



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.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or “the Department”) is issuing this notice of proposed rulemaking (NPRM) to solicit public comment on its proposal to modify its regulations regarding medications for the treatment of opioid use disorder.

DATES: Comments due on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may submit electronic comments at <https://www.regulations.gov>. Follow the instructions at <https://www.regulations.gov> for submitting electronic comments. Attachments should be in Microsoft Word or Portable Document Format (PDF), and please refer to RIN 0930-AA39 in all comments.
- *Regular, Express, or Overnight Mail:* You may mail written comments (one original and two copies) to the following address only: The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, 5600 Fishers Lane, Room 13-E-30, Rockville, MD, 20857.

Note: Due to the COVID-19 pandemic, SAMHSA notes receipt of mail may be delayed and encourages submission of comments electronically to the docket.

Inspection of Public Comments: All comments received by the accepted methods and due date specified above may be posted without change to content to

<https://www.regulations.gov>, which may include personal information provided about the commenter, and such posting may occur after the closing of the comment period.

However, the Department may redact certain content from comments before posting, including threatening language, hate speech, profanity, graphic images, or individually identifiable information about a third-party individual other than the commenter.

Because of the large number of public comments normally received on Federal Register documents, SAMHSA is not able to provide individual acknowledgments of receipt.

Please allow sufficient time for mailed comments to be received timely in the event of delivery or security delays. Comments submitted by fax or email, and those submitted after the comment period will not be accepted.

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 need for the proposed rule changes, a section-by-section description of the proposed modifications, and the impact statement and other required regulatory analyses. The Department solicits public comment on all aspects of the proposed rule. Persons interested in commenting on the provisions of the proposed rules can assist the Department by preceding discussion of any particular provision or topic with a citation to the section of the proposed rule being discussed.

Executive Summary

A. Overview

The Controlled Substances Act (CSA), under 21 U.S.C. 823(g)(1), requires “practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment” to “obtain annually a separate registration for that purpose” except as provided under 21 U.S.C. 823(g)(2). Section 823(g)(1) also 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.” 21 U.S.C. 823(g)(1)(A)-(C). The standards authorized under section 823(g)(1) have been published as regulations under part 8 of title 42 of the Code of Federal Regulations (42 CFR part 8 or “part 8”).¹ 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. See 42 CFR 8.1. In addition, “a 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(g)(1)” is described as an “Opioid Treatment Program” (OTP). See 42 CFR 8.2.²

¹ 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.

² 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”.

The statute, at 21 U.S.C. 823(g)(2), also authorizes a waiver from the registration requirements of 21 U.S.C. 823(g)(1) for qualifying practitioners seeking to dispense or prescribe schedule III, IV, or V controlled substances that are Food and Drug Administration (FDA)-approved for use in “maintenance and detoxification treatment.” Practitioners with a waiver under section 823(g)(2) are limited in the number of patients with opioid use disorder they may treat at any one time, and depending on the practitioner’s experience or qualifications, this statutory limitation is set at either 30, 100, or 275. See 21 U.S.C. 823(g)(2)(B)(iii). The Secretary is also authorized to change the patient limitations by regulation, and qualifying practitioners must satisfy the requirements of 42 CFR 8.610 through 8.655 “(or successor regulations)” in order to treat up to 275 patients, which is the maximum number under existing law. See 21 U.S.C. 823(g)(2)(B)(iii)(II)(dd).³

In this NPRM, the Department proposes to modify certain provisions of part 8 to update OTP accreditation and certification standards, treatment standards for the provision of medications for opioid use disorder (MOUD) as dispensed by OTPs, and requirements for individual practitioners eligible to dispense (including by prescribing) certain types of MOUD with a waiver under 21 U.S.C. 823(g)(2).

The proposal 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 social distancing and to preserve patient and staff safety among OTPs. In March 2020, SAMHSA published flexibilities in the provision of unsupervised doses of methadone and the use of telehealth in initiating buprenorphine.⁴ These flexibilities

³ See <https://www.govinfo.gov/content/pkg/USCODE-2016-title21/html/USCODE-2016-title21-chap13-subchapI-partC-sec823.htm>.

⁴ 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>.

represented the first substantial change to OTP treatment and medication delivery standards in over 20 years. A growing body of research has demonstrated that these flexibilities facilitate access to treatment and eliminate criteria that promote stigma and discourage people from accessing care from OTPs.

This proposed rule not only makes these 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 proposing to update part 8 to: promote practitioner autonomy; remove stigmatizing 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.^{5,6,7}

To this end, the definition of a qualifying practitioner has been expanded to include a provider who is appropriately licensed by the state to prescribe (including dispense) covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2). Admission criteria have been updated to remove significant barriers to entry, such as the one-year requirement for opioid use disorder (OUD),⁸ while also defining the scope and purpose of the ‘initial’ and ‘periodic’ medical examinations. The proposed rule also includes new definitions to expand access to evidence-based practices such as split dosing, telehealth and harm reduction activities. Further to this, outdated terms such as ‘detoxification’ have been revised to remove stigmatizing language.

⁵ 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.

⁶ 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.

⁷ 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.

⁸ See 42 CFR 8.12(e)(1).

The Department promotes practitioner autonomy and individualized care by proposing to revise the provision containing the criteria for unsupervised doses of methadone. This includes removal of consideration of the length of time an individual has been in treatment, as well as 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 recognizes the importance of the practitioner-patient relationship, and is consistent with modern treatment standards. It also allows for greater flexibility in creating plans of care that promote recovery activities such as employment, while also eliminating the barrier of frequent visits for individuals without access to reliable transportation.⁹

Accreditation and certification standards have been reviewed to codify the use of online/electronic forms, to eliminate types of certification that are no longer in use, and to update existing types of certification in a manner that reflects established practice. 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 proposed rule also clarifies administrative issues pertaining to mobile medication units and interim treatment.

The proposed changes seek to make treatment in OTPs more accessible to patients, easier to deliver for providers and supportive of evidence-based and patient-centered care. In proposing these changes, SAMHSA has relied on published evidence, stakeholder feedback and the need to expand access to care in the face of a growing overdose epidemic, exacerbated by the COVID-19 PHE.¹⁰ This is brought further into

⁹ 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.000000000000295.

¹⁰ 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.

focus by the HHS declaration of a public health emergency for the opioid crisis which has been regularly renewed since 2017.¹¹ The proposed changes are expansive but are focused on permanently implementing existing flexibilities and updating practices. In this way, SAMHSA believes that much of what is proposed in the rule will not represent a significant burden for OTPs and, in fact, will offer many benefits to providers and patients. The proposed rule, therefore, supports OTPs in their on-going provision of equitable and evidence-based care to often marginalized patients with OUD. The proposed rule also is consistent with the HHS Overdose Prevention Strategy which calls for increasing access to and the uptake of evidence-based treatments for substance use disorders.¹²

B. Effective and Compliance Dates

The proposed effective date of a final rule would be 60 days after publication of the final rule and the compliance date would be 6 months after the effective date. Entities subject to the final rule would have until the compliance date to achieve compliance with this rule.

C. Summary of Major Proposals

The Department proposes the following changes to 42 CFR part 8 that revise, delete, replace, or add sections. This section summarizes major proposals in this NPRM. Additional proposed revisions are not listed here because they are not considered major.¹³ All proposed changes are discussed in detail in section III of this NPRM:

SUDORS Data Brief, No 2. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2022.

¹¹ See <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

¹² See <https://www.hhs.gov/overdose-prevention/>.

¹³ Generally, the proposals not listed make wording changes, not substantive changes. These proposals are reviewable in the regulatory text.

1. *Heading.*

The heading of part 8 has been changed from *Medication Assisted Treatment for Opioid Use Disorders* to *Medications for the Treatment of Opioid Use Disorder* to reflect currently accepted medical terminology and to remove language that is widely viewed to be stigmatizing.

2. *Subpart A.*

Subpart A currently addresses accreditation and includes steps that accreditation bodies must follow to obtain approval to accredit OTPs. It also sets forth accreditation bodies' responsibilities, including the use of accreditation elements, during accreditation surveys. In the proposed rule, these specifications are relocated to subpart B, which still would include Certification of Opioid Treatment Programs. The proposed rule limits subpart A to the preamble and definitions.

3. *Section 8.1 – Scope.*

Revised § 8.1 to reflect modern medical terminology, to detail updated acronyms, and for clarity. Of note, the term medication assisted treatment (MAT) has been updated to MOUD, and the term treatment program has been changed to opioid treatment program throughout the proposed rule.

4. *Section 8.2 – Definitions.*

Revised § 8.2 to add 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.

5. *Section 8.3 – Application for approval as an accreditation body.*

Added 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. A correction has been made to the email address to which the accreditation application is submitted. The current rule calls for the accreditation bodies' training policies to be provided as part of their application process. Furthermore, this regulation would be updated to ensure that accreditation bodies provide training policies specifically related to training of survey team members. In addition to state or territorial governments, the proposed rule also provides for Indian Tribes to apply for approval as an accreditation body.

6. *Section 8.4 – Accreditation body responsibilities.*

Amended to clarify expectations for cooperation of accreditation bodies with SAMHSA's oversight. These include 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. Time frames are also established for submission of survey reports. The proposed rule adds a 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 the proposed rule adds a requirement that accreditation bodies notify SAMHSA of all aspects of a complaint response within 5 days of receipt. The current 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 amended to update categories of certification, to clarify SAMHSA's expectation that OTPs maintain certification, and to establish procedures for OTPs whose certification has lapsed. Current terms for the extension of certification are amended to clarify the circumstances in which an extension could be requested, and

the means of requesting an extension are defined in the proposed rule. The proposed 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.

The proposed rule removes “transitional certification” which expired as a category of certification in 2003. 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. The chapter of the Controlled Substances Act with which OTPs are expected to comply has been added; the chapter number is not included in the current version of the rule.

The conditions for approval of interim treatment have been amended 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. A reference to section 1923 of the Public Health Service Act (21 U.S.C. 300x-23) is removed. The proposed 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.

The services that can be provided in medication units have been clarified 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 incorporated in this section aim 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 substances, has been removed and patient-centered language is added.

The paragraph on staff credentials is amended to expand the definition of “qualifying practitioners” to a “physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife who is appropriately licensed by a State to prescribe covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2).” The expectation that all licensed and credentialed staff maintain licensure and/or certification has been added.

