Small Entity Compliance Guide

Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts; and COVID-19 Interim Final Rules.

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42 CFR Parts 405, 410, 411, 414, 415, 423, 424, 425, and 455

[CMS-1770-F, CMS-1751-F2, CMS-1744-F2, CMS-5531-IFC]

RIN 0938-AU81

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides." Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act (RFA).

The complete text of this final rule can be found on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1770-F.html.

Summary

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117-103, March 15, 2022), Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117-71, December 10, 2021), Infrastructure Investment and Jobs Act (Pub. L. 117-58, November 15, 2021), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116-260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115-271, October 24, 2018), related to Medicare Part B payment. In addition, this major final rule includes provisions regarding other Medicare payment policies described in sections III. and IV.

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Background

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. Per the statute, RVUs must be established for three categories of resources (work, practice expense (PE); and malpractice expense) and we must establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

Provisions of the Final Rule

● ***CY 2023 PFS Ratesetting:***

We are establishing work RVUs (based on the recommendations from the AMA's Relative Value Scale Update Committee) with refinements to approximately 50 percent of the 150 plus codes reviewed this year. We are addressing several issues related to how practice expenses are considered in setting rates, including the implementation of the second year of the clinical labor pricing update.

Last year, we finalized a 4-year transition to update the clinical labor pricing to maintain payment stability and mitigate potential negative effects on healthcare providers by gradually phasing in the changes over a period of time. We believe that the ongoing trend of market consolidation and site of service differentials highlight the need to update the overall PFS practice expense input data comprehensively, including a full accounting of indirect/overhead costs, to account for current trends in the delivery of health care, especially with regard to independent versus facility-based practices. We believe that CMS efforts to improve pricing accuracy would improve the sustainability of the PFS and the broader health system, improve access to care, and reduce inequitable disparities.

● ***Medicare Shared Savings Program:***

The policies advance Medicare's overall value-based care strategy of growth, alignment, and equity. The final policies are designed to increase the percentage of people with Medicare in accountable care arrangements, while balancing the need to sustain program participation, especially from ACOs that entered the program early on and have had positive performance, as well as address interested parties concerns on regional ACO financial benchmark adjustments from increasing program participation. The final rule changes are estimated to reduce overall program spending by $14.8 billion over 12 years relative to the $4.2 billion cost anticipated for the trajectory of the program at baseline, or $10.6 billion in absolute terms relative to a baseline without a Shared Savings Program in fee for service (FFS) Medicare.

● ***Audiology Services – Physician Order Requirement:***

We reviewed our regulatory provisions for diagnostic services to inform our policy objective to increase beneficiary access to diagnostic tests personally furnished by audiologists. We are finalizing our proposal to increase access to these specific services that will be personally furnished by an audiologist and will allow beneficiaries to receive care for non-acute hearing issues unrelated

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to balance assessments or hearing aids or examinations to prescribe, fit, or change hearing aids. We are finalizing our proposal to permit this direct access once every 12 months.

● ***Coding and Payment for Chronic Pain Management:***

We solicited comments in the CY 2022 PFS proposed rule on improving access to comprehensive chronic pain management. After considering public comments, we are establishing coding and payment for new physician and RHC/FQHC services that will allow practitioners to furnish services that address chronic pain.

● ***Telehealth:***

We are finalizing provisions in this year's rule, including:

++ Adding many of the services that are available temporarily for the duration of the PHE as Category 3, to continue to be available at least through the end of 2023.

++ Allowing several services that are available temporarily for the duration of the PHE, but are set to end with the end of the PHE, to remain available as Medicare telehealth for an additional 151 days after the end of the PHE, in alignment with the 151-day extension of many flexibilities enacted in the Consolidated Appropriations Act, 2022.

++ Adding newly requested therapy services on a temporary basis (Category 3 – available as Medicare telehealth through the end of CY 2023), based on utilization during 2021 and a belief that these may be furnished safely via two-way, audio/video communication technology.

++ Adding and updating modifiers and place of service codes to improve tracking of how and where Medicare telehealth services are furnished.

++ Taking action on interested party requests for adding services to the Medicare telehealth list. This process is part of the annual PFS rulemaking process.

