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DEPARTM

Centers for Medicare & Medicaid Services

42 CFR Parts 410

[CMS-1751-IFC]

RIN 0938-AU95

Medicare Program; Opioid Treatment Programs: CY 2022 Methadone Payment Exception

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) freezes the payment to Opioid Treatment Programs for methadone in CY 2022 at the CY 2021 rate because it would not be appropriate to implement a decrease to the rate when substance use and overdoses have been exacerbated by the Coronavirus Disease 2019 (COVID-19) pandemic.

DATES: *Effective date:* These regulations are effective on January 1, 2022.

Comment date: To be assured consideration, comments on CMS-1751-IFC must be received at one of the addresses provided below, no later than 5 p.m. January 3, 2022.

ADDRESSES: Please refer to file code CMS-1751-IFC when commenting on issues in the interim final rule with comment period.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to **http://www.regulations.gov**. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1751-IFC,
P.O. Box 8016,
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1751-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

FOR FURTHER INFORMATION CONTACT: Lindsey Baldwin, (410) 786-1694, and Michele Franklin, (410) 786-9226.

SUPPLEMENTARY INFORMATION:

I. Background

A. Methadone

The Food and Drug Administration (FDA) has approved three medications for the treatment of opioid use disorder (OUD): methadone, buprenorphine, and naltrexone. These are referred to as medications for opioid use disorder (MOUD). The combination of MOUD with counseling and behavioral therapies to provide a "whole-patient" approach to OUD care is referred to as medication-assisted treatment (MAT). Opioid treatment programs (OTPs) are clinically driven and tailored to meet each patient's needs.[1] MOUD are also used to prevent or reduce opioid overdose. These medications are safe to use for months, years, or even a lifetime.[2]

As discussed in the CY 2020 PFS final rule (84 FR 62630), when used to treat those with a confirmed diagnosis of OUD, methadone cannot be dispensed by a pharmacy like certain other MOUD treatments (that is buprenorphine, buprenorphine-naloxone combination products, or naltrexone products) and therefore is not covered under Medicare Part D. Methadone is a schedule II controlled substance that is highly regulated because it has a potential for misuse and

[1] https://www.samhsa.gov/medication-assisted-treatment.
[2] https://www.samhsa.gov/medication-assisted-treatment.

serious adverse effects if taken by opioid-naïve individuals. Methadone is also used as an analgesic to treat chronic pain. When used for the treatment of OUD, methadone is taken daily and is available in tablet, tablet for suspension, and solution forms and can only be dispensed and administered by an OTP as provided under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) and 42 CFR part 8. In the CY 2020 PFS final rule, we noted that approximately 74 percent of patients receiving services from OTPs receive methadone for OUD treatment, with the vast majority of the remaining patients receiving buprenorphine (84 FR 62631).[3] In monitoring utilization of OTP services furnished under the new Medicare benefit, we have observed the percentage of Medicare beneficiaries receiving methadone to be closer to 95 percent.

According to SAMHSA's website, MAT has been shown to improve patient survival and increase retention in treatment.[4] Several studies indicate that retention in MAT is associated with lower mortality rates. One study stated that "Retention in MAT of over one year was associated with a lower mortality rate than that with retention of less than one year. Improved coverage and adherence to MAT and post-treatment follow-up are crucial to reduce the mortality.[5]"

B. Effects of the COVID-19 pandemic on the Opioid Crisis

The United States is now facing a fourth wave of the overdose crisis as a result of rising polysubstance use, such as the co-use of opioids and psychostimulants (for example, methamphetamine, cocaine). Recent CDC estimates of overdose deaths now exceed 96,000 for the 12-month period to March 2021[6], with overdose death rates surging among Black and Latino

[3] https://www.cdc.gov/drugoverdose/deaths/index.html.
[4] https://www.samhsa.gov/medication-assisted-treatment.
[5] Ma, J., Bao, YP., Wang, RJ. *et al.* Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. *Mol Psychiatry* **24,** 1868–1883 (2019). https://doi.org/10.1038/s41380-018-0094-5.
[6] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