Criteria for admission to treatment removes reference to the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV and eliminates the requirement for a one-year history of OUD. The proposed rule instead 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 amended to assure 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 removed. 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 amended 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 penal institutions, pregnant patients or previously enrolled individuals has been removed.

Throughout the document, “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 “Required services” paragraph is revised to incorporate patient-centered language, establish flexible terminology, promote use of clinical judgment, and clarify SAMHSA’s expectations of OTPs. The proposed 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 amended 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 proposed 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 has also been addressed in the proposed rule. Additionally, the paragraph on special services for pregnant people is amended to specify that confirmation of pregnancy is required for

priority treatment admissions. The option to use split dosing for patients is also added.

The components of initial and periodic medical examinations have been expanded in the proposed rule 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 amended so as to assure information is gathered on 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 added, such as "services a patient needs and wishes to pursue".

The proposed rule expands the definition of 'counseling services' 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 revised 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 amended to remove the word "formal"; the proposed rule calls for a "documented agreement" to provide such services.

Language that addresses drug testing services has been amended to remove stigmatizing phrases, such as "drug abuse", and to remove content on short-term withdrawal management ("detoxification"). Further to this, the requirement to use drug tests that have received the FDA's marketing authorization was added.

Rules that address recordkeeping and efforts to avoid simultaneous enrollment in multiple OTPs are amended 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 proposed 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.

Specification of disciplines authorized to administer or dispense MOUD is removed from the rule. LAAM, also known as Levacetylmethadol, 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. The regulation of an initial dose of methadone remains at 30mg, not to exceed 40mg on the first day, with the incorporation of a provision 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 proposed rule, while redundant language was removed.

Rules on the provision of unsupervised (or take home) doses of methadone are substantially amended to incorporate flexibilities issued in response to the COVID-19 pandemic. Stigmatizing language is removed, and the criteria for decision-making is reframed to promote use of clinical judgement and patient-centered care. In general, the revised 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 was continued, and patient education on safe transport and storage of take home doses is added, including documentation of the provision of this education in the patient’s clinical record.

Consistent with the conditions for approval of interim treatment, the proposed 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 proposed rule removes the requirement for observation of all daily doses during interim treatment. It clarifies 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 was added to the proposed rule.

9. *Section 8.13 – Revocation of accreditation and accreditation body approval.*

Changes in this section were limited to referring to an OTP as a “program” instead of a “facility”.

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

This section refines steps SAMHSA may take when immediate action is necessary to protect public health or safety.

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.*

Language referencing “treatment program” in this section was changed to “OTP” for document consistency.

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

This subpart has been amended to change the format from the prior Question-and-Answer style to a standard format.

13. *Section 8.610 – Practitioner eligibility requirements for a 3-year 275-patient limit.*

Modernized language to refer to MOUD and to remove stigmatizing language that referred to ‘legitimate medications’. The proposed rule also clarified that the 275-patient waiver is limited to three years in duration, requiring renewal.

14. Section 8.635 – What are the reporting requirements for practitioners whose 275 Request for Patient Limit is approved?

The proposed rule removes reporting requirements for practitioners approved to treat up to 275 patients, eliminating § 8.635 in its entirety.

Background and Need for Proposed Rule

As of June 2022 there are over 1,920 OTPs in the United States, providing care to over 650,000 patients. These are the only settings within which methadone, a schedule II opioid receptor agonist, can be legally provided to people with OUD outside the context of hospital admission or certain other special circumstances.¹⁴

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. Currently, these include methadone and buprenorphine, a schedule III partial opioid receptor agonist. Other pharmacotherapies, such as naltrexone, may be provided but are not subject to regulations under part 8. For purposes of certification, OTPs must also provide adequate medical, counseling, vocational, educational, and other assessment and treatment services either onsite or by referral to an outside agency or practitioner.¹⁵ Buprenorphine can also be dispensed (including by prescribing) to treat OUD by eligible practitioners with a waiver

¹⁴ See 21 CFR 1306.07.

¹⁵ 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.

under 21 U.S.C. 823(g)(2) in settings outside of OTPs given its different scheduling and treatment under the Controlled Substances Act.¹⁶

Practitioners treating OUD and the OTPs in which they practice must continuously adapt to evolving patterns of drug misuse. Over the past 40 years, this has been complicated by rapid changes in 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.¹⁷ By 2010, however, the U.S. began to see rapid increases in overdose deaths involving heroin¹⁸ and then by 2013, synthetic opioids other than methadone – primarily illicitly manufactured fentanyl – contributed to a further rise in overdose-related deaths.^{19,20}

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 107,375 Americans died from a drug overdose in the 12-month period ending in January 2022.²¹ 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 2021.²² Overdose deaths involving cocaine also increased by 22 percent from 2019 to 2020. These deaths are likely linked to

¹⁶ 21 U.S.C. 823(g)(2); 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.

¹⁷ 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.

¹⁸ Rudd RA, Paulozzi LJ, Bauer MJ, Bureson 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.

¹⁹ 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.

²⁰ 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.

²¹ Ahmad, F.B., Rossen, L.M., Sutton, P. (2021). Provisional drug overdose death counts. National Center for Health Statistics.

²² Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2022. Available at <https://wonder.cdc.gov>.

co-use or mixing (by illicit producers) of cocaine with illicitly manufactured fentanyl or heroin.²³ 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 also adverse patient outcomes.

A. 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) in treatment and withdrawal management (referred to as detoxification) of OUD. The final rule repealed the treatment regulations enforced by the 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 study by the Institute 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. Since publication of the final rule in 2001, it has been updated to include new medications, such as buprenorphine, while also updating or adding new rules governing the provision of such medications.

Between 1972 and 2001, Federal regulatory oversight of OTPs was enforced by the FDA before responsibility for oversight was transferred to SAMHSA. Periodic reviews, studies, and reports on the Federal oversight system culminated with the 1995 IOM Report entitled Federal Regulation of Methadone Treatment.²⁴ The IOM report recommended that the FDA process-oriented regulations should be reduced in scope to

²³ Ibid.

²⁴ For full text, see: <https://www.ncbi.nlm.nih.gov/books/NBK232108/>.

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 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 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 addresses accreditation and includes steps that accreditation bodies must follow to achieve approval to accredit OTPs. It also sets forth the accreditation bodies’ responsibilities, including the use of accreditation elements during accreditation surveys. Subpart C describes the sequence and

requirements for obtaining certification, and addresses how and when programs must apply for initial certification and renewal of their certification. Subpart D elucidates the procedures for review of the withdrawal of approval of the accreditation body or the suspension and proposed revocation of an OTP certification. Subpart F, added in 2016, describes criteria for increasing the patient limit for those meeting Federal requirements to prescribe buprenorphine to 275.²⁵

In 2001 there were close to 900 OTPs, but that number has grown to over 1900 by 2022.²⁶ Over this period of time, the incidence of fentanyl misuse has increased, escalating with the onset of the COVID-19 public health emergency 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 unsupervised doses of methadone and also initiation of buprenorphine via telehealth, that allowed for continued treatment of OUD with reduced direct patient contact. Each of these flexibilities represented a significant change to treatment standards, and are discussed in detail below.

Flexibility for Methadone Medication Take Homes 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 homes 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 8.²⁷ These criteria can pose

²⁵ See <https://www.federalregister.gov/documents/2016/07/08/2016-16120/medication-assisted-treatment-for-opioid-use-disorders>.

²⁶ SAMHSA treatment locator. See <https://dpt2.samhsa.gov/treatment/directory.aspx>.

²⁷ <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8?toc=1>.

disruption to employment and 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 allowed 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.²⁸ With this flexibility, SAMHSA allowed OTPs to dispense 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.”²⁹ 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”³⁰

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 could 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, care for loved ones and engage in other required activities of daily living.

²⁸ HHS Guidance for Opioid Treatment Programs. <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>.

²⁹ See <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>.

³⁰ 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,³¹ OTPs,³² and state authorities.³³ Patients reported that increased take home doses of methadone left them feeling more respected as responsible individuals.³¹ In a recent 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. 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.³⁴ Additionally, a recent survey found that diversion of methadone is low among patients receiving take home doses under the COVID-19 PHE flexibility.^{35,36} 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.³⁷

Recognizing the importance of this flexibility, SAMHSA released guidance on November 18, 2021, that extended the methadone take home flexibility for one year past the end of COVID PHE. This was to accommodate the rule making process that proposes

³¹ 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.

³² 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.

³³ "To Save Lives From Opioid Overdose Deaths, Bring Methadone Into Mainstream Medicine", *Health Affairs Forefront*, May 27, 2022.

³⁴ National Institute on Drug Abuse (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.

³⁵ 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>.

³⁶ 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>.

³⁷ 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>.

to make this flexibility permanent. In this proposed rule, SAMHSA has reviewed and updated criteria used to determine eligibility for take home doses of methadone, while also promoting shared decision making that is supported by availability of unsupervised doses of methadone from entry into treatment. Individuals receiving take home doses of methadone are supported through individually tailored telehealth visits to practitioners, counselors and other services as indicated. Further to this, the proposed changes highlight practitioner autonomy in determining eligibility for unsupervised doses of methadone. This is a significant change to treatment standards, but it is grounded in evidence that demonstrates the safety and efficacy of promoting patient and provider autonomy.

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.^{38,39,40} Between 2016 and 2019, use of telehealth, in general, doubled from 14 to 28 percent,⁴¹ while substance use disorder (SUD) treatment, offered through telehealth over the same period, increased

³⁸ 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.

³⁹ Lustig, T. (2012). The role of telehealth in an evolving health care environment: Workshop summary. National Academies Press.

⁴⁰ 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.

⁴¹ 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>.

from 13.5 to 17.4 percent.⁴² This trend has rapidly increased between 2019 and 2021, due to the COVID-19 pandemic.⁴³

The pandemic spurred use of telemedicine for the treatment of OUD using 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 of new patients to ensure that initial doses do not exceed an individual's tolerance for the medication. The Drug Addiction Treatment Act of 2000 (DATA 2000) allowed practitioners to treat OUD outside of OTPs using buprenorphine, generally with an initial in-person medical evaluation before prescribing.

On March 16, 2020, the Secretary of HHS, with the concurrence of the Acting DEA Administrator, designated that the telemedicine exception under 21 U.S.C. 802(54)(D), applied to all schedule II-V controlled substances.⁴⁴ Accordingly, DEA-registered, DATA-Waived practitioners may issue buprenorphine prescriptions through telemedicine to new patients for whom they have not conducted an in-person medical evaluation, provided certain conditions are met during the COVID-19 public health emergency.

