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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 8

RIN 0930-AA39

Medications for the Treatment of Opioid Use Disorder

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services ("HHS" or "the Department").

ACTION: Final rule.

SUMMARY: This final rule modifies and updates certain provisions of regulations related to Opioid Treatment Program (OTP) accreditation, certification, and standards for the treatment of Opioid Use Disorder (OUD) with Medications for Opioid Use Disorder (MOUD) in OTPs. This includes making flexibilities put forth during the COVID-19 Public Health Emergency (PHE) permanent, as well as expanding access to care and evidence-based treatment for OUD. The final rule also removes all language and rules pertaining to the Drug Addiction and Treatment Act (DATA) Waiver from the regulations pursuant to the "Consolidated Appropriations Act, 2023".

DATES: The effective date of this final rule is April 2, 2024, and the compliance date is April 2, 2026.

FOR FURTHER INFORMATION CONTACT: Robert Baillieu, MD, MPH, Physician and Senior Advisor, SAMHSA/CSAT, 5600 Fishers Lane, Room 13-E-30, Rockville, MD, 20857, Phone: 202-923-0996, Email: Robert.Baillieu@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: The discussion below includes an Executive Summary and overview describing the rule, responses to public comments, an impact statement, and other required regulatory analyses.

Executive Summary

A. Overview

This regulation finalizes the Department's proposed rule concerning Medications for the Treatment of Opioid Use Disorder published in the Federal Register on December 16, 2022 (87 FR 77330). It also finalizes proposals found in the Department's supplemental notice of proposed rulemaking concerning removal of the DATA-2000 Waiver requirements issued in the Federal Register on February 13, 2023 (88 FR 9221). The final rule makes changes to the Department's existing regulations concerning OTPs at 42 CFR part 8.

The Controlled Substances Act (CSA), under 21 U.S.C. 823(h)(1)-(3), provides that "[t]he Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)" if, among other things, the applicant "is determined by the Secretary to be qualified (under standards established by the Secretary [of HHS]) to engage in the treatment with respect to which registration is sought[,]" and "if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment."[1] The Secretary's standards authorized under section 823(h) have been published as regulations under part 8 of title 42 of the Code of Federal Regulations ("42 CFR part 8" or "part 8").[2] Among other things, these regulations establish the procedures by which the Secretary of HHS determines whether a program is qualified to dispense opioid agonist medications in the treatment of opioid use disorders, and standards regarding the appropriate quantities of opioid agonist medications that may be provided for unsupervised use by individuals undergoing such treatment.[3] In addition, "a

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[1] *See* 21 U.S.C. 823(h)(1)-(3).
[2] For readability, the Department refers to specific sections of 42 CFR part 8 using a shortened citation with the "§" symbol except where necessary to distinguish title 42 citations from other CFR titles, such as title 45 CFR, and in footnotes where the full reference is used.
[3] *See* 42 CFR 8.1

program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication" that is also "registered under 21 U.S.C. 823(h)(1)" is described as an "Opioid Treatment Program" (OTP).[4]

On December 29, 2022, the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117-328) was enacted, resulting in the removal of requirements to obtain a waiver from the registration requirements of 21 U.S.C. 823(h)(1) for qualifying practitioners seeking to dispense or prescribe schedule III, IV, or V controlled substances that are FDA-approved for use in "maintenance and detoxification treatment." Practitioners with a waiver under section 823(h)(2) were limited in the number of patients with OUD they may treat at any one time, and depending on the practitioner's experience or qualifications, this statutory limitation was set at either 30, 100, or 275.[5] The Secretary was also authorized to change the patient limitations by regulation, and qualifying practitioners had to satisfy the requirements of 42 CFR 8.610 through 8.655 "(or successor regulations)" in order to treat up to 275 patients, which was the maximum number under the law.[6]

In this final rule, the Department modifies certain provisions of part 8 to update OTP accreditation and certification standards, as well as treatment standards for the provision of medications for opioid use disorder (MOUD) as dispensed by OTPs. Pursuant to the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117-328), the final rule also removes language pertaining to requirements for individual practitioners to dispense (including by prescribing) certain types of MOUD with a waiver under 21 U.S.C. 823(h)(2). SAMHSA has developed this final rule in consultation with the Drug Enforcement Administration.

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[4] The terms "narcotic drugs" and "detoxification treatment" included in this paragraph are found in statute. SAMHSA recognizes that these terms can be stigmatizing for some people, and not aligned with current terminology. SAMHSA uses "opioid agonist medications" (see Treatment Improvement Protocol (TIP) 63) as an alternative to "narcotic drugs" and "withdrawal management" as the alternative to "detoxification treatment".
[5] Formally under 21 U.S.C. 823(h)(2)(B)(iii)
[6] Formally under 21 U.S.C. 823(h)(2)(B)(iii)(II)(dd). *See* https://www.govinfo.gov/content/pkg/USCODE-2016-title21/html/USCODE-2016-title21-chap13-subchapI-partC-sec823.htm.

The final rule draws on experience from the COVID-19 Public Health Emergency (PHE), as well as more than 20 years of practice-based research. The COVID-19 PHE necessitated changes to policy guidance and legal exemptions to protect the public's health, promote physical distancing and to preserve patient and OTP staff safety. In March 2020, SAMHSA published guidance regarding flexibilities that could be leveraged in the provision of unsupervised doses of methadone and the use of telehealth when initiating buprenorphine.[7] These flexibilities represented the first substantial change to OTP treatment and medication delivery standards in more than 20 years, and their role in facilitating access to treatment is supported by research.

This final rule not only makes these COVID-19-related flexibilities permanent, but also updates standards to reflect an accreditation and treatment environment that has evolved since part 8 went into effect in 2001. Accordingly, the Department is updating part 8 to promote practitioner autonomy; remove discriminatory or outdated language; create a patient-centered perspective; and reduce barriers to receiving care. These elements have been identified in the literature and in feedback as being essential to promoting effective treatment in OTPs.[8,9,10]

To this end, the definition of a practitioner has been modified to refer to a provider who is appropriately licensed by the State to prescribe (including dispense) medications. Admission criteria have been updated, as required by section 1252(b) of the 'Consolidated Appropriations Act, 2023', to remove significant barriers to entry, such as the one-year requirement for opioid use disorder (OUD),[11] while also defining the scope and purpose of the 'initial' and 'periodic'

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[7] *See* https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf and https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

[8] Suen LW, Coe WH, Wyatt JP, Adams ZM, Gandhi M, Batchelor HM, Castellanos S, Joshi N, Satterwhite S, Pérez-Rodríguez R, Rodríguez-Guerra E, Albizu-Garcia CE, Knight KR, Jordan A. Structural Adaptations to Methadone Maintenance Treatment and Take-Home Dosing for Opioid Use Disorder in the Era of COVID-19. Am J Public Health. 2022 Apr;112(S2):S112-S116. doi: 10.2105/AJPH.2021.306654. PMID: 35349324; PMCID: PMC8965183.

[9] Kleinman MB, Felton JW, Johnson A, Magidson JF. "I have to be around people that are doing what I'm doing": The importance of expanding the peer recovery coach role in treatment of opioid use disorder in the face of COVID-19 health disparities. J Subst Abuse Treat. 2021 Mar;122:108182. doi: 10.1016/j.jsat.2020.108182. Epub 2020 Oct 21. PMID: 33160763; PMCID: PMC7577312.

[10] Suen LW, Castellanos S, Joshi N, Satterwhite S, Knight KR. "The idea is to help people achieve greater success and liberty": A qualitative study of expanded methadone take-home access in opioid use disorder treatment. Subst Abus. 2022;43(1):1143-1150. doi: 10.1080/08897077.2022.2060438. PMID: 35499469.

[11] *See* 42 CFR 8.12(e)(1).

medical examinations. The final rule also includes new definitions to expand access to evidence-based practices such as split dosing, telehealth and harm reduction activities. In addition, outdated terms such as 'detoxification' have been revised to remove stigmatizing language.

The Department promotes practitioner autonomy and individualized care by finalizing the provision containing the criteria for unsupervised doses of methadone. This includes removal from sole consideration the length of time an individual has been in treatment and requirements for rigid reliance on toxicology testing results that demonstrate complete and sustained abstinence from all substances prone to misuse. Based on the clinical judgment of the treating provider, patients may be eligible for unsupervised, take-home doses of methadone upon entry into treatment. This change recognizes the importance of the practitioner-patient relationship and is consistent with modern substance use disorder treatment standards.[12] It also allows for greater flexibility in creating plans of care that promote recovery activities such as employment or education, while also eliminating the barrier of frequent OTP visits for individuals without access to reliable transportation.[13]

Accreditation and certification standards have been updated to codify the use of online/electronic forms, and to reflect a modern treatment environment. Part 8 has also been updated to facilitate information sharing between Accreditation Bodies and SAMHSA, particularly in those circumstances where there have been changes or violations in accreditation. The final rule also clarifies administrative issues pertaining to accreditation, mobile medication units and interim treatment.

This final rule makes treatment in OTPs more accessible to patients, while also supporting evidence-based and patient-centered care. In creating these changes, SAMHSA has relied on

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[12] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

[13] Ware OD, Frey JJ, Cloeren M, Mosby A, Imboden R, Bazell AT, Huffman M, Hochheimer M, Greenblatt AD, Sherman SA. Examining Employment and Employment Barriers Among a Sample of Patients in Medication-Assisted Treatment in the United States, Addictive Disorders & Their Treatment: December 2021 - Volume 20 - Issue 4 - p 578-586 doi: 10.1097/ADT.0000000000000295.

published evidence, stakeholder feedback, public comments to the proposed rule and the need to expand access to care in the face of a growing overdose epidemic, exacerbated by the COVID-19 pandemic.[14] This is brought further into focus by the HHS declaration of a public health emergency for the opioid crisis which has been renewed regularly since 2017.[15] While the COVID-19 public health emergency expired as of May 11, 2023,[16] the lessons learned from the COVID-19 pandemic remain relevant for ensuring access to safe and effective substance use disorder treatment. The changes created by this final rule are expansive but are focused on permanently implementing the existing flexibilities and updating policies and practices that are based on evidence. In this way, SAMHSA believes that much of what is contained in the rule will not represent a significant burden for OTPs and, in fact, will reduce burdens and confer many benefits to providers and patients. The final rule, therefore, supports OTPs in their on-going provision of equitable and evidence-based care to often marginalized patients with OUD. The final rule also is consistent with the HHS Overdose Prevention Strategy and the National Drug Control Strategy, both of which call for increasing access to and the uptake of evidence-based treatments for substance use disorders.[17]

B. Background

As of June 2023, there are over 2,000 OTPs in the United States, providing care to over 650,000 patients.[18] These are the only settings within which methadone, a schedule II opioid

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[14] Tanz LJ, Dinwiddie AT, Snodgrass S, O'Donnell J, Mattson CL, Davis NL. A qualitative assessment of circumstances surrounding drug overdose deaths during the early stages of the COVID-19 pandemic. SUDORS Data Brief, No 2. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2022.
[15] *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.
[16] *See* https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html
[17] *See* https://www.hhs.gov/overdose-prevention/. *See also* https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/21/fact-sheet-white-house-releases-2022-national-drug-control-strategy-that-outlines-comprehensive-path-forward-to-address-addiction-and-the-overdose-epidemic/
[18] Data from the U.S. Department of Health and Human Services, Treatment Locator, at https://findtreatment.gov/

receptor agonist, can be legally provided to patients with OUD outside the context of hospital admission or certain other special circumstances.[19]

An OTP is an accredited treatment program with SAMHSA certification and Drug Enforcement Administration (DEA) registration to administer and dispense opioid agonist medications that are approved by FDA to treat OUD. Such medications include methadone, buprenorphine, a schedule III partial opioid receptor agonist, and naltrexone which is an opioid receptor antagonist. For purposes of certification, OTPs must also offer adequate medical, counseling, vocational, educational, as well as other assessment and treatment services either onsite or by referral to an outside entity or practitioner.[20]

Practitioners treating OUD and the OTPs in which they practice must continuously adapt to evolving patterns of drug misuse. This is increasingly complicated by changes in controlled medication prescribing practices, supply chains and patterns of drug use. Indeed, the early opioid epidemic of the 1990s was characterized by an increased supply of prescription opioids.[21] By 2010, however, the U.S. began to see rapid increases in overdose deaths involving heroin[22] and then by 2013, synthetic opioids other than methadone – primarily illicitly manufactured fentanyl – contributed to a further rise in overdose-related deaths.[23,24] The introduction of xylazine into the illicit drug supply and its associated harms further adds to an evolving, complex, and dangerous situation.[25]

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[19] See 21 CFR 1306.07.
[20] Substance Abuse and Mental Health Services Administration. (2015). Federal guidelines for opioid treatment programs. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration.
[21] Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. MMWR MorbMortal Wkly Rep. 2011 Nov 4; 60(43):1487-1492.
[22] Rudd RA, Paulozzi LJ, Bauer MJ, Burleson RW, Carlson RE, Dao D, Davis JW, Dudek J, Eichler BA, Fernandes JC, Fondario A. Increases in heroin overdose deaths—28 states, 2010 to 2012.MMWR MorbMortal Wkly Rep. 2014 Oct 3; 63(39):849.
[23] Gladden RM, Martinez P, Seth P. Fentanyl law enforcement submissions and increases in synthetic opioid-involved overdose deaths—27 states, 2013–2014. MMWR MorbMortal Wkly Rep. 2016; 65:837–43.
[24] O'Donnell JK, Gladden RM, Seth P. Trends in deaths involving heroin and synthetic opioids excluding methadone, and law enforcement drug product reports, by census region—United States, 2006–2015. MMWR MorbMortal Wkly Rep. 2017; 66:897–903.
[25] *See* https://www.samhsa.gov/sites/default/files/colleague-letter-xylazine.pdf

The isolation, anxiety and reduced access to resources experienced by many during the COVID-19 pandemic has exacerbated substance misuse and overdose deaths. According to provisional data from the Centers for Disease Control and Prevention (CDC), a predicted 109,940 Americans died from a drug overdose in the 12-month period ending in January 2023.[26] Synthetic opioids (primarily illicitly manufactured fentanyl) appear to be the principal driver of overdose deaths, increasing 55 percent from 2019 to 2020 and further increasing 26 percent from 2020 to 2021.[27] Overdose deaths involving cocaine also increased by 22 percent from 2019 to 2020. These deaths are likely linked to co-use or mixing (by illicit producers) of cocaine with illicitly manufactured fentanyl or heroin.[28] The rise in fentanyl use or exposure, concurrent substance misuse, as well as overdose deaths, necessitates changes to part 8 that expand access to care, and promote engagement in OTP services, while also maintaining oversight and accreditation activities. Oversight and accreditation standards are supported as a means of promoting evidence-based care, while minimizing diversion and adverse patient and public health outcomes.

C. Regulatory Background

On January 17, 2001 (66 FR 4075), the Department issued final regulations for the use of opioid agonist medications (referred to as narcotic drugs at that time) in treatment and withdrawal management (referred to as detoxification at that time) of OUD. The final rule repealed the treatment regulations enforced by the Food and Drug Administration (FDA), and created a new regulatory system based on an accreditation model. In addition, the final rule shifted administrative responsibility and oversight from the FDA to SAMHSA. This rulemaking initiative followed a 1995 study, 'Federal Regulation of Methadone Treatment'[29] by the Institute

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[26] Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2023.
[27] Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2023. Available at http://wonder.cdc.gov.
[28] Ibid.
[29] For full text, see: https://www.ncbi.nlm.nih.gov/books/NBK232108/

of Medicine (IOM, now known as the National Academy of Medicine) and reflected recommendations by the IOM and several other entities to improve the treatment of OUD by allowing for increased medical judgment in the care of patients with OUD. The IOM report recommended that the FDA process-oriented regulations should be reduced in scope to allow more clinical judgment in treatment and greater reliance on guidelines. The IOM report also recommended designing a single inspection format, having multiple elements, that would (1) provide for consolidated, comprehensive inspections conducted by one agency (under a delegation of Federal authority, if necessary), which serves all agencies (Federal, State, local) and (2) improve the efficiency of the provision of methadone services by reducing the number of inspections and consolidating their purposes.

To address these recommendations, SAMHSA proposed a "certification" system based on accreditation. Under the system, an applicant organization who intended to dispense opioid agonist medications in the treatment of OUD must first obtain from SAMHSA, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification depended upon the applicant organization obtaining accreditation from a private nonprofit entity, or from a State agency, that had been approved by SAMHSA to accredit OTPs.

Accreditation Bodies were directed to base accreditation decisions on a review of an application for accreditation and on surveys (onsite inspections) conducted every three years by OUD treatment experts. In addition, Accreditation Bodies must apply specific opioid treatment accreditation elements that reflect "state-of-the-art" opioid treatment guidelines. Further to this, accreditation standards required that OTPs have quality assurance systems that consider patient outcomes.

The 2001 final regulations replaced FDA 'approval' of programs, with direct government inspection in accordance with more detailed process-oriented regulations. These process-oriented regulations continue to prescribe many aspects of oversight and treatment. To this end, subpart B

of the regulation addressed accreditation and includes steps that Accreditation Bodies must follow to achieve approval to accredit OTPs. It also set forth the Accreditation Bodies' responsibilities, including the use of accreditation elements during accreditation surveys. Subpart C described the sequence and requirements for obtaining certification and addressed how and when programs must apply for initial certification and renewal of their certification. Subpart D elucidated the procedures for review of the withdrawal of approval of the Accreditation Body or the suspension and proposed revocation of an OTP certification.

Since publication of the final rule in 2001, it has been updated on occasion to include new medications, such as buprenorphine, while also updating or adding new rules governing the provision of such medications. Subpart F, added in 2016, described criteria for increasing the patient limit for those practitioners meeting Federal requirements to prescribe buprenorphine to 275.[30]

On December 29, 2022, the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117-328), was signed into law and immediately eliminated the requirement for individual practitioners to obtain a waiver to prescribe certain schedule III – V medications for the treatment of OUD, commonly known as the "DATA-Waiver." Before the Consolidated Appropriations Act, 2023 was enacted, "qualifying practitioners" were required to obtain waivers (formerly under 21 U.S.C. § 823(h)(2)) from the separate DEA registration requirement, under 21 U.S.C. § 823(h), that is needed to enable dispensing of certain controlled medications used in maintenance or withdrawal management ("detoxification") treatment of OUD. Section 1252(b) of the 'Consolidated Appropriations Act, 2023' (Pub. L. No: 117-328) also required removal of the one-year history of opioid misuse prior to admission to an OTP. This was included in the part 8 NPRM (87 FR 77330), and public comments supported the change.

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[30] See https://www.federalregister.gov/documents/2016/07/08/2016-16120/medication-assisted-treatment-for-opioid-use-disorders.