Americans.[7] While overdose deaths were already increasing in the months preceding the COVID-19 pandemic, the latest numbers suggest an acceleration of overdose deaths during the pandemic. Public comments received in response to the CY 2022 PFS proposed rule described the recent increases in overdose deaths. One commenter stated that drug overdose deaths have reached historic highs in this country. According to the commenter, these spikes in substance use and overdose deaths reflect a combination of increasingly deadly illicit drug supplies, as well as treatment disruptions, social isolation, and other hardships imposed by the COVID-19 pandemic, but they also reflect the longstanding inadequacy of our medical infrastructure when it comes to preventing and treating substance use disorders (SUD) (for example, alcohol, tobacco, cannabis, opioids). Even before the COVID-19 pandemic began, more than 21 million Americans aged 12 or over in 2019 needed treatment for a SUD in the past year, but only about 4.2 million of them received any treatment or ancillary services for it.[8]

C. Opioid Use Disorders (OUDs) in the Medicare Population

Nearly one million adults aged 65 and older live with a SUD, as reported in 2018 data.[9] According to a Data Highlight published by CMS' Office of Minority Health, Medicare beneficiaries represent a growing proportion of individuals with OUD. Overall, 2.8 percent of Medicare Fee-for-Service (FFS) beneficiaries had an opioid use disorder (OUD) in 2018 out of a total of 38,665,082 Medicare FFS beneficiaries.[10] The problems associated with OUD in the Medicare population are compounded by chronic pain-associated conditions more common in later life, as well as the increased prevalence of multiple comorbidities and polypharmacy risks that exist among older adults.[11] A public comment received in response to the CY 2022 PFS

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[7] Drake, J., Charles, C., Bourgeois, J.W., Daniel, E.S., & Kwende, M. (January 2020). Exploring the impact of the opioid epidemic in Black and Hispanic communities in the United States. Drug Science, Policy and Law. doi:10.1177/2050324520940428.

[8] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-07-01-001, NSDUH Series H-55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[9] https://www.drugabuse.gov/publications/substance-use-in-older-adults-drugfacts.

[10] https://www.cms.gov/research-statistics-data-systems/cms-program-statistics/2018-medicare-enrollment-section.

[11] https://www.cms.gov/files/document/oud-disparities-prevalence-2018-medicare-ffs-dh-002.pdf.

proposed rule referred to increases in overdose deaths in individuals over age 65, stating that data from the CDC indicates that drug overdose deaths are increasing across all age groups, including those over age 65. Additionally, a recent Office of Inspector General (OIG) analysis of Medicare data reported that opioid overdoses have resulted in more than 200,000 deaths among Medicare beneficiaries nationwide since 2015. From 2016 to 2019, Medicare Part D saw a steady decline in opioid use, along with an increased use of drugs for treatment of OUD. OIG also noted that COVID-19 poses specific dangers for people using opioids, as respiratory diseases like COVID-19 can increase the risk of fatal overdose among those taking opioids and those with OUD are more likely to contract COVID-19 and suffer complications. With the onset of COVID-19 and the new dangers it poses for beneficiaries taking opioids, the OIG report states that it is imperative that the HHS closely monitor opioid use during this unprecedented time. During the first 8 months of 2020, about 5,000 Medicare Part D beneficiaries per month had an opioid overdose.[12]

II. Methadone Pricing

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy in § 410.67(d)(2)(i) under which the payment for the drug component of episodes of care will be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. Under the policy finalized at § 410.67(d)(2)(i)(B), for oral medications, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in 42 CFR part 414, subpart J and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate. The payment amount for methadone furnished by OTPs during an episode of care in CY

[12] Opioid Use in Medicare Part D During the Onset of the COVID-19 Pandemic. U.S. Department of Health and Human Services Office of Inspector General. Data Snapshot, OEI-02-20-00400. Published February 2021.

2021 is $37.38[13], which is 100 percent of ASP, as determined based on voluntarily submitted ASP data for the methadone.