On March 25, 2020, the DEA also granted a "temporary exception" to its regulations that allows practitioners to prescribe controlled medications in states in which they are not registered, if the practitioner is registered with the DEA in at least one state and is authorized by both the state where the practitioner is registered with DEA and the

⁴² 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.

⁴³ 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.

⁴⁴ See <https://www.deadiversion.usdoj.gov/coronavirus.html>.

state where the dispensing occurs.⁴⁵ According to the DEA, practitioners may utilize this temporary exception via in-person prescribing or prescribing via telemedicine. The DEA also specified that this exception is granted through “the duration of the COVID-19 public health emergency as declared by the Secretary of Health and Human Services.”⁴⁶

Building upon this, SAMHSA implemented OTP regulatory flexibilities designed to help address the impact of the COVID-19 pandemic on OTPs and their patients.⁴⁷ 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 will 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, determines that an adequate evaluation of the patient can 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”,⁴⁸ 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,⁴⁹ and that among those requiring treatment with buprenorphine, there are high levels of satisfaction with the use of telehealth services.⁵⁰ Additionally, there are no significant differences between

⁴⁵ See Exception to Separate Registration Requirements Across State Lines (DEA067), [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-018\)\(DEA067\)%20DEA%20state%20reciprocity%20\(final\)\(Signed\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf).

⁴⁶ With respect to methadone delivery, during the COVID-19 public health emergency, the DEA has also authorized employees of OTPs to personally deliver methadone to patients who otherwise cannot travel to the OTP, and has issued a waiver to permit law enforcement and National Guard personnel to deliver methadone directly to patients of OTPs. See https://www.deadiversion.usdoj.gov/faq/coronavirus_faq.htm#NTP_FAQ.

⁴⁷ OTPs are authorized to dispense narcotic maintenance and detoxification medication under 21 U.S.C. 823(g)(1) and regulated under 42 CFR part 8.

⁴⁸ See <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

⁴⁹ 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.

⁵⁰ 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.

telehealth and in-person buprenorphine induction in the rate of continued substance use, retention in treatment or engagement in services.^{38,51} Research also shows that there is no significant difference in client and provider ratings of therapeutic alliance when using telehealth technology platforms.³⁹

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. The proposed rule makes permanent criteria of initiation of buprenorphine via audio-only or audio-visual telehealth technology if an OTP physician, primary care 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 telehealth.

SAMHSA believes that evidence underlying the initiation of buprenorphine using telehealth translates, to some degree, 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.⁵² The proposed 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 with methadone because methadone, in comparison to buprenorphine, holds a higher risk profile for sedation in patients

⁵¹ 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>.

⁵² 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.

presenting with mild somnolence which may be easier to identify through an audio-visual telehealth platform. The proposed rule is not applicable to, and does not authorize, the prescription of methadone pursuant to a telehealth visit. Instead, this proposed change 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 an audio-visual telehealth platforms on the basis of their disability has an equal opportunity to benefit from treatment with MOUD. Similarly, Federal civil rights laws that prohibit discrimination on the basis of national origin (including language ability), require recipients to take reasonable steps to provide meaningful access to LEP individuals, which 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 requirements 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.⁵³ On September 21, 2021, SAMHSA released guidance on the establishment of mobile and non-mobile medication units and allowable services.⁵⁴ While part 8 currently allows OTPs certified by SAMHSA to establish medication units (as defined under 42 CFR 8.2), the proposed rule further defines mobile units and clarifies potential services, interventions and accreditation processes.

Additionally, the proposed rule defines harm reduction and promotes expansion of harm reduction services to OTP patients.⁵⁵ The importance of this has been highlighted during the COVID-19 pandemic, principally with the CDC and SAMHSA's April 7, 2021, joint announcement that Federal funding could be used to purchase rapid fentanyl test strips (FTS).⁵⁶ This was proposed in an effort 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. Other important harm reduction activities highlighted in the proposed rule include: counseling on preventing exposure to, and the transmission of, HIV, viral hepatitis, and STIs; providing access to services and treatments for those with HIV, viral hepatitis or an STI; provision of patient-centered harm reduction education; and distribution of opioid overdose reversal medications (e.g., naloxone).⁵⁷

The need to facilitate access to services has been highlighted during the COVID-19 pandemic. This is particularly important in the face of increased exposure to fentanyl.

⁵³ See 86 FR 33861; <https://www.federalregister.gov/documents/2021/06/28/2021-13519/registration-requirements-for-narcotic-treatment-programs-with-mobile-components>.

⁵⁴ See <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines#mobile>.

⁵⁵The proposed rule does not permit OTPs to engage in any activities that would violate Federal, State, or local law.

⁵⁶ See <https://www.cdc.gov/media/releases/2021/p0407-Fentanyl-Test-Strips.html>.

⁵⁷ See <https://www.samhsa.gov/blog/new-samhsa-guide-highlights-hiv-prevention-treatment-people-substance-use-and-or-mental>.

Section 8.12(e)(1) of the proposed rule eliminates the requirement that a person must have had an addiction to opioids for one year before admission to treatment and receipt of OTP services, and permits access to those: who meet diagnostic criteria for a moderate to severe OUD; individuals with active moderate to severe OUD, or OUD in remission; or those individuals who are at high risk for overdose or recurrence of use. Admission to the OTP is contingent upon appropriate informed consent and education, as well as appropriate documentation of consent in the patient's clinical record.

These activities are supported, in the proposed rule, through defining a practitioner (in § 8.2) as being “a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife who is appropriately licensed by a State to prescribe covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2).” Further to this, the proposed rule expands decision making capacity of OTP practitioners to: admission of patients; the provision of treatment activities; and service provision. This is supported by the use of telehealth, described above, and involvement of outside practitioners. Indeed, § 8.12(f)(2) of the proposed rule allows for the initial medical examination to be completed by a practitioner external to the OTP no more than seven days prior to admission, provided that it is verified by an OTP practitioner. This expands access to OTP services and is consistent with current medical practice.

In this way, the proposed rule draws on evidence from the COVID-19 pandemic as well as over 20 years of practice-based research. The proposed rule makes permanent or expands upon flexibilities initiated during the COVID-19 PHE and recognizes the efficacy and safety of creating a less restrictive and patient-centered treatment environment. Further to this, the evidence demonstrates the positive impact of not requiring frequent patient visits to the OTP. This has been shown to promote recovery behaviors, such as sustained employment, as well as support those individuals who live a

long distance from the OTP.⁵⁸ The integration of telehealth into the proposed rule further supports this and allows OTPs flexibility in initiating MOUD.

Section-by-Section Description of Proposed Amendments to 42 CFR Part 8

Below, the Department describes the proposals in this NPRM to amend 42 CFR part 8. The Department believes that the proposed rule expands access to evidence-based and patient-centered care, limits use of stigmatizing language, and promotes the practitioner-patient relationship. These changes are in line with evidence-based practice, and the Department welcomes feedback on all aspects of the proposed rule.

In particular, the Department is interested in feedback on the proposal to increase the allowable time for interim treatment from 120 days to 180 days. This is intended to accommodate OTPs and states as they address important issues such as staff shortages. It may also serve as a way of engaging individuals in care. Such issues underlie the need for this service approach, and while SAMHSA is working with other Federal and State agencies to build workforce capacity, the use of interim treatment adds to the care continuum for people with OUD.

The Department also seeks feedback on other paradigms of care promoted in the proposed rule. Split-dosing and delivery of services via telehealth are, for example, evidence-based interventions that promote patient-centered care. The Department proposes to expand access to evidence-based treatment through the addition of such practices, and seeks guidance on the proposed use of these interventions and their integration into the practice environment.

⁵⁸ Treitler, P. C., Bowden, C. F., Lloyd, J., Enich, M., Nyaku, A. N., & Crystal, S. (2022). Perspectives of opioid use disorder treatment providers during COVID-19: Adapting to flexibilities and sustaining reforms. *Journal of substance abuse treatment*, 132, 108514. <https://doi.org/10.1016/j.jsat.2021.108514>

Also proposed are new criteria to support decision making around take home doses of methadone. The take home flexibility issued at the start of the COVID-19 pandemic demonstrated that length of time in treatment, as well as strict negative toxicology test results were not central to positive outcomes.⁵⁸ This is reflected in the proposed rule, and feedback is solicited on the proposed criteria, as well as the schedule for providing unsupervised doses of methadone.

The Department further requests comment on all proposals described in the following paragraphs of this NPRM. In addition, the Department requests comment on all aspects of the Regulatory Impact Analysis, including the assumptions and estimates about the costs and benefits of the proposed changes, and the alternatives the Department considered when developing the proposals in this NPRM.

The Department proposes the following amendments to part 8:

A. Heading

The Department proposes to revise the heading to *Medications for the Treatment of Opioid Use Disorder* to reflect current medical terminology and to remove 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.⁵⁹ The amended heading reflects current medical terminology and highlights that OUD is a chronic, treatable condition.

⁵⁹ 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-professionals-education/words-matter-terms-to-use-avoid-when-talking-about-addiction>.

B. Subpart A

Subpart A currently addresses accreditation and includes steps that accreditation bodies will follow to achieve approval to accredit OTPs under the new rules. It also sets forth the accreditation bodies' responsibilities, including the use of accreditation elements during accreditation surveys. In the proposed rule, these specifications are relocated to subpart B, which still includes Certification of Opioid Treatment Programs. In this way, subpart A is now limited to the overview of part 8 and definitions. This improves categorization and provides clear flow within the proposed rule.

C. Section 8.1—Scope

This section has been revised to reflect modern medical terminology and to detail updated acronyms. Historically, pharmacological treatment for opioid use disorder was referred to as “medication assisted treatment” (MAT). There is an increasing movement towards the more medically accurate term “medication for opioid use disorder” (MOUD) since this precisely describes the medications that are being provided, carries less stigma, and aligns with treatment approaches to all other health conditions. Further to this, the term ‘MAT’ implies that these medications are simply adjuncts to a broader treatment strategy.⁶⁰ In fact, these medications are one critical element of a comprehensive, long-term treatment and recovery strategy.⁶⁰ As such, the acronym MAT has been removed from the proposed rule and replaced with MOUD throughout. The proposed rule identifies other treatment modalities, such as counseling, by their individual component

⁶⁰ 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.

names, similar to the manner by which elements of other chronic disease care are described.

D. Section 8.2—Definitions

In the 21 years since part 8 was first published, definitions and paradigms of care for OUD have changed. In particular, treatment for OUD has evolved from being prescriptive to multimodal and patient-centered.⁶¹ This reflects an understanding that OUD is a chronic condition⁶² and that to be successful, treatment interventions should be individualized and include harm reduction and recovery support services. Further to this, flexibilities expanded under the COVID-19 PHE demonstrated the safety of telehealth interventions.⁶³ Accordingly, telehealth is defined in this section using a standard definition. The proposed rule updates other definitions to reflect current evidence and practice in the provision of care in OTPs. This is seen in an expanded definition of ‘practitioner’. Patients have benefitted for years from the care provided by nurse practitioners (NPs) and physician assistants (PAs) in OTPs, and the proposed rule expands the definition of practitioner to include a “physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.” Finally, the proposed rule removes the term “detoxification treatment” and replaces it with “withdrawal management.” The term detoxification is customarily called medically supervised withdrawal management to destigmatize the process and

⁶¹ Mark TL, Hinde J, Henretty K, Padwa H, Treiman K. How Patient Centered Are Addiction Treatment Intake Processes? *J Addict Med.* 2021 Apr 1;15(2):134-142. doi: 10.1097/ADM.0000000000000714. PMID: 32826618.

⁶² Russell HA, Sanders M, Meyer JKV, Loomis E, Mullaney T, Fiscella K. Increasing Access to Medications for Opioid Use Disorder in Primary Care: Removing the Training Requirement May Not Be Enough. *J Am Board Fam Med.* 2021 Nov-Dec;34(6):1212-1215. doi: 10.3122/jabfm.2021.06.210209. PMID: 34772776.

⁶³ Langabeer JR 2nd, Yatsco A, Champagne-Langabeer T. Telehealth sustains patient engagement in OUD treatment during COVID-19. *J Subst Abuse Treat.* 2021 Mar;122:108215. doi: 10.1016/j.jsat.2020.108215. Epub 2020 Nov 24. PMID: 33248863; PMCID: PMC7685137.

more accurately reflect what patients undergo, and healthcare practitioners provide, in response to withdrawal from a variety of substances or medications to which physiologic tolerance develops.⁶⁴

E. Section 8.3—Application for approval as an accreditation body

This section adds details of policies and procedures expected of accreditation bodies for clarity and completeness. In § 8.3(b) the email address for submission of accreditation body applications is updated. Changes to § 8.3(b)(6) reflect the expectation that physicians with experience in managing MOUD are employed by accreditation bodies to assure appropriate medical standards of care are established and included in review of OTPs. Further amendments are incorporated to promote communication between the accreditation bodies and SAMHSA, and to ensure that accreditation bodies focus on OTP adherence to 42 CFR part 8. Expectations about training provided for survey team members are added to promote consistency in OTP reviews with Federal standards and to reduce the risk of unnecessary and overly burdensome accreditation activities. Further to this, the proposed rule also provides for Indian Tribes to apply for approval as an accreditation body.

F. Section 8.4—Accreditation body responsibilities

SAMHSA is responsible for oversight of the accreditation bodies. A thorough review of its oversight procedures resulted in several proposed changes to improve processes, to assure documentation of accreditation decisions, and to establish steps to be

⁶⁴ 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.

taken to assure OTP adherence to 42 CFR part 8. For example, making records available to SAMHSA on request is added to assure that SAMHSA can review survey processes and information, and confirm decisions of survey outcomes. Other amendments, such as accreditation body policies for training survey team members, have been added to address concerns regarding inconsistent application of accreditation standards and regulations. The documentation and sharing of information regarding conflict or perceived conflict of interest has been added to ensure any conflict of interest and action taken by the accreditation body is disclosed to SAMHSA.

G. Section 8.11—Opioid Treatment Program certification

The requirements for certification and renewal have been in place since 2001. Therefore, it is necessary to update these as some certifications and processes no longer apply. For example, “transitional certification” expired as a category in May 2003. Other revisions have been incorporated based on SAMHSA’s 20-years of experience in OTP certification.

The category of “provisional” certification required clarification as to when provisional certification is available. Moreover, the current rule only designates three-year certifications for OTPs, whether the accreditation survey resulted in a “full” (3-year) or “conditional” 1-year accreditation status. The proposed rule establishes the category of “conditional certification” to allow an OTP granted a temporary one-year accreditation to continue treatment services while the OTP takes steps to address issues identified during the accreditation process. The current regulation limits extension of certification status to OTPs with provisional certification only. Circumstances related to the COVID-19 PHE necessitated expansion of extensions for renewal of any category of certification.

The expectation that OTPs comply with HIPAA regulations when applicable is added to emphasize rules that govern practice that have come into effect since 2001. Documentation of change of sponsors or medical directors is added to assure written records are available, and a reference to the applicable chapter of the Controlled Substances Act for OTPs was added to clarify the DEA regulations to which OTPs must adhere.

Interim treatment means that on a temporary basis, a patient may receive services from an OTP, while awaiting access to more comprehensive treatment services. The extension of interim treatment approval from 120 days to 180 days is intended to better accommodate OTPs and states in addressing underlying causes necessitating this category of treatment, such as staff shortages. This approach may also serve to engage individuals with OUD who otherwise may not seek care. Given the significant mortality risk of illicit fentanyl and data demonstrating reductions in overdose death with methadone treatment, interim services add an opportunity for low-threshold access to life-saving services. The expectation that individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner is to assure continuity of and engagement in care for the individual as an interim step to a comprehensive treatment program where additional services are available. The reference to section 1923 of the Public Health Service Act (PHSA) (42 U.S.C. 300x-23) is removed because it does not specifically pertain to time in interim treatment. The proposed rule also changes 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 (SOTA) of the state in which the OTP operates. This change was made to streamline and centralize the application process.

An overall goal of these revisions is to expand access to MOUD, specifically to OTP services. Accordingly, the range of services that can be provided in medication units

has been clarified to improve access to the services OTPs offer, especially in geographic areas in which distances are a key barrier to accessing treatment.

H. Section 8.12—Federal Opioid Use Disorder treatment standards

OTP regulations currently do not reflect the changes in OUD treatment standards that have occurred over the past 20 years. The dual challenges of the COVID-19 pandemic and the evolving opioid overdose epidemic necessitated review and revision of these regulations. Significant lessons have been learned from adapting treatment in response to the need for physical distancing and quarantine, and from the results of implementing flexibilities for take home doses and use of telehealth under the COVID-19 PHE.

Overcoming the opioid crisis through the expansion of prevention, treatment, and recovery support services is a primary priority for SAMHSA, and SAMHSA seeks to expand access to quality treatment services, encourage the use of MOUD, and improve engagement and retention in treatment and recovery support services. Consistent with that goal, amendments to treatment standards incorporated in this section are intended to improve access to care and improve patient satisfaction and engagement in services, while also promoting flexibility and medical judgment in decision-making to reduce the burden of patient participation in OTPs.

Changes to the “Required services” paragraph incorporate patient-centered language, and promote flexibility in the use of clinical judgment. For example, required services are amended to assure that OTPs meet patient needs, and “shared decision making” is added to ensure that the patient be included in the development and implementation of their care plan. In several instances, the intent of standards was not changed, but stigmatizing wording such as “legitimate treatment use” of controlled

substances has been removed. These amendments are incorporated as a means of reducing the use of stigmatizing attitudes, practices and language within OTPs that may contribute to discrimination and impede access to treatment.⁶⁵

Other revisions in this section are included to ensure alignment with laws and regulations that have been issued since 2001 and to emphasize their importance to OTPs. These include HIPAA, the Comprehensive Addiction and Recovery Act (CARA), and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act. Section 303 of CARA, for example, expanded the definition of “qualifying practitioners” from physicians to include nurse practitioners and physician assistants who meet certain criteria; this change has been included in the section on staff credentials and is in alignment with the professionalization of SUD treatment services that has occurred over the last 20 years.^{66,67}

A significant change in OTP access is the removal of the requirement that patients must have had an addiction to opioids for at least one year prior to admission for MOUD; this is a vestige of prior versions of the DSM and has posed a barrier to access to treatment. OUD includes signs and symptoms that are associated with compulsive, prolonged use of opioid substances for non-medical purposes, despite harm and negative consequences to the individual with OUD. Therefore, the assessment of OUD is refocused, in the proposed rule, to consideration of problematic patterns of opioid use that are in line with the current version of the DSM diagnostic categories.⁶⁸ The proposed

⁶⁵ See <https://www.justice.gov/opa/pr/justice-department-issues-guidance-protections-people-opioid-use-disorder-under-americans>.

⁶⁶ Center for Substance Abuse Treatment. Competencies for Substance Abuse Treatment Clinical Supervisors. Technical Assistance Publication (TAP) Series 21-A. HHS Publication No. (SMA) 12-4243. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2007/2013.

⁶⁷ Center for Substance Abuse Treatment. Clinical Supervision and Professional Development of the Substance Abuse Counselor. Treatment Improvement Protocol (TIP) Series 52. HHS Publication No. (SMA) 14-4435. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2009/2014.

⁶⁸ See <https://www.aoaam.org/resources/Documents/Clinical%20Tools/DSM-V%20Criteria%20for%20opioid%20use%20disorder%20.pdf>.

rules also recognize the potential for recurrence of OUD in individuals who have sustained remission and recovery and the high mortality risk associated with these situations. The revised definition allows for clinical judgment and consideration of severity of use and comorbid conditions. The new rules also remove the requirement that individuals under 18 must have two documented unsuccessful attempts at treatment within one year to be eligible for MOUD. Except where not required by state law, parental consent to treatment remains a requirement for patients under age 18. In recognition of the use of telehealth and the limitation of obtaining written consent, the requirement for a written form of consent to treatment was removed for adult patients.