In 2001 there were close to 900 OTPs, but that number has grown to over 2,000 by 2023.[31] Over this period, the incidence of fentanyl misuse has increased, escalating with the onset of the COVID-19 pandemic in early 2020. To protect the public's health and reduce the risk of COVID-19 infection among patients and providers, SAMHSA issued flexibilities in the provision of take-home doses of methadone and initiation of buprenorphine via telehealth, including through audio-only platforms, that allowed for continued treatment of OUD with reduced direct patient contact. Each of these flexibilities represented a significant change to previous treatment standards and are discussed in detail below. It is important to note that SAMHSA has issued extensions to both the initiation of buprenorphine via telehealth flexibility and methadone take-home flexibility, effective upon expiration of the COVID-19 Public Health Emergency, and in effect for the period of one year from the end of the COVID-19 Public Health Emergency, or until such time that the U.S. Department of Health and Human Services publishes final rules revising 42 C.F.R part 8, whichever occurs sooner.[32]

Flexibility For Methadone Medication Take-Home Doses in Opioid Treatment Programs

Among the existing standards for medication administration and dispensing of methadone are limitations on unsupervised or "take-home" use. These prior standards were established early in the history of methadone as a medication for OUD, and the criteria for determining whether a patient may be allowed take-home doses were restrictive, requiring daily visits to the OTP for extended periods of time, and adherence to strict measures of sustained stability as described in 42 CFR part 8.[33] These criteria can pose disruption to employment, education and

[31] SAMHSA treatment locator. See https://dpt2.samhsa.gov/treatment/directory.aspx.
[32] *See* https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance; and https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/buprenorphine-at-opioid-treatment-programs
[33] https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8?toc=1.

other daily activities for patients, and several of the criteria reflect outdated biases that promote stigma and discourage people from engaging in care in OTPs.

In March 2020, as a result of the pandemic, SAMHSA issued exemptions that permitted State regulatory authorities to request blanket exceptions to allow patients to take-home more doses of methadone; 43 States and the District of Columbia did so.[34] With this flexibility, SAMHSA allowed OTPs to dispense up to 28 days of "take-home" methadone doses to "stable" patients for the treatment of OUD, and up to 14 doses of "take-home" methadone for "less stable" patients "who the OTP believes can safely handle this level of take-home medication."[35] Although the duration of this flexibility was not initially specified, a SAMHSA FAQ published in April 2020, indicated that the flexibility was tied with the duration of "the current national health emergency . . . ."[36]

The intention of the methadone take-home flexibility was to reduce the risk of COVID-19 infection among patients and providers. Beyond this, the flexibility promotes individualized care that considers patient characteristics and program involvement beyond time in treatment. By reducing the burden on patients to visit the OTP daily, this flexibility may reduce stigma for those seeking treatment, while also providing more equitable access to care as telemedicine in OTPs is expanded. It also allows those who reside far from an OTP or who lack access to reliable transportation to receive treatment, while also being able to gain or maintain employment, attend school, care for loved ones and engage in other required activities of daily living.

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[34] HHS Guidance for Opioid Treatment Programs. https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.
[35] *See* https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf.
[36] See https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

The methadone take-home flexibility has been met with widespread support among patients,[37] OTPs,[38] and State authorities.[39] Patients reported that increased take-home doses of methadone left them feeling more respected as responsible individuals.[37,40] In a national meeting, State authorities reported that the flexibilities were appreciated by patients and OTPs alike, with no significant change in rates of diversion seen since the COVID-19 PHE was declared.[41] Indeed, analysis of the relevant data indicates that the actual level of misuse, diversion or harm from methadone is more likely to occur when it is prescribed for pain as opposed to OUD, and that the rate of diversion is lower than that of oxycodone or hydrocodone.[42] Additionally, a survey found that diversion of methadone is low among patients receiving take-home doses under the COVID-19 PHE flexibility.[43,44] Further to this, analysis of data on fatal overdoses from January 2019 to August 2021 demonstrated that this flexibility did not lead to more deaths involving methadone.[45]

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[37] Hatch-Maillette MA, Peavy KM, Tsui JI, Banta-Green CJ, Woolworth S, Grekin P. Re-thinking patient stability for methadone in opioid treatment programs during a global pandemic: Provider perspectives. J Subst Abuse Treat. 2021 May;124:108223. doi: 10.1016/j.jsat.2020.108223. Epub 2020 Dec 5. PMID: 33342667; PMCID: PMC8005420.

[38] Joseph G, Torres-Lockhart K, Stein MR, Mund PA, Nahvi S. Reimagining patient-centered care in opioid treatment programs: Lessons from the Bronx during COVID-19. J Subst Abuse Treat. 2021 Mar;122:108219. doi: 10.1016/j.jsat.2020.108219. Epub 2020 Dec 3. PMID: 33353790; PMCID: PMC7833302.

[39] "To Save Lives From Opioid Overdose Deaths, Bring Methadone Into Mainstream Medicine", Health Affairs Forefront, May 27, 2022.

[40] Krawczyk, N., Rivera, B. D., Levin, E., & Dooling, B. C. E. (2023). Synthesizing evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. The Lancet. Public health, 8(3), e238–e246. https://doi.org/10.1016/S2468-2667(23)00023-3

[41] The 2022 American Association for the Treatment of Opioid Dependence (AATOD) Conference, Baltimore, Maryland, October 30 - November 3, 2022.

[42] NIDA. 2018, June. Medications to Treat Opioid Use Disorder. Retrieved from https://irp.drugabuse.gov/wp-content/uploads/2019/12/NIDA-Medications-to-treat-opioid-use-disorder_2018.pdf.

[43] Figgatt, MC, Salazar Z, Day E, Vincent L, Dasgupta N. Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19, Journal of Substance Abuse Treatment, Volume 123, 2021, https://doi.org/10.1016/j.jsat.2021.108276.

[44] Dooling, B.C.E. & Stanley, L.E. (2021). *Unsupervised use of opioid treatment medications: Report II of the extending pandemic flexibilities for opioid use disorder treatment project*. GW Regulatory Studies Center. https://regulatorystudies.columbian.gwu.edu/unsupervised-use-opioid-treatment-medications.

[45] Jones, C. M., Compton, W. M., Han, B., Baldwin, G., & Volkow, N. D. (2022). Methadone-Involved Overdose Deaths in the US Before and After Federal Policy Changes Expanding Take-Home Methadone Doses From Opioid Treatment Programs. JAMA psychiatry, e221776. Advance online publication. https://doi.org/10.1001/jamapsychiatry.2022.1776.

Recognizing the importance of this flexibility, SAMHSA released guidance on November 18, 2021, (subsequently updated on April 19, 2023[46]) that extended the methadone take-home flexibility for one year past the end of COVID-19 PHE (May 11, 2024), or until such time that the Department publishes this final rule, whichever occurs sooner.

The Opioid Treatment Program Flexibility to Prescribe MOUD via Telehealth Without An Initial In-Person Physical Evaluation

Telehealth is a mode of service delivery that has been used in clinical settings for over 60 years and empirically studied for just over 20 years.[47,48,49] Between 2016 and 2019, use of telehealth, in general, doubled from 14 to 28 percent[50] while substance use disorder (SUD) treatment, offered through telehealth over the same period, increased from 13.5 to 17.4 percent.[51] This trend has rapidly increased between 2019 and 2021, due to the COVID-19 pandemic.[52]

The pandemic spurred use of telehealth for the treatment of OUD with buprenorphine, a schedule III partial opioid receptor agonist. Prior to buprenorphine's development, the only opioid agonist that could be used to treat OUD was methadone dispensed through OTPs. Methadone has a relatively complicated pharmacological profile, necessitating closer observation

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[46] *See* https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance

[47] Bashshur, R. L., Shannon, G. W., Bashshur, N., & Yellowlees, P. M. (2016). The empirical evidence for telemedicine interventions in mental disorders. Telemedicine and e-Health, 22(2), 87-113.

[48] Lustig, T. (2012). The role of telehealth in an evolving health care environment: Workshop summary. National Academies Press.

[49] Mace, S., Boccanelli, A., & Dormond, M. (2018). The use of telehealth within behavioral health settings: Utilization, opportunities, and challenges. University of Michigan School of Public Health, Behavioral Health Workforce Research Center.

[50] American Medical Association (2019). Telehealth implementation playbook. Digital Health Implementation Playbook Series. https://www.ama-assn.org/system/files/2020-04/ama-telehealthimplementation-playbook.pdf

[51] Uscher-Pines, L., Cantor, J., Huskamp, H. A., Mehrotra, A., Busch, A., & Barnett, M. (2020). Adoption of telemedicine services by substance abuse treatment facilities in the U.S. Journal of Substance Abuse Treatment, 117, 108060.

[52] Melamed OC, deRuiter WK, Buckley L, Selby P. Coronavirus Disease 2019 and the Impact on Substance Use Disorder Treatments. Psychiatr Clin North Am. 2022 Mar;45(1):95-107. doi: 10.1016/j.psc.2021.11.006. Epub 2021 Nov 12. PMID: 35219445; PMCID: PMC8585604.

of new patients to ensure that initial doses do not exceed an individual's tolerance for the medication.[53]

In response to the COVID-19 PHE, as declared by Secretary Azar on January 31, 2020, pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247), the DEA granted temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations under 21 U.S.C. 802(54)(D), one of the seven distinct categories of telemedicine envisioned under the statutory definition of the practice of telemedicine. In order to prevent lapses in care, these exceptions allowed for the prescribing of controlled medications via telemedicine encounters even when the prescribing practitioner had not conducted an in-person medical evaluation of the patient.

These telemedicine flexibilities authorized practitioners to prescribe schedule II-V controlled medications via audio-video telemedicine encounters, including schedule III-V narcotic controlled medications approved by the Food and Drug Administration (FDA) for maintenance and withdrawal management treatment of opioid use disorder via audio-only telemedicine encounters, provided that such prescriptions otherwise comply with the requirements outlined in DEA guidance documents, DEA regulations, and applicable Federal and State law. DEA granted those temporary exceptions to the *Ryan Haight Act* and DEA's implementing regulations via two letters published in March 2020: the March 25, 2020 "Dear Registrant" letter signed by William T. McDermott, DEA's then-Assistant Administrator, Diversion Control Division,[54] and the March 31, 2020 "Dear Registrant" letter signed by Thomas W. Prevoznik, DEA's then-Deputy Assistant Administrator, Diversion Control Division.[55]

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[53] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.
[54] William T. McDermott, DEA Dear Registrant letter, Drug Enforcement Administration (March 25, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf.
[55] Thomas W. Prevoznik, DEA Dear Registrant letter, Drug Enforcement Administration (March 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf

Building upon this, SAMHSA implemented OTP regulatory flexibilities designed to help address the impact of the COVID-19 pandemic on OTPs and their patients.[56] In April 2020, SAMHSA exempted OTPs from the requirement to perform an in-person physical evaluation (under 42 CFR 8.12(f)(2)) for any patient who was to be treated by the OTP with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determined that an adequate evaluation of the patient could be accomplished via telehealth. The duration of this exemption was specifically tied with the "period of the national emergency declared in response to the COVID-19 pandemic",[57] and the exemption did not include induction of methadone via telehealth technology.

Recent research has demonstrated that telehealth can be an effective tool in integrating care and extending the reach of specialty providers,[58] and that among those patients requiring treatment with buprenorphine, there are high levels of satisfaction with the use of telehealth services.[59] Additionally, there are no significant differences between telehealth and in-person buprenorphine induction in the rate of continued substance use, retention in treatment or engagement in services.[58,60] Research also shows that there is no significant difference in client and provider ratings of therapeutic alliance when using telehealth technology platforms.[59] Further to this, research demonstrates that actions to facilitate access to buprenorphine-based treatment for OUD during the COVID-19 pandemic were not associated with an increased proportion of overdose deaths involving buprenorphine.[61]

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[56] OTPs are authorized to dispense narcotic maintenance and detoxification medication under 21 U.S.C. 823(h)(1) and regulated under 42 CFR part 8.

[57] *See* https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

[58] Guille, C., Simpson, A. N., Douglas, E., Boyars, L., Cristaldi, K., McElligott, J., Johnson, D., & Brady, K. (2020). Treatment of opioid use disorder in pregnant women via telemedicine: A nonrandomized controlled trial. JAMA Network Open, 3(1), e1920177-e1920177.

[59] King, V. L., Brooner, R. K., Peirce, J. M., Kolodner, K., & Kidorf, M. S. (2014). A randomized trial of web-based videoconferencing for substance abuse counseling. Journal of Substance Abuse Treatment, 46(1), 36-42.

[60] Vakkalanka, J. P., Lund, B. C., Ward, M. M., Arndt, S., Field, R. W., Charlton, M., & Carnahan, R. M. (2022). Telehealth Utilization Is Associated with Lower Risk of Discontinuation of Buprenorphine: a Retrospective Cohort Study of US Veterans. Journal of general internal medicine, 37(7), 1610–1618. https://doi.org/10.1007/s11606-021-06969-1.

[61] Tanz, L. J., Jones, C. M., Davis, N. L., Compton, W. M., Baldwin, G. T., Han, B., & Volkow, N. D. (2023). Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic. JAMA network open, 6(1), e2251856. https://doi.org/10.1001/jamanetworkopen.2022.51856

On May 9, 2023, SAMHSA issued guidance[62] that extended the buprenorphine telehealth flexibility for OTPs for one year past the end of COVID-19 PHE, or until such time that the Department publishes this final rule, whichever occurs sooner. In the face of an escalating overdose crisis and an increasing need to reach remote and underserved communities, making the buprenorphine telehealth flexibility permanent is of paramount importance. This final rule permits initiation of buprenorphine at the OTP, by the OTP practitioner, if an OTP physician, primary care physician, or other authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be, or was, accomplished via audio-only or audio-visual telehealth technology.

SAMHSA believes that evidence underlying the initiation of buprenorphine using telehealth also is applicable to the treatment of OUD with methadone, and warrants expanding access to methadone therapy by applying some of the buprenorphine in-person examination flexibilities to treatment with methadone in OTPs.[63] However, SAMHSA also acknowledges that there are differences between these two medications. Accordingly, this final rule allows for the use of audio-visual telehealth for any new patient who will be treated by the OTP with methadone if a program physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via an audio-visual telehealth platform. SAMHSA is not extending this change to the use of audio-only telehealth platforms in assessing new patients who will be treated by the OTP with methadone because methadone, in comparison to buprenorphine, holds a higher risk profile for sedation in patients presenting with mild somnolence which may be easier to identify through an audio-visual telehealth platform. The final rule is not applicable to, and does not authorize, the prescription of methadone pursuant to a telehealth visit. Instead, this change

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[62] See: https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/buprenorphine-at-opioid-treatment-programs

[63] Chan B, Bougatsos C, Priest KC, McCarty D, Grusing S, Chou R. Opioid treatment programs, telemedicine and COVID-19: A scoping review. Subst Abus. 2022;43(1):539-546. doi: 10.1080/08897077.2021.1967836. Epub 2021 Sep 14. PMID: 34520702.

applies to the ordering of methadone by appropriately licensed OTP practitioners and dispensed to the individual patient by the OTP under existing OTP procedures.

Further to this, health care providers who receive Federal financial assistance are reminded of their obligations to ensure that their audio-only and audio-visual telehealth platforms are accessible to individuals with disabilities and afford an opportunity for meaningful access for limited English proficient (LEP) individuals. Federal civil rights laws prohibit discrimination on the basis of disability and may require health care providers to make reasonable modifications to their policies, practices, or procedures to ensure that a person who is not able to use audio-visual telehealth platforms based on their disability has an equal opportunity to benefit from treatment with MOUD. Similarly, Federal civil rights laws prohibit discrimination on the basis of national origin (including language ability) and require recipients to take reasonable steps to provide meaningful access to LEP individuals. This may require the provision of a qualified interpreter and/or translated material, such that they have the opportunity benefit from treatment with MOUD.

Expanding Access to Services

On June 28, 2021, the DEA introduced allowance for OTPs to add a "mobile component" to their existing registration and waived any obligation for an OTP mobile medication unit complying with these requirements to separately register at the remote locations where it dispenses.[64] On September 21, 2021, SAMHSA released guidance on the establishment of mobile and non-mobile medication units and allowable services.[65] While part 8 currently allows

[64] *See* https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-for-narcotic-treatment-programs-with-mobile-components.
[65] *See* https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines#mobile.

OTPs certified by SAMHSA to establish medication units (as defined under 42 CFR 8.2), the final rule further defines mobile units and clarifies potential services, interventions and accreditation processes.

Additionally, the COVID-19 pandemic highlighted the importance of providing harm reduction services to OTP patients. On April 7, 2021, the CDC and SAMHSA jointly announced that Federal funding could be used to purchase rapid fentanyl test strips (FTS) for drug checking purposes.[66] This was proposed in part to help curb the dramatic spike in drug overdose deaths largely driven by the use (both intentional and unintentional) of potent synthetic opioids, primarily illicitly manufactured fentanyl. FTS can be used to determine if drugs have been mixed or cut with fentanyl, providing people who use drugs and their communities with important information about fentanyl in the illicit drug supply so they can take steps to reduce their risk of overdose.

On December 16, 2022, HHS issued a notice of proposed rulemaking (NPRM) entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330). In that NPRM, the Department proposed to modify certain provisions of part 8 to update Opioid Treatment Program (OTP) accreditation and certification standards, treatment standards for the provision of medications for opioid use disorder as dispensed by OTPs, and requirements for individual practitioners eligible to dispense (including by prescribing) certain types of Medication for Opioid Use Disorder (MOUD) with a waiver under 21 U.S.C. 823(h)(2). Proposed changes sought to make flexibilities put forth during the COVID-19 PHE permanent, and to also update standards to reflect an OTP accreditation and treatment environment that has evolved since 42 CFR part 8 came into effect in 2001. To this end, the Department proposed to update part 8 by: removing outdated language; fostering a more patient-centered perspective; and reducing barriers to receiving care. These elements have been identified in the literature and in feedback as being essential to promoting effective treatment and retention in care provided by OTPs.

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[66] *See* https://www.samhsa.gov/newsroom/press-announcements/202104070200

To expand access to care, the Department proposed to update OTP admission criteria as described in 42 CFR part 8. This included removal of the one-year requirement for opioid addiction before admission to an OTP, in favor of consideration of problematic patterns of opioid use. Indeed, evidence-based standards of care demonstrate that it is more prudent to admit those individuals who either: meet diagnostic criteria for active moderate to severe OUD; are in OUD remission; or are at high risk for recurrence or overdose. In conjunction with updated standards that include extended take-home doses of methadone and access to telehealth, this is likely to expand access while also improving retention in treatment.

Additionally, the Department proposed to update 42 CFR part 8 to reflect evidence-based practice, treatment standards, and the workforce currently providing services in OTPs. Proposed changes included: expanding the definition of a treatment practitioner to include any provider who is appropriately licensed to dispense and/or prescribe approved medications; addition of evidence-based paradigms of care such as split dosing, telehealth and harm reduction activities; removing outdated terms such as 'detoxification'; review of criteria for provision of take-home doses of methadone; strengthening the patient-practitioner relationship through promotion of shared and evidence-based decision making; allowing for early access to take-home doses of methadone for all patients to promote flexibility in creation of plans of care that promote recovery activities such as employment or education, while also allowing those with unstable access to reliable transportation the opportunity to also receive treatment; promotion of mobile medication units to expand an OTP's geographic reach; and review accreditation standards. The proposed changes sought to organize existing flexibilities and practice updates in a manner that makes them permanent and cohesive.

Removal of DATA-Waiver Requirements

Section 1262(a)(1) of the Consolidated Appropriations Act, 2023 (Pub. L. No: 117-328), which was enacted on December 29, 2022, amended the CSA (21 USC 823(h)) by eliminating

the requirement that practitioners obtain a waiver to prescribe certain schedule III – V medications for the treatment of opioid use disorder (OUD). This immediately removed the requirement for practitioners to submit a notification of intent and to receive the Drug Addiction Treatment Act of 2000 (DATA)-Waiver before prescribing buprenorphine.