Quarterly ASP pricing files are typically posted on the CMS website prior to the beginning of the quarter in which Medicare payments will be effective, which allows drug manufacturers that are required to submit their sales data to review and identify any issues. Due to the timing of CY PFS rulemaking and because ASP drug pricing file data is updated on a quarterly basis, the most recent ASP drug pricing file data available for this CY 2022 PFS final rule is the October 2021 update. For payment limits effective October 1, 2021, CMS posted the ASP drug pricing file on September 9, 2021.

In early September 2021, while gathering available manufacturer-reported ASP data for the annual update to the OTP drug pricing for CY 2022, we found that the volume-weighted ASP for oral methadone had decreased by just over 50 percent compared to last year's rate, from $37.38 to $17.64.[14] This reduction is due to inclusion of newly reported ASP data for methadone tablets, whereas previously the manufacturer-reported ASP data reflected only sales of the methadone oral concentrate. The ASP is volume-weighted; however, ASP reporting is not required for oral methadone and only a small subset of methadone manufacturers voluntarily submit ASP data. Of the nearly 50 available NDCs for oral methadone preparations with available pricing in the Red Book® compendia, voluntarily submitted ASP data is available for only three of these NDCs. Pricing for oral methadone is distinct from most other drug pricing based on ASP because oral methadone is not separately payable as a drug or biological under Medicare Part B, and manufacturers are not subject to ASP reporting requirements under section 1927(b)(3)(A)(iii) of the Act for those NDCs. Additionally, we do not currently have utilization data on the different forms of methadone that can be dispensed or administered at the OTPs.

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[13] https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf.

[14] The TRICARE rate for the drug portion of its weekly bundled payment for methadone treatment is $24.04 for 2022, which would also be a decrease from the CY 2021 payment rate under Medicare and cannot be used to set the Medicare payment rate for methadone in CY 2022 under § 410.67(d)(2)(i)(B) because ASP data is available for methadone.

That is, at this time we do not have data showing whether OTPs utilize oral methadone concentrate or tablets more often, or if the two formulations are utilized equally. When we researched OTP practice patterns as we were preparing to implement this new benefit, we received anecdotal reports that several OTPs used the oral concentrate exclusively.

For these reasons, we have questions as to whether the current ASP data, which reflects voluntarily reported data from only a very small subset of methadone manufacturers, is representative of utilization of the two forms of oral methadone by the Medicare beneficiaries receiving OUD treatment services in OTPs.

Given recent reports regarding the effects of the public health emergency (PHE) for COVID-19 on individuals with SUD, including OUD, and the questions we have related to whether the ASP data we have for methadone is reflective of OTP utilization due to the distinct nature of methadone pricing, as described above, we believe it is in the public's best interest not to implement a significant decrease in the payment rate for methadone furnished by OTPs as part of OUD treatment services without first having an opportunity to review the issue, seek input from the OTP stakeholder community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs. We note that section 1834(w)(2) of the Act allows for flexibility to consider the scope of services furnished, the characteristics of the individuals receiving services, and such other factors as the Secretary determines appropriate, in determining the rates paid to OTPs under Medicare.

Therefore, in this interim final rule with comment period (IFC), we are establishing a limited exception to the current methodology for determining the payment amount for the drug component of an episode of care in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the payment amount that was determined for CY 2021. We are also revising the regulation at § 410.67(d)(2)(i)(B), which governs the determination of

the payment amount for oral medications, to reflect this exception and to make a conforming change to the reference to 42 CFR part 414, subpart J.

Under this exception, the payment amount for the drug component of the methadone bundle described by HCPCS code G2067 (*Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*)) and the methadone add-on code described by HCPCS code G2078 (*Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*) will be maintained at the CY 2021 rate of $37.38 for the duration of CY 2022. We will apply the annual update to the non-drug component of HCPCS G2067 for CY 2022 as required under § 410.67(d)(4)(iii). We believe that maintaining the payment amount for methadone at the CY 2021 rate during CY 2022 will allow time for CMS to study the issue further and, if appropriate, to develop an alternative payment methodology for methadone that could be proposed through notice-and-comment rulemaking for CY 2023.

