

# New Federal Regulations for Opioid Treatment Programs

## An Overview of Key Changes to 42 CFR Part 8



On February 2, 2024, the Department of Health and Human Services (HHS) published its Final Rule, [Medications for the Treatment of Opioid Use Disorder](#), revising the federal regulations governing opioid treatment programs (OTPs). The new rule is effective April 2, 2024, and OTPs must fully comply with the new rule no later than October 2, 2024. SAMHSA also plans corresponding updates to its [2015 Federal Guidelines for OTPs](#) to align with the new rules and evidence-based practices.<sup>1</sup>

**This resource provides a summary of key sections of the Final Rule and the improvements it makes relative to prior federal OTP regulations. It is not a comprehensive overview of the entire Final Rule (e.g., this resource does not address changes to OTP accreditation). The resource also does not address the Final Rule’s significant limitations, including how the continued tethering of methadone to the rigid OTP system perpetuates barriers to care.<sup>2,3,4</sup>**

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## New Federal Regulations for Opioid Treatment Programs

### Key Components of the Final Rule

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| <ul style="list-style-type: none"> <li>+ Substantive, procedural, and linguistic changes to adopt a more patient-centered approach to treatment in OTPs.</li> <li>+ Permanent authorization for expanded take-home methadone, including up to a 7-day take-home supply during the first 14 days of treatment.<sup>5</sup></li> <li>+ Permanent authorization for OTPs to conduct patient screenings and full examinations via telehealth, including for patients being evaluated for treatment with methadone.</li> <li>+ Authorization for non-OTP practitioners to conduct initial screenings and examinations outside of an OTP.</li> </ul> | <ul style="list-style-type: none"> <li>+ Prohibiting the denial of MOUD based on a patient's refusal of counseling services.</li> <li>+ Elimination of non-evidence-based admissions criteria (e.g., the requirement that a patient must have a 1-year history of OUD, with limited exceptions).</li> <li>+ Improvements to interim treatment, including access to take-home doses.</li> <li>+ Elimination of outdated regulatory provisions related to the X-waiver.</li> </ul> |
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**The Final Rule does not affect the applicability of state laws, including state laws that are more restrictive than federal law.<sup>6</sup>** Many states regulate certain aspects of methadone treatment more strictly than the Final Rule (e.g., admission requirements, methadone take-homes, and drug testing frequency). Information on state laws regulating methadone treatment in OTPs is available from [The Pew Charitable Trusts](#) and [PDAPS.org](#). **OTPs also frequently implement stricter policies and practices than required by state and federal law**, which can limit patient access to flexibilities such as increased methadone take-home supplies.

All citations to 42 CFR Part 8 refer to the Final Rule unless stated otherwise.

## Detailed Overview of the Final Rule

### Global Changes

The Final Rule makes several global changes to the OTP regulations, such as:

- + **Replacing stigmatizing and outdated language.** Examples include replacing “medication-assisted treatment (MAT)” with “medication for opioid use disorder (MOUD),” “maintenance treatment” with “comprehensive treatment,” and “detoxification treatment” with “withdrawal management,” as well as the deletion of phrases such as “drug abuse.”
- + **Emphasis on patient-centered care and shared decision-making.** Numerous provisions within the Final Rule emphasize the importance of patient-centered care and shared decision-making between a patient and their OTP.

For example,

- A patient care plan must “include[] 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.*”<sup>7</sup> Periodic revisions to the care plan must reflect a patient’s “current needs for and interests in” services.<sup>8</sup>
  - Other aspects of treatment similarly must be mutually agreed-upon by the patient and care team (combination and frequency of services, SUD counseling and psychoeducation, and ancillary services).<sup>9</sup>
- + **Incorporation of harm reduction and recovery supports.** The Final Rule adds definitions for “harm reduction”<sup>10</sup> and “recovery support services.”<sup>11</sup>

Additionally:

- The definition of “comprehensive treatment” includes “harm reduction ... and recovery support services.”<sup>12</sup>
- Patient care plans may include “harm reduction interventions” based on “the patient’s goals and mutually agreed-upon actions for the patient to meet those goals.”<sup>13</sup>
- Patient SUD counseling and psychoeducation may include “harm reduction education and recovery-oriented counseling.”<sup>14</sup>
- OTPs may dispense “legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.”<sup>15</sup>

## Admissions Criteria

The Final Rule eliminates several non-evidence-based admissions criteria, including the requirement that a person “became addicted” to opioids at least one year before their admission to an OTP.