Before the Consolidated Appropriations Act, 2023 was enacted, "qualifying practitioners" were required to obtain waivers (formerly under 21 U.S.C. § 823(h)(2)) from a separate registration requirement, under 21 U.S.C. § 823(h), that is needed to enable dispensing of certain schedule II – V narcotic medications used in maintenance or detoxification treatment. Practitioners with a waiver of this kind were limited in the number of patients they could treat with this type of medication at any one time.

In July 2016, SAMHSA published a final rule (81 FR 44711) that added 'subpart F' to 42 CFR part 8 under the authority of former 21 U.S.C. 823(h)(2)(B)(iii)(III). Among other things, subpart F authorized eligible practitioners with a waiver under 21 U.S.C. 823(h)(2) to request approval to treat up to 275 patients under certain conditions. The December 16, 2022, NPRM entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330), proposed three changes to subpart F: 1) altering section headings to remove the current question-and-answer style and replacing it with a standard format; 2) updating Section 8.610 to remove stigmatizing language and to also clarify that the 275-patient waiver is limited to three years in duration and; 3) removing Section 8.635 to eliminate annual reporting requirements for practitioners approved to treat up to 275 patients.

Pursuant to section 1262 of the Consolidated Appropriations Act, 2023, the Department published a supplemental notice of proposed rulemaking (SNPRM), entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA-2000 Waiver Requirements' (88 FR 9221), on February 13, 2023. This SNPRM proposed to remove in its entirety subpart F of 42 CFR part 8 in addition to language throughout 42 CFR part 8 that specifically references or implicates the DATA-2000 waiver process.

D. Analysis and Discussion of Comments

On December 16, 2022, the Department published a notice of proposed rulemaking entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330). The public comment period ended on February 14, 2023, and a total of 373 comments were received. On February 13, 2023, the Department also released a supplemental NPRM entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA-2000 Waiver Requirements' (88 FR 9221), to bring proposed changes to 42 CFR part 8 rule into alignment with the 'Consolidated Appropriations Act, 2023' (Pub. L. 116 – 260). The supplemental NPRM closed for public comments on March 14, 2023. An additional 27 comments were received, the majority of which pertained to the December 16, 2022, NPRM.

General Comments

Terminology changes, and reducing stigma

Comments conveyed widespread approval of terminology and language changes aimed at expanding care while also reducing stigmatization for patients receiving treatment for OUD. Some commenters noted that language changes alone will not be sufficient to eliminate, stigma, injustice, and institutionalized marginalization. Others were concerned that updated language was not accurate - for example, that it detracts focus from other forms of treatment. One commenter additionally suggested that SAMHSA and other authorities consider updating their organizations' names to maintain consistency with destigmatizing language changes. Such changes have been proposed by SAMHSA and HHS[67], but not yet enacted by Congress as of this date.

[67] *See* https://www.samhsa.gov/sites/default/files/samhsa-fy-2024-cj.pdf

Another commenter suggested eliminating or reducing the requirements for random toxicology testing as an important method to further reduce stigma and loss of bodily autonomy among a population that has often faced violent and punitive treatment. They also suggest reexamining the differential regulation of methadone versus buprenorphine.

Response: SAMHSA recognizes the role of language in perpetuating stigma and discrimination, and is committed to taking steps to use language that is positive, patient-centered, productive and inclusive. It recognizes that changing language, alone, will not immediately eliminate harms suffered by those struggling with and in recovery from substance use disorders. SAMHSA and its Federal, State, local, Tribal and territorial partners have been working to impact health equities and promote justice through its programs, services and regulations, as evidenced in the improvements made in this regulatory language. SAMHSA has also emphasized support for recovery and recovery services.[68] It will take time to assure consistency of language throughout documents; changing names of Federal agencies requires legislative action. Toxicology testing is a clinical tool that is used to inform the treatment process, should never be used punitively, and must be conducted in a way that is respectful of the individual and in accordance with clinical and professional standards.[69] Also, the different regulation of methadone (in schedule II) versus buprenorphine (in schedule III) stems from how these substances are scheduled and from how they are regulated under 21 USC 823(h), which requires "practitioners who dispense narcotic drugs (other than narcotic drugs in schedule III, IV, or V) to individuals for maintenance treatment or detoxification treatment" to obtain an annual separate registration for that purpose.

<u>Error in citations</u>

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[68] *See* https://www.samhsa.gov/find-help/recovery?
[69] *See* https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf

One commenter expressed concern that several cited research studies were not accurately interpreted as used for this NPRM. For example, citation 103 is used as justification for provision of counseling at OTPs, but the study was done in a primary care setting. Another commenter stated that the same reference, 103, is incorrect and the citation in the body does not match the DOI link – one references HIV testing in Africa while it appears they intend to reference the HSU study on psychiatric comorbidity.

Response: SAMHSA made every effort to ensure that the citations listed were correct. The error noted with citation 103 has been rectified. Within the body of the text, the citation is appropriate as the text explicitly describes this study and highlights that in combination with other evidence, a comprehensive approach to treatment is associated with improved outcomes. Indeed, the proposed rule also includes evidence from other settings such as Emergency Departments. It is important to note that economic analysis of OUD treatment interventions is uncommon and so assessment of such evidence requires consideration of all sources.

Comments on Accreditation Standards

<u>One-year accreditation following one recommendation</u>

Many commenters opposed the proposed change under Section 8.4, that provides, based on their understanding, only one-year accreditations to OTPs with recommendations. They believe this change in accreditation regulations will essentially end three-year accreditations. Commenters stated that with the number of standard ratable elements it is unreasonable to expect facilities to meet every accreditation element. With about 1,400 elements evaluated during each survey, not having even one recommendation is an unobtainable standard for many OTPs. Commenters stressed that having such a high standard would result in a substantial number, if not all, of OTPs having to submit to an annual accreditation inspection.

Response: Section 8.4 addresses the responsibilities of the Accreditation Bodies. Since 2001, Section 8.4(b), in response to noncompliant programs stated "(1) If an Accreditation Body receives or discovers information that suggests that an OTP is not meeting Federal opioid use disorder treatment standards, or if survey of the OTP by the Accreditation Body otherwise demonstrates one or more deficiencies in the OTP, the Accreditation Body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies." The proposed rule retained language about noncompliance with one or more standards as it refined expectations for Accrediting Bodies' follow up with these programs. Based on comments, this final rule clarifies the intent of this subpart and survey and accreditation requirements, while also explicitly clarifying that non-critical findings would not result in only a one-year accreditation.

Implementation schedule not to exceed 60 days

One comment drew attention to the 33% reduction in time this proposed change allows for submitting an implementation schedule, pursuant to Section 8.4. The commenter believes this would introduce significant new barriers to the delivery of care to persons with OUD while doing nothing to improve the standard of care. Other commenters agreed that 60 days is an insufficient amount of time to adequately address recommendations in a manner that improves patient care.

Response: SAMHSA thanks commenters for this information. Based on the comments, the time frames allotted for noncompliant OTPs to implement corrections in section 8.4 were extended to 180 days. This recognizes that some corrective measures may take more than 60 days to successfully implement.

Surveyor subjectivity and need for flexibility

In reference to Section 8.4, several commenters mentioned that accreditation surveys are affected by the subjective interpretations of individual auditors, and that this subjectivity contributes to their objection to one recommendation being a preclusion for a three-year accreditation. Some OTP guidelines may no longer be consistent with newly proposed rules and are inconsistent with current evidence-based practices. Further, several commenters urged flexibility in accreditation decisions as the unique situations of many OTPs prevents constant, exact compliance. In other words, commenters urged flexibility in decision making based on center needs and circumstances as well as the seriousness of the recommendation(s) and its effect on patient care and safety.

Response: SAMHSA reviews the policies and procedures of all Accreditation Bodies, including those related to the training and supervision of surveyors. SAMHSA meets regularly with the Accrediting Bodies to assure consistency in the application and interpretation of 42 CFR part 8. It also reviews the performance of Accreditation Bodies by inspecting a selected sample of the OTPs accredited by the respective Body each year, and, under section 8.4 will receive reports of OTP surveys when deficiencies are discovered. Together, these help to ensure consistency across and within Accreditation Bodies. Following finalization of this rule, SAMHSA intends to update the 2015 Federal Guidelines for OTPs[70] to assure the OTP guidelines are consistent with newly proposed rules and with current evidence-based practices.

Cost burden

Commenters reported concern that proposed changes to accreditation, in Section 8.4, will result in more frequent inspections, which will require significant time and financial expenditures. Commenters expressed their conviction that the increased frequency of inspections will take providers away from patient care and direct the focus of both providers and administrators away

[70] *See* https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf

from patient needs. Furthermore, inspections have financial costs for OTPs; some commenters asserted that the cost to some OTPs of more frequent surveys might be more than the OTP can financially bear. Many commenters fear that the additional administrative and financial costs will lead to fewer OTPs and thus reduced options for patients in dire need of treatment.

Response: SAMHSA has made changes to Section 8.4 of this final rule to respond to commenter concerns about potentially increased rates of one-year accreditation results. In the final rule, Section 8.4(b) has been altered to not only clarify the criteria for one-year or three-year accreditation, but to also remove potential misunderstanding around whether a specific number of recommendations might lead to less than three-year accreditations. Rather than implement a specific number of recommendations that might lead to less than three-year accreditation, the final rule determines the length of accreditation based on the severity of the non-compliance. With this clarification in the final rule, rates of one year accreditation and repeat surveys are not expected to increase.

Comments on Treatment Standards

MOUD treatment criteria changes

Commenters overwhelmingly conveyed support for discontinuing requirements for a one-year history of OUD to access treatment as well as support for those changes that update admission criteria for minors. Some commenters also suggested that SAMHSA should remove the requirement that individuals cannot initiate methadone treatment more than twice a year.

Response: The final rule removes the requirement, previously at 8.12(e)(2), that minors are required to have had two documented unsuccessful attempts at short-term "detoxification", or withdrawal management, or drug-free treatment within a 12-month period to be eligible for maintenance treatment, and that those seeking withdrawal management, previously under

8.12(e)(4), cannot initiate methadone treatment more than twice per year. Instead, OTPs shall ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: the person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. There is nothing stated within the Federal regulations or statutes that limits the number of times a person can initiate treatment with methadone or any other medication.

Interim treatment

Comments supported extending interim treatment from 120 days to at least 180. Commenters request the availability of interim maintenance treatment through all OTPs and not just public and private not-for-profit OTPs, pursuant to 8.12(j)(1). Some commentors suggested interim treatment provision in primary care providers' offices.

Response: Interim treatment was developed to expand access to OTP services in urgent circumstances. The proposed rule specifically amended the duration of interim treatment from 120 days to 180 days so that on a temporary basis, a patient may receive services from an OTP, while awaiting access to more comprehensive treatment services. Language pertaining to public and not-for-profit OTPs has been removed from the final rule in order to expand access to interim treatment among all OTPs. This is done in recognition of a need to bring individuals into treatment and in response to public comment.

Expanding the definition of long-term care facilities

There is widespread support among commenters for the addition of jails and prisons under the definition of long-term care facilities at 8.11(h)(3), thus expanding the waiver of OTP certification to better allow for equitable access to treatment and reduce the potential for civil

rights violations. Group homes and withdrawal management programs are also mentioned by some commenters in this context, as well as any licensed non-hospital residential treatment programs with medical staffing, a DEA registration and the ability to administer/store/dispense prescription medications. Several commenters also requested the removal of waiver language that specifies the OUD diagnosis be secondary to another condition.

Response: Language has been added to the final rule, at Section 8.11(h)(3), to highlight that these flexibilities may apply to a correctional facility that has registered with the DEA as a hospital/clinic. If a correctional facility has registered as a hospital/clinic, a physician or authorized staff may administer or dispense narcotic drugs to maintain or manage withdrawal for an inmate as an incidental adjunct to medical or surgical treatment of conditions other than addiction. Rules regarding controlled substance dispensing that is outside the context of OTPs, such as waiver language that specifies the OUD diagnosis be secondary to another condition, is beyond the scope of this rulemaking. SAMHSA notes that the Centers for Medicare & Medicaid Services released new guidance encouraging States to apply for a new Medicaid re-entry Section 1115 waiver demonstration project for those persons leaving jails and prisons that this final rule may help facilitate.[71]

Expanding methods of access via OTPs and their mobile units

Commenters support easing pathways, under section 8.11, for opening new OTPs by enacting changes to ease or eliminate barriers, such as extending certification periods, providing funding opportunities, or encouraging existing syringe service programs to grow into new OTPs. Commenters also support expanding geographical access at current OTPs by easing regulations on their mobile units. They remarked on transportation challenges for people with OUD and that

[71] *See* https://www.cms.gov/newsroom/press-releases/hhs-releases-new-guidance-encourage-states-apply-new-medicaid-reentry-section-1115-demonstration

having access to mobile units will assist those who otherwise might not be able to attend a clinic in a fixed location.

Response: Recognizing the many pathways to expanding access, the final rule makes permanent flexibilities implemented during the COVID-19 PHE and updates the overall regulations to reflect ways in which the accreditation and treatment environment has evolved since part 8 went into effect in 2001. Proposed changes that facilitate delivery of comprehensive services in mobile units, such as the use of telehealth, have been made permanent as they reduce barriers to receiving care, among other goals. Regulations regarding mobile units were eased by the DEA and SAMHSA, and use of funds allocated to States under the Block Grant were approved for use in the purchase of mobile units.[72] Some commenters reference State-specific regulations that limit mobile units, but Federal OTP regulations do not preempt separate State requirements. SAMHSA fully encourages and facilitates additional OTP applications.[73]

Expanding methods of access via office and community settings

Many commenters emphasized that methadone treatment must be allowed outside of OTPs, such as in office-based settings or dispensing in community pharmacies, as many communities do not have access to OTPs. Commenters asserted that this approach has been successfully implemented in other countries and SAMHSA must work with the DEA to move in this direction. Furthermore, this may help to address stigma associated with and criticism of some OTPs and will help promote the cultural view of OUD as a chronic disease that necessitates respectful patient-centered care.

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[72] *See* https://www.samhsa.gov/sites/default/files/2021-letter-state-authorities-mobile.pdf
[73] *See* https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program

Response: The final 42 CFR part 8 rule only applies to dispensing of methadone in OTPs. SAMHSA continues to work with Federal partners to explore ways through which access to MOUD might be expanded.

Expanding the definition of a practitioner

There was strong support from commenters regarding expanding the definition of providers, under Section 8.2, who are able to prescribe or order medications. Commenters expressed that allowing licensed practitioners, such as physician assistants, nurse practitioners, and certified nurse midwives, will result in improved access to patients, especially in areas with a high level of provider shortages. There was further support to add pharmacists to the definition of qualified providers. Commenters felt that including pharmacists as qualified providers will further improve accessibility for people suffering with OUD.

Response: Pursuant to the supplemental notice of proposed rulemaking entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA-2000 Waiver Requirements' (88 FR 9221) requirements for staff credentials are finalized to include the definition of a practitioner as "a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP". The scope of 42 CFR part 8 is also limited to activities within an OTP.

One commenter requested clarification on the context of certified nurse-midwives (CNMs) practice with MOUD. Another commenter requested clarification on scope of practice for physician assistants and nurse practitioners prescribing methadone, as there appear to be more restrictions compared to buprenorphine.

Response: As noted above, the definition of a practitioner was modified. However, not all States allow CNMs, nurse practitioners, physician assistants, or pharmacists to order methadone unless supervised by a physician. Notwithstanding additional flexibilities provided in this final rule, practitioners must continue to adhere to State requirements that may apply to the provision of methadone and scope of practice. As also noted, this final rule does not apply to the prescribing of methadone for OUD outside of OTPs.

Food and Drug Administration (FDA) approval of testing supplies

Some commenters requested the removal of the proposed change requiring drug testing services be FDA approved, under Section 8.12(f)(6), as this would impede their ability to test for fentanyl with an instant testing method. Another commenter requested more clarity, stating that this rule could preclude what they view as medically necessary definitive testing at qualified laboratories, despite the lack of an FDA review pathway for such testing. As the drug supply continues to rapidly evolve, OTP medical directors need the flexibility to use the best available tests, regardless of FDA approval, to provide effective patient care.

Response: SAMHSA has amended Section 8.12(f)(6) to specifically allow for distribution of testing strips for drug checking, to those patients who wish to test their supply for adulteration, where not prohibited by law. The final rule also clarifies that FDA approved tests be used when conducting random drug testing with patients, including urine or saliva samples, at the OTP.

Support for provision of resources with patient-centered care plans

Commenters were supportive of Section 8.12(5)(i) that requires OTPs to work with patients to provide additional services such as counseling and harm reduction (including education, testing,

and treatment for HIV, viral hepatitis, and sexually transmitted infections (STIs) when helpful), but some commenters cautioned requiring provision of these services without establishing their funding and requested in the meantime that the language be amended to include assessment and referral. Additionally, comments overwhelmingly conveyed support for clarifying that attending counseling is not a condition of MOUD treatment, and that treatment plans should be patient centered.

Response: Part 8 defines what is expected in the provision of methadone for the treatment of OUD. Although it is expected that OTPs plan for their fiscal viability to assure continuity of medication and other treatment services, funding and sustainability are beyond the scope of these regulations.

OTPs are expected to offer adequate medical, counseling, vocational, educational, and other assessment, and treatment services either onsite or by referral to an outside agency or practitioner. The revisions in this final rule promote a patient-centered approach to care that does not make medication continuity contingent upon involvement in counseling services but fosters greater shared decision-making. The revisions also relaxed the requirement that an OTP have a formal documented agreement with outside agencies; under Section 8.12(f)(1) the final rule calls for a "documented agreement" to provide such services.[74]

Further consideration of Tribal communities

Some commenters advocate for increased Tribal sovereignty by including Indian Tribes as potential Accreditation Bodies. Additionally, while the Indian Health Service is included in the list of exceptions for State law compliance, OTPs operated by Indian Tribes must also be

[74] *See* https://www.samhsa.gov/sites/default/files/dear-colleague-letter-fda-samhsa.pdf

included to align with Tribal sovereignty. Accordingly, when States or "State law" is referenced, they urge SAMHSA to also include Tribes or "Tribal law".

Another commenter communicates concern about lack of safe transportation and funding to access treatment on some Tribal reservations, institutionalized racism and marginalization, as well as lack of positive integration of American Indian/Alaska Native culture into treatment for those populations. The commenter indicates that it is vital that SAMHSA alter the rule to explicitly include addressing the needs of marginalized communities, including Tribes and Tribal entities.

Response: SAMHSA recognizes the need for culturally supportive care that addresses race, ethnicity, Tribal sovereignty, sexual orientation, religion and gender identity, and social determinants of health, such as housing and transportation, that may pose barriers to treatment engagement, or harm reduction and recovery support service needs. Patient-centered language in the NPRM was finalized in this rule to ensure that the care provided is consistent with the patient's needs, and self-identified goals for treatment and recovery. SAMHSA encourages OTPs serving American Indians and Alaska Natives to implement culturally competent and patient-centered care. SAMHSA notes that it and other agencies have developed resources that may be helpful in developing culturally sensitive approaches for AI/AN populations.[75]

The Department has not included 'Tribal law' whenever 'State law' is referenced, as Tribal laws vary widely. Accordingly, understanding what the reference means, or its scope, in some situations may be ambiguous. Therefore, it would be inappropriate to include Tribal law in this context.