++ Making technical updates to the Medicare Telehealth Services List in alignment with active CPT coding.

● ***Payment and Coding for Skin Substitutes:***

After considering the issues raised in public comments, we are not finalizing the payment approach outlined in the proposed rule where we considered establishing payment for skin substitute products under our typical approach for incident to supplies. Instead, we intend to conduct a Town Hall with interested parties in early CY 2023 to discuss alternative potential payment approaches for skin substitute products prior to CY 2024 rulemaking in order to achieve a transition to equitable payment for like products. We believe revising our policies overall would provide further payment clarity and consistency for practitioners who furnish services that include these products to ensure that beneficiaries have increased access to affordable treatment options. Patients who receive skin substitutes or wound dressings often have diabetes or chronic wounds that may result in amputations, have poor circulation, are bedridden/wheelchair users, and are more likely to be minorities.

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● ***Rebasing and Revising of the Medicare Economic Index (MEI) Cost Share weights for CY 2023:***
We are finalizing our proposal to rebase and revise the MEI using publicly available data sources for input costs that represent all types of physician practice ownership, not limited to only self-employed physicians. We typically use the MEI weights (that is, the share of overall costs attributable to professional work compared to practice expense or premium liability insurance) to determine payment rates and calculate geographic cost indices under the PFS. However, we estimate that using the updated MEI weights to update PFS rates would significantly impact payment amounts for certain clinicians (in particular, clinicians such as behavioral health specialists, who provide care with relatively low practice expense relative to clinician work would see significant decreases).

● ***Proposals for Part B Payment for Dental and Oral Health Care Services and RFI:***

To provide greater clarity to our current policies and respond to issues raised by interested parties, we are finalizing our proposal to codify certain existing Medicare FFS payment policies for medically necessary dental services and including payment for other dental services that are inextricably linked and significantly integral to the success of certain covered medical services. We are also finalizing a process to review public submissions of other potentially analogous medical services where dental services are inextricably linked. Further, beginning in CY 2024, we are finalizing Medicare FFS payment for certain dental services, such as dental exams and necessary treatments prior to the treatment for head and neck cancers.

● ***Behavioral Health Proposals:***

In order to improve access to behavioral health services, we are finalizing a number of policies in this year's rule, including:

++ Amending the direct supervision requirement under our "incident to" regulation at § 410.26 to allow behavioral health services be furnished under the general supervision of a physician or non-physician practitioner (NPP) when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. We believe that this change will facilitate utilization and extend the reach of behavioral health services.

++ Creating new coding describing General Behavioral Health Integration performed by clinical psychologists (CPs) or clinical social workers (CSWs) and those in RHCs and FQHCs to account for monthly care integration where the mental health services furnished by a CP or CSW are serving as the focal point of care integration.

● ***Evaluation & Management (E/M) Services:***

For CY 2021, we finalized coding and payment policies for office/outpatient E/M visits based on recommendations from the American Medical Association (AMA) that were widely supported by the physician community. As part of the ongoing updates to E/M visits and related coding guidelines, the AMA CPT Editorial Panel approved revised coding and updated guidelines for Other E/M services, effective January 1, 2023. We are adopting most of these changes in coding and documentation (which include hospital inpatient, hospital observation, emergency department, nursing facility, home or residence services, and cognitive impairment assessment) effective January 1, 2023.

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● ***PFS Conversion Factor (CF):***

We finalized coding and payment policies for office/outpatient E/M visits and several analogous services for CY 2021 that resulted in historic increases in payment for these services. Collectively, these policies resulted in a 9 percent decrease to the CF due to the statutory requirement that the PFS maintain budget neutrality. After we finalized the CY 2021 payments, Congress passed legislation in 2021 and 2022 mandating a 3.75 and 3.0 percent supplement to PFS payments for CY 2021 and CY 2022, respectively. These supplements offset the overall reduction to the conversion factor in both years due to the increased valuation of the E/M visits. In this rule, we are adopting revised AMA valuation recommendations for the E/M visits in non-office/outpatient settings. These codes, like the office/outpatient E/M visits, represent approximately 20 percent of payments under the PFS and will have a sizable impact to the CF due to the statutory requirement that the PFS maintain budget neutrality. We also note that the 3.0 percent payment supplement that applied for payments in CY 2022 is set to expire at the end of this payment year and the PFS CF will reflect this reduction, required under current statute. We are projecting the CF to decrease by approximately -4.47 percent from $34.61 in CY 2022 to approximately $33.06 in CY 2023.

● ***Opioid Treatment Programs (OTPs):***

We are finalizing modifications related to coverage for Opioid Use Disorder treatment services furnished by OTPs, including stabilizing the price for methadone, for CY 2023 and subsequent years, by revising our methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone. We will base the payment amount for the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone on the payment amount for methadone in CY 2021 and update this amount annually to account for inflation using the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription).

● ***Provider Enrollment:***

We are finalizing revisions to our provider enrollment regulations to prevent providers and suppliers that could present a risk of fraud, waste, or abuse from enrolling or maintaining enrollment in Medicare. The most noteworthy are:

++ Expanding our authority to deny or revoke a provider's or supplier's enrollment based on an OIG exclusion or felony conviction of an officer, director, or managing organization of the provider or supplier.

++ Permitting denial of payment to a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that does not meet licensure requirements.

++ Subjecting skilled nursing facilities (SNFs) to the highest level of provider enrollment screening, which involves requiring the SNF's 5 percent or greater owners to submit fingerprints for a criminal background check.

++ Requiring DMEPOS suppliers, home health agencies, opioid treatment programs, and Medicare Diabetes Treatment Programs that are undergoing any change in ownership to submit the fingerprints of their 5 percent or greater owners for a criminal background check.

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● **Medical Necessity and Documentation Requirements for Nonemergency, Scheduled, Repetitive Ambulance Services:**

We are clarifying our requirements for nonemergency, scheduled, repetitive ambulance services. Specifically, we clarify that:

++ The physician certification statement and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance; and

++ Coverage includes observation or other services rendered by qualified ambulance personnel.

● ***Quality Payment Program: MVP Update Proposals:***

We are finalizing the following changes:

++ MVPs: Revise seven previously finalized MVPs and add five new MVPs.

++ Subgroups:

-- Finalizing technical policies to clarify subgroup expectations, eligibility, and registration requirements.

-- Finalizing subgroup scoring clarifications: A subgroup will be scored using their affiliated group score, if available, for administrative claims-based measures in quality and cost.

● ***Quality Payment Program: Alternative Payment Model (APM) Entity Reporting Update Proposals:***

We are finalizing the option for APM Entities to report the Promoting Interoperability performance category at that APM Entity level.

● ***Quality Payment Program: MIPS: Program Update Proposals:***

We are finalizing the following:

++ Quality Performance Category:

-- Expanding the definition of a high priority measure to include health equity measures.

-- Changing the Consumer Assessment of Healthcare Providers and Systems for MIPS case-mix adjustor to use the "language other than English spoken at home" variable.

-- Increasing the data completeness criteria threshold from 70 to 75 percent for CY 2024 and 2025.

-- Establishing a set of 195 quality measures.

++ Cost Performance Category

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-- Establishing a maximum cost improvement score of 1 percentage point out of 100 starting with the CY 2022 performance period.

-- Updating the operational list of care episode and patient condition groups and codes by adding the Medicare Spending Per Beneficiary Clinician cost measure.

++ Improvement Activities Performance Category: Modifying the inventory by: adding four new, modifying five existing, and removing five improvement activities.

++ Promoting Interoperability Performance Category:

-- Requiring and modifying the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program measure.

-- Adding a new Health Information Exchange Objective option, the Enabling Exchange under the Trusted Exchange Framework and Common Agreement measure.

-- Consolidating from three to two levels of active engagement for the Public Health and Clinical Data Exchange Objective and requiring the reporting of active engagement option selected for the measures under the objective.

-- Modifying the scoring methodology for Promoting Interoperability and continuing to reweight the category for certain types of NPP MIPS eligible clinicians.

++ Performance Threshold: Using the CY 2019 MIPS payment year's rounded mean final score of 75 points as the performance threshold for the CY 2025 MIPS payment year.

++ Scoring: Scoring administrative claims measures using performance period benchmarks and clarifying the topped-out measure lifecycle when a measure is suppressed or a benchmark removed.

++ Third Party Intermediaries:

-- Clarifying the Qualified Clinical Data Registry (QCDR) measure self-nomination requirements, which includes a delay in the QCDR measure testing requirement for traditional MIPS, until the CY 2024 performance period.

-- Revising remedial action and termination policies.

++ Public Reporting/Care Compare: Expanding the information available to patients and caregivers when choosing a clinician; publicly reporting on individual clinician and group profile pages.

● ***Updates to the Electronic Prescribing for Controlled Substances (EPCS) for a covered Part D drug under a prescription drug plan or an MA-PD plan (section 2003 of the SUPPORT Act):***

We are finalizing updates to the small prescriber exception measurement period from the preceding to current year to align with all EPCS exceptions, extending the initial compliance action of sending letters to non-compliant prescribers to encompass CY 2023 and 2024.

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● ***Finalizing Provisions from Interim Final Rules for the Duration of the COVID-19 PHE:***

For RHCs and FQHCs, we are finalizing that certain flexibilities regarding virtual communications, visiting nursing services, and bed count data (related to provider-based RHCs) implemented on an interim final basis will terminate at the end of the COVID-19 PHE.

Small Entities Affected

For purposes of the RFA, physicians, nonphysician practitioners (NPPs), and suppliers including independent diagnostic testing facilities (IDTFs) are considered small businesses if they generate revenues of $10 million or less, according to the Small Business Administration size schedule. We estimate that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in section VI. of the final rule (Regulatory Impact Analysis), as well as elsewhere in the final rule are intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities. (See Table 148 (CY 2023 PFS Estimated Impact on Total Allowed Charges by Specialty) of the final rule, which show the payment impact on PFS services of the policies contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 148.)

For the Quality Payment Program, we estimate that between 144,700 and 186,000 clinicians will become Qualifying APM Participants (QPs) in the 2023 QP Performance. We estimate that approximately 719,516 clinicians will be MIPS eligible clinicians for the 2023 MIPS performance period. We estimate that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments and positive MIPS payment adjustments ($698 million redistributed) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality.

Section 101(a) of the Medicare Access and CHIP Reauthorization Act of 2015 repealed the previous statutory update formula (known as the Sustainable Growth Rate) and specified the PFS update for CY 2015 and beyond. The PFS update for CY 2023 is -0.5 percent, which is due to the removal of a 3.0 percent increase that applied for 2022 and the application of a 2.5 percent increase for 2023 as specified by the Consolidated Appropriations Act, 2023.

After applying the required budget neutrality adjustment, the conversion factor for January 1, 2023 through December 31, 2023 will be $33.89."

Please refer to section VI. of the final rule for the full regulatory impact analysis.

This rule imposes no direct federal compliance requirements with significant economic impacts on small entities. In order to assist physicians, NPPs, and suppliers including IDTFs in understanding and adapting to changes in Medicare billing and payment procedures, we have developed webpages that include additional material on the PFS at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html, https://qpp.cms.gov/ and https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.

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FOR FURTHER INFORMATION CONTACT:

MedicarePhysicianFeeSchedule@cms.hhs.gov, for any issues not identified below. Please indicate the specific issue in the subject line of the email.

Michael Soracoe, (410) 786-6312, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Kris Corwin, (410) 786-8864, for issues related to the comment solicitation on strategies for updates to practice expense data collection and methodology.

Sarah Leipnik, (410) 786-3933, and Anne Blackfield, (410) 786-8518, for issues related to the comment solicitation on strategies for improving global surgical package valuation.

Larry Chan, (410) 786-6864, for issues related to potentially misvalued services under the PFS.

Kris Corwin, (410) 786-8864, Patrick Sartini, (410) 786-9252, and Larry Chan, (410) 786-6864, for issues related to telehealth services and other services involving communications technology.

Regina Walker-Wren, (410) 786-9160, for issues related to nurse practitioner and clinical nurse specialist certification by the Nurse Portfolio Credentialing Center (NPCC).

Lindsey Baldwin, (410) 786-1694, or MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to PFS payment for behavioral health services.

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to PFS payment for evaluation and management services.

Geri Mondowney, (410) 786-1172, Morgan Kitzmiller, (410) 786-1623, Julie Rauch, (410) 786-8932, and Tamika Brock, (312) 886-7904, for issues related to malpractice RVUs and geographic practice cost indices (GPCIs).

MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to non-face-to-face nonphysician services/remote therapeutic monitoring services (RTM).

Zehra Hussain, (214) 767-4463, or MedicarePhysicianFeeSchedule@cms.hhs.gov, for issues related to payment of skin substitutes.

Pamela West, (410) 786-2302, for issues related to revisions to regulations to allow audiologists to furnish diagnostic tests, as appropriate without a physician order.

Emily Forrest, (410) 786-8011, Laura Ashbaugh, (410) 786-1113, Anne Blackfield, (410) 786-8518, and Erick Carrera, (410) 786-8949, for issues related to PFS payment for dental services.

Heidi Oumarou, (410) 786-7942, for issues related to the rebasing and revising of the Medicare Economic Index (MEI).

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Laura Kennedy, (410) 786-3377, Adam Brooks, (202) 205-0671, and Rachel Radzyner, (410) 786-8215, for issues related to requiring manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B to provide refunds with respect to discarded amounts.

Laura Ashbaugh, (410) 786-1113, and Rasheeda Arthur, (410) 786-3434, for issues related to Clinical Laboratory Fee Schedule.

Lisa Parker, (410) 786-4949, or FQHC-PPS@cms.hhs.gov, for issues related to FQHCs.

Michele Franklin, (410) 786-9226, or RHC@cms.hhs.gov, for issues related to RHCs.

Daniel Feller, (410) 786-6913, and Elizabeth Truong (410) 786-6005, for issues related to coverage of colorectal cancer screening.

Heather Hostetler, (410) 786-4515, for issues related to removal of selected national coverage determinations.

Lindsey Baldwin, (410) 786-1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Sabrina Ahmed, (410) 786-7499, or SharedSavingsProgram@cms.hhs.gov, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard and quality reporting requirements.

Aryanna Abouzari, (415) 744-3668, or SharedSavingsProgram@cms.hhs.gov, for issues related to the Shared Savings Program burden reduction proposal on OHCAs.

Janae James, (410) 786-0801, or Elizabeth November, (410) 786-4518, or SharedSavingsProgram@cms.hhs.gov, for issues related to Shared Savings Program beneficiary assignment and financial methodology.

Lucy Bertocci, (410) 786-4008, or SharedSavingsProgram@cms.hhs.gov, for inquiries related to Shared Savings Program advance investment payments, participation options and burden reduction policies.

Rachel Radzyner, (410) 786-8215, and Michelle Cruse, (443) 478-6390, for issues related to vaccine administration services.

Katie Parker, (410) 786-0537, for issues related to medical necessity and documentation requirements for nonemergency, scheduled, repetitive ambulance services.

Frank Whelan, (410) 786-1302, for issues related to Medicare provider enrollment regulation updates (including for skilled nursing facilities), State options for implementing Medicaid provider enrollment affiliation provisions, and conditions of payment for DMEPOS suppliers.

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Mei Zhang, (410) 786-7837, and Kimberly Go, (410)786-4560, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA-PD plan (section 2003 of the SUPPORT Act).

Amy Gruber, (410) 786-1542, or AmbulanceDataCollection@cms.hhs.gov, for issues related to the Medicare Ground Ambulance Data Collection System and Ambulance Fee Schedule (AFS).

Sundus Ashar, Sundus.ashar1@cms.hhs.gov, for issues related to HCPCS Level II Coding for skin substitutes.

Renee O'Neill, (410) 786-8821, or Kati Moore, (410) 786-5471, for inquiries related to Merit-based Incentive Payment System (MIPS).

Richard Jensen, (410) 786-6126, for inquiries related to Alternative Payment Models (APMs).

Lindsey Baldwin, (410) 786-1694 for inquiries related to Opioid Treatment Programs: CY 2022 Methadone Payment Exception.

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