrediting body. For SAMHSA certification, OTPs must comply with all pertinent state laws and regulations and all regulations enforced by the Drug Enforcement Administration.

- The payer mix for OTPs currently includes Medicaid, private payers, and TRICARE, as well as individual pay patients.

- Medicare previously covered office-based opioid treatment with buprenorphine and naltrexone, but has historically not covered services furnished in OTPs, which are the only entities authorized to use methadone to treat OUD. Medicare coverage of OTPs is a new benefit that we anticipate will expand access to care.

Definition of an OTP per 42 CFR 8.2

- Enrolled in Medicare
- Fully certified by SAMHSA
- Accredited by an accrediting body approved by SAMHSA
- Meets such additional conditions as the Secretary may find necessary to ensure:
  - The health and safety of individuals being furnished services under such program
  - The effective and efficient furnishing of such services

OUD Services Provided by OTPs

OUD treatment services provided by OTPs includes the following:

- U.S. Food and Drug Administration (FDA)-approved opioid agonist and antagonist medications for the treatment of OUD
- Dispensing and administering such medications (if applicable)
- Substance use counseling
- Individual and group therapy
- Toxicology testing, including presumptive and definitive testing
- Intake activities
- Periodic assessments

We will allow OTPs to furnish the substance use counseling, individual therapy, and group therapy included in the bundle via two-way interactive audio/video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries.

Flexibilities During the Public Health Emergency (PHE) for the COVID-19 pandemic

- *Counseling and Therapy:* In light of the PHE for the COVID-19 pandemic, CMS revised regulation text at § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles of services furnished by OTPs, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met.

- *Periodic Assessments:* CMS also revised § 410.67(b)(7) to allow periodic assessments to be furnished during the PHE for the COVID-19 pandemic via two-way interactive audio-video communication technology. In cases where beneficiaries do not have access to two-way audio-video communications technology, the periodic assessments may be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met.

Payment and Coding

- The codes describing OTP treatment services are not considered physicians' services and are paid outside the PFS, and therefore are not assigned Relative Value Units (RVUs). These services are assigned flat dollar payment amounts.
- We adopted a coding structure for OUD treatment services that includes the non-drug services and varies by the medication administered.
- We established 9 HCPCS G-codes (G2067-G2075) and 5 add-on G-codes (G2076-G2080) for weekly (a 7-day contiguous period) separate corresponding bundles describing treatment with:
    - Methadone (G2067)
    - Oral buprenorphine (G2068), injectable buprenorphine (G2069), buprenorphine implants (insertion, removal, and insertion/removal) (G2070, G2071, and G2072)
    - Extended-release injectable naltrexone (G2073)
    - Medication not otherwise specified (G2075)
    - A non-drug bundle (G2074)
- Only one weekly G-code (listed above) can be billed in any 7-day contiguous period per beneficiary except in limited clinical circumstances (e.g., guest dosing).
- View our Billing & Payment page for more information.

Payment and Coding

Each bundled payment is composed of a:

- **Drug component**
  - The typical maintenance dose determines the drug costs for each of the bundles
  - CMS finalized a payment of average sales price (ASP) +0 percent, when ASP data are available. For methadone, CMS will use TRICARE pricing when ASP is not reported. For oral buprenorphine, CMS will use National Average Drug Acquisition Cost pricing when ASP is not reported.

- **Non-drug component**
  - The non-drug component includes payment for counseling, therapy, toxicology testing, and drug dispensing and administration (as applicable)
  - We finalized an increased payment rate for the non-drug bundle payment rate using a building block methodology that uses the payment rates for similar services paid under Medicare in the non-facility setting.

The threshold for billing the weekly episode is the delivery of at least one service in the weekly bundle (from either the drug or non-drug component).

View the CY2020 payment rates. Rates for the non-drug component will be adjusted by geographic locality and will be updated on an annual basis.

Payment and Coding

Add-On Adjustments
We will adjust the bundled payment rates through the use of add-on codes in order to account for instances in which:

- Intake activities or periodic assessments are performed
- Additional counseling or therapy is furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan
- Take home dosing for methadone or oral buprenorphine is provided to a patient

OTPs can only bill Medicare using the specific codes for OTP services. OTPs cannot bill Medicare for non-OTP services. No other provider or supplier type except for an OTP can bill for OTP services.

Partial Episodes
The proposal to establish a partial episode was not finalized, based on public comment, but CMS may consider creating partial episodes in the future

Beneficiary Copayment

- We set the copayment at zero for fee-for-service Medicare Part B as we believe this will minimize barriers to patient access for OUD treatment services.