Intake

[75] *See* https://www.samhsa.gov/behavioral-health-equity/ai-an

Commenters requested clarification on the application of the new intake rules under Section 8.12(f)(2). Some commenters requested that clarification include explicit descriptions of rule application to clinical scenarios such as care transitions from hospital or non-OTP settings to OTPs. Commenters were supportive of allowing non-OTP clinicians to complete the intake screening and full examinations to expedite access during this process, though some commentors specified that the OTP provider must later review and approve the exams completed outside of an OTP. Some commentors stated that more frequent regular medical exams may be helpful during the first year of treatment to ensure safety and efficacy of treatment. One commenter requested clarification as to whether the full physical exam includes a mental status exam or an assessment of psychiatric symptoms, due to the high incidence of such symptoms among these patients. Another commenter requested clarity as to whether methadone may be initiated during the 14-day grace period for full OTP intake and screening/full examination, as some State regulations interpret this differently.

Response: The final regulations, under Section 8.12(f)(2)(a), facilitate initial screening to allow for medication to commence at time of initial intake; SAMHSA recommends methadone medication induction not be delayed until the full examination is completed.[76] The purpose of the initial screening is to ensure that there are no contraindications to prescribing methadone; this may require a psychiatric screening or evaluation of psychiatric symptoms, if clinically indicated. If mental health is not assessed at the time of screening, it should be completed subsequently as part of the patient's assessment to identify any service needs. Proposed regulations were finalized as written, since they explicitly address these comments.

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[76] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

Commenters were concerned about the requirement to complete a psychosocial assessment within 14 days, stating that patients often experience instability at the time of entry into treatment, which makes this difficult; some commenters suggest providing 30 days to complete the assessment. One commenter also requested an exception be provided to ensure patients diagnosed with OUD are not excluded from MOUD because of documented failure or that only documentation of reasonable effort to complete this assessment is required. Another commenter adds that this short, prescriptive timeframe is not always conducive to developing therapeutic rapport between patients and providers and may force programs to be overly restrictive, disrupting patient engagement at a critical time.

Response: Patients entering treatment for OUD are often in crisis and this is the basis for the requirement that a complete psychosocial assessment be conducted within 14 days. This is especially important because the final rule allows patients new to treatment to receive up to 7 take-home doses of methadone. The psychosocial assessment informs part of the initial examination, and as such, it is the basis of continued assessment and management as indicated. There is no requirement for a definitive list of diagnoses to be created at this time. Rather, this is an opportunity to create a detailed plan of care which might include continued assessment and monitoring of psychosocial status. To facilitate timely completion of the assessment, the final rule includes flexibilities for the use of telehealth.

Serology Testing

For serology testing, comments recommend the patient should explicitly retain the right to refuse or defer testing unless the medical provider deems it necessary for patient safety. Others asked for clarification on the deadline (14-day or 30-day) stating that 8.12 (f)(2)(B)(iii) and (iv) as proposed appeared contradictory.

Response: An individual patient always has the right to refuse testing, and this provision therefore has been clarified in the final rule. Specifically at 8.12(f)(2)(i)(b), now states that a "patient's refusal to undergo lab testing should not preclude them from access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications". In regard to the suggested 14-day or 30-day discrepancy, these timeframes refer to use of serology results: it is permissible to use serology results drawn no more than 30 days prior to admission to the OTP, or up to 14 days after admission to the OTP to complete the full examination. Thus, these two provisions are not inconsistent.

Treatment discharge concerns

Several comments expressed concern over removal of language in the proposed rule concerning discharge, asserting that this change removes important patient protections that have helped to promote humane discharge processes. Whether patients are discharged for nonpayment or other reasons, commenters emphasize that tapering schedules must be based on clinical and safety considerations.

Response: The importance of discharge planning has been highlighted in the final rule. Specifically, under Section 8.11(f)(2)(iv) discharge decisions have been enumerated to require a patient-centered approach. Such decisions must be documented, and planned in a manner that ensures, to the greatest extent possible, that patient treatment is not disrupted. Proposed language from the NPRM pertaining to discharge planning throughout Section 8.12 has been finalized.

Split dosing

Numerous commenters support the expansion of split dosing for all OTP patients receiving take-home doses, defined in Section 8.2, based on the clinical judgement of the OTP practitioner, and urge SAMHSA to add language specifying that additional testing and submission of

documentation for split dosing is unnecessary if the clinician has clearly documented in the medical record that split dosing will benefit the patient. Commenters also emphasize that take-home doses are essential for split dosing, especially for pregnant patients and patients driving long distances to receive medication.

Response: The final rule does not specify requirements of any additional testing or documentation beyond that of routine clinical practice. There is nothing in the final rule that precludes provision of split doses for take-home doses of methadone.

Dosage during treatment induction

At Section 8.12(h)(3)(ii) commenters emphasize that higher initial and next day doses are often clinically appropriate and necessary to prevent withdrawal and treatment attrition, especially for patients exposed to fentanyl, as well as for patients in the later stages of pregnancy, and that clinicians require more clarification on this. Commenters questioned whether the additional medication is administered as one higher dose or additional, incremental dose(s) at several hour interval(s). They worry that lack of clarity will result in underutilization and thus lower treatment retention. Some commenters suggest eliminating induction dosing guidelines (which they view as a reflection of longstanding stigma and discrimination against patients in OTP treatment). These commenters suggest entrusting these decisions to practitioners, noting that other medication dosage decisions for many medical conditions are left to judgment and discretion of medical providers. Some commenters also caution that higher induction doses must not be discouraged when medically necessary for efficacious treatment.

Response: A primary purpose of the final rule is to promote use of clinical judgement as well as patient-centered care. These comments speak to the need for “shared decision-making” in the

practitioner-patient relationship, and the final rule supports this through empowering practitioners to work with patients to create individualized plans of care. Section 8.12(h)(3)(ii) has been clarified in a manner that does not prohibit higher induction doses, but requires the rationale for higher induction doses to be documented in the patient's record.

Audio-only telehealth

Commenters emphasize that audio-only telehealth is an important permanent provision for counseling and buprenorphine initiation to ensure more equitable access to OTPs.

Response: SAMHSA agrees with commenters that telehealth, including audio-only telehealth, can be an important tool to enhance access to treatment. SAMHSA also recognizes scientific evidence that further supports integration of telehealth provisions in the final rule consistent with clinical guidelines and safety requirements. The final rule accordingly states that in evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used at the patient and provider's preference. For schedule II medications (such as Methadone), the rule allows for audio-visual telehealth initiation by the OTP practitioner. When audio-visual technologies are not available or their use is not feasible for a patient, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. This is because, as noted, in the proposed rule, schedule II medications such as methadone pose increased risk compared to schedule III medications such as buprenorphine. In all cases, medications for the treatment of OUD shall be ordered by the OTP practitioner.

Audio/visual telehealth for medical intake and "annual physical" appointments

Video-based telehealth, under section 8.12(f)(2)(B)(v), is overwhelmingly supported by commenters for medical intake, periodic medical assessments, and methadone or buprenorphine initiation by OTP practitioners. Onsite staff can supplement telehealth care by gathering vital sign and toxicology data, when necessary. One comment questioned if any appropriate limits, for example on the number of patients a single physician could oversee via telehealth should be added.

Response: SAMHSA appreciates these comments and has finalized proposed changes in the final rule. Requirements pertaining to telehealth, including the number of patients that a practitioner may see, are governed by applicable State and Federal laws. As noted above, however, provisions in this final rule support use of telehealth as part of patient treatment.

Take-home or unsupervised doses

Provisions expanding take-home or unsupervised methadone medication doses, under Section 8.12(i), are mostly supported, with commenters citing increased patient autonomy and pride, improved outcomes and treatment retention, and reduced barriers to treatment. The removal of the eight take-home criteria is accordingly supported by some, though others note that toxicology testing is important to help maintain public and patient safety. Some commenters expressed concern about potentially increased diversion, while another commented that diversion is a sign of unmet community need and should be addressed as such, rather than criminalized. Some commenters worried that the revised take-home allowances are too flexible and some proposed different guidelines; others supported them or even wanted them eliminated entirely, trusting providers with that responsibility. Yet, other commenters worried that leaving decisions about

take-homes completely to the discretion of providers could result in provider abuse and suggested that some parameters are necessary.

Many commenters expressed frustration that not all patients receive equitable access to take-homes, whether for insurance reasons or lack of clinic/state implementation. Some commenters suggest the addition of take-home metrics during the OTP survey process to help address this. Another commenter suggested SAMHSA provide a method of recourse for patients dissatisfied with decisions made about their take-home eligibility. One commenter requested clarification on insurance coverage of take-home doses, specifically with Medicare or Medicare Part D. One commenter asked that SAMHSA end the requirement for requested program exceptions when closing or dispensing extra take-home doses for weather emergencies and state holidays, and that patient suitability documentation for days the clinic is closed is only required for patients denied take-home medication.

Response: SAMHSA recognizes that its proposed provisions concerning take-homes were significant. Proposed changes have been finalized without alteration. While this approach promotes practitioner discretion, determining risk factors and preventing diversion has required team input since the original regulations were promulgated over 20 years ago.

A standard for treatment that is common to all Accreditation Bodies is that OTPs have policies regarding patient complaints and procedures that protect patients from retaliation. SAMHSA requires that Accreditation Bodies have policies and procedures in place to respond to complaints received from the Secretary, patients, facility staff, and others. Therefore, patients who have complaints about take-homes shall have access to recourse through required patient complaint and grievance procedures.

Determinations about insurance coverage and reimbursement for MOUD, while important, are outside the scope of this rulemaking.

Need for more data

Several commenters expressed an ongoing need for more data to ensure treatment changes (such as additional take-home medication doses, induction dosing schedules, expansion of the definition of a qualified provider) are safe, especially post COVID-19 public health emergency (PHE) as circumstances and environments change. Some had concerns that changes provided too much flexibility, especially with respect to take-home doses during the first week(s) of treatment, due to less patient stability/functionality during this transitional period. Others mentioned that patients might handle medications differently outside of the COVID-19 PHE environment, due to lack of behavior-modifying factors present during the PHE, such as isolation and fear for continued treatment. Other commenters expressed the need for more data related to induction dosing and best practices for rapid induction to effective doses while minimizing risk.

Response: Data is important to performance monitoring and evaluations of health care interventions. Accreditation standards require that OTPs have quality assurance systems that consider patient outcomes. The data related recommendations noted in these comments are items that could be incorporated into the OTPs quality assurance processes. These recommendations are better addressed in the revision of the Federal OTP guidelines that SAMHSA will complete following this rulemaking. SAMHSA and its partners, including the Centers for Disease Control and Prevention, FDA and National Institutes of Health (NIH), support further research on these issues, and SAMHSA will monitor the impact of this rule. As one example, FDA, SAMHSA and the Reagan-Udall Foundation held a meeting in May 2023 regarding 'Considerations for Buprenorphine Initiation and Maintenance Care' to "explore real-world experiences and scientific evidence for buprenorphine initiation strategies as well as medication dosing and management during continued treatment across different care settings."[77] SAMHSA and NIH

[77] *See* https://reaganudall.org/news-and-events/events/considerations-buprenorphine-initiation-and-maintenance-care

similarly collaborate to support the Helping to End Addiction Long-term® Initiative which focuses on improving pain treatment and developing community-level solutions to opioid addiction.[78] SAMHSA will continue on its own and with other agencies and stakeholders to explore and support research on these issues.

Pregnancy testing

Several commenters advised against requiring pregnancy testing, under Section 8.12(f)(B)(iii), for pregnant OTP patients. They reasoned that, in a time when States are increasingly restricting and even criminalizing reproductive options, pregnancy testing may dissuade patients of child-bearing potential from seeking treatment.

Response: Pregnancy testing is often necessary for appropriate clinical care, and the final rule clarifies that pregnancy testing should be requested only when clinically appropriate, and that refusal of such testing should not preclude access to treatment. Safeguarding patient privacy and health is essential, and in all cases, providers must adhere to State and Federal laws and regulations, clinical requirements and professional guidelines when considering screening and disclosure of testing results. For instance, the 2015 'American College of Obstetricians and Gynecologists policy on Alcohol Abuse and Other Substance Use Disorders: Ethical Issues in Obstetric and Gynecologic Practice', emphasizes the importance of patient informed consent for testing.[79]

Ramifications of dependency diagnosis

One commenter expressed concern that under Section 8.12(f)(2), all patients receiving opioids must be documented in the medical chart with an opioid dependence diagnosis, even if the

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[78] *See* https://heal.nih.gov/

[79] *See* https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/06/alcohol-abuse-and-other-substance-use-disorders-ethical-issues-in-obstetric-and-gynecologic-practice

patient is a pain patient and the doctor has no dependency concerns. One commenter is concerned that this could affect eligibility for future organ transplants.

Response: These regulations establish the procedures by which the Secretary of HHS determines whether a program is qualified to dispense methadone and other medications in the treatment of opioid use disorders and standards regarding the use of these medications for treatment purposes, in accordance with the Controlled Substances Act (CSA) under 21 U.S.C. 823(h). As a result, a diagnosis of opioid use disorder is required. SAMHSA notes that opioid dependence is an older diagnostic term that, in the U.S., has been replaced with the diagnostic term of opioid use disorder and associated diagnostic criteria. Proposed changes, as written, were finalized in the rule.

Protecting patient data

Central registries are often queried to detect and prevent potential multiple enrollments in more than one OTP. Central registries are briefly described in 42 CFR part 2 (Confidentiality of Substance Use Disorder Patient Records) regulations, but one commenter is concerned that there do not appear to be limits on their collection and sharing of sensitive patient information and requests regulations better clarify appropriate practices.

Response: Central registries are State-based operations. Although the patient information is protected, procedures for assuring protection and relevant regulations such as 42 CFR part 2 and the Health Insurance Portability and Accountability Act are outside the scope of these Part 8 regulations.

Alignment of State and Federal guidelines

There were many commenters that expressed concerns with State regulations as they intersect with proposed SAMHSA changes. If States have more restrictive regulations, especially related to medication administration, for instance, then patients in those States may not benefit from Federal changes, some commenters asserted. These commenters urged that States be required to align with Federal regulations, even if it means withholding funds to States who refuse to adopt new Federal regulations. Some commentors also requested language be added mandating State Opioid Treatment Authorities (SOTAs) are included in communications such as when and how an OTP is not meeting standards, withdrawal of approval of Accreditation Bodies, and others.

Response: These rules do not mandate that States promulgate less restrictive rules to match provisions of Federal law that may provide more flexibility. SAMHSA works closely and collaboratively with the SOTAs and State mental health and substance use disorder treatment authorities, the Accreditation Bodies, as well as other Federal agencies to encourage State and Federal alignment and information-sharing.

Other themes

There were two comments that urged keeping Levomethadyl acetate (LAAM) on the list of approved treatment medications. These comments suggested that research could indicate it is an effective treatment for opioid use disorder and that it may soon be available for use again. Additionally, other comments advocated integration of other FDA-cleared treatment options like neuromodulation and other medical technology.

Response: Currently, LAAM is not available in the United States. For this reason, it was removed from the list of currently approved and available medications for OUD. The list provided in the rule is current, and there is nothing that precludes changes to the list of medications used to treat OUD in the future. Technology is not currently addressed in 42 CFR

part 8 as devices and available applications are an adjunct to treatment with MOUD. SAMHSA will monitor the development and approval of new medical devices by FDA for the treatment of chronic opioid use disorder and will consider updates to part 8 as needed.

E. Summary of the Final Rule

The Department has finalized the following changes to 42 CFR part 8 that revise, delete, replace, or add sections. This section summarizes changes in the final rule, and discusses changes made after review of public comments on the NPRM entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330), and the SNPRM entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA-2000 Waiver Requirements' (88 FR 9221).

1. *Title.*

   The Department has finalized the title, originally proposed in the NPRM, as being: *Medications for the Treatment of Opioid Use Disorder*. As discussed in the NPRM, this title reflects current medical terminology and removes stigmatizing language. The term 'opioid use disorder' more precisely reflects the diagnosis for which medications are indicated. Further to this, the terms 'maintenance' and 'detoxification' reference outdated terminology that has potentially hindered adoption of evidence-based treatments for OUD.[80] The amended title reflects current medical terminology and highlights that OUD is a chronic, treatable condition.

2. *Subpart A.*

   Reorganization of subpart A, as proposed in the NPRM and SNPRM, has been finalized and includes the scope and definitions.

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[80] NIDA. 2021, November 29. Words Matter - Terms to Use and Avoid When Talking About Addiction. Retrieved from https://nida.nih.gov/nidamed-medical-health-professionals/health-professions-education/words-matter-terms-to-use-avoid-when-talking-about-addiction.

3. *Section 8.1 – Scope.*

   Pursuant to the NPRM and SNPRM, § 8.1 is finalized to reflect modern medical terminology, to detail updated acronyms, and for clarity. Of note, the term medication assisted treatment (MAT) has been updated to medications for opioid use disorder (MOUD), and the term treatment program has been changed to opioid treatment program throughout the final rule. Pursuant to proposed changes set forth in the SNPRM entitled 'Medications for the Treatment of Opioid Use Disorder: Removal of the DATA-2000 Waiver Requirements' (88 FR 9221), reference to subpart F has been removed.

4. *Section 8.2 – Definitions.*

   Changes proposed by the NPRM and SNPRM have been finalized in § 8.2 to add, remove and update definitions. Added definitions include: care plan; harm reduction; individualized dose; long-term care facility; recovery support services; split dosing; and telehealth. Existing definitions updated include: comprehensive treatment; medication for opioid use disorder; and practitioner. The term detoxification treatment is removed and replaced with withdrawal management. Definitions for additional credentialing, approval term, covered medications, and emergency situation have been removed.

5. *Section 8.3 – Application for approval as an Accreditation Body.*

   Changes proposed by the NPRM are finalized to include details of policies and procedures expected of Accreditation Bodies, particularly that Accreditation Bodies shall include staff physician(s) with experience in treating OUD with MOUD in their survey team. Furthermore, this regulation is updated, pursuant to the NPRM, to ensure that Accreditation Bodies provide training policies specifically related to training of survey team members. As described in the NPRM, the final rule also provides for Indian Tribes, in addition to State or territorial governments, to apply for approval as an Accreditation Body.

6. *Section 8.4 – Accreditation Body responsibilities.*

In response to public comments, language that clarifies SAMHSA's oversight of Accreditation Bodies, and associated expectations, has been updated and finalized. To this end, the Department has provided clarification on the steps to be taken by Accreditation Bodies in response to OTPs that are found to not be complying with accreditation or certification standards, such as follow up on corrective measures and confirmation of timely corrections. In particular, section 8.4(b) of the final rule includes: provisions requiring categorization of the types of non-compliance; provisions that differentiate between accreditation duration based on the severity of non-compliance; and adds provisions detailing procedures for severe non-compliance. Time frames for submission of survey reports are also finalized. Pursuant to the NPRM, the Department has finalized the requirement that all records of accreditation activities be made available to SAMHSA upon request. Current requirements regarding Accreditation Body follow up on complaints are maintained but, as per the NPRM, the final rule adds a requirement that Accreditation Bodies notify SAMHSA of all aspects of a complaint response within 5 days of receipt. Similarly, the previous rule requiring surveyors to recuse themselves from surveys due to conflict of interest is amended to clarify that such conflicts must be documented by the Accreditation Body and made available to SAMHSA.