Throughout the document, “detoxification” and the corresponding definition and standards for short-and long-term detoxification have been removed as the word “detoxification” is considered a pejorative term and not accurately reflective of the process of managing or experiencing the withdrawal associated with substances or medications to which physiologic tolerance develops. Detoxification is an outdated term that was used to distinguish opioid dependence from OUD based on the Narcotic Addiction Treatment Act of 1974 (NATA). Practice-based evidence and extensive research shows that treatment with MOUD is more effective than withdrawal management at reducing OUD recurrence and associated mortality and morbidity risk.⁶⁹ However, it is recognized that some patients may choose, or need, to taper off MOUD. Therefore, “withdrawal management” and terms for tapering from MOUD are included in the section of the regulations that currently refer to “detoxification.”

Language used in the current rule about the initial medical examination required clarification to distinguish between an initial “screening” exam and a more comprehensive “examination.” For patients with OUD, initiating MOUD is of utmost

⁶⁹ Kleber HD. Pharmacologic treatments for opioid dependence: detoxification and maintenance options. *Dialogues Clin Neurosci.* 2007;9(4):455-70. doi: 10.31887/DCNS.2007.9.2/hkleber. PMID: 18286804; PMCID: PMC3202507.

importance to suppress withdrawal, engage the individual in additional services, and improve retention. The need to improve access to treatment necessitates expanding the qualifications of those practitioners able to complete screening examinations. The proposed rule allows practitioners who work outside of the OTP (with limitations and specific instructions) to undertake screening. This is likely to reduce delays in diagnosing OUD, initiating MOUD, and in beginning comprehensive treatment. This section also improves medical services by setting expectations for lab testing, establishing time frames for examinations, and incorporating use of telehealth. Special services for pregnant people have been revised to specify that confirmation of pregnancy is required for priority treatment admissions to prevent misuse of priority status. The option to use split dosing for patients was added to this section, as well.

Changes to the initial and periodic medical services sections are intended to promote key issues for OTP medical practitioners and the OTP multi-disciplinary team to address with a patient as part of treatment. This includes areas that may increase the risk of a patient leaving care prematurely, such as unmet mental health or other disability, medical and oral health needs, the need for culturally supportive care that addresses race, ethnicity, sexual orientation, religion or 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 was added to ensure that the care provided is consistent with the patient's needs, and self-identified goals for treatment and recovery. The time frames for completion of the care plan are included as a measure of quality. Also included is the requirement in § 8.12(f)(4)(i) that individuals starting treatment be screened for imminent risk of harm to self or others. This recognizes that risk for suicide is increased among

individuals who misuse substances⁷⁰ and that appropriate screening, intervention, and referrals for care are vital to health and engagement in treatment activities.⁷¹

Counseling services have been more finely described to align OTP services with the current paradigm for evidence-based SUD treatment. This includes the delineation of psychoeducational services, overdose prevention and other harm reduction counseling, and recovery-oriented counseling services. Specific counseling on reducing HIV, hepatitis C, and other STIs, and linkage to treatment for anyone with positive test results from OTP-provided laboratory testing, was added to improve quality of care. Language about services that must be provided directly or through referral has also been revised to infuse a more patient-centered approach, such as in “identified and mutually agreed-upon as beneficial by the patient and program staff,” rather than the program staff determining that the patient is “in need of such services.”

Drug testing services have been revised to remove the stigmatizing language of “drug abuse,” to remove content on short-term withdrawal management (“detoxification”), and to improve readability. The requirement for use of drug tests that have received FDA’s marketing authorization was added to assure valid assays are used.

The current regulations require OTPs to review whether a patient is enrolled in another OTP prior to admission. Simultaneous enrollment in multiple OTPs risks patients obtaining more medication than is needed. Good faith efforts to prevent this must be documented. Therefore, the language regarding verification of non-enrollment changed from “review” to “determine” in order to ensure that evidence of good faith efforts is available. This section 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

⁷⁰ Substance Abuse and Mental Health Services Administration (2015). Substance Use and Suicide: A Nexus Requiring a Public Health Approach. In Brief.

⁷¹ Lynch FL, Peterson EL, Lu CY, Hu Y, Rossom RC, Waitzfelder BE, Owen-Smith AA, Hubley S, Prabhakar D, Keoki Williams L, Beck A, Simon GE, Ahmedani BK. Substance use disorders and risk of suicide in a general US population: a case control study. *Addict Sci Clin Pract.* 2020 Feb 21;15(1):14. doi: 10.1186/s13722-020-0181-1. PMID: 32085800; PMCID: PMC7035727.

the OTP of record. Experiences of state and OTP responses to occurrence of natural disasters gave evidence of the need to incorporate this allowance on behalf of patients.

In § 8.12(h) (Medication administration, dispensing, and use), the specific disciplines authorized to administer or dispense MOUD have been removed to accommodate variations among states regarding disciplines allowed to provide this service. Among medications used by OTPs, LAAM has been removed as it has black box warnings and is no longer commercially available, while other medications approved since 2001 (naltrexone) were added. Although the maximum initial dose of methadone remains at 30 mg, use of clinical judgment in dose adjustments is underscored, due to higher opioid tolerance associated with increasing rates of fentanyl exposure and opioid overdose. Should 30 mg be insufficient to control symptoms of withdrawal, the program physician or practitioner may increase the dosage, provided that the rationale for this change is appropriately documented. The requirement that the program physician be familiar with the most up-to-date product labeling has been removed as § 8.12(d) requires that 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. This is inclusive of the expectation that all program medical practitioners maintain familiarity with the most up-to-date product labeling for the medications they administer and dispense to patients.

The exemption policies promulgated by SAMHSA in response to COVID-19 allowed OTPs to provide more take home doses of methadone to patients on a more rapid schedule than is permitted in the current regulations. In the two years since implementation, there have been few reports of overdose or harm related to take homes, misuse, or other negative consequences of this flexibility. Evidence from multiple studies has shown that increases in take home doses following the SAMHSA exemption did not lead to worse treatment outcomes, higher overdose rates, or diversion of medication, but

instead resulted in increased treatment engagement and improved patient satisfaction with care.^{72,73,74,75} There are sufficient studies to conclude that this exemption has enhanced and encouraged use of and retention in OTP services; therefore, the proposed rule for unsupervised (take home) doses fully incorporates the flexibilities for take home medication issued during the COVID-19 PHE.

The proposed rule removes stigmatizing language in favor of person-centered approaches and person-first terminology. Changes focus on the well-being of the individual and reframe the criteria for unsupervised medication from rule-based to clinical judgment-based decisions. When determining take home medication schedules under the proposed rule, SAMHSA recommends that the best interest of each patient and the public's health be taken into consideration, and that clinical judgement, not rigid rules, determine if the therapeutic benefit of take home medication outweighs the risks to the patient and public health. The proposed rule is meant to address barriers to care associated with the requirement for regular clinic attendance while also improving patient satisfaction and treatment engagement in a manner that also balances patient and public health safety.

The conditions for interim treatment extend the potential duration of this approach from 120 days to 180 days. This is based on SAMHSA's experience and reports from states that the underlying issues which prompted interim treatment, such as staff

⁷² Figgatt, M. C., Salazar, Z., Day, E., Vincent, L., & Dasgupta, N. (2021). Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19. *Journal of substance abuse treatment*, 123, 108276. <https://doi.org/10.1016/j.jsat.2021.108276>.

⁷³ Joseph, G., Torres-Lockhart, K., Stein, M. R., Mund, P. A., & Nahvi, S. (2021). Reimagining patient-centered care in opioid treatment programs: Lessons from the Bronx during COVID-19. *Journal of substance abuse treatment*, 122, 108219. <https://doi.org/10.1016/j.jsat.2020.108219>.

⁷⁴ Amram, O., Amiri, S., Panwala, V., Lutz, R., Joudrey, P. J., & Socias, E. (2021). The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 era. *The American journal of drug and alcohol abuse*, 47(6), 722–729. <https://doi.org/10.1080/00952990.2021.1979991>.

⁷⁵ Brothers S, Viera A, Heimer R. Changes in methadone program practices and fatal methadone overdose rates in Connecticut during COVID-19 *Journal of Substance Abuse Treatment*. 2021 Dec;131:108449. doi: 10.1016/j.jsat.2021.108449. Epub 2021 Apr 29. PMID: 34098303.

shortages, are not easily resolved in 120 days.^{76,77} In addition, interim services may serve as a low-threshold approach to engaging individuals with OUD in care, particularly in areas where OTPs offering more comprehensive services are not as readily available. Clarification of language in this section also ensures that patients in interim treatment have documented plans for continuation of treatment beyond 180 days, and are not discharged based on length of time in interim care. The circumstances in which a patient could receive interim services required clarification from “cannot be placed in a public or nonprofit private program” to “if comprehensive services are not readily available.” Services to be provided in this category are revised to assure alignment of quality expectations for interim care between OTPs and SAMHSA.

On July 28, 2021, the DEA published a final rule that permits DEA registrants who are authorized to dispense methadone for OUD to add a “mobile component” to their existing registration – waiving any requirement that mobile medication units of OTPs operating in compliance with the rule separately register at their remote dispensing locations (86 FR 33861). This expanded opportunities for OTPs to provide needed services in remote or underserved areas. Through use of Substance Abuse Prevention and Treatment Block Grant (SABG) funds, SAMHSA encouraged OTPs to establish medication units as a means of making treatment more readily available, especially to those people in remote, rural, or underserved areas. To further the goal of improving and expanding access, the range of services that can be provided in medication units are described in the proposed rule. Such services must be delivered in accordance with the nondiscrimination provision at 42 U.S.C. 300x–57, which state that: “No person shall on the ground of sex (including, in the case of a woman, on the ground that the woman is

⁷⁶ Sigmon SC. Interim treatment: Bridging delays to opioid treatment access. *Prev Med.* 2015;80:32-36. doi:10.1016/j.ypmed.2015.04.017.

⁷⁷ Oleskiewicz TN, Ochalek TA, Peck KR, Badger GJ, Sigmon SC. Within-subject evaluation of interim buprenorphine treatment during waitlist delays. *Drug Alcohol Depend.* 2021 Mar 1;220:108532. doi: 10.1016/j.drugalcdep.2021.108532. Epub 2021 Jan 20. PMID: 33508690; PMCID: PMC8148627.

pregnant), or on the ground of religion, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 300x or 300x–21 of this title.”

I. Section 8.14—Suspension or revocation of certification

This section clarifies the actions that SAMHSA may take when immediate intervention is necessary to protect the public’s health or safety. The proposed rule specifies the administrative actions available to SAMHSA in the event that a program sponsor, or any employee of an OTP has: been found guilty of 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.