- Setting the copayment at zero also ensures Medicare-enrolled OTP providers receive the full Medicare payment amount for Medicare beneficiaries if secondary payers are not available or do not pay the copayment, especially for those dually eligible for Medicare and Medicaid.

- The Part B deductible will apply for OUD treatment services, as mandated for all Part B services by section 1833(b) of the Social Security Act.

Dually Eligible Beneficiaries

Sharon Donovan

For Dually Eligible Beneficiaries

Along with creating the OTP benefit, the SUPPORT Act also mandates all states cover OTP in their Medicaid programs effective October 2020, subject to an exception process as defined by the Secretary.

Starting January 1, 2020, Medicare will be the primary payer for OTP services for dually eligible beneficiaries (those enrolled in both Medicare and Medicaid) who currently get OTP services through Medicaid. Briefly, Medicaid:

- Must pay for services delivered to these beneficiaries by OTP providers who are not yet enrolled in Medicare but are enrolled in Medicaid, to the extent the service is covered in the state plan
- Will later recoup the Medicaid payments made to the OTP, back to the effective date of the OTP's Medicare enrollment, and the OTP will then bill Medicare for those services

OTP providers should enroll in Medicare now to be able to bill for services starting January 1, 2020.

Bookmark our OTP page for Medicaid.

Medicare Advantage Beneficiaries

Marty Abeln

For Medicare Advantage Beneficiaries

In covering the OTP benefit, Medicare Advantage (MA) plans must use only OTP providers that meet the same requirements as those providing services under Medicare Part B, who are both certified by SAMHSA and enrolled in Medicare.

MA plans may furnish access to the OTP by directly contracting with OTPs or by allowing enrollees to access services from an OTP on a non-contract basis.

MA plans must furnish enrollees access to the OTP benefit that is as good or better than what is available to beneficiaries in Original Medicare through Medicare qualified OTPs.

We will inform MA plans that for all enrollees, including the dually eligible individuals, who are currently in treatment with an OTP provider with whom the plan does not contract, the plan should create a transition process in which the individual can continue to see the current OTP provider while the plan works with the individual to transition to a network provider.

Bookmark our OTP page for Medicare Advantage Plans.

Enrolling in Medicare

Joe Schultz

Getting Started

Review our OTP Enrollment Fact Sheet to learn:

- What information and documents you need to apply
- How to submit your application
- What to expect after you submit your application

Preparing to Enroll: Gather Documentation

Before you begin the application process, make sure you have all the necessary information and documentation you need, including:

- A copy of your SAMHSA letter of certification, also referred to as the “renewal letter”
- A detailed organizational chart (like the one used for SAMHSA certification)
- Names, contact information, and Tax Identification Numbers (TINs) and/or Social Security Numbers (SSNs) for all individuals or organizations with managing control and/or ownership interest in the OTP
- Addresses and phone numbers for all practice locations of the OTP
- Copies of legal records regarding any convictions, exclusions, revocations, and suspensions associated with the OTP and the individual and organizations reported on the application

Preparing to Enroll: Get a National Provider Identifier

You must have a National Provider Identifier (NPI) and include it in multiple sections of the enrollment application.

- If your OTP already has an NPI used to bill Medicaid or other payers, you can skip this step
- Get your NPI **before** beginning Medicare enrollment

Three ways to get an NPI:

- **Electronically** – First, get an Identity & Access (I&A) Management system account; this gives you access to other CMS systems you'll need for the enrollment process. Use this account to access the National Plan and Provider Enumeration System (NPPES).
- **Paper Application** – Complete, sign, and mail a paper application to the NPI Enumerator
- **Via an Electronic File Interchange Organization (EFIO)** – Give permission to an organization that submits application data through the bulk enumeration process. Visit the CMS EFI webpage for more information.

Identify your Medicare Administrative Contractor (MAC)

MACs are contractors that process Medicare Fee-For-Service (FFS) claims (also known as Medicare Part A and Part B claims) and enrollment applications on a jurisdiction-by-jurisdiction basis.

As an OTP, you are a Part B provider.

MACs also:

- Pay providers for Medicare FFS claims
- Answer providers' inquiries
- Educate providers about Medicare FFS billing requirements

If your OTP offers services in more than one state and those states are in different MAC jurisdictions, complete a separate enrollment application (CMS-855B) for each MAC jurisdiction. See the MAC Website List to find your MAC by state.