7. *Section 8.11 – Opioid Treatment Program certification.*

This section is finalized, pursuant to the NPRM, to update categories of certification, to clarify the requirement that OTPs maintain certification, and to establish procedures for OTPs whose certification has lapsed. Terms for the extension of certification are finalized, as are the means of requesting an extension. The final rule also updates the certification application process to reflect the shift from paper applications to electronic submission, and the email address for submission of supporting documents is corrected.

As described in the NPRM, the final rule removes "Transitional certification" which expired as a category of certification in 2003. Further, the wording of "Provisional

certification" is amended to clarify that it is a category of certification available only to new programs that have not been previously certified, and a new category of "Conditional Certification" has been added for OTPs that have received a one-year conditional accreditation status from an Accrediting Body - an organization that has been approved by the Secretary of HHS to accredit OTPs - in order for operations to continue or resume as the OTP takes steps needed to achieve permanent certification. The criteria for granting certification extensions outside of routine certification renewals has been expanded to address extensions needed under extraordinary circumstances. The grammar used in describing procedures for requesting an extension was revised.

The applicability of Health Insurance Portability and Accountability Act (HIPAA) privacy protections have been explained, along with clarification that changes in the status of the program sponsor or medical director must be submitted to SAMHSA in writing.

Pursuant to the NPRM, the conditions for approval of interim treatment have been finalized to increase the duration of interim treatment from 120 days to 180 days, with the stipulation that individuals shall not be discharged without the approval of an OTP practitioner while awaiting transfer to a comprehensive treatment program. In response to public comments on the NPRM, availability of interim treatment is also expanded to all OTPs. For clarity, reference to section 1923 of the Public Health Service Act (21 U.S.C. 300x-23) is removed. The NPRM and final rule also shifts the need to seek approval from the 'chief public health officer' of the State in which the OTP operates to the State Opioid Treatment Authority in the State in which the OTP operates.

As described in the NPRM, the services that can be provided in medication units have been finalized to explicitly allow the full range of OTP services, based on space and privacy available in the medication unit.

8. *Section 8.12 – Federal Opioid Use Disorder treatment standards.*

Revisions of treatment standards, as described in the NPRM, are finalized in order to improve access to treatment, improve patient satisfaction and engagement in services and support use of clinical judgment in decision-making. In several instances, stigmatizing language such as "legitimate treatment use" of controlled medications, has been removed and patient-centered language is added.

The paragraph on staff credentials, found in the NPRM, is finalized to expand the definition of a practitioner to a "a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP." The expectation that all licensed and credentialed staff maintain licensure and/or certification has been finalized.

Criteria for admission to treatment, as discussed in the NPRM, removes reference to the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV and eliminates the requirement for a one-year history of OUD. Instead, the final rule specifies that the individual should either: meet diagnostic criteria for active moderate to severe OUD; that the individual may be in OUD remission; or at high risk for recurrence or overdose. The section is finalized to ensure that the basis for the admission decision is documented in the patient's record. In recognition of the use of telehealth and its limitation in obtaining physical signatures, the requirement to obtain written patient consent to treatment is altered to the extent that consent may be provided verbally or electronically, and documented as such. The requirement that individuals under age 18 have two documented unsuccessful attempts at short term withdrawal management ("detoxification") or drug free treatment is also finalized so to allow consent of a parent, legal guardian, or responsible adult. Further to this, the rule requiring a 1-year history of OUD for people recently released from correctional settings, pregnant patients or previously enrolled individuals has been removed.

Throughout the document, as described in the NPRM, "detoxification" and the corresponding definition and standards for short-and long-term detoxification treatment have

been removed. “Withdrawal management” and terms for tapering from MOUD are added on behalf of individuals who seek this approach or who elect or need to reduce and/or discontinue MOUD.

The paragraph on “Required services” is finalized to incorporate patient-centered language, establish flexible terminology, promote use of clinical judgment, and clarify SAMHSA’s expectations of OTPs. The final rule creates the requirement that services be available that meet patient needs, and “shared decision making” is added as the method to be used in developing care plans.

The paragraph describing the initial medical examination has been finalized, pursuant to the NPRM, to clarify the terms “screening” medical exam and “comprehensive examination”, while also expanding the qualifications of practitioners able to complete such examinations. These include practitioners outside of the OTP (with limitations and specific instructions). The final rule also creates criteria for lab testing conducted prior to a screening medical exam, as well as a permissible timeframe. The use of telehealth in undertaking the screening medical exam and initiation of MOUD at the OTP, by the OTP practitioner, has also been finalized in the rule. Additionally, the paragraph on special services for pregnant people is finalized to specify that confirmation of pregnancy should be requested for priority treatment admissions. The option to use split dosing for patients, as described in the NPRM, is also finalized.

The components of initial and periodic medical examinations have been finalized, pursuant to the NPRM, to incorporate assessment of behavioral health, risk of self-harm or harm to others, and to specify time frames for completion of the care plan. Areas of psychosocial assessment are finalized so as to assure information is gathered in the context of the patient’s whole life such as their mental health, housing, recovery support and harm reduction resources. Additionally, patient-centered language has been finalized, such as “services a patient needs and wishes to pursue”.

The final rule expands the provision of 'counseling services' that are provided by OTPs to include psychoeducational services, harm reduction and recovery-oriented services, and counseling and linkage to treatment for anyone with positive test results on human immunodeficiency virus (HIV), viral hepatitis, and other sexually transmitted infection (STI) panels, or from OTP-provided medical examinations. Language about services that must be provided directly or through referral is finalized to promote a patient-centered approach to care that does not make medication continuity contingent upon involvement in counseling services but fosters shared decision-making for all care plans.

The requirement that an OTP have a formal documented agreement with outside agencies is finalized to remove the word "formal"; the final rule calls for a "documented agreement" to provide such services.

Language that addresses drug testing services has been finalized to remove stigmatizing phrases, such as "drug abuse", and to remove content on short-term withdrawal management ("detoxification"). Further to this, the final rule clarifies that the requirement to use drug tests that have received the Food and Drug Administration (FDA)'s marketing authorization is limited to random drug testing using samples obtained from patients, including urine or saliva. Pursuant to public comments on the NPRM, the final rule does not preclude distribution of legally permissible testing supplies, that check for adulteration of an individual's personal drug supply.

Rules that address recordkeeping and efforts to avoid simultaneous enrollment in multiple OTPs are finalized, as per the NPRM, to be more declarative, such as changing the word "review" to "determine" whether or not a patient is enrolled in another OTP, and documenting review efforts in the patient's record to demonstrate the good faith efforts made. The final rule also expands the circumstances in which a patient may obtain treatment at another OTP to include instances when there is an inability to access care at the OTP of record.

As described in the NPRM, specification of disciplines authorized to administer or dispense MOUD is removed from the final rule. LAAM, also known as Levomethadyl acetate, is removed from the list of treatment medications because it is no longer available, and other medications approved since prior revisions to this rule were added. In response to public comments, the regulation of an initial dose of methadone has been increased to 50mg on the first day, with the clarification of allowance for higher doses if clinically indicated, and documented in the patient's record. The rule to ensure documentation of any significant deviation from FDA-approved labeling has been maintained in the final rule, while redundant language was removed.

Rules on the provision of unsupervised (or take-home) doses of methadone are finalized, as per the NPRM, to incorporate flexibilities issued in response to the COVID-19 pandemic. In general, the final criteria allow up to 7 days of take-home doses during the first 14 days of treatment, up to 14 take-home doses from 15 days of treatment and up to 28 take-home doses from 31 days in treatment. The requirement that OTPs maintain procedures to protect take-homes from theft and diversion is finalized, as well as patient education on safe transport and storage of take-home doses, including documentation of the provision of this education in the patient's clinical record.

Consistent with the conditions for approval of interim treatment, the final rule extends the potential duration of interim treatment from 120 days to 180 days. It also clarifies the circumstances in which interim treatment may apply and maintains priority access to comprehensive services for pregnant individuals. The rule finalizes removal of the requirement for observation of all daily doses during interim treatment. It also finalizes the expectation that crisis services and information pertaining to locally available, community-based resources for ancillary services be made available to individual patients in interim treatment. A requirement of a plan for continuing treatment beyond 180 days of interim services is also finalized.

9. *Section 8.13 – Revocation of accreditation and Accreditation Body approval.*

   References to an OTP as a "program" instead of a "facility" are finalized.

10. *Section 8.14 – Suspension or revocation of certification.*

    Pursuant to the NPRM, this section finalizes the actions that SAMHSA may take when immediate intervention is necessary to protect the public's health or safety. The final rule specifies the administrative actions available to SAMHSA in the event that a program sponsor, or any employee of an OTP has: been found to have engaged in misrepresentation in obtaining certification; failed to comply with the Federal Opioid Use Disorder treatment standards; failed to comply with reasonable requests from SAMHSA or from an Accreditation Body for records; or refused a reasonable request of a duly designated SAMHSA inspector, DEA Inspector, State Inspector, or Accreditation Body representative for permission to inspect the program or the program's operations or its records.

11. *Subpart D—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body.*

    References to an OTP as a "program" instead of a "facility" are finalized.

12. *Subpart F—Authorization to Increase Patient Limit to 275 Patients.*

    This subpart and corresponding sections are removed from the final rule, as described in the SNPRM.

Severability

The Department asserts that provisions in this final rule are severable. If any provision of this rule, or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of this rule that can be given effect without the invalid provision or application.

This rule has been organized in a way that separates out the major provisions into distinct sections and subparts. Many of the provisions in this rule are independent of each other

and could function sensibly even without certain other provisions being in effect. For example, the provisions in subparts A, B and C related to accreditation and certification are distinct from the Treatment Standards enumerated in subpart C section 8.12. Rules related to take-home dosing of methadone are also severable from other rules, such as those regarding telehealth and interim treatment.

If any specific provision of this rule is found unconstitutional or invalid, the Department intends that the remainder would still operate independently. The Department believes that each provision in this rule offers a distinct benefit to the public, patients, and healthcare providers. Therefore, if any specific application or provision is invalidated, the remainder of the legally valid provisions should remain in effect.

Regulatory Impact Analysis

The Department has examined the impact of the final rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (October 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (January 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (August 10, 1999); Executive Order 13175 on Consultation and Coordination with Indian Tribal Governments, 65 FR 67249 (November 9, 2000); Executive Order 13985 Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 FR 7009 (January 25, 2021); the Congressional Review Act, Pub. L. 104-121, sec. 251, 110 Stat. 847 (March 29, 1996); the Unfunded Mandates Reform Act of 1995, Pub. L. 104-4, 109 Stat.48 (March 22, 1995); the Regulatory Flexibility Act, Pub. L. 96-354, 94 Stat. 1164 (September 19, 1980); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (August 16, 2002); the Assessment of Federal Regulations and Policies on Families, Pub. L. 105-277, sec. 654, 112 Stat. 2681 (October 21, 1998); and the Paperwork Reduction Act of 1995, Pub. L. 104-13, 109 Stat. 163 (May 22, 1995).

Statement of Need

This final rule is being issued to update part 8 in response to increasing opioid overdose deaths, exacerbated by the COVID-19 pandemic.[81] Across the United States in 2021, 9.2 million people aged 12 or older misused heroin or misused prescription pain relievers in the preceding twelve months.[82] The percentage was highest among young adults aged 26 or older (3.5 percent or 7.7 million people), followed by adults aged 18 to 25 (3.1 percent or 1 million people). It was lowest among adolescents aged 12 to 17 (1.9 percent or 497,000 people).[83] These numbers likely underestimate the true prevalence of opioid misuse and opioid use disorder (OUD), since the use of illicitly manufactured fentanyl has not to date been considered in the National Survey on Drug Use and Health (NSDUH), and populations likely to have high prevalence of opioid misuse and use disorder, such as individuals in the criminal justice system, other institutionalized settings, and individuals experiencing homelessness and not living in shelters, are not included in the NSDUH.

Further to this, there are important equity considerations evidenced by the data. A recent analysis by the Centers for Disease Control and Prevention (CDC) demonstrates high levels of overdose among non-Hispanic Black, American Indian and Alaska Native communities over the course of the pandemic.[83] This study showed that overdose death rates rose 44 percent in 2020 for Black people and 39 percent for American Indian and Alaska Native people, compared with 22 percent for white people.[83] Black youth ages 15 to 24 saw an 86 percent increase in overdose deaths, the largest spike of any age or race group, while Black men 65 and older were nearly

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[81] Cartus AR, Li Y, Macmadu A, Goedel WC, Allen B, Cerdá M, Marshall BDL. Forecasted and Observed Drug Overdose Deaths in the US During the COVID-19 Pandemic in 2020. JAMA Netw Open. 2022 Mar 1;5(3):e223418. doi: 10.1001/jamanetworkopen.2022.3418. PMID: 35311967; PMCID: PMC8938716.

[82] Substance Abuse and Mental Health Services Administration. (2022). Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report

[83] Kariisa M, Davis NL, Kumar S, et al. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:940–947. DOI: http://dx.doi.org/10.15585/mmwr.mm7129e2. See also https://www.seattletimes.com/nation-world/nation/addiction-treatment-medicine-is-vastly-underprescribed-especially-by-race-study-finds/

seven times as likely than white men to die from an overdose.[83] It was also found that Black people were less than half as likely as white people to have received substance use treatment. As SAMHSA has noted, the Hispanic community also has been adversely impacted by opioid overdoses.[84]

Research demonstrates that MOUD can reduce mortality from overdose by up to 59% (based on results of multivariable Cox proportional hazards models adjusted for age; sex; baseline anxiety diagnosis; depression diagnosis; receipt of methadone, buprenorphine, opioid, and benzodiazepine prescriptions in the 12 months before index nonfatal opioid overdose; and time-varying receipt of opioid prescriptions, benzodiazepine prescriptions, withdrawal management episode, and short- and long-term residential treatments[85]), yet few people who may benefit from these medications have immediate and sustained access to them.[86]

The pattern of enrollment in programs providing methadone was established in the latter part of the 20th century.[87] Research reveals that the rate of methadone treatment at that time was highest in low-income urban areas.[88] These patterns have remained relatively unchanged since the expansion of access to buprenorphine in 2002. Research demonstrates that there are extensive 'treatment deserts' where there is little to no physical access to OTPs, especially in rural areas.[89] SAMHSA believes that changes to part 8 will, as described above, facilitate:

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[84] Substance Abuse and Mental Health Services Administration: The Opioid Crisis and the Hispanic-Latino 1opulatiorgent Issue. Publication No. PEP20-05-02-002. Office of Behavioral Health Equity. Substance Abuse and Mental Health Services Administration, 2020. https://store.samhsa.gov/sites/default/files/pep20-05-02-002.pdf.
[85] Larochelle MR, Bernson D, Land T, Stopka TJ, Wang N, Xuan Z, Bagley SM, Liebschutz JM, Walley AY (2018). Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality: A Cohort Study. Ann Intern Med. Aug 7;169(3):137-145. doi: 10.7326/M17-3107.
[86] Winograd RP, Presnall N, Stringfellow E, Wood C, Horn P, Duello A, Green L, Rudder T. (2019). The case for a medication first approach to the treatment of opioid use disorder. Am J Drug Alcohol Abuse. 2019;45(4):333-340. doi: 10.1080/00952990.2019.1605372. Epub 2019 May 14. PMID: 31084515.
[87] D'Aunno T, Pollack HA. (2002). Changes in methadone treatment practices: results from a national panel study, 1988-2000. JAMA. 2002;288(7):850-856. doi:10.1001/jama.288.7.850.
[88] Strain EC, Stitzer ML, Liebson IA, Bigelow GE. (1994). Comparison of buprenorphine and methadone in the treatment of opioid dependence. Am J Psychiatry. 1994 Jul;151(7):1025-30. doi: 10.1176/ajp.151.7.1025. PMID: 8010359.
[89] Mitchell P, Samsel S, Curtin KM, Price A, Turner D, Tramp R, Hudnall M, Parton J, Lewis D. (2022). Geographic disparities in access to Medication for Opioid Use Disorder across US census tracts based on treatment utilization behavior. Soc Sci Med. 2022 Jun;302:114992. doi: 10.1016/j.socscimed.2022.114992. Epub 2022 Apr 28. PMID: 35512612.

- Enhanced access to medications for opioid use disorder, such as through take-home doses of methadone and extending interim treatment to 180 days;
- Reduced stigma and discrimination based on changes to ensure updated language and terminology;
- Clarification of standards applying to Accreditation Bodies; and
- Revising Federal Opioid Use Disorder Treatment Standards.

SAMHSA notes below that these changes are associated with limited burden as the final rule does not substantially alter reporting or accreditation activities. The changes will support SAMHSA in its role of overseeing Accrediting Bodies and OTPs, modernizing language and expectations in response to current challenges and anticipated future trends.

A. Executive Orders 12866 and 13563 and Related Executive Orders on Regulatory Review

Executive Order 12866 directs 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). Executive Order 13563 is supplemental to, and reaffirms the principles, structures, and definitions governing regulatory review as established in, Executive Order 12866.

This final rule is partially regulatory and partially deregulatory. The Department estimates that because much of what has been finalized does not substantially alter current practice as implemented over the past 3 years under the COVID PHE, the final rule will not result in significantly altered costs. Further to this, the final rule creates efficiencies in service delivery and in administration. These include strengthening the patient-practitioner relationship in a manner that promotes efficient, evidence-based and patient-centered care, updating accreditation procedures and providing a stable regulatory environment. Additionally, the final rule makes permanent some OTP treatment flexibilities implemented within the past three years.

B. Executive Order 13985 Advancing Racial Equity and Support for Underserved Communities Through the Federal Government

A recent analysis by the Centers for Disease Control and Prevention (CDC) demonstrates high levels of overdose among Black, American Indian and Alaska Native communities over the course of the pandemic.[90] While these trends existed long before the COVID-19 PHE, this study highlights that overdose death rates rose 44 percent in 2020 for Black people and 39 percent for American Indian and Alaska Native people, compared with 22 percent for white people.[91] Black youth ages 15 to 24 saw an 86 percent increase in overdose deaths, the largest spike of any age or race group, while Black men 65 and older were nearly seven times as likely than white men to die from an overdose.[90] It was also found that Black people were less than half as likely as white people to have received substance use treatment.

This disparity amplifies the importance of promoting patient-centered care that is culturally appropriate and responsive to patient need, while also fostering a treatment environment that promotes and sustains patient engagement. The final rule facilitates the practitioner-patient relationship in a manner that espouses these principles, while also expanding the reach of OTPs (through activities such as mobile medication units) to physically engage communities that are in need of intervention. Further to this, the final rule promotes examination of a patient's cultural needs as they engage in treatment services. This is consistent with evidence-based and culturally responsive paradigms of care.

The final rule also facilitates patient engagement through removing, at the practitioner's discretion, the requirement to attend an OTP each day. Indeed, the ability to provide unsupervised doses of methadone early in treatment allows those with unstable access to transportation, for example, to focus on recovery activities in their own community. Evidence from the past three years demonstrates safety, as well as high patient and practitioner satisfaction

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[90] Kariisa M, Davis NL, Kumar S, et al. Vital Signs: Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:940–947. DOI: http://dx.doi.org/10.15585/mmwr.mm7129e2.

with take-home doses of methadone.[91] This is principally because take-home doses of methadone allow individuals the opportunity to engage in employment, education and other activities that are supportive of recovery and longer-term community involvement.

1. Cost-Benefit Analysis

a. Overview

The U.S. estimated economic cost of opioid use disorder ($471 billion) and fatal opioid overdose ($550 billion), prior to the pandemic, totaled $1,021 billion.[92] Among the 39 jurisdictions reviewed in this analysis, combined costs of opioid use disorder and fatal opioid overdose varied from $985 million in Wyoming to $72.6 billion in Ohio. Per capita combined costs varied from $1,204 in Hawaii to $7,247 in West Virginia. States with high per capita combined costs were located mainly in the Ohio Valley and New England. Across many studies, reduced quality of life is the largest component of the cost of opioid use disorder.[93]

A recent study showed that in the absence of treatment, 42,717 overdoses (4,132 fatal, 38,585 nonfatal) and 12,660 deaths were estimated to occur in a cohort of 100,000 patients over 5 years.[94] An estimated reduction in overdoses was associated with methadone treatment (10.7%), buprenorphine or naltrexone treatment (22.0%), and medication treatment combined with psychotherapeutic interventions (range, 21.0%-31.4%).[95] Estimated decreased deaths were associated with treatment with methadone (6%), buprenorphine or naltrexone (13.9%), and the

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[91] Krawczyk, N., Rivera, B. D., Levin, E., & Dooling, B. C. E. (2023). Synthesizing evidence of the effects of COVID-19 regulatory changes on methadone treatment for opioid use disorder: implications for policy. The Lancet. Public health, 8(3), e238–e246. https://doi.org/10.1016/S2468-2667(23)00023-3

[92] Luo, F., Li, M., & Florence, C. (2021). State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose - United States, 2017. MMWR. Morbidity and mortality weekly report, 70(15), 541–546. https://doi.org/10.15585/mmwr.mm7015a1. See also https://trumpwhitehouse.archives.gov/briefings-statements/cea-report-underestimated-cost-opioid-crisis/ citing a Council of Economic Advisors study estimating 2015 costs at $504 billion and a Congressional study using the CDC methodology estimating 2020 opioid crisis costs as $1.5 trillion. See https://beyer.house.gov/news/documentsingle.aspx

[93] Mitchell, S. G., Gryczynski, J., Schwartz, R. P., Myers, C. P., O'Grady, K. E., Olsen, Y. K., & Jaffe, J. H. (2015). Changes in Quality of Life following Buprenorphine Treatment: Relationship with Treatment Retention and Illicit Opioid Use. Journal of psychoactive drugs, 47(2), 149–157. https://doi.org/10.1080/02791072.2015.1014948.

[94] Fairley M, Humphreys K, Joyce VR, et al. (2021). Cost-effectiveness of Treatments for Opioid Use Disorder. JAMA Psychiatry. 2021;78(7):767–777. doi:10.1001/jamapsychiatry.2021.0247.

combination of medications and psychotherapy (16.9%). When criminal justice costs were included, all forms of MOUD (with buprenorphine, methadone, and naltrexone) were associated with cost savings compared with no treatment, yielding savings of $25,000 to $105,000 in lifetime costs per person.

McAdam-Marx et al. reported in 2010 that Medicaid beneficiaries with opioid use disorder, physical dependence on opioids, or poisoning had nearly triple the total medical costs adjusted for baseline sample characteristics compared to beneficiaries matched by age, gender, and state with no opioid misuse diagnosis ($23,556 vs. $8436; P <0.001).[95] The opioid dependence/abuse group (using an older version of the Diagnostic and Statistical Manual of Mental Disorders) also had higher prevalence of comorbidities, such as psychiatric disorders, pain-related diagnoses, and other substance use conditions. While this study considered overall cost, it did not address medication costs in particular, or any impact treatment may have had on overall cost.

OTPs provide comprehensive interventions including medications, counseling and services designed to offer a whole-person approach to care and ameliorate social determinants of health that contribute to substance misuse. Numerous studies have demonstrated that treatment with pharmacotherapy and counseling services can reduce overall healthcare costs for patients with OUD.[96,97,98] For example, a 2019 analysis demonstrated that a comprehensive approach to OUD treatment is associated with improved health and economic outcomes.[99] This study assessed patients with OUD treated at a comprehensive primary care center (CCP) and other

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[95] McAdam-Marx C, Roland CL, Cleveland J, Oderda GM (2010). Costs of opioid abuse and misuse determined from a Medicaid database. J Pain Palliat Care Pharmacother. 2010 Mar;24(1):5-18. doi: 10.3109/15360280903544877. PMID: 20345194.

[96] Murphy SM, Polsky D (2016). Economic Evaluations of Opioid Use Disorder Interventions. Pharmacoeconomics. 2016 Sep;34(9):863-87. doi: 10.1007/s40273-016-0400-5. PMID: 27002518; PMCID: PMC5572804.

[97] Baser O, Chalk M, Fiellin DA, Gastfriend DR (2011). Cost and utilization outcomes of opioid-dependence treatments. Am J Manag Care. 2011 Jun;17 Suppl 8:S235-48. PMID: 21761950.

[98] Lynch FL, McCarty D, Mertens J, Perrin NA, Green CA, Parthasarathy S, Dickerson JF, Anderson BM, Pating D (2014). Costs of care for persons with opioid dependence in commercial integrated health systems. Addict Sci Clin Pract. 2014 Aug 14;9(1):16. doi: 10.1186/1940-0640-9-16. PMID: 25123823; PMCID: PMC4142137.

[99] Hsu, Y. J., Marsteller, J. A., Kachur, S. G., & Fingerhood, M. I. (2019). Integration of Buprenorphine Treatment with Primary Care: Comparative Effectiveness on Retention, Utilization, and Cost. Population health management, 22(4), 292–299. https://doi.org/10.1089/pop.2018.0163

Maryland facilities in a large State Medicaid program and demonstrated cost savings with a comprehensive approach to care. Compared to the non-CCP patient group (n = 867), the CCP group (n = 131) had a higher 6-month buprenorphine treatment retention rate (P<0.001), fewer hospital stays in the 12-month follow-up period (P = 0.005), and lower total cost (US$10,942 vs. $13,097, P < 0.001) and hospital stay cost (US$1448 vs. $4265, P = 0.001).[100] Other measures, including emergency department utilization and cost, substance use-related cost, and non-buprenorphine pharmacy cost, were not statistically different between the 2 groups. Results suggested that patients, as well as the health care system, can benefit from a comprehensive model of care for OUD with better treatment retention, fewer hospital stays, and lower costs.

These findings are consistent with a 2016 cross sectional study that evaluated medical claims for Vermont Medicaid beneficiaries with opioid dependence or addiction between 2008 and 2013. In their analysis, Mohlman and colleagues determined that medication combined with psychosocial counseling is associated with reduced general health care expenditures and utilization, such as inpatient hospital admissions and outpatient emergency department visits, for Medicaid beneficiaries with opioid misuse.[100] Two prior studies assessed data from commercial health insurance claims on the overall health care costs and utilization rates for those taking MOUD compared to those treated without MOUD.[101,102] The first study found that over a five-year period, members on MOUD had 50% lower total annual health plan costs than those who had two or more visits to an addiction treatment setting and no treatment, and 62% lower than those with zero or one visit for addiction treatment and no intervention.[101] The other study found that after a six-month period, those taking MOUD had significantly lower overall annual health

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[100] Mohlman MK, Tanzman B, Finison K, Pinette M, Jones C. Impact of Medication-Assisted Treatment for Opioid Addiction on Medicaid Expenditures and Health Services Utilization Rates in Vermont. J Subst Abuse Treat. 2016 Aug; 67:9-14. doi: 10.1016/j.jsat.2016.05.002. Epub 2016 May 9. PMID: 27296656.

[101] McCarty D, Perrin NA, Green CA, Polen MR, Leo MC, Lynch F (2010). Methadone maintenance and the cost and utilization of health care among individuals dependent on opioids in a commercial health plan. Drug Alcohol Depend. 2010 Oct 1;111(3):235-40. doi: 10.1016/j.drugalcdep.2010.04.018. PMID: 20627427; PMCID: PMC2950212.

[102] Baser O, Chalk M, Fiellin DA, Gastfriend DR. (2011). Cost and utilization outcomes of opioid-dependence treatments. Am J Manag Care. 2011 Jun;17 Suppl 8:S235-48. PMID: 21761950.

plan costs compared to those with no medication ($10,192 vs. $14,353; p-value <0.0001).[102] The difference was driven largely by lower inpatient services and non-opioid-related outpatient services for the group receiving medication.

The regulatory impact analysis (RIA) outlined below, relies on data provided to SAMHSA by OTP Accreditation Bodies for the year 2020-2021. Pursuant to 42 CFR part 8, Accreditation Bodies and OTPs are required to submit information to SAMHSA's Center for Substance Abuse Treatment (CSAT). The annualized burden of information collection for OTPs and Accreditation Bodies under the rule is set forth in the tables that follow.

This rule does not substantially alter current reporting burden requirements, or accreditation activities. The total number of burden hours reported in 2020-2021 for Accreditation Body respondents was approximately 394.70 hours. The total number of burden hours for OTP respondents during the same period was 1,868.95 hours. The annual burden associated with this rule and the associated forms was estimated to be 2,263.65 hours.

b. Estimated Costs of Reporting Burdens for OTPs and Accreditation Bodies

In developing its estimates of the potential costs of the final regulation, the Department relied substantially on recent estimates of burden and cost pertaining to requirements set forth in 42 CFR part 8.

Hourly labor costs involved in reporting requirements vary greatly between programs. Based on wage estimates obtained from the U.S. Department of Labor, Bureau of Labor Statistics, and Occupational Employment Statistics website, it is estimated that employees involved in complying with reporting requirements range from minimum wage ($7.25) clerical workers, to counselors averaging $22.14 an hour, managers, licensed practical nurses and registered nurses averaging $35.36 per hour, administrators averaging $52.58 per hour, and physicians averaging $96.26 per hour. The estimated average hourly wage for program personnel involved in reporting requirements, calculated as a simple mean, is $42.71.

Multiplying the estimated average hourly wage by 2.0 to account for fringe benefits and overhead costs, an estimated hourly labor cost of $85.42 is obtained. The cost to Accreditation Bodies for applying for initial and ongoing approval with Form SMA-163, as well as for complying with the reporting requirements under 42 CFR 8.4 and 8.6 may be estimated at $33,672.56, using the $85.42 hourly cost figure. The estimated total annualized cost to the treatment program respondents for preparing the Form SMA-162 and for complying with other reporting requirements pursuant to 42 CFR 8.11, 8.24, 8.25, 8.26, and 8.28, using $85.42 as the hourly cost figure, is $16,140.11.

Items	Preparation Time (Hours)	Cost / Hour	Total Cost
Form SMA-163, compliance with the reporting requirements under 42 CFR 8.4 and 8.6	394.2	$85.42	$33,672.56
Form SMA-162, compliance with other reporting requirements under 21 CFR 8.11, 8.24, 8.25, 8.26, and 8.28	188.95	$85.42	$16,140.11
Form SMA-168, Exception Request and Record of Justification Under 42 CFR 8.11(h)	2,135	$85.42	$182,371.70
SUB TOTAL			$232,184.37

c. Cost Pertaining To Record Keeping

The record-keeping requirements set forth in 42 CFR 8.4 and 8.12 include maintenance of the following: a patient's medical examination when admitted to treatment; a patient's history; a care plan; any prenatal support provided to the patient; justification of unusually large initial doses; changes in a patient's dosage schedule; the rationale for decreasing a patient's clinic attendance; services provided; and documentation of physiologic tolerance.

SAMHSA believes that the record-keeping requirements are customary and usual practices within the medical and behavioral health treatment communities. Accreditation Bodies also maintain accreditation records for 5 or more years as a customary and usual practice.

SAMHSA has neither calculated a response burden or a cost burden for these activities, nor did commenters provide such information.

Costs Pertaining to Disclosure

The final rule includes requirements that OTPs and accreditation organizations disclose information. For example, § 8.12(e)(1) requires that a practitioner explain the facts concerning the use of MOUD to each patient. This type of disclosure is consistent with common medical practice and is not considered an additional burden. Further, the rule requires, under § 8.4(i)(1), that accreditation organizations shall make public their fee structure. This type of disclosure is standard business practice and is not considered a burden in this analysis.

e. Estimate of Annualized Non-hourly Cost Burden to Respondents

The final rule does not impose new capital or startup costs beyond the normal office and laboratory equipment required for achieving regulatory compliance. It is estimated that there are some costs associated with preparation for the accreditation site visit itself; assuming that OTP staff spend approximately 180 hours preparing for the site visit at an average cost of $85.42 per hour and an average of 1.33 site visits per facility, the total cost would be $20,450 or an annualized cost of $15,376 per facility. For the current approximately 2,000 affected OTPs these total annual costs are estimated to be $30,752,000. The percentage of this total cost that is associated with record keeping and reporting-only is difficult to estimate, but it is considered to be a small fraction of the total associated with accreditation.

i. Estimate of Annualized Cost to the Government

The total annualized cost to SAMHSA for administering 42 CFR part 8 is estimated at $450,000. This estimate includes the cost of an outside contractor to develop and maintain an extensive on-line protected website for day-to-day regulatory activities that can be used by

SAMHSA, opioid treatment programs, State Opioid Treatment Authorities, Accreditation Bodies and other stakeholders. This estimate does not include funds that SAMHSA/Center for Substance Abuse Treatment (CSAT) allocates to its "look back" program that monitors the adequacy of accreditation surveys. Of this amount, the total annualized cost to SAMHSA for Paperwork Reduction Act activities as a result of this regulation is estimated as $221,434, as shown in the following table.

Annualized Cost to SAMHSA/CSAT

Item (Purpose)	Responses	Hours per Response	Total Hours	Total Cost @ $85.42 per hour
SMA-162 (New Programs)	42	1.5	63	$5,381
SMA-162 (Renewal)	386	.75	289.5	$24,729
SMA-162 (Relocation)	35	.25	8.75	$747
Notification of Provisional Certification	40	.50	20	$1,708
Notification of Extension of Provisional Certification	15	.50	7.5	$641
Notification of Sponsor or Medical Director Change	60	0.33	19.8	$1,691
Documentation to SAMHSA for Interim Treatment	1	0.50	0.5	$43
Requests to SAMHSA for Exemption from §§ 8.11 and 8.12 (including SMA-168)	24,000	0.07	1680	$143,506
Notification to SAMHSA Before Establishing Medication Units	20	1.00	20	$1,708
Review of Submissions under Part C	2	2.00	4	$342
Accreditation Body Initial Application (SMA-163)	3	40	120	$10,250
Accreditation Body Renewal (SMA-163)	3	40	120	$10,250
Relinquishment Notification	1	.50	0.5	$43
Notification for Serious Non-Compliant Programs	2	.50	1	$85

Item (Purpose)	Responses	Hours per Response	Total Hours	Total Cost @ $85.42 per hour
General Documents to SAMHSA Upon Request	10	1.00	10	$854
Accreditation Survey to SAMHSA Upon Request	383	.50	191.5	$16,358
Less Than Full Accreditation Report to SAMHSA	10	1.00	10	$854
Summaries of Inspections	12	1.00	12	$1,025
Notification of Complaints to SAMHSA	10	1.00	10	$854
Submission of 90-Day Corrective Plan to SAMHSA	1	4.25	4.25	$363
SUB TOTAL	25,03625,036	97.15	2592.3	$221,434

2. Consideration of Regulatory Alternatives

The Department has completed rulemaking to make flexibilities issued during the COVID-19 PHE permanent, while also updating accreditation and treatment standards to reflect evidence-based practices and current medical terminology and approaches to OUD treatment given the current overdose crisis. The alternative would be to allow the current flexibilities to lapse with the end of the COVID-19 PHE, or to renew them periodically as may be needed during future emergencies or changed circumstances. This is considered to be suboptimal as it creates uncertainty among patients and OTPs, while also constraining access to care. Rulemaking, on the other hand, allows OTPs and their patients to operate in a stable and regulated environment that promotes access to evidence-based interventions. Other changes in the rule impact Accreditation Body oversight and procedures. Such changes can only be effectuated in a regulatory setting.

B. Regulatory Flexibility Act

The Department has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Act defines "small entities" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, and (3) a small government jurisdiction of less than 50,000 population. Because 90 percent or more of all health care providers meet the SBA size standard for a small business or are nonprofit organizations, the Department generally treats all health care providers as small entities for purposes of performing a regulatory flexibility analysis. The SBA size standard for health care providers ranges between a maximum of $8 million and $41.5 million in annual receipts, depending upon the type of entity.

Pursuant to the RFA (5 U.S.C. 601–612), the Department asserts a factual basis for its certification that the rule will not have a significant economic impact on a substantial number of small entities. As discussed in the Regulatory Impact Analysis (RIA) the costs associated with compliance are minimal. As such, the Department certifies that the proposed rule will not impose a significant economic impact. The RIA contains the factual details supporting this certification, affirming the conclusion that the financial impact of compliance is insubstantial in relation to the affected entities' financial operations.

C. Unfunded Mandates Reform Act

Section 202(a) of The Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending that may result in expenditures in any one year of $100 million in 1995 dollars, updated annually for inflation. As of 2023, this threshold is $165 million. The Department does not

anticipate that this final rule would result in the expenditure by State, local, and Tribal governments, taken together, or by the private sector, of $165 million or more in any one year.

D. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. The Department does not believe that this rulemaking would have any significant federalism implications, impose significant costs on State or local governments or preempt State law.

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999[103] requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Department believes that the final regulations would positively impact the ability of patients and families to access treatment for OUD. The Department does not anticipate negative impacts on family well-being as a result of this rule.

F. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (Pub. L. 104-13), agencies are required to submit to the Office of Management and Budget (OMB) for review and approval any reporting or recordkeeping requirements inherent in a proposed or final rule, and are required to publish such requirements for public comment. The PRA requires agencies to provide a 60-day notice in the ***Federal Register*** and solicit public comment on a proposed collection of

[103] Pub. L. 105-277, 112 Stat. 2681 (October 21, 1998).

information before it is submitted to OMB for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;

2. The accuracy of the agency's estimate of the information collection burden;

3. The quality, utility, and clarity of the information to be collected; and

4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department explicitly sought public comment on its assumptions as they relate to the PRA requirements summarized in this section. No applicable comments were received.

As discussed below, the Department estimates a total OTP burden associated with all information collections of 1,868.95 hours, and a total number of burden hours for Accreditation Body respondents of approximately 394.70 hours each year. The annual burden associated with this rule and the associated forms is therefore estimated to be 2,263.65 hours.

1. Explanation of Estimated Annualized Burden Hours for 42 CFR Part 8

The Department presents, in separate tables below, burden estimates for the annual reporting requirement for Accreditation Bodies and OTPs pursuant to the final rule.

Estimated Annual Reporting Requirement Burden for Accreditation Bodies

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.3(b)(1) through (11)	Initial approval (SMA-163)	1	1	1	6.0	6

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.3(c)	Renewal of approval (SMA-163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA	6	5	30	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status	1	185	185	0.3	55.5
SUB TOTAL		54		1,407		394.70

Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.11(b)	Renewal of approval (SMA-162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA-162)	35	1	35	1.17	40.95
8.11(d)	Application for provisional certification	42	1	42	1	42.00
8.11(f)	Application for extension of provisional certification	30	1	30	0.25	7.50
8.11(g)(5)	Notification of sponsor or medical director change (SMA-162)	60	1	60	0.1	6.00
8.11(h)(2)	Documentation to SAMHSA for interim treatment	1	1	1	1	1.00
8.11(i)	Request to SAMHSA for Exemption from §§ 8.11 and 8.12 (including SMA-168)	1,200	20	24,000	0.07	1,680
8.11(j)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA-162)	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Opioid Treatment Authority For Interim Treatment	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension	2	1	2	0.25	.50
8.25(a)	Informal Review Request	2	1	2	1.00	2.00

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.26(a)	Appellant's Review File and Written Statement	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement	2	1	2	5.00	10.00
SUB TOTAL		1,775		24,594		1,868.95
TOTAL		1,829		26,001		2,263.65

The tables above reflect current estimates of burden, as the final rule does not effectively add or alter new reporting requirements. The estimates are derived from SAMHSA's data and are reflective of work from over the preceding eighteen months. Further to this, the estimates of burden do not substantially differ from previously submitted estimates provided to The Office of Management and Budget. Recognizing the importance of expanding access to care, the Department has been careful to limit additional burden.

The final rule does not alter reporting requirements as these have been shown to be effective in the safe administration of OTPs. The accreditation system provides effective oversight, while OTP reporting requirements support accreditation activities and the provision of safe treatment. Further to this, the final rule retains requirements that OTP's and accreditation organizations disclose information related to patient care and clinic policies and procedures for the treatment of OUD with MOUD. For example, § 8.12(e)(1) requires that a health care practitioner explain the facts concerning the use of MOUD to each patient. This type of disclosure is considered to be consistent with common medical practice and is not considered an additional burden. Further, the requirement under § 8.4(i)(1) that each accreditation organization

shall make public its fee structure is considered standard business practice and is not considered a burden in this analysis.

List of Subjects in 42 CFR Part 8

Administrative practice and procedure, Health professions, Methadone, Reporting and recordkeeping requirements, Substance misuse.

For the reasons stated in the preamble, the Department of Health and Human Services proposes to revise 42 CFR part 8 to read as set forth below:

PART 8—MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER

Subpart A – General Provisions

Sec.

8.1 Scope.
8.2 Definitions.

Subpart B—Accreditation of Opioid Treatment Programs

8.3 Application for approval as an Accreditation Body.
8.4 Accreditation Body responsibilities.
8.5 Periodic evaluation of Accreditation Bodies.
8.6 Withdrawal of approval of Accreditation Bodies.

Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

8.11 Opioid Treatment Program certification.
8.12 Federal Opioid Use Disorder treatment standards.
8.13 Revocation of accreditation and Accreditation Body approval.
8.14 Suspension or revocation of certification.
8.15 Forms.

Subpart D—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

8.21 Applicability.
8.22 Definitions.
8.23 Limitation on issues subject to review.
8.24 Specifying who represents the parties.
8.25 Informal review and the reviewing official's response.
8.26 Preparation of the review file and written arguments.
8.27 Opportunity for oral presentation.
8.28 Expedited procedures for review of immediate suspension.
8.29 Ex parte communications.

8.30 Transmission of written communications by reviewing official and calculation of deadlines.
8.31 Authority and responsibilities of the reviewing official.
8.32 Administrative record.
8.33 Written decision.
8.34 Court review of final administrative action; exhaustion of administrative remedies.

Subpart E [Reserved]

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a), 300y-11.

Subpart A—General Provisions

§ 8.1 Scope.

(a) *Scope*. This subpart and subparts B through D of this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether an applicant seeking to become an Opioid Treatment Program (OTP) is qualified under section 303(h) of the Controlled Substances Act (CSA) (21 U.S.C. 823(h)) to dispense Medications for Opioid Use Disorder (MOUD) in the treatment of Opioid Use Disorder (OUD), and establishes the Secretary's standards regarding the appropriate quantities of MOUD that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(h)). Under this subpart and subparts B through D, an applicant seeking to become an OTP must first obtain from the Secretary or, by delegation, from the Assistant Secretary for Mental Health and Substance Use, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the applicant obtaining accreditation from an Accreditation Body that has been approved by the Secretary. This subpart and subparts B through D also establish the procedures whereby an entity can apply to become an approved Accreditation Body, and the requirements and general standards for Accreditation Bodies to ensure that OTPs are consistently evaluated for compliance with the Secretary's standards for treatment of OUD with MOUD.

(b) *Severability*. Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be

construed so as to give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 8.2 Definitions.

The following definitions apply to this part:

Accreditation Body or *"the Body"* means an organization that has been approved by the Secretary in this part to accredit OTPs dispensing MOUD.

Accreditation Body application means the application filed with the Secretary for purposes of obtaining approval as an Accreditation Body, as described in § 8.3(b).

Accreditation elements mean the elements or standards that are developed and adopted by an Accreditation Body and approved by the Secretary.

Accreditation survey means an onsite or virtual review and evaluation of an OTP by an Accreditation Body for the purpose of determining compliance with the Federal opioid use disorder treatment standards described in § 8.12.

Accredited OTP means an OTP that is the subject of a current, valid accreditation from an Accreditation Body approved by the Secretary under § 8.3(d).

Behavioral health services means any intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered clinical interventions (e.g., cognitive behavior therapy or insight-oriented psychotherapy) delivered in-person, or remotely via telehealth or telemedicine, which has been shown to facilitate treatment outcomes, or non-clinical interventions.

Care plan means an individualized treatment and/or recovery plan that outlines attainable treatment goals that have been identified and agreed upon between the patient and the OTP clinical team, and which specifies the services to be provided, as well as the proposed frequency and schedule for their provision.

Certification means the process by which the Secretary determines that an OTP is qualified to provide OUD treatment under the Federal Opioid Use Disorder treatment standards.

Certification application means the application filed by an OTP for purposes of obtaining certification from the Secretary, as described in § 8.11(b).

Certified opioid treatment program means an OTP that is the subject of a current, valid certification under § 8.11.

Comprehensive treatment is treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services.

Conditional certification is a type of temporary certification granted to an OTP that has requested renewal of its certification and that has received temporary accreditation for one year by an approved Accreditation Body. The one-year accreditation period is to allow the OTP to address areas of significant non-conformance with accreditation standards that do not involve immediate, high-risk health and/or safety concerns.

Continuous medication treatment means the uninterrupted treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period in excess of 21 days.

Dispense means to deliver a controlled medication to an ultimate user by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled medication.

Diversion control plan means a set of documented procedures that reduce the possibility that controlled medications will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed.

Federal Opioid Use Disorder treatment standards means the standards established by the Secretary in § 8.12 that are used to determine whether an OTP is qualified to engage in OUD treatment. The Federal Opioid Use Disorder treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of MOUD which may be provided for unsupervised, take-home use.

For-cause inspection means an inspection, by the Secretary, an Accreditation Body, or a State authority, of an OTP that may be operating in violation of Federal Opioid Use Disorder treatment standards, may be providing substandard treatment, may be serving as a possible source of diverted medications, or where patient well-being is at risk.

Harm reduction refers to practical and legal evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services.

Individualized dose means the dose of a medication for opioid use disorder, ordered by an OTP practitioner and dispensed to a patient, that sufficiently suppresses opioid withdrawal

symptoms. Individualized doses may also include split doses of a medication for opioid use disorder, where such dosing regimens are indicated.

Interim treatment means that on a temporary basis, a patient may receive some services from an OTP, while awaiting access to more comprehensive treatment services. The duration of interim treatment is limited to 180 days.

Long-term care facilities mean those facilities that provide rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include: extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; and chronic care hospitals.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for all medical and behavioral health services provided by the program, including their administration. A medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed non-physician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable Federal and State laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.

Medication for Opioid Use Disorder or *MOUD* means medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for use in the treatment of OUD. As used in this part, "continuous medication treatment" is intended to be synonymous with the term "maintenance" treatment as used in 21 U.S.C. 823(h)(1), and the term "withdrawal management" is intended to be synonymous with the term "detoxification" as used in 21 U.S.C. 823(h)(1).

Medication unit means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit.

Nationally recognized evidence-based guidelines mean a document produced by a national or international medical professional association, public health agency, such as the World Health Organization, or governmental body with the aim of assuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions for the management of OUD and other health conditions that are widely recognized within the United States.

Opioid Treatment Program or *OTP* means a program engaged in OUD treatment of individuals with MOUD registered under 21 U.S.C. 823(h)(1).

Opioid Treatment Program certification means the process by which the Secretary determines that an OTP applicant is qualified to provide Opioid Use Disorder treatment under the Federal Opioid Use Disorder treatment standards described in § 8.12.

Opioid Use Disorder means a cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress within a 12-month period.

Opioid Use Disorder treatment means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan, to an individual to alleviate the combination of adverse medical, psychological, or physical effects associated with an OUD.

Patient, for purposes of this part, means any individual who receives continuous treatment or withdrawal management in an OTP.

Physical and behavioral health services include services such as medical and psychiatric screening, assessments, evaluations, examinations, and interventions, counseling, health education, peer support services, and social services (e.g., vocational and educational guidance, employment training), that are intended to help patients receiving care in OTPs achieve and sustain remission and recovery.

Practitioner, for purposes of this part, means a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.

Program sponsor means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the OTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall ensure that an actively licensed physician occupies the position of medical director within an OTP.

Recovery support services means:

(1) *Recovery* is the process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential.

(2) *Recovery support services* can include, but are not limited to, community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of care

by strengthening and complementing substance use disorder (SUD) treatment interventions in different settings and stages.

Split dosing means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.

State Opioid Treatment Authority (SOTA) is the agency designated by the Governor of a State, or other appropriate official designated by the Governor, to exercise the responsibility and authority within the State or Territory for governing the treatment of OUD with MOUD in OTPs.

Telehealth or *telemedicine, for purposes of this part,* is the delivery and facilitation of health and health-related services including medical care, counseling, practitioner, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies. This includes Health Insurance Portability and Accountability Act (HIPAA)-compliant video and audio-only communication platforms.

Withdrawal management means the dispensing of a MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period. Long-term withdrawal management refers to the process of medication tapering that exceeds 30 days.

Subpart B—Accreditation of Opioid Treatment Programs

§ 8.3 Application for approval as an Accreditation Body.

(a) *Eligibility*. Private nonprofit organizations, State or territorial governmental entities, or political subdivisions thereof, and Indian Tribes as defined by the Federally Recognized Indian Tribe List Act of 1994, that are capable of meeting the requirements of this part may apply for approval as an Accreditation Body.

(b) *Application for initial approval*. Electronic copies of an Accreditation Body application form [SMA-167] shall be submitted to: https://dpt2.samhsa.gov/sma163/. Accreditation Body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the Accreditation Body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State or territorial governmental entity, Indian Tribe, or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid use disorder treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decision-making process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a

complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and the Secretary of deficiencies, for monitoring corrections of deficiencies by OTPs and for reporting corrections to the Secretary;

(v) Policies and procedures for determining OTPs level of adherence to this part and Accrediting Body standards and level of accreditation;

(vi) Policies and procedures for suspending or revoking an OTP's accreditation;

(vii) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by the Secretary; and

(viii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions;

(5) Policies and procedures established by the Accreditation Body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician with experience treating OUD with MOUD on the applicant's staff;

(7) A description of the applicant's survey team training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the Body will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an Accreditation Body; and

(11) Any other supporting information the Secretary may require.

(c) *Application for renewal of approval*. An Accreditation Body that intends to continue to serve as an Accreditation Body beyond its current term shall apply to the Secretary for renewal, or notify the Secretary of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an Accreditation Body's term of approval, the Body shall inform the Secretary in writing of its intent to seek renewal.

(2) The Secretary will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the Accreditation Body's term of approval, the applicant shall send to the Secretary electronically a renewal application containing the information, materials, and supporting documentation requested by the Secretary under paragraph (c)(2) of this section.

(4) An Accreditation Body that does not intend to renew its approval shall so notify the Secretary at least 9 months before the expiration of the Body's term of approval.

(d) *Rulings on applications for initial approval or renewal of approval*. (1) The Secretary will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the Accreditation Body requirements of this subpart.

(2) If the Secretary determines that the applicant does not substantially meet the requirements set forth in this subpart, the Secretary will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of the Secretary within the 90-day time period, the Body will be approved as an Accreditation Body. If the deficiencies have not been resolved to the satisfaction of the Secretary within the 90-day time period, the application for approval as an Accreditation Body will be denied.

(3) If the Secretary does not reach a final decision on a renewal application before the expiration of an Accreditation Body's term of approval, the approval will be deemed extended until the Secretary reaches a final decision, unless an Accreditation Body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of approval*. An Accreditation Body that intends to relinquish its accreditation approval before expiration of the Body's term of approval shall submit a letter of such intent to the Secretary, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) *Notification*. An Accreditation Body that does not apply for renewal of approval, or is denied such approval by the Secretary, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by the Secretary to a location, including another Accreditation Body, and according to a schedule approved by the Secretary; and

(2) Notify, in a manner and time period approved by the Secretary, all OTPs accredited or seeking accreditation by the Body that the Body will no longer have approval to provide accreditation services.

(g) *Term of approval*. An Accreditation Body's term of approval is for a period not to exceed 5 years.

(h) *State, territorial, or Indian Tribe Accreditation Bodies*. State, territorial, and Indian Tribe entities, including political subdivisions thereof, may establish organizational units that may act as Accreditation Bodies, provided such units meet the requirements of this section, are approved by the Secretary under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support MOUD.

§ 8.4 Accreditation Body responsibilities.

(a) *Accreditation surveys and for cause inspections*. (1) Accreditation Bodies shall conduct routine accreditation surveys for initial accreditation, and then at least every three years to allow for renewal of certification.

(2) Accreditation Bodies must agree to conduct for-cause inspections upon the request of the Secretary.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved Accreditation Body application.

(b) *Response to noncompliant programs*. (1) If an Accreditation Body receives or discovers information that suggests that an OTP is not meeting applicable accreditation or certification standards established or authorized under this part, or if a survey of the OTP by the Accreditation Body demonstrates that such standards are not being met, the Accreditation Body shall, within 60 days following discovery of the non-compliant condition(s) or applicable survey date:

(i) Provide written notice to the OTP that identifies each area of non-compliance, categorizes each non-compliant condition as either "minor" or "significant" as determined by the Accrediting Body, and requires the OTP to take corrective action to address the area(s) of non-compliance within a schedule, not to exceed 180 days, that the Accrediting Body deems appropriate based on the severity of the non-compliant conditions; and

(ii) Provide the Secretary with a copy of the written notice required under paragraph (b)(1)(i) of this section.

(2) Once an Accreditation Body provides an OTP with the notice described in paragraph (b)(1)(i) of this section, it shall verify the implementation of the corrective measures by the OTP within the specified schedule. Within 30 days following the last day of the specified schedule, the Accreditation Body shall provide written notice to the Secretary regarding whether the OTP has implemented the corrective measures.

(3) OTPs that are meeting the requirements of § 8.12, but are only required to correct minor non-compliant conditions shall be granted a three-year accreditation, beginning from the end date of the current and expiring accreditation period. Minor non-compliant conditions, found at the time of the survey that are not resolved, as determined by the Accreditation Body, within the OTP's three-year accreditation period and that remain areas of non-compliance during the OTP's subsequent three-year accreditation renewal survey, shall automatically be categorized

as “significant” non-compliant conditions for purposes of the renewal survey and must be corrected in accordance with paragraph (b)(1)(i) of this section.

(4) OTPs that are required to correct significant non-compliant conditions shall be granted a one-year accreditation, beginning from the end date of the current and expiring accreditation period. An OTP’s accreditation must be revoked if it fails to correct significant non-compliant conditions within the schedule provided under paragraph (b)(1)(i) of this section. If an Accrediting Body verifies that an OTP has corrected the significant non-compliant conditions identified within the specified schedule, it shall extend the OTP’s accreditation period by an additional two years.

(5) In cases of severe non-compliance with the requirements of § 8.12 that pose immediate risks to patient health and safety, the Accreditation Body shall inform the OTP and Secretary within 48 hours and provide a detailed written report of the non-compliance within 5 business days. The Accreditation Body shall give the OTP 30 days from the date of the non-compliance report to correct the non-compliance issue(s). A follow-up survey shall be conducted by the Accreditation Body within 30 days of the expected correction date to ensure successful remediation. Should the OTP not rectify the non-compliance within the 30-day period, the Accreditation Body shall revoke the OTP’s accreditation. The Secretary will then make a decision regarding the OTP’s certification in accordance with the procedures under § 8.13.

(c) *Recordkeeping*. (1) Accreditation Bodies shall maintain, and make available as requested by the Secretary, records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the Accreditation Body.

(2) Accreditation Bodies shall establish procedures to protect confidential information collected or received in their role as Accreditation Bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out Accreditation Body responsibilities shall not be used for any other purpose or disclosed, other than to the Secretary or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that the Secretary shares with the Accreditation Body concerning an OTP shall not be further disclosed except with the written permission of the Secretary.

(d) *Reporting*. (1) Accreditation Bodies shall provide to the Secretary any documents and information requested by the Secretary within 5 days of receipt of the request.

(2) Accreditation Bodies shall submit a summary of the results of each accreditation survey to the Secretary within 90 days following the survey visit. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation Bodies shall provide the Secretary a list of each OTP surveyed, and the identity of all individuals involved in the conducting and reporting of survey results.

(4) Accreditation Bodies shall submit to the Secretary the name of each OTP for which the Accreditation Body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to the Secretary under paragraphs (d)(1) through (4) of this section, each Accreditation Body shall submit to the Secretary semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of

each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to the Secretary at the address specified in § 8.3(b).

(e) *Complaint response*. Accreditation Bodies shall have policies and procedures in place to respond to complaints received from the Secretary, patients, facility staff, and others within 5 business days from the receipt of the complaint. Accreditation Bodies shall also agree to notify the Secretary within 5 business days of receipt of a complaint from a patient, facility, staff or others, and to inform the Secretary of their response to the complaint.

(f) *Modifications of accreditation elements*. Accreditation Bodies shall obtain the Secretary's written authorization prior to making any substantive (i.e., noneditorial) change in accreditation elements.

(g) *Conflicts of interest*. The Accreditation Body shall maintain and apply policies and procedures that the Secretary has approved in accordance with § 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the Accreditation Body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) *Accreditation teams*. (1) An Accreditation Body survey team shall consist of healthcare professionals with expertise in OUD treatment. The Accreditation Body shall consider factors such as the size of the OTP, the anticipated number of survey non-compliance issues, and the OTP's accreditation history in determining the composition of the team. At a minimum,

survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of medications subject to control under the Controlled Substances Act (21 U.S.C. 801 et seq.);

(ii) Medical issues relating to the dosing and administration of MOUD for the treatment of OUD;

(iii) Psychosocial counseling of individuals receiving OUD treatment; and

(iv) Organizational and administrative issues associated with OTPs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest. Conflict or perceived conflict of interest must be documented by the Accreditation Body and made available to the Secretary.