J. Subpart F—Authorization to Increase Patient Limit to 275 Patients

This subpart is amended to change the format from a Question-and-Answer style to a standard narrative text format. This is for consistency with the format found throughout the proposed rule.

K. Section 8.610—Practitioner eligibility requirements for a 3-year 275-patient limit

This section clarifies the 3-year limit to the 275-patient limit.

L. Section 8.635—What are the reporting requirements for practitioners whose 275 Request for Patient Limit is approved?

As of May 2022, there were 8,641 practitioners waived at the 275-level and of these, 5,905 were Doctors of Medicine and Doctors of Osteopathic Medicine (MD/DOs). The proposed rule removes reporting requirements for practitioners at this level. Practitioners have found the submission of these reports to be burdensome and a disincentive to treating a higher number of patients.⁷⁸ As increasing numbers of Americans lose their lives to overdose, it is essential to support practitioners and to remove perceived disincentives or barriers to treating more patients. In this way, the extent of the overdose crisis as a result of the COVID-19 PHE outweighs the potential value of data obtained from compliant reporters. The proposed rule removes reporting requirements for those who are authorized to treat up to 275 patients with buprenorphine. Rather than expect practitioners to submit reports, SAMHSA will seek to work in partnership with other Federal agencies for monitoring purposes.

Further to this, reporting requirements are known to perpetuate stigma towards MOUD and to potentially reduce prescribing of a life-saving medication.⁷⁹ Negative attitudes and beliefs toward use of medications in treating OUD is common among healthcare professionals, members of law enforcement and others in justice settings, in the wider community, and even among persons with OUD themselves.⁸⁰ Of primary care physicians in a national survey, just over three quarters (77.5%) perceived buprenorphine

⁷⁸ Lanham, H. J., Papac, J., Olmos, D. I., Heydemann, E. L., Simonetti, N., Schmidt, S., & Potter, J. S. (2022). Survey of Barriers and Facilitators to Prescribing Buprenorphine and Clinician Perceptions on the Drug Addiction Treatment Act of 2000 Waiver. *JAMA network open*, 5(5), e2212419. <https://doi.org/10.1001/jamanetworkopen.2022.12419>.

⁷⁹ Pew Charitable Trusts (2019). Why Aren't More People With Opioid Use Disorder Getting Buprenorphine? Available at: <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/07/31/why-arent-more-people-with-opioid-use-disorder-getting-buprenorphine>.

⁸⁰ Scorsone, K. L., Haozous, E. A., Hayes, L., & Cox, K. J. (2020). Overcoming Barriers: Individual Experiences Obtaining Medication-Assisted Treatment for Opioid Use Disorder. *Qualitative health research*, 30(13), 2103–2117. <https://doi.org/10.1177/1049732320938689>.

to be an effective treatment for OUD.⁸¹ Many treatment programs and support groups discourage participants from using medications, including MOUD.⁸² Young adults with OUD experience difficulties obtaining or remaining on buprenorphine as a result of stigma from healthcare providers, 12-step programs, residential treatment programs, and parents.⁸³ Prejudice against MOUD even exists among specialist SUD treatment providers. One 2020 national survey of residential OUD treatment programs found that less than a third (29%) offered maintenance treatment with buprenorphine-naloxone; many programs actively discouraged the use of medication, which are the standard of care, revealing that there is a vast knowledge gap about MOUD among treatment providers.⁸⁴

Proposed changes to part 8 seek to reduce discriminatory attitudes and beliefs, and to incorporate evidence-based principles on practitioner autonomy, patient-centered decision making and individualized care plans. This is in line with the chronic disease model of care,⁸⁵ and represents a departure from the prescriptive model of care currently in place. In this way, The Department seeks to support practitioners in providing evidence-based and compassionate care to patients while also engaging them in recovery. This is an essential means of reducing stigma among practitioners and community members, while also positively addressing a patient's internalized stigma.⁸⁶

⁸¹ McGinty, E. E., Stone, E. M., Kennedy-Hendricks, A., Bachhuber, M. A., & Barry, C. L. (2020). Medication for Opioid Use Disorder: A National Survey of Primary Care Physicians. *Annals of internal medicine*, 173(2), 160–162. <https://doi.org/10.7326/M19-3975>.

⁸² Beetham, T., Saloner, B., Gaye, M., Wakeman, S. E., Frank, R. G., & Barnett, M. L. (2020). Therapies Offered at Residential Addiction Treatment Programs in the United States. *JAMA*, 324(8), 804–806. <https://doi.org/10.1001/jama.2020.8969>.

⁸³ Hadland, S. E., Park, T. W., & Bagley, S. M. (2018). Stigma associated with medication treatment for young adults with opioid use disorder: a case series. *Addiction science & clinical practice*, 13(1), 15. <https://doi.org/10.1186/s13722-018-0116-2>.

⁸⁴ Beetham, T., Saloner, B., Gaye, M., Wakeman, S. E., Frank, R. G., & Barnett, M. L. (2020). Therapies Offered at Residential Addiction Treatment Programs in the United States. *JAMA*, 324(8), 804–806. <https://doi.org/10.1001/jama.2020.8969>.

⁸⁵ Grover, A., & Joshi, A. (2014). An overview of chronic disease models: a systematic literature review. *Global journal of health science*, 7(2), 210–227. <https://doi.org/10.5539/gjhs.v7n2p210>.

⁸⁶ Idemudia, E. S., Olasupo, M. O., & Modibo, M. W. (2018). Stigma and chronic illness: A comparative study of people living with HIV and/or AIDS and people living with hypertension in Limpopo Province, South Africa. *Curationis*, 41(1), e1–e5. <https://doi.org/10.4102/curationis.v41i1.1879>.

Request for Comments

The Department requests public comment on all aspects of the proposed amendments to the regulations at 42 CFR part 8, *Medications for the Treatment of Opioid Use Disorder*. The Department welcomes public comment on any benefits or drawbacks of the proposed amendments set forth above in this proposed rule. Of particular interest are comments pertaining to: interim treatment; split dosing; telehealth; and take home doses of methadone.

Public Participation

The Department seeks comment on all issues raised by the proposed regulation, including any potential unintended adverse consequences. Because of the large number of public comments normally received on *Federal Register* documents, the Department is not able to acknowledge or respond to them individually. In developing the final rule, the Department will consider all comments that are received by the date and time specified in the **DATES** section of the Preamble.

Because mailed comments may be subject to delays due to security procedures, please allow sufficient time for mailed comments to be received by the deadline in the event of delivery delays. Any attachments submitted with electronic comments on www.regulations.gov should be in Microsoft Word or Portable Document Format (PDF). Please note that comments submitted by fax or email and those submitted after the comment period deadline will not be accepted.

Regulatory Impact Analysis

The Department has examined the impact of the proposed 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 proposed rule is being issued to update part 8 in response to increasing opioid overdose deaths, exacerbated by the COVID-19 pandemic.⁸⁷ Across the United States in 2020, 9.5 million people aged 12 or older misused heroin or prescription pain relievers.⁸⁸ The percentage was highest among young adults aged 18 to 25 (4.1 percent or 1.4 million people), followed by adults aged 26 or older (3.4 percent or 7.5 million people). It was lowest among adolescents aged 12 to 17 (1.6 percent or 396,000 people).⁸⁸ These numbers likely underestimate the true prevalence of opioid misuse and OUD, since the use of illicitly manufactured fentanyl has not to date been considered in the National Survey on Drug Use and Health (NSDUH) survey, and populations likely to

⁸⁷ 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.

⁸⁸ Substance Abuse and Mental Health Services Administration. (2021). Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health (HHS Publication No. PEP21-07-01-003, NSDUH Series H-56). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>.

have high prevalence of opioid misuse and use disorder, such as individuals in the criminal justice system, other institutionalized settings, and individuals experiencing homelessness 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 Black, American Indian and Alaska Native communities over the course of the pandemic.⁸⁹ 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.⁸⁹ 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.⁸⁹ It was also found that Black people were less than half as likely as white people to have received substance use treatment.

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 treatments⁹⁰), yet few people who may benefit from these medications have immediate and sustained access to them.⁹¹

⁸⁹ 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: <https://dx.doi.org/10.15585/mmwr.mm7129e2>.

⁹⁰ Laroche 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.

⁹¹ 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.

The pattern of enrollment in programs providing methadone was established in the latter part of the 20th century.⁹² Research reveals that the rate of methadone treatment at that time was highest in low income urban areas.⁹³ 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.⁹⁴ SAMHSA believes that proposed changes to part 8 will, as described above, facilitate:

- Enhanced access to medications for opioid use disorder, such as through take home doses of methadone and extending interim treatment to 180 days;
- Changes to ensure updated language and terminology;
- Clarification of standards applying to accreditation bodies;
- Revising Federal Opioid Use Disorder Treatment Standards; and
- Removing reporting requirements for practitioners approved to treat up to 275 patients.

SAMHSA notes below that these changes are associated with limited burden as the proposed rule does not substantially alter reporting or accreditation activities. The changes proposed 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. SAMHSA invites comments on the assumptions of costs and benefits identified below, including citations to any publicly available studies or reports that could elucidate and improve this analysis.

⁹² 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.

⁹³ 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.

⁹⁴ 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.

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 proposed rule is partially regulatory and partially deregulatory. The Department estimates that because much of what is being proposed does not substantially alter current practice as implemented over the past 2 years under the COVID PHE, the proposed rule will not result in significantly altered costs. Further to this, the proposed 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 proposed rule makes permanent some OTP treatment flexibilities implemented within the past two 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.⁹⁵ 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,

⁹⁵ 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: <https://dx.doi.org/10.15585/mmwr.mm7129e2>.

compared with 22 percent for white people.⁹⁵ 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.⁹⁵ 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 person-centered care that is culturally appropriate and responsive to patient need, while also fostering a treatment environment that promotes and sustains patient engagement. The proposed changes facilitate 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 proposed changes promote 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 proposed changes also facilitate 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 two years demonstrates safety, as well as high patient and practitioner satisfaction with take-home doses of methadone. This is principally because unsupervised doses of methadone allow individuals the opportunity to engage in employment or 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.⁹⁶ 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.⁹⁷

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.⁹⁸ 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%).⁹⁸ Estimated decreased deaths were associated with treatment with methadone (6%), buprenorphine or naltrexone (13.9%), and the 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.

⁹⁶ 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>.

⁹⁷ 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>.

⁹⁸ 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.

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; $P < 0.001$).⁹⁹ 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.^{100,101,102} For example, a 2019 analysis demonstrated that a comprehensive approach to OUD treatment is associated with improved health and economic outcomes.¹⁰³ This study assessed patients with OUD treated at a comprehensive primary care center (CCP) and other Maryland facilities in a large state Medicaid program, and demonstrated cost savings with a comprehensive

⁹⁹ 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.

¹⁰⁰ 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.

¹⁰¹ 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.

¹⁰² 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.

¹⁰³ Hsu YJ, Marsteller JA, Kachur SG, Fingerhood MI (2019). Integration of Buprenorphine Treatment with Primary Care: Comparative Effectiveness on Retention, Utilization, and Cost. *Idemudia, E. S., Olasupo, M. O., & Modibo, M. W. (2018). Stigma and chronic illness: A comparative study of people living with HIV and/or AIDS and people living with hypertension in Limpopo Province, South Africa. Curationis, 41(1), e1–e5. https://doi.org/10.4102/curationis.v41i1.1879.*

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).¹⁰³ 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.¹⁰⁴ Two prior studies assessed data from commercial health insurance claims on the overall health care costs and utilization rates for those using MOUD compared to those treated without MOUD.^{101,105} 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.¹⁰⁵ The other study found that after a six-month period, those on MOUD had significantly lower overall annual

¹⁰⁴ 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.

¹⁰⁵ 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.

health plan costs compared to those with no medication (\$10,192 vs. \$14,353; p-value <0.0001).¹⁰¹ 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 proposed rule does not substantially alter reporting burden 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.

This analysis quantifies a few limited categories of paperwork-related costs, but there are more substantive actions (with associated costs and benefits) that would be necessary in the chain of cause and effect between the rule's most direct effects and the health and mortality consequences that are implied, above, as being potentially large if this proposal is finalized. For instance, relative to the appropriate analytic baseline (the future in the absence of the rule), the proposed rule would facilitate the expansion of mobile methadone units via their inclusion in operations, and such expansion would entail both new use of resources (costs¹⁰⁶) and then, contingent upon such costs being incurred, the types of benefits described above. As a further example, the accrual of health and overdose-mortality-avoidance benefits due to removal of the one-year

¹⁰⁶ It would be incorrect to interpret this analytic discussion as implying that the proposed rule changes authorization procedures for mobile methadone units.

requirement for opioid addiction before patient admission to an OTP would generally be contingent upon increasing resource use associated with such admission.

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

In developing its estimates of the potential costs of the proposed 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 Recordkeeping

The recordkeeping 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 recordkeeping 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 nor a cost burden for these activities.

d. Costs Pertaining to Disclosure

The proposed 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 proposed 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 1,920 affected OTPs these total annual costs are estimated to be \$29,521,920. The percentage of this total cost that is associated with recordkeeping 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 system for SAMHSA, opioid treatment programs, State opioid treatment authorities, accreditation organizations, and others to have use a protected website for day-to-day regulatory activities. This estimate does not include funds that SAMHSA/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
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	25,03625,0 36	97.15	2592.3	\$221,434

2. Consideration of Regulatory Alternatives

The Department has initiated 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.

3. Request for Comments on Costs and Benefits

The Department requests public comment on all the estimates, assumptions, and analyses within the cost-benefits analysis. As part of this request, feedback is welcome on the extent to which cited papers follow sound scientific practices, such as: clearly stating null hypotheses and presenting estimating equations; ensuring that appendices or other supplementary materials are available online, if claimed to be so in the main body of a paper; using compelling identification strategies if making causal claims (for example, establishing parallel trends pre-intervention if using a difference-in-differences method¹⁰⁷); and avoiding the types of errors that Kim et al. (2020¹⁰⁸) and Sanders et al.

¹⁰⁷ Wing C, Simon K, Bello-Gomez RA (2018). Designing difference in difference studies: best practices for public health policy research. *Annual Review of Public Health* 39: 453-469.

¹⁰⁸ Kim DD, Silver MC, Kunst N, et al. (2020). Perspective and costing in cost-effectiveness analysis, 1974–2018. *Pharmacoeconomics* 38: 1135–1145.

(2016¹⁰⁹) indicate are common in published cost-effectiveness analyses. The Department also requests comments on any relevant information or data that would inform a quantitative analysis of proposed reforms that the Department qualitatively addresses in this RIA. The Department also requests comments on whether there may be other indirect costs and benefits resulting from the proposed changes in the proposed rule and welcomes additional information that may help quantify those costs and benefits.

B. Regulatory Flexibility Act

The Department has examined the economic implications of this proposed 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.

¹⁰⁹ Sanders GD, Neumann PJ, Basu A, et al. (2016). Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: second panel on cost-effectiveness in health and medicine, JAMA, 1093-1103.

For the reasons stated above, it is not expected that the cost of compliance would be significant for OTPs or accreditation bodies. Therefore, this proposed rule would not result in a significant negative impact.

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 2022, this threshold is \$165 million. The Department does not anticipate that this proposed 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 proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. 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 1999¹¹⁰ requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative,

¹¹⁰ Pub. L. 105-277, 112 Stat. 2681 (October 21, 1998).

then the Department or agency must prepare an impact assessment to address criteria specified in the law. The Department believes that the proposed 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 rulemaking as described.

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 proposed 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 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 seeks, and will consider, public comment on its assumptions as they relate to the PRA requirements summarized in this section.

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 also OTPs pursuant to the proposed 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
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

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
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

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
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
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 proposed 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 twelve months. Further to this, the estimates of burden do not substantially differ from previously submitted estimates provided to The Office of Management and Budget.

The proposed 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 proposed 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 qualifying 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

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Subpart E [Reserved]

Subpart F—Authorization to Increase Patient Limit to 275 Patients

- 8.610 Practitioner eligibility requirements for a 3-year 275-patient limit.**
- 8.615 Definition of a qualified practice setting.**
- 8.620 Applying for a 275-patient limit.**
- 8.625 Processing a 275 Request for Patient Limit Increase.**
- 8.630 Practitioner requirements to maintain a 275-patient limit.**
- 8.640 Renewal process for a 3-year 275 Request for Patient Limit Increase.**
- 8.645 Practitioner responsibility when no renewal request for patient limit increase is submitted, or whose renewal request is denied.**
- 8.650 Suspension or revocation of the Secretary's approval of a practitioner's request for patient limit increase.**
- 8.655 Temporary increase to treat up to 275 patients in emergency situations.**

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) 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(g) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)(1)) 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(g)(1)). 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) The regulations in subpart F of this part establish the procedures and requirements that practitioners who are authorized to treat up to 100 patients with OUD pursuant to a waiver obtained under section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)),

must satisfy in order to treat up to 275 patients with medications covered under section 303(g)(2)(C) of the CSA.

§ 8.2 Definitions.

The following definitions apply to this part:

Accreditation 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 review and evaluation of an OTP by an accreditation body for the purpose of determining compliance with the Federal opioid 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).

Additional credentialing means board certification in Addiction Medicine or Addiction Psychiatry by the American Board of Addiction Medicine, the American Board of Medical Specialties, or the American Osteopathic Association or certification by the American Board of Addiction Medicine, the American Society of Addiction Medicine.

Approval term means the 3-year period in which a practitioner is approved to treat up to 275 patients with OUD that commences when a practitioner's Request for Patient Limit Increase is approved in accordance with § 8.625.

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 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 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.

Covered medications means the medications or combinations of such medications that are covered under 21 U.S.C. 823(g)(2)(C).

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.

Emergency situation means that an existing State, tribal, or local system for substance use disorder services is overwhelmed or unable to meet the existing need for the provision of MOUD as a direct consequence of a clear precipitating event. This precipitating event must have an abrupt onset, such as: practitioner incapacity; natural or human-caused disaster; an outbreak associated with drug use; and result in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

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 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, 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 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(g)(1), and the term "withdrawal management" is intended to be synonymous with the term "detoxification" as used in 21 U.S.C. 823(g)(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(g)(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 subparts B through D of this part, means any individual who receives continuous treatment or withdrawal management in an OTP. The word patient

encompasses client, person in treatment, or any other definition accepted by the treatment community or those with lived experience. For purposes of subpart F of this part, *patient* means any individual who is dispensed or prescribed covered medications by a practitioner.

Patient limit means the maximum number of individual patients that a practitioner may dispense or prescribe covered medications to at any one time.

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 in OTPs achieve and sustain remission and recovery.

Practitioner, for purposes of this subpart and subparts B through D of this part, means a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorder within an OTP. The term *practitioner*, for purposes of subpart F of this part, means a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife who is appropriately licensed by a State to prescribe and/or dispense schedule III, IV, and V medications for opioid use disorder, and who possesses a waiver under 21 U.S.C. 823(g)(2).

Practitioner incapacity means the inability of a practitioner as a result of an involuntary event to physically or mentally perform the tasks and duties required to provide OUD treatment in accordance with nationally recognized evidence-based guidelines.

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 use other medications or 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 is the delivery and facilitation of health and health-related services including medical care, counselling, 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 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 either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.

(i) Accreditation bodies shall either not accredit or shall revoke the accreditation of any OTP that substantially fails to meet the Federal Opioid Use Disorder treatment standards.

(ii) Accreditation bodies shall notify the Secretary as soon as possible but in no case longer than 48 hours after becoming aware of any practice or condition in an OTP that may pose a serious risk to public health or safety or patient care.

(iii) If an accreditation body determines that an OTP is meeting the Federal Opioid Use Disorder treatment standards, as defined in § 8.12, but is not meeting one or more accreditation elements within 60 days of survey completion, the accreditation body shall determine the necessary corrective measures to be taken by the OTP, establish a schedule for implementation of such measures not to exceed 60 days, and notify the OTP in writing that it must implement such measures within the specified schedule in order to ensure continued accreditation. The accreditation body shall verify that the necessary corrective measures are implemented by the OTP within the schedule specified and that all accreditation elements are met within the specified schedule. Within 60 days after the specified schedule for implementation, the accreditation body will notify the Secretary, in writing, whether or not the OTP has completed the corrective measures.

(2) Nothing in this part shall prevent accreditation bodies from granting accreditation, contingent on the implementation of programmatic or performance changes, to OTPs with less substantial violations. Less substantial violations refers to non-conformance with accreditation standards that do not involve immediate, high-risk health and safety concerns. Such accreditation shall not exceed 12 months during which time a resurvey or reinspection must occur to determine whether the applicable changes have been implemented. OTPs that have been granted such accreditation must have their

accreditation revoked if they fail to implement the applicable changes upon resurvey or reinspection.

(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(g)(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 who 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 1 year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year accreditation, 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 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. Federal agencies operating OTPs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal OTPs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(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 or Substance Abuse and Mental Health Services Administration (SAMHSA), by accreditation bodies, by the DEA, and by authorized employees of any relevant State or Federal governmental authority.

(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) A treatment program 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.

(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 a public or nonprofit private OTP may provide interim treatment, the program 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 public or nonprofit private 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, which is 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.

(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 will not be required for the continuous medication treatment or withdrawal management of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than OUD and who requires medication continuity or withdrawal management during the period of their stay in that long-term care facility when such treatment is permitted under applicable Federal law. The term “long-term care facility” is defined in § 8.2. Nothing in this section is intended to relieve long-term care facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

§ 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 qualifying 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 qualifying 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.

(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, such as a pregnancy test, 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 with either buprenorphine or methadone, if a qualified 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.

(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.

(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.* OTPs must provide 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.

(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 a program, the initial dose of methadone shall be individually determined, and is not to exceed 30 milligrams, and the total dose for the first day shall not exceed 40 milligrams. Should this not be sufficient to suppress symptoms of withdrawal, the OTP practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, must document in the patient's record a specific rationale indicating that 40

milligrams did not adequately suppress opioid withdrawal symptoms, and that a higher dose was clinically indicated and thus provided to the patient.

(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) Treatment program 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 a public or nonprofit, private 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 in this section apply to interim treatment with the following exceptions:

(i) A primary counselor is not required to be assigned to the patient, but crisis services 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, and educational 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 guilty of 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, 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 and shall state that the OTP may seek review of the action in accordance with the procedures in this subpart.

(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 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 an opportunity for a 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 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 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 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, either of which will be made a part of the record.

(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 and the transcript shall be made a part of the record. 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) through (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.

Except for routine administrative and procedural matters, 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 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]

Subpart F—Authorization to Increase Patient Limit to 275 Patients

§ 8.610 Practitioner eligibility requirements for a 3-year 275-patient limit.

The total number of patients that a practitioner may dispense or prescribe covered medications to at any one time for purposes of 21 U.S.C. 823(g)(2)(B)(iii) is 275 if:

(a) The practitioner possesses a current waiver to treat up to 100 patients with OUD under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) and has maintained the waiver in accordance with applicable statutory requirements without interruption for at least one year since the practitioner's notification of intent (NOI) under section 303(g)(2)(B) to treat up to 100 patients was approved;

(b) The practitioner:

(1) Holds additional credentialing as defined in § 8.2; or

(2) Provides OUD treatment utilizing covered medications in a qualified practice setting as defined in § 8.615;

(c) The practitioner has not had his or her enrollment and billing privileges in the Medicare program revoked under § 424.535 of this title; and

(d) The practitioner has not been found to have violated the Controlled Substances Act pursuant to 21 U.S.C. 824(a).

§ 8.615 Definition of a qualified practice setting.

A qualified practice setting is a practice setting that:

(a) Provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;

(b) Provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as physical, behavioral, social, housing, employment, educational, or other related services;

(c) Uses health information technology (health IT) systems such as electronic health records, if otherwise required to use these systems in the practice setting. Health IT means the electronic systems that health care professionals and patients use to store, share, and analyze health information;

(d) Is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law. PDMP means a statewide electronic database that collects designated data on controlled medications dispensed in

the State. For practitioners providing care in their capacity as employees or contractors of a Federal Government agency, participation in a PDMP is required only when such participation is not restricted based on their State of licensure and is in accordance with Federal statutes and regulations; and

(e) Accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.

§ 8.620 Applying for a 275-patient limit.

In order for a practitioner to receive approval for a 3-year patient limit of 275, a practitioner must meet all of the requirements specified in § 8.610 and submit a Request for Patient Limit Increase to the Secretary that includes all of the following:

(a) Completed Request for Patient Limit Increase form;

(b) Statement certifying that the practitioner:

(1) Will adhere to nationally recognized evidence-based guidelines for the treatment of patients with OUD;

(2) Will provide patients with necessary behavioral health services as defined in § 8.2 or through an established formal agreement with another entity to provide behavioral health services;

(3) Will provide appropriate releases of information, in accordance with Federal and State laws and regulations, including the Health Information Portability and Accountability Act Privacy Rule (45 CFR part 160 and 45 CFR part 164, subparts A and E) and 42 CFR part 2, if applicable, to permit the coordination of care with behavioral health, medical, and other service practitioners;

(4) Will use patient data to inform the improvement of outcomes;

(5) Will adhere to a diversion control plan to manage the covered medications and reduce the possibility of diversion of covered medications from prescribed treatment use;

(6) Has considered how to assure continuous access to care in the event of practitioner incapacity or an emergency-situation that would impact a patient's access to care as defined in § 8.2; and

(7) Will notify all patients above the 100-patient level, in the event that the request for the higher patient limit is not renewed or the renewal request is denied, that the practitioner will no longer be able to provide buprenorphine treatment to them and make every effort to transfer patients to other treatment providers; and

(c) Any additional documentation to demonstrate compliance with § 8.610 as requested by the Secretary.

§ 8.625 Processing a 275 Request for Patient Limit Increase.

(a) Not later than 45 days after the date on which the Secretary receives a practitioner's Request for Patient Limit Increase as described in § 8.620, or renewal Request for Patient Limit Increase as described in § 8.640, the Secretary shall approve or deny the request.

(1) A practitioner's Request for Patient Limit Increase will be approved if the practitioner satisfies all applicable requirements under §§ 8.610 and 8.620. The Secretary will thereafter notify the practitioner who requested the patient limit increase, and the DEA, that the practitioner has been approved to treat up to 275 patients using covered medications. A practitioner's approval to treat up to 275 patients under this section will extend for a term not to exceed 3 years.

(2) The Secretary may deny a practitioner's Request for Patient Limit Increase if the Secretary determines that:

(i) The Request for Patient Limit Increase is deficient in any respect; or

(ii) The practitioner has knowingly submitted false statements or made misrepresentations of fact in the practitioner's Request for Patient Limit Increase.

(b) If the Secretary denies a practitioner's Request for Patient Limit Increase (or renewal), the Secretary shall notify the practitioner of the reasons for the denial.

(c) If the Secretary denies a practitioner's Request for Patient Limit Increase (or renewal) based solely on deficiencies that can be resolved, and the deficiencies are resolved to the satisfaction of the Secretary in a manner and time period approved by the Secretary, the practitioner's Request for Patient Limit Increase will be approved. If the deficiencies have not been resolved to the satisfaction of the Secretary within the designated time period, the Request for Patient Limit Increase may be denied.

§ 8.630 Practitioner requirements to maintain a 275-patient limit.

A practitioner whose Request for Patient Limit Increase is approved in accordance with § 8.625 shall maintain all eligibility requirements specified in § 8.610, and all attestations made in accordance with § 8.620(b), during the practitioner's 3-year approval term. Failure to do so may result in the Secretary withdrawing its approval of a practitioner's Request for Patient Limit Increase.

§ 8.640 Renewal process for a 3-year 275 Request for Patient Limit Increase.

(a) Practitioners who intend to continue to treat up to 275 patients beyond their current 3-year approval term must submit a renewal Request for Patient Limit Increase in

accordance with the procedures outlined under § 8.620 no more than 30 days before the expiration of their current approval term.

(b) If the Secretary does not reach a final decision on a renewal Request for Patient Limit Increase before the expiration of a practitioner's approval term, the practitioner's existing approval term will be deemed extended until the Secretary reaches a final decision.

§ 8.645 Practitioner responsibility when no renewal request for patient limit increase is submitted, or whose renewal request is denied.

Practitioners who are approved to treat up to 275 patients in accordance with § 8.625, but who do not renew their Request for Patient Limit Increase, or whose renewal request is denied, shall notify, under § 8.620(b)(7) in a time period specified by the Secretary, all patients affected above the 100-patient limit, that the practitioner will no longer be able to provide OUD treatment services using covered medications and make every effort to transfer patients to other treatment providers.

§ 8.650 Suspension or revocation of the Secretary's approval of a practitioner's request for patient limit increase.

The Secretary, at any time during a practitioner's 3-year approval term, may suspend or revoke its approval of a practitioner's Request for Patient Limit Increase under § 8.625 if it is determined that:

(a) Immediate action is necessary to protect public health or safety;

(b) The practitioner made misrepresentations in the practitioner's Request for Patient Limit Increase;

(c) The practitioner no longer satisfies the requirements of this subpart; or

(d) The practitioner has been found to have violated the CSA pursuant to 21 U.S.C. 824(a).

§ 8.655 Temporary increase to treat up to 275 patients in emergency situations.

(a) Practitioners with a current waiver to prescribe up to 100 patients and who are not otherwise eligible to treat up to 275 patients under § 8.610 may request a temporary increase of 6-months to treat up to 275 patients in order to address emergency situations as defined in § 8.2. Practitioners may not be granted more than 2 consecutive emergency 275-patient limit requests. To apply for a 6-month emergency 275-patient limit, the practitioner must provide information and documentation that:

(1) Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the situation qualifies as an emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit;

(2) Identifies a period of time, not longer than 6 months, in which the higher patient limit should apply, and provides a rationale for the period of time requested; and

(3) Describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to 275 patients expires.

(b) Prior to taking action on a practitioner's request under this section, the Secretary shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an immediate increase in the higher patient limit.

(c) If the Secretary determines that a practitioner's request under this section should be granted, the Secretary will notify the practitioner that his or her request has been approved. The period of such approval shall not exceed six months.

(d) If practitioners wish to receive an extension of the approval period granted under this section, they must submit a request to the Secretary at least 30 days before the expiration of the six-month period and certify that the emergency situation as defined in § 8.2 necessitating an increased patient limit continues. Prior to taking action on a practitioner's extension request under this section, the Secretary shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an extension of an increase in the higher patient limit.

(e) Except as provided in this section and § 8.650, requirements in other sections under this subpart do not apply to practitioners receiving waivers in this section.

Xavier Becerra,

Secretary,

Department of Health and Human Services.