We seek comment on the exception to the payment methodology for the drug component of an episode of care that we are adopting in this IFC in order to maintain the payment rate for methadone at the CY 2021 payment amount during CY 2022. Additionally, we are seeking comment on OTP utilization patterns for methadone, particularly, the frequency with which methadone oral concentrate is used compared to methadone tablets in the OTP setting, including any applicable data on this topic. As the OTP benefit is still new under Medicare, we have not had the opportunity to fully understand how changes in the payment rates may affect OTP operations and beneficiary access to treatment. However, it is our intent to continue to refine our payment policies in order to best meet the needs of Medicare beneficiaries. We will consider the comments received in determining how best to determine the payment rate for methadone in CY 2023, including whether we should propose changes in future rulemaking to the structure of OTP

coding and payment in order to account for differences in pricing and utilization for the different formulations of methadone.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and consider public comment on the proposed rule before the provisions of the rule are finalized and take effect, either as proposed or as amended, in accordance with the Administrative Procedure Act (APA) (Pub. L. 79-404), 5 U.S.C. 553 and, where applicable, section 1871 of the Act. Specifically, 5 U.S.C. 553 requires the agency to publish a notice of proposed rulemaking in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Section 553(c) of the APA further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment for rulemaking carrying out the administration of the insurance programs under Title XVIII of the Act. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

According to the National Quality Forum (NQF) September 2021 Report, *Addressing Opioid-Related Outcomes Among Individuals With Co-occurring Behavioral Health Conditions*, "the ongoing opioid and SUDs crisis has been amplified by COVID-19 pandemic. The convergence of these two public health emergencies has led to an acceleration in overdose deaths. As information continues to emerge related to the long-term impacts of the pandemic, it has become increasingly clear that individuals with SUDs have been disproportionately affected by the disruption to daily life. Not only are individuals with a recent diagnosis of SUDs—

particularly OUD and tobacco use disorder—at a significantly increased risk for COVID-19, but individuals with SUDs and COVID-19 had significantly worse outcomes than other COVID-19 individuals (for example, death and hospitalization). The mental health ramifications of social distancing and isolation also have far reaching impacts, especially for individuals with SUDs. In particular, younger adults and racial/ethnic minorities experienced disproportionally worse mental health outcomes during the pandemic, including increased substance use and suicidal ideation."[15]

Additionally, the NQF September 2021 Report states, "OUD is often associated with a high risk for morbidity, mortality, and other adverse health and social conditions. Adverse events include, but are not limited to, overdose, infection, injury, hospitalization, and suicide. Individuals with OUD and/or other SUDs may face challenges across multiple facets of their lives, such as unemployment or underemployment, fractured family structures, and involvement with the criminal justice system." It goes on to say that "with over 255 individuals dying each day from a drug overdose—and with just over 70 percent of all drug overdose deaths involving an opioid—it is essential for stakeholders to take action to address overdose and mortality related to the ongoing SUD crisis.[10,16]

We believe that it would be contrary to the public interest to allow the payment rate for methadone furnished by OTPs to decrease to $17.64, a decrease of over 50 percent from the current payment rate of $37.38, on January 1, 2022, as required under the current regulation. As described in section I. of this IFC, the PHE for COVID-19 has had a significant impact on individuals with SUD, including OUD. We believe it is essential to ensure that Medicare beneficiaries retain access to treatment for OUD at OTPs at a time when overdose deaths are increasing. As we previously discussed, this is the second year we have updated the payment

[15] https://www.qualityforum.org/ProjectMaterials.aspx?projectID=93434.
[16] Ahmad F, Rossen L, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/nvss/vsrr/drugoverdose-data.htm. Published August 5, 2021. Last accessed August 2021.

rates for OTPs. This benefit was established by the SUPPORT Act as part of the strategy to fight the opioid crisis. This benefit is still building the trust and confidence of OTPs to enroll in Medicare and furnish OUD treatment services and we have heard stakeholder feedback regarding the shortage of available behavioral health specialists for treatment of SUDs. According to a report by the National Academies of Sciences, Engineering, and Medicine Committee on Medication-Assisted Treatment for Opioid Use Disorder, "the barriers preventing broader access to life-saving medications for OUD include stigma, inadequate professional education and training related to the evidence base for using medication, and challenges in connecting individuals with medication-based treatment due to delivery system fragmentation, regulatory and legal barriers, barriers related to public and private health insurance coverage, and reimbursement and payment policies that do not incentivize the provision of high-value care for OUD"[17]. From 2010 through 2019, we have seen that the Medicare population has a growing need for OUD treatment. Specifically, analyzing Medicare data regarding chronic condition counts, we found that in 2010 there were approximately 311,000 beneficiaries with OUD and this number has grown to approximately 983,000 beneficiaries as of 2019.[18] We anticipate that this data will continue to trend upward and that the number of Medicare beneficiaries with OUD will increase as well as the need for access to these lifesaving services. We are still studying the payment system implemented in CY 2020 and the implications of the payment methodologies put into place. We had not contemplated that there could be such a significant fluctuation in payment at this point especially for one of the most commonly used medications for OUD treatment.

In addition, as discussed in section II. of this IFC, we have questions with respect to whether the ASP data we have for methadone is reflective of OTP utilization due to the distinct

[17]National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Medication-Assisted Treatment for Opioid Use Disorder; Mancher M, Leshner AI, editors. Washington (DC): National Academies Press (US); 2019 Mar 30. https://www.ncbi.nlm.nih.gov/books/NBK541389/.

[18] https://www2.ccwdata.org/web/guest/medicare-tables-reports.

nature of methadone pricing and anecdotal reports that the more expensive methadone oral concentrate is more commonly used by OTPs. We note that public comments received in response to the CY 2020 PFS proposed rule described that OTPs incur costs associated with rigorous storage and inventory tracking systems required by the DEA and suggested a cautious approach to pricing the drugs to ensure the success of these programs (84 FR 62656). Regarding the annual update to the rates, commenters also indicated that if the OTP rates were not adequately updated, this would create access to care issues as federal and state mandated OTP costs grow faster than Medicare reimbursements (84 FR 62668). Additionally, in the CY 2017 PFS final rule, we referred to the shortage of available psychiatric and other mental health professionals in many parts of the country, and stated we believe it is important to identify and make accurate payment for models of care that facilitate access to psychiatric and other behavioral health specialty care (81 FR 80233). As a result, we believe it is in the public's best interest not to decrease the payment rate for methadone furnished by OTPs as part of OUD treatment services and risk restricting access to OUD treatment services without first having an opportunity to review the issue, seek input from the OTP stakeholder community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs.

As explained in section II. of this IFC, we identified the reduction in the payment rate for methadone in September as part of determining the annual update to the drug component of the OTP payment rates under § 410.67(d)(2)(i) in conjunction with the development of the CY 2022 PFS final rule. Because we did not propose any change to the payment methodology for methadone in the CY 2022 PFS proposed rule, it was not possible for us to address the payment decrease in the CY 2022 PFS final rule. In addition, we have determined that it would be impracticable to undertake a new notice-and-comment rulemaking process in order to freeze the

payment rate for methadone before the payment rate decrease required under the current regulations takes effect on January 1, 2022.

If we were to proceed with notice-and-comment rulemaking procedures to propose a change to the payment methodology for methadone, we estimate the process would take at least 6 months to complete, which would require that the decreased rate take effect on January 1, 2022, and remain in effect for several months before we would be able to issue a final rule to modify the payment rate. For the reasons explained previously, we believe that allowing the payment decrease to take effect could cause harm to the Medicare beneficiaries who rely on OTP services during a time where stable and predictable access to OUD treatment services is needed the most. We believe that implementing a sudden and significant decrease in the rate for methadone could affect the ability of OTPs to continue to offer services to Medicare beneficiaries, thereby impeding access to treatment for OUD, at a time when overdose deaths are at an all-time high. As noted in section I. of this IFC, estimates of total drug overdose deaths now exceed 96,000 for the 12-month period to March 2021. Therefore, we believe that maintaining the payment amount for methadone at the CY 2021 rate while we seek information about OTP utilization patterns and explore other alternatives for addressing our payment methodology is of life-saving importance. Thus, in light of the timing constraints and the potential consequences of allowing the payment reduction to take effect, we have determined that it would be impracticable and contrary to the public interest to undertake notice-and-comment rulemaking before freezing the payment rate for methadone during CY 2022.