Contact your MAC if you have questions about enrolling in Medicare.

Enrollment Application (Form CMS-855B)

Decide if you will submit your application electronically or by paper form:

- Submit electronically through the Internet-based Provider Enrollment, Chain and Ownership System (PECOS):
  - PECOS is an online system that lets you complete most of your enrollment activities online, including
    - submitting your enrollment application
    - changing existing Medicare enrollment record information

OR

- Submit a paper enrollment application form to the MAC. Complete the paper-based applications using the Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers (Form CMS-855B).

Complete the Application

You must complete the following sections of the CMS-855B Medicare Enrollment Application Clinics/Groups Practices And Certain Other Suppliers or Electronic Equivalent:

- Section 1: Basic Information
- Section 2: Identifying Information
- Section 3: Final Adverse Legal Actions/Convictions
- Section 4: Practice Location Information
- Sections 5: Ownership Interest and/or Managing Control Information (For Organizations)
- Section 6: Ownership Interesting and/or Managing Control Information (For Individuals)
- Section 8: Billing Agency Information
- Section 13: Contact Person
- Section 15 Certification Statement
- Section 16: Delegated Official (Optional)
- Section 17: Supporting Documents

For a step-by-step walkthrough of each section and the information needed, please visit pages 8-17 of our OTP Enrollment fact sheet.

Setting up your Electronic Funds Transfer (Form CMS-588)

- All providers must receive payment electronically
- Fill out the CMS Form-588
- Bank account **must** be in the name of the enrolling OTP and **must** match the NPI registry

Pay the Enrollment Fee

The Medicare enrollment application fee applies to OTP providers.

- The application fee for CY2019 is $586
- There are two ways to pay:
  - Online through PECOS
  - The Medicare Enrollment for Providers and Suppliers webpage for paper applications

Help with Submitting Your Application

CMS has an External User Services (EUS) help desk to assist you with questions

- This resource supports people with I & A, PECOS, and other system questions. The help desk may not be able to give specific information about the Opioid Treatment Program.

Other resources:

- OTP Enrollment Fact Sheet
- OTP Enrollment Webpage
- "Who Should I Call?" CMS Provider Enrollment Assistance Guide

MAC Review of Enrollment Application

- MACs take approximately 45 days to review submitted applications
  - It may take longer if you use the paper application

- MACs may send development requests when they need more information or need you to take action
  - Reply quickly to these requests to avoid enrollment delay or denial
  - To avoid these requests and additional delays, complete all information and requirements before you submit your application

Fingerprinting & Site Visits

MACs may request fingerprints for individuals who have a 5% or greater direct/indirect ownership, as a partner of an OTP provider, when:

- Initially enrolling
- SAMHSA-certified after October 23, 2018

CMS will initiate an observational site visit for:

- Initial enrollment
- Revalidation
- When you add a practice location

Approval & Billing

If approved, your MAC will send:

- An enrollment approval letter
  - The letter will include your Provider Transaction Access Number (PTAN) – a Medicare-only number issued to providers
- A copy of the provider agreement

As an enrolled provider, your billing effective date is the later of:

- The date the MAC received your application
- The date you began delivering services at a new practice location

You can get a retrospective billing date for up to 30 days prior to the effective date but no earlier than January 1, 2020.

Changes to Your Application and Revalidation

Within 30 Days of the Change

- Changes in ownership and/or adverse legal action history

Within 90 Days of the Change

- All other changes (i.e. managing employees, practice locations, billing agencies.

OTPs will be required to revalidate on a 5 year cycle

Enroll in Medicare EDI for Claims Submission

- Identify the contractor responsible for your Electronic Data Interchange (EDI) connectivity
- Visit the Medicare Parts A/B and DME EDI Help Lines for more information on the level of contractor support available for entities that exchange Medicare Health Insurance Portability and Accountability Act (HIPAA) EDI transactions
- **The EDI Enrollment Form must be completed prior to submitting electronic media claims (EMC) or other EDI transactions to Medicare**

Question & Answer Session

Resources

- OTP Webpage : Enrollment, Medicaid, Medicare Advantage, Frequently Asked Questions
- New OTP Enrollment Fact Sheet
- SUPPORT for Patients and Communities Act
- CMS Roadmap: Fighting the Opioid Crisis

If we were unable to address your question, you may send it to OTP_Medicare@cms.hhs.gov.

Thank You

Visit:

- MLN Events webpage for more information on our conference call and webcast presentations
- Medicare Learning Network homepage for other free educational materials for health care professionals

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