(i) *Accreditation fees*. Fees charged to OTPs for accreditation shall be reasonable. the Secretary generally will find fees to be reasonable if the fees are limited to recovering costs to the Accreditation Body, including overhead incurred. Accreditation Body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The Accreditation Body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At the Secretary's request, Accreditation Bodies shall provide to the Secretary financial records or other materials, in a manner specified by the Secretary, to assist in assessing the reasonableness of Accreditation Body fees.

§ 8.5 Periodic evaluation of Accreditation Bodies.

The Secretary will periodically evaluate the performance of Accreditation Bodies primarily by inspecting a selected sample of the OTPs accredited by the Accrediting Body, and by evaluating the Accreditation Body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the Accreditation Body are in compliance with applicable standards under this part. The evaluation will include a determination of whether there are major deficiencies in the Accreditation Body's performance that, if not corrected, would warrant withdrawal of the approval of the Accreditation Body under § 8.6.

§ 8.6 Withdrawal of approval of Accreditation Bodies.

If the Secretary determines that an Accreditation Body is not in substantial compliance with this subpart, the Secretary shall take appropriate action as follows:

(a) *Major deficiencies*. If the Secretary determines that the Accreditation Body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, the Secretary shall withdraw approval of that Accreditation Body.

(1) In the event of a major deficiency, the Secretary shall notify the Accreditation Body of the agency's action and the grounds on which the approval was withdrawn.

(2) An Accreditation Body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the Accreditation Body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by the Secretary.

(b) *Minor deficiencies*. If the Secretary determines that the Accreditation Body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, the Secretary will notify the Body that it has 90 days to submit to the Secretary a plan of corrective action. The plan must

include a summary of corrective actions and a schedule for their implementation. The Secretary may place the Body on probationary status for a period of time determined by the Secretary, or may withdraw approval of the Body if corrective action is not taken.

(1) If the Secretary places an Accreditation Body on probationary status, the Body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the Accreditation Body's probationary status within a time period and in a manner approved by the Secretary.

(2) Probationary status will remain in effect until such time as the Body can demonstrate to the satisfaction of the Secretary that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If the Secretary determines that an Accreditation Body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, the Secretary may withdraw approval of the Accreditation Body. The Accreditation Body shall notify all OTPs that have been accredited, or are seeking accreditation, of the Accreditation Body's loss of the Secretary’s approval within a time period and in a manner approved by the Secretary.

(c) *Reapplication*. (1) An Accreditation Body that has had its approval withdrawn may submit a new application for approval if the Body can provide information to the Secretary to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If the Secretary determines that the new application demonstrates that the Body satisfactorily has addressed the causes of its previous unacceptable performance, the Secretary may reinstate approval of the Accreditation Body.

(3) The Secretary may request additional information or establish additional conditions that must be met before the Secretary approves the reapplication.

(4) The Secretary may refuse to accept an application from a former Accreditation Body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings*. An opportunity to challenge an adverse action taken regarding withdrawal of approval of an Accreditation Body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in § 8.28 for expedited review of an immediate suspension would not apply to an Accreditation Body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

§ 8.11 Opioid Treatment Program certification.

(a) *General*. (1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.

(2) To obtain certification from the Secretary, an OTP must meet the Federal Opioid Use Disorder treatment standards in § 8.12, must be the subject of a current, valid accreditation by an Accreditation Body or other entity designated by the Secretary and must comply with any other conditions for certification established by the Secretary.

(3) OTPs are expected to maintain certification with the Secretary and to comply with any other conditions for certification established by the Secretary. Certification shall be granted for a term not to exceed 3 years, except that certification may be renewed during the final certification year if the OTP applies for certification renewal in accordance with the steps outlined in paragraph (a)(4) of this section.

(4) OTPs which satisfy the criteria for certification under this section may apply for renewal of their certification. OTPs are expected to apply for certification renewal during the final year of the OTP's certification period. OTPs should take steps to ensure that administrative tasks associated with renewal are completed before the OTP's certification expires. OTPs may apply for certification renewal in accordance with the procedures as outlined in paragraph (b) of this section. If an OTP anticipates any delays in routine certification renewal, an extension may be requested by submitting to the Secretary a statement justifying the extension in accordance with paragraph (e) of this section.

(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for one year by an Accreditation Body as provided under § 8.4(b)(1)(iii), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.

(6) OTPs whose certification has expired, and who seek re-certification, will be considered "new" programs and will be required to apply for provisional certification in accordance with paragraph (d) of this section.

(b) *Application for initial or renewal certifications and re-certification*. Applications for certification must be submitted by the OTP using form SMA-162. The application for initial or renewal of certification shall include, as determined by the Secretary:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding;

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (g) of this section; and

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(8) Applications for re-certification shall include an explanation of why the OTP's most recent certification expired and information regarding the schedule for an accreditation survey.

(c) *Action on application*. (1) Following the Secretary's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, the Secretary may grant the application for certification, or renew an existing certification, if the Secretary determines that the OTP has satisfied the requirements for certification or renewal of certification in this section.

(2) The Secretary may deny the application if the Secretary determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal Opioid Use Disorder treatment standards established under § 8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification in this section, the Secretary will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide OUD treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Provisional certification*. New OTPs that have not received the Secretary's certification previously, except as provided in paragraph (a)(6) of this section, who are applying for certification from the Secretary, and who have applied for accreditation with an Accreditation Body, are eligible to receive provisional certification for up to 1 year. To receive provisional certification, an OTP shall submit the information required by paragraph (b) of this section to the Secretary along with a statement identifying the Accreditation Body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph (d), unless the

Secretary determines that patient health would be adversely affected by the granting of provisional certification.

(e) *Requirements for certification*. (1) OTPs shall comply with all pertinent Federal and State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of MOUD in the treatment of OUD. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of the Department of Health and Human Services (HHS) or Substance Abuse and Mental Health Services Administration (SAMHSA), by Accreditation Bodies, by the Drug Enforcement Administration (DEA), and by authorized employees of any other Federal governmental entity with legal authority to conduct inspections or surveys on an OTP's premises.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164, and every program must comply with these regulations, as applicable. Records on the receipt, storage, and distribution of MOUD are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). Federally sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) An OTP or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Department of Health and Human Services or

SAMHSA to have access to and to copy all records on the use of MOUD in accordance with the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164.

(5) OTPs shall notify the Secretary in writing within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II and must be registered by the DEA before administering or dispensing MOUD.

(7) OTPs must operate in accordance with Federal Opioid Use Disorder treatment standards and approved accreditation elements.

(f) *Conditions for interim treatment program approval*. (1) Before an OTP may provide interim treatment, the OTP must receive the approval of both the Secretary and the SOTA of the State in which the OTP operates.

(2) Before the Secretary may grant such approval, the OTP must provide the Secretary with documentation from the SOTA of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to provide access for patients in a comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek treatment for OUD;

(iii) The authorization of the OTP to provide interim treatment will not otherwise reduce the capacity of comprehensive treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) OTPs providing interim treatment will arrange for each individual's transfer to a comprehensive treatment program no later than 180 days from the date on which each individual

first requested treatment. Individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner, who shall consider on-going and patient-centered treatment needs, which are to be documented in the patient record, while awaiting transfer to a comprehensive treatment program.

(3) The Secretary will provide notice to the OTP denying or approving the request to provide interim treatment. The OTP shall not provide such treatment until it has received such notice from the Secretary.

(g) *Exemptions*. An OTP may, at the time of application for certification or any time thereafter, request from the Secretary exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no OUD treatment services geographically accessible, and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. The Secretary will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. The Secretary shall consult with the appropriate State authority prior to taking action on an exemption request.

(h) *Medication units, long-term care facilities and hospitals*. (1) Certified OTPs may establish medication units that are authorized to dispense MOUD. Before establishing a medication unit, a certified OTP must notify the Secretary by submitting form SMA-162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent State laws and regulations. Medication units include both mobile and brick and mortar facilities.

(2) Specifically, any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space.

(3) Certification as an OTP under this part is not required for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.

(i) The term "long-term care facility" is defined in § 8.2. Nothing in this section is intended to relieve hospitals, or long-term care facilities and correctional facilities that are registered with the Drug Enforcement Administration as a hospital/clinic, from their obligations to obtain appropriate registration from the Attorney General, under section 303(g) of the Controlled Substances Act. Treatment provided under this section should always comply with applicable Federal laws.

(ii) [Reserved]

§ 8.12 Federal Opioid Use Disorder treatment standards.

(a) *General*. OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure*. (1) An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally

designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part.

(2) The medical director shall assume responsibility for all medical and behavioral health services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement*. (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of dispensed MOUD, and that assigns specific responsibility to the OTP providers and administrative staff for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials*. Each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All practitioners and other licensed/certified health care providers, including counselors, must comply with the credentialing and maintenance of licensure and/or certification requirements of their respective professions.

(e) *Patient admission criteria*—(1) *Comprehensive treatment*. An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: The person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. Such decisions must be

appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

(2) *Comprehensive treatment for persons under age 18*. Except in States where State law grants persons under 18 years of age the ability to consent to OTP treatment without the consent of another, no person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) *Withdrawal management*. An OTP shall maintain current procedures that are designed to ensure that those patients who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.

(f) *Required services*—(1) *General*. OTPs shall provide adequate medical, counseling, vocational, educational, and other screening, assessment, and treatment services to meet patient needs, with the combination and frequency of services tailored to each individual patient based on an individualized assessment and the patient's care plan that was created after shared decision making between the patient and the clinical team. These services must be available at the primary facility, except where the program sponsor has entered into a documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) *Initial medical examination*. (i) OTPs shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts:

(A) A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD; and

(B) A full history and examination, to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

(ii) Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.

(iii) A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

(iv) Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination.

(v) The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply:

(A) In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(B) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(3) *Special services for pregnant patients*. OTPs must maintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant. Pregnancy should be confirmed. Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol. Prenatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners. Specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.

(4) *Initial and periodic physical and behavioral health assessment services*. (i) Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, within 14 calendar days following admission, and periodically by appropriately licensed/credentialed personnel. These assessments must address the need for and/or response to treatment, adjust treatment interventions, including MOUD, as necessary, and provide a patient-centered plan of care. The full, initial psychosocial assessment must be completed within 14 calendar days of admission and include preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue. The care plan also must identify the recommended frequency with which services are to be provided. The plan must be reviewed and updated to reflect responses to treatment and recovery support services, and adjustments made that reflect changes in the context of the person's life, their current needs for and interests in medical, psychiatric, social, and psychological services, and current needs for and interests in education, vocational training, and employment services.

(ii) The periodic physical examination should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.

(5) *Counseling and psychoeducational services*. (i) OTPs must provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm reduction education and recovery-oriented counseling. This

counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and engage with patients, to contribute to the appropriate care plan for the patient and to monitor and update patient progress. Patient refusal of counseling shall not preclude them from receiving MOUD.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff.

(6) *Drug testing services*. When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

(g) *Recordkeeping and patient confidentiality*. (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is

required to comply with all Federal and State reporting requirements relevant to MOUD approved for use in treatment of OUD. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to determine whether the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in circumstances involving an inability to access care at the patient's OTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure. If the medical director or program practitioner of the OTP in which the patient is enrolled determines that such circumstances exist, the patient may seek treatment at another OTP, provided the justification for the particular circumstances are noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the MOUD.

(h) *Medication administration, dispensing, and use*. (1) OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law.

(2) OTPs shall use only those MOUD that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of OUD. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for

investigational use in the treatment of OUD. Currently the following MOUD will be considered to be approved by the Food and Drug Administration for use in the treatment of OUD:

(i) Methadone;

(ii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD; and

(iii) Naltrexone.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral misuse.

(ii) For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

(4) OTPs shall maintain current procedures adequate to ensure that each MOUD used by the program is administered and dispensed in accordance with its FDA approved product labeling. The program must ensure that any significant deviations from the approved labeling, including

deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) *Unsupervised or "take-home" medication doses*. Unsupervised or "take-home" medication doses may be provided under the following circumstances:

(1) Any patient in comprehensive treatment may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (e.g., Sunday) and State and Federal holidays, no matter their length of time in treatment.

(2) OTP decisions on dispensing MOUD to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section shall be determined by an appropriately licensed OTP medical practitioner or the medical director. In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;

(ii) Regularity of attendance for supervised medication administration;

(iii) Absence of serious behavioral problems that endanger the patient, the public or others;

(iv) Absence of known recent diversion activity;

(v) Whether take-home medication can be safely transported and stored; and

(vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(ii) of this section.

(i) During the first 14 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(ii) From 15 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(iii) From 31 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(4) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91-601 (15 U.S.C. 1471 et seq.)). Programs must provide education to each patient on: Safely transporting medication from the OTP to their place of residence; and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

(j) *Interim treatment*. (1) The program sponsor of an OTP may admit an individual, who is eligible for admission to comprehensive treatment, into interim treatment if comprehensive services are not readily available within a reasonable geographic area and within 14 days of the individual's seeking treatment. At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment. A program shall establish and follow reasonable criteria for establishing priorities for moving patients from interim to comprehensive treatment. These transition criteria shall be in writing and shall include, at a minimum, prioritization of pregnant patients in admitting patients to interim treatment and from interim to comprehensive treatment. Interim treatment shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).

(2) The program shall notify the SOTA when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of transfer to comprehensive services, and shall document such notifications.

(3) The Secretary may revoke the interim authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, the Secretary will consider revoking the

interim authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(h).

(4) All requirements for comprehensive treatment apply to interim treatment with the following exceptions:

(i) A primary counselor is not required to be assigned to the patient, but crisis services, including shelter support, should be available;

(ii) Interim treatment cannot be provided for longer than 180 days in any 12-month period;

(iii) By day 120, a plan for continuing treatment beyond 180 days must be created, and documented in the patient's clinical record; and

(iv) Formal counseling, vocational training, employment, economic, legal, educational, and other recovery support services described in paragraphs (f)(4) and (f)(5)(i) and (iii) of this section are not required to be offered to the patient. However, information pertaining to locally available, community-based resources for ancillary services should be made available to individual patients in interim treatment.

§ 8.13 Revocation of accreditation and Accreditation Body approval.

(a) *The Secretary's action following revocation of accreditation*. If an Accreditation Body revokes an OTP's accreditation, the Secretary may conduct an investigation into the reasons for the revocation. Following such investigation, the Secretary may determine that the OTP's certification should no longer be in effect, at which time the Secretary will initiate procedures to revoke the program's certification in accordance with § 8.14. Alternatively, the Secretary may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation Body approval*. (1) If the Secretary withdraws the approval of an Accreditation Body under § 8.6, the certifications of OTPs accredited by such Body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the Accreditation Body, unless the Secretary determines that to protect public health or safety, or because the Accreditation Body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. The Secretary may extend the time in which a certification remains in effect under this paragraph (b)(1) on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an Accreditation Body, or within any shorter period of time established by the Secretary, OTPs currently accredited by the Accreditation Body must obtain accreditation from another Accreditation Body. The Secretary may extend the time period for obtaining reaccreditation on a case-by-case basis.

§ 8.14 Suspension or revocation of certification.

(a) *Revocation*. Except as provided in paragraph (b) of this section, the Secretary may revoke the certification of an OTP if the Secretary finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with this subpart, that the program sponsor, or any employee of the OTP:

(1) Has been found to have engaged in misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal Opioid Use Disorder treatment standards in any respect;

(3) Has failed to comply with reasonable requests from the Secretary or from an Accreditation Body for records, information, reports, or materials that are necessary to determine

the continued eligibility of the OTP for certification or continued compliance with the Federal Opioid Use Disorder treatment standards; or

(4) Has refused a reasonable request of a duly designated inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or Accreditation Body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension*. Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, the Secretary may immediately suspend the certification of an OTP, and notify the Attorney General that the OTP's registration should be suspended, before holding a hearing under this subpart. The Secretary may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under this subpart if the Secretary makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal Opioid Use Disorder treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal Opioid Use Disorder treatment standards was intentional or was associated with fraud.

(c) *Written notification*. In the event that the Secretary suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, the Secretary shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action, state that the OTP may seek

review of the action in accordance with the procedures in this subpart, and identify the reviewing official to whom a written request for review may be submitted.

(d) *Procedure*. (1) If the Secretary suspends certification in accordance with paragraph (b) of this section:

(i) The Secretary will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) the Secretary will provide an opportunity for a hearing under this subpart.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

§ 8.15 Forms.

(a) SMA-162—Application for Certification to Use Medications for Opioid Use Disorder.

(b) SMA-163—Application for Becoming an Accreditation Body under § 8.3.

Subpart D—Procedures for Informal Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

§ 8.21 Applicability.

The procedures in this subpart apply when:

(a) The Secretary has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that the Secretary proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing to the reviewing official, an opportunity for an informal review of the suspension or proposed revocation.

(c) The Secretary has notified an Accreditation Body of an adverse action taken regarding withdrawal of approval of the Accreditation Body under the regulations in subpart A of this part; and

(d) The Accreditation Body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

§ 8.22 Definitions.

The following definitions apply to this subpart:

Appellant means:

(1) The OTP which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation; or

(2) The Accreditation Body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

Respondent means SAMHSA.

Reviewing official means the person or persons designated by the Secretary who will informally review the suspension or proposed revocation. The reviewing official may be assisted by one or more Department of Health and Human Services (HHS) officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

§ 8.23 Limitation on issues subject to review.

The scope of this informal review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts, the regulations in this subpart, and other relevant law.

§ 8.24 Specifying who represents the parties.

The appellant's request for an informal review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

§ 8.25 Informal review and the reviewing official's response.

(a) *Request for review*. Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose

revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) *Acknowledgment*. Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

§ 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's documents and brief*. Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the Accreditation Body is incorrect (appellant's brief).

(b) *Respondent's documents and brief*. Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, or approval as an Accreditation Body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) *Reply briefs*. Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts*. Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation*. The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) *Discovery*. The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

§ 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation*. If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official*. The reviewing official or designee will be the presiding official responsible for managing the oral presentations.

(c) *Preliminary conference*. The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference.

(d) *Time and place of oral presentation*. The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation*—(1) *General*. The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of proof/standard of proof*. In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) *Admission of evidence*. The rules of evidence do not apply, and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions*. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts*. The presiding official shall have the oral presentation transcribed. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements*. Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) *Post-hearing procedures*. At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

§ 8.28 Expedited procedures for review of immediate suspension.

(a) *Applicability*. When the Secretary notifies an OTP in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response*. As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs*. Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation*. If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with § 8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties.

The presiding official may hold a pre-hearing conference in accordance with § 8.27(c) and will conduct the oral presentation in accordance with the procedures of § 8.27(e), (f), and (g).

(e) *Written decision*. The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in § 8.33 apply.

(f) *Transmission of written communications*. Because of the importance of timeliness for the expedited procedures in this section, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

§ 8.29 Ex parte communications.

For the purposes of maintaining the equity of informal review proceedings, except for routine administrative and procedural matters or as described in §§ 8.22(2) and 8.27(e), a party shall not communicate with the reviewing or presiding official without notice to the other party.

§ 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) *Timely review*. Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) *Due date*. In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

§ 8.31 Authority and responsibilities of the reviewing official.

In addition to any other authority specified in this subpart, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify the procedures in this subpart in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision*. The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the

reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision*. The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA)*. (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the Federal Register. The Secretary will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the Federal Register. The Secretary will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

Subpart E [Reserved]

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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