Therefore, we find good cause to waive notice-and-comment procedures and to issue this IFC. We are providing a 60-day public comment period as specified in the **DATES** section of this document. The agency will carefully consider any comments received before taking any future action with respect to this policy.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

This IFC is necessary to make policy changes under Medicare fee-for-service. Specifically, this IFC freezes payment to Opioid Treatment Programs for methadone in CY 2022 at the CY 2021 rate because it would not be appropriate to implement a decrease to the payment rate when substance use and overdoses have been exacerbated by the COVID-19 pandemic.

We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this IFC. The relevant sections of this IFC contain a description of significant alternatives, if applicable.

In the CY 2020 PFS final rule (84 FR 62667), we finalized a policy under which the payment to opioid treatment programs (OTPs) for the drug component of episodes of care will be updated annually using the most recent data available from the applicable pricing mechanism at the time of ratesetting for the applicable calendar year. However, in gathering available manufacturer-reported ASP data for the annual update to the OTP drug pricing for CY 2022, we found that the volume-weighted ASP for oral methadone had decreased by just over 50 percent compared to last year’s rate because it now includes newly reported ASP data for methadone

tablets, whereas previously only manufacturer-reported data for methadone oral concentrate had been included. The ASP is volume-weighted; however, because ASP reporting is not required for oral methadone, we have questions as to whether this data is representative of utilization of the two types of oral methadone in OTPs. Given the recent reports on the effects of the PHE for COVID-19 on individuals with substance use disorders, including opioid use disorder, and the questions we have related to whether the ASP data we have for methadone is reflective of OTP utilization, we believe it is in the public's best interest not to implement a significant decrease in the payment rate for methadone furnished by OTPs without first having an opportunity to review the issue, seek input from the OTP stakeholder community regarding utilization of methadone oral concentrate compared to utilization of methadone tablets in the OTP setting, and consider how this information should factor into the determination of the payment rate for methadone furnished by OTPs. Therefore, in this IFC we are modifying our payment methodology in order to maintain the price for the drug component of the methadone bundle described by HCPCS code G2067 (*Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program*) and the methadone add-on code described by HCPCS code G2078 (*Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure*) at the CY 2021 rate of $37.38 on an interim final basis for the duration of CY 2022.

Based on an analysis of the 2020 and 2021 utilization of the OTP benefit, we estimate that the Part B cost impact of maintaining the CY 2021 price for the drug component of the methadone bundle and the methadone add-on code for take-home supplies of methadone on an interim final basis for the duration of CY 2022 rather than implementing the decrease in the available manufacturer-reported ASP data will be approximately $25 million. Additionally, we believe that not implementing the decrease based on the available manufacturer-reported ASP

data is in the public's best interest given the recent reports on the effects of the PHE for COVID-19 on individuals with OUD, especially as it pertains to overdose deaths. We note that we are also seeking public comment on patterns of utilization of oral methadone by OTPs in order to inform future rulemaking on this topic.

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this IFC will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This

analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this IFC will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2021.

List of Subjects in 42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

2. Amend § 410.67 by revising paragraph (d)(2)(i)(B) to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(B) *For oral medications*. (*1*) Except as provided under paragraph (d)(2)(i)(B)(*2*) of this section, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart J of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate and for buprenorphine will be calculated using the National Average Drug Acquisition Cost.

(*2*) For CY 2022, the payment amount for methadone is the payment amount determined under paragraph (d)(i)(B)(*1*) of this section for methadone in CY 2021.

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Dated: October 29, 2021.

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Xavier Becerra,

Secretary,
Department of Health and Human Services.

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