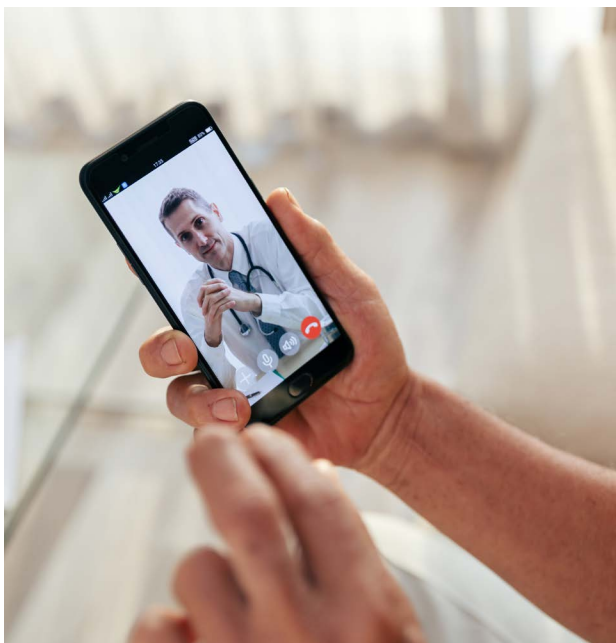
	Final Rule	Old Rule
<b>Comprehensive Treatment, General (Maintenance)</b>	<ul style="list-style-type: none"> <li>+ Eliminates 1-year addiction requirement.<sup>16</sup></li> <li>+ Patient “meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose.”<sup>17</sup></li> </ul>	<ul style="list-style-type: none"> <li>+ Patient must have 1-year history of OUD, with limited exceptions.<sup>18</sup></li> </ul>
<b>Comprehensive Treatment, Minors (Maintenance)</b>	<ul style="list-style-type: none"> <li>+ Eliminates need for a minor patient to have 2 unsuccessful attempts at detoxification or drug-free treatment.<sup>19</sup></li> <li>+ Parental, guardian, or designated responsible adult consent necessary unless not required by state law.<sup>20</sup></li> </ul>	<ul style="list-style-type: none"> <li>+ Minor patients must have 2 documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period.</li> <li>+ Parental, guardian, or designated responsible adult consent necessary regardless of state law.</li> </ul>
<b>Withdrawal Management (Detoxification)</b>	<ul style="list-style-type: none"> <li>+ Focuses on “patients who <i>choose</i> to taper from MOUD” and requires such tapering to occur “at a <i>mutually agreed-upon</i> rate that minimizes taper-related risks.”<sup>21</sup></li> <li>+ No limit on number of admissions for withdrawal management per year.<sup>22</sup></li> </ul>	<ul style="list-style-type: none"> <li>+ Appropriateness determined by OTP medical personnel.</li> <li>+ OTP may not admit a patient for more than two detoxification treatment episodes in one year.</li> </ul>

## Admissions Process

The Final Rule divides the required initial medical examination into two parts:

1. A **screening examination** to “ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD.”<sup>23</sup>
  - a. Must occur *before* a patient commences treatment with MOUD.<sup>24</sup> However, SAMHSA specifically “recommends methadone medication induction *not* be delayed until the full examination is completed.”<sup>25</sup>
  - b. May be completed outside of an OTP and by a licensed practitioner that is *not* an OTP practitioner.<sup>26</sup>
2. A **full examination** to “determine the patient’s broader health status, with lab testing as determined to be required by an appropriately licensed practitioner.”<sup>27</sup>
  - a. Must be completed within 14 calendar days following admission to an OTP.<sup>28</sup>
  - b. May be completed by a non-OTP practitioner.<sup>29</sup>
  - c. OTPs may not deny treatment to a patient based on the patient’s refusal to undergo lab testing for co-occurring physical health conditions unless the refusal may negatively impact medication treatment.<sup>30</sup>

This contrasts with previous regulations that required a complete, fully documented physical examination before admission to the OTP.



Both the screening examination and full examination may be completed via **telehealth**.<sup>31</sup>

- + Methadone generally requires use of an audio-visual telehealth platform.<sup>32</sup> Audio-only devices may be used to evaluate a patient for methadone treatment only if an audio-visual telehealth platform is not available to the patient and the patient is in the presence of a licensed practitioner authorized to prescribe controlled substances.<sup>33</sup>
- + Audio-only platforms may be used for buprenorphine or naltrexone.<sup>34</sup>

## Required Services

### Initial and Periodic Physical and Behavioral Health Assessments

OTPs must conduct physical, behavioral health, and psychosocial assessments within 14 days after a patient's admission and periodically thereafter,<sup>35</sup> with the periodic physical examination occurring at least once per year.<sup>36</sup>

- + The **physical and behavioral health 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.”<sup>37</sup>
- + The **psychosocial assessment** must include “preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals.”<sup>38</sup> The care plan “must identify the recommended frequency with which services are to be provided,” and be periodically reviewed and updated.<sup>39</sup>

### Counseling

OTPs are required to “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.”<sup>40</sup> **Importantly, however, the Final Rule specifies that “[p]atient refusal of counseling shall not preclude them from receiving MOUD.”**<sup>41</sup>

#### OTPs must also:

- + Provide “counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs).”<sup>42</sup>
- + Directly provide or actively link to treatment each admitted or readmitted patient with a positive test for HIV, viral hepatitis, or STIs.<sup>43</sup>
- + Provide vocational training, education, and employment services directly or by referral, as needed and desired by the patient.<sup>44</sup>

### Drug Testing

The Final Rule maintains the general requirement that OTPs conduct a minimum of eight random drug tests per year while establishing a new, limited exception allowing fewer drug tests based on “extenuating circumstances at the individual patient level.”<sup>45</sup> OTPs also,

- + Must use drug tests that have received FDA marketing authorization.<sup>46</sup>
- + Must conduct random drug testing “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.”<sup>47</sup>

Although the preamble to the Final Rule states that “[t]oxicology testing is a clinical tool that is used to inform the treatment process [and] should never be used punitively,”<sup>48</sup> the Final Rule does *not* include additional protections or guidance on how OTPs should respond to drug test results.



### Pregnant and Postpartum Patients

The Final Rule addresses special services for pregnant and postpartum patients, which are largely consistent with prior regulations.

#### More specifically, OTPs must:

- + “[M]aintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant.”<sup>49</sup>
- + Provide, directly or by referral, “[p]renatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients.”<sup>50</sup> The inclusion of reproductive health services and postpartum patients differs from the prior regulations.<sup>51</sup>

The Final Rule also excludes language that would have explicitly mandated pregnancy testing, a response to public comments explaining that “in a time when States are increasingly restricting and even criminalizing reproductive options, pregnancy testing may dissuade patients of child-bearing potential from seeking treatment.”<sup>52</sup> HHS emphasized that while “[p]regnancy testing is often necessary for appropriate clinical care ... pregnancy testing should be requested only when clinically appropriate, and that refusal of such testing should not preclude access to treatment.”<sup>53</sup> Importantly, however, the Final Rule still specifies that “[p]regnancy should be confirmed,” which may be interpreted as a requirement to conduct pregnancy testing.<sup>54</sup>



## Take-Home Doses

The Final Rule changes the **stability criteria** and **time-in-treatment requirements** for take-home methadone. Buprenorphine remains exempt from the time-in-treatment requirements.<sup>55</sup> OTPs maintain discretion to provide fewer than the maximum number of take-home doses.<sup>56</sup>

	Final Rule	Old Rule
<p><b>Stability Criteria for Methadone Take-Homes<sup>57</sup></b></p>	<ul style="list-style-type: none"> <li>+ 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.</li> <li>+ Regularity of attendance for supervised medication administration.</li> <li>+ Absence of serious behavioral problems that endanger the patient, the public or others.</li> <li>+ Absence of known recent diversion activity.</li> <li>+ Whether take-home medication can be safely transported and stored.</li> <li>+ Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.</li> <li>+ Other pertinent factors that indicate the therapeutic benefits of unsupervised doses outweigh the risks.<sup>58</sup></li> </ul>	<ul style="list-style-type: none"> <li>+ Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol.</li> <li>+ Regularity of clinic attendance.</li> <li>+ Absence of serious behavioral problems at the clinic.</li> <li>+ Absence of known recent criminal activity, e.g., drug dealing.</li> <li>+ Stability of the patient's home environment and social relationships.</li> <li>+ Length of time in comprehensive maintenance treatment.</li> <li>+ Assurance that take-home medication can be safely stored within the patient's home.</li> <li>+ Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.</li> </ul>



<b>Time-in-Treatment for Methadone Take-Homes<sup>59</sup></b>	<b>Final Rule</b>	<b>Old Rule</b>
<b>1-14 Days</b>	Up to 7-day supply	1 dose/week
<b>15-30 Days</b>	Up to 14-day supply	1 dose/week
<b>31-90 Days</b>	Up to 28-day supply	1 dose/week
<b>91-180 Days</b>	Up to 28-day supply	2 doses/week
<b>181-270 Days</b>	Up to 28-day supply	3 doses/week
<b>271 Days to 1 Year</b>	Up to 28-day supply	Up to a 6-day supply
<b>1 Year to 2 Years</b>	Up to 28-day supply	Up to a 2-week supply
<b>2+ Years</b>	Up to 28-day supply	Up to a 1-month supply

## Interim Treatment

The Final Rule makes several notable changes to interim treatment, including extending the maximum time for interim treatment, allowing take-home doses, and reducing the minimum number of drug screens.

	<b>Final Rule</b>	<b>Old Rule</b>
<b>Maximum Time</b>	180 days in any 12-month period. <sup>60</sup>	120 days in any 12-month period.
<b>Take-Home Doses</b>	Permitted in accordance with generally applicable take-home regulations. <sup>61</sup>	Prohibited.
<b>Drug Screening</b>	Minimum of two during max 180 days. <sup>62</sup>	Minimum of three (initial + at least two others during max 120 days).
<b>Treatment Plan</b>	Required by day 120. <sup>63</sup>	Not addressed.
<b>Discharge</b>	Patients may not be discharged without approval of an OTP practitioner. <sup>64</sup>	Not addressed.
<b>OTP Eligibility</b>	All OTPs. <sup>65</sup>	Public and nonprofit private OTPs only.
<b>Approvals</b>	SAMHSA & State Opioid Treatment Authority (SOTA). <sup>66</sup>	SAMHSA & state “chief public health officer.”

## Additional Changes

### Methadone Dosing

The Final Rule modifies provisions related to initial dosages and guest dosing and adopts new provisions related to split dosing.

	Final Rule	Old Rule
<b>Initial Dosages</b>	<ul style="list-style-type: none"> <li>+ Requires OTPs to consider “the type(s) of opioid(s) involved in the patient’s opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal.”<sup>67</sup></li> <li>+ Specifies that the total dose for the first day should not exceed 50mg unless the OTP practitioner finds and documents sufficient medical rationale for a higher dose.<sup>68</sup></li> </ul>	<ul style="list-style-type: none"> <li>+ Initial dose limited to 30mg.</li> <li>+ Total dose for the first day limited to 40mg unless the program physician documented that 40mg “did not suppress opioid abstinence symptoms.”</li> </ul>
<b>Split Dosing<sup>69</sup></b>	<ul style="list-style-type: none"> <li>+ Authorizes OTPs to provide split doses of MOUD, including methadone, “where such dosing regimens are indicated.”<sup>70</sup></li> <li>+ Includes split doses for take-home doses of methadone.<sup>71</sup></li> </ul>	<ul style="list-style-type: none"> <li>+ Not addressed.</li> </ul>
<b>Guest Dosing</b>	<ul style="list-style-type: none"> <li>+ Patient may obtain treatment at another OTP “in circumstances involving an inability to access care at the patient’s OTP of record,” as determined by the medical director or program practitioner of the patient’s OTP.<sup>72</sup></li> <li>+ Circumstances include, but are not limited to, “travel for work or family events, temporary relocation, or an OTP’s temporary closure.”<sup>73</sup></li> </ul>	<ul style="list-style-type: none"> <li>+ Prohibited patient from obtaining “treatment in any other OTP except in exceptional circumstances.”</li> </ul>

## Medication Units

The Final Rule revises the definition of “Medication unit”<sup>74</sup> and corresponding regulations to clarify that medication units may provide all OTP services<sup>75</sup> and can be a brick-and-mortar location or a mobile unit.<sup>76</sup> This is consistent with longstanding SAMHSA guidance but was not clearly stated in prior regulations.

## Long-Term Care and Correctional Facilities

The Final Rule specifies that a hospital, long-term care facility,<sup>77</sup> or correctional facility that is not certified as an OTP may treat a patient’s OUD with methadone if:

1. The hospital, long-term care facility, or correctional facility is registered with the DEA as a hospital/clinic;
2. The patient is admitted for the treatment of medical conditions *other than* OUD; and
3. The treatment is permitted under applicable federal law.<sup>78</sup>

**Importantly, this provision merely restates existing law** – it does *not* establish any new ability for hospitals, long-term care facilities, or correctional facilities to provide methadone for OUD without becoming an OTP.<sup>79</sup> Moreover, because a person must be receiving treatment for a medical condition other than addiction for this exception to apply, the scope of the exception is necessarily limited and insufficient to meet correctional settings’ legal obligations under federal civil rights laws to provide MOUD to individuals in their custody.

## X-Waiver References

The Final Rule eliminates all provisions related to the X-Waiver, including definitions and substantive regulations (e.g., 42 CFR Part 8, Subpart F on Authorization to Increase Patient Limit to 275 Patients).<sup>80</sup>

## Tribal and Territorial Accreditation Bodies

The Final Rule includes federally recognized “Indian Tribes” and territorial governments as entities that may become an OTP accreditation body.<sup>81</sup> Prior regulations limited accreditation bodies to private nonprofit organizations and state or local government entities.

## Additional Resources

### **The Methadone Manifesto**

*Urban Survivors Union*

<https://ohrn.org/wp-content/uploads/2021/05/THE-METHADONE-MANIFESTO.pdf>

### **Medications for the Treatment of Opioid Use Disorder (Final Rule)**

*U.S. Department of Health and Human Services (HHS)*

<https://www.federalregister.gov/documents/2024/02/02/2024-01693/medications-for-the-treatment-of-opioid-use-disorder>

### **42 CFR Part 8 Final Rule - Frequently Asked Questions**

*Substance Abuse and Mental Health Services Administration (SAMHSA)*

<https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8/faqs>

### **State Opioid Treatment Program Regulations Put Evidence-Based Care Out of Reach for Many**

*The Pew Charitable Trusts*

<https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2022/state-opioid-treatment-program-regulations-put-evidence-based-care-out-of-reach-for-many>

### **Overview of Opioid Treatment Program Regulations by State**

*The Pew Charitable Trusts*

<https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2022/09/overview-of-opioid-treatment-program-regulations-by-state>

### **Requirements for Licensure and Operations of Medications for Opioid Use Disorder Treatment**

*PDAPS.org*

<https://pdaps.org/datasets/medication-assisted-treatment-licensure-and-operations-1580241579>

### **New Federal Rules Cannot Improve Methadone Delivery Without State Actions**

*The Pew Charitable Trusts*

<https://www.pewtrusts.org/en/research-and-analysis/articles/2024/02/21/new-federal-rules-cannot-improve-methadone-delivery-without-state-actions>

### **State Opioid Treatment Authorities**

*Substance Abuse and Mental Health Services Administration (SAMHSA)*

<https://www.samhsa.gov/medications-substance-use-disorders/sota>

### **A Vast and Discretionary Regime: Federal Regulation of Methadone as a Treatment for Opioid Use Disorder**

*Bridget C.E. Dooling and Laura Stanley*

<https://regulatorystudies.columbian.gwu.edu/federal-regulation-of-methadone>

## Endnotes

<sup>1</sup> 89 Fed. Reg. 7535.

<sup>2</sup> See Urban Survivors Union. The Methadone Manifesto. Accessed February 20, 2024. <https://ohrn.org/wp-content/uploads/2021/05/THE-METHADONE-MANIFESTO.pdf>.

<sup>3</sup> See Dooling BCE, Stanley L. A Vast and Discretionary Regime: Federal Regulation of Methadone as a Treatment for Opioid Use Disorder; 2022. <https://regulatorystudies.columbian.gwu.edu/federal-regulation-of-methadone>. Accessed February 20, 2024.

<sup>4</sup> See Vital Strategies' Public Comment on the Substance Abuse and Mental Health Administration's (SAMHSA) Proposed Regulation "Medications for the Treatment of Opioid Use Disorder" (February 13, 2023). <https://www.regulations.gov/comment/SAMHSA-2023-0001-0234>. Accessed February 20, 2024.

<sup>5</sup> The Final Rule's preamble states that "[b]ased on the clinical judgment of the treating provider, patients may be eligible for unsupervised, take-home doses of methadone upon entry into treatment," 89 Fed. Reg. 7529 (emphasis added), and "the final rule allows patients new to treatment to receive up to 7 take-home doses of methadone." 89 Fed. Reg. 7538 (emphasis added).

<sup>6</sup> See 89 Fed. Reg. 7536 ("Federal OTP regulations do not preempt separate State requirements"); 89 Fed. Reg. 7540 ("These rules do not mandate that States promulgate less restrictive rules to match provisions of Federal law that may provide more flexibility").

<sup>7</sup> 42 CFR § 8.12(f)(4)(i) (emphasis added). "Care plan" is defined as "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." 42 CFR § 8.2 (emphasis added).

<sup>8</sup> 42 CFR § 8.12(f)(4)(i).

<sup>9</sup> 42 CFR § 8.12(f)(1) (The "combination and frequency of services" must be "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.") (emphasis added); 42 CFR § 8.12(f)(5)(i) (SUD counseling and psychoeducation must be provided "to each patient as clinically indicated and mutually agreed-upon.") (emphasis added); 42 CFR § 8.12(f)(5)(iii) (OTPs are required to provide ancillary services like vocational training and employment services only "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.") (emphasis added).

<sup>10</sup> "Harm reduction refers to practical and legal evidence-based strategies, including: overdose education;

testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services." 42 CFR § 8.2.

<sup>11</sup> "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." 42 CFR § 8.2.

<sup>12</sup> 42 CFR § 8.2.

<sup>13</sup> 42 CFR § 8.12(f)(4)(i).

<sup>14</sup> 42 CFR § 8.12(f)(5)(i).

<sup>15</sup> 42 CFR § 8.12(f)(6).

<sup>16</sup> 89 Fed. Reg. 7542.

<sup>17</sup> 42 CFR § 8.12(e)(1).

<sup>18</sup> The 1-year addiction requirement was waivable for (1) patients released from penal institutions (within 6 months after release); (2) pregnant patients; and (3) previously treated patients (up to 2 years after discharge).

<sup>19</sup> 89 Fed. Reg. 7536.

<sup>20</sup> 42 CFR § 8.12(e)(2).

<sup>21</sup> 42 CFR § 8.12(e)(3) (emphasis added).

<sup>22</sup> 89 Fed. Reg. 7536 ("The final rule removes the requirement ... that those seeking withdrawal management, previously under 8.12(e)(4), cannot initiate methadone treatment more than twice per year.")

<sup>23</sup> 42 CFR § 8.12(f)(2)(i)(A).

<sup>24</sup> 42 CFR § 8.12(f)(2)(ii).

<sup>25</sup> 89 Fed. Reg. 7538 (emphasis added).

<sup>26</sup> 42 CFR § 8.12(f)(2)(ii) (If the licensed practitioner is not an OTP practitioner, the screening exam must occur no more than 7 days prior to OTP admission. If performed outside an 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.")

<sup>27</sup> 42 CFR § 8.12(f)(2)(i)(B).

<sup>28</sup> 42 CFR § 8.12(f)(2)(iii).

<sup>29</sup> 42 CFR § 8.12(f)(2)(iii) (If completed by a non-OTP practitioner, "the exam [must be] verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.")

<sup>30</sup> 42 CFR § 8.12(f)(2)(i)(B).

<sup>31</sup> 42 CFR § 8.12(f)(2)(v) (“The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth.”)

<sup>32</sup> 42 CFR § 8.12(f)(2)(v)(A).

<sup>33</sup> 42 CFR § 8.12(f)(2)(v)(A).

<sup>34</sup> 42 CFR § 8.12(f)(2)(v)(B).

<sup>35</sup> 42 CFR § 8.12(f)(4)(i).

<sup>36</sup> 42 CFR § 8.12(f)(4)(ii) (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.”)

<sup>37</sup> 42 CFR § 8.12(f)(4)(i) (This includes “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.”)

<sup>38</sup> 42 CFR § 8.12(f)(4)(i).

<sup>39</sup> 42 CFR § 8.12(f)(4)(i) (Updates to the care plan must “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.”)

<sup>40</sup> 42 CFR § 8.12(f)(5)(i).

<sup>41</sup> 42 CFR § 8.12(f)(5)(i).

<sup>42</sup> 42 CFR § 8.12(f)(5)(ii).

<sup>43</sup> 42 CFR § 8.12(f)(5)(ii).

<sup>44</sup> 42 CFR § 8.12(f)(5)(iii).

<sup>45</sup> 42 CFR § 8.12(f)(6).

<sup>46</sup> 42 CFR § 8.12(f)(6) (“When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration’s (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment.”)

<sup>47</sup> 42 CFR § 8.12(f)(6).

<sup>48</sup> 89 Fed. Reg. 7534–7535 (“Toxicology testing is a clinical tool that is used to inform the treatment process, should never be used punitively, and must be conducted in a way that is respectful of the individual and in accordance with clinical and professional standards.”)

<sup>49</sup> 42 CFR § 8.12(f)(3).

<sup>50</sup> 42 CFR § 8.12(f)(3).

<sup>51</sup> Prior regulations specified that “[p]renatal care and other gender specific services for pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.”

<sup>52</sup> 89 Fed. Reg. 7540.

<sup>53</sup> 89 Fed. Reg. 7540.

<sup>54</sup> See 42 CFR 8.12(f)(3) (“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.*”) (emphasis added).

<sup>55</sup> 42 CFR § 8.12(i)(3).

<sup>56</sup> 42 CFR § 8.12(i)(3)(i) (“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.”) See also 42 CFR § 8.12(i)(3)(ii)–(iii).

<sup>57</sup> 42 CFR § 8.12(i)(2).

<sup>58</sup> The Final Rule characterizes this as an overarching consideration rather than as an enumerated criterion. Compare new 42 CFR § 8.12(i)(2) (“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”) with former 42 CFR § 8.12(i)(2)(viii) (including in the enumerated criteria “whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.”) It is unclear whether this difference is intended as a substantive change or merely stylistic.

<sup>59</sup> 42 CFR § 8.12(i)(3).

<sup>60</sup> 42 CFR § 8.12(j)(4)(ii).

<sup>61</sup> 42 CFR § 8.12(j)(4). See also 89 Fed. Reg. 7543 (“The rule finalizes removal of the requirement for observation of all daily doses during interim treatment.”)

<sup>62</sup> 42 CFR § 8.12(j)(1).

<sup>63</sup> 42 CFR § 8.12(j)(4)(iii).

<sup>64</sup> 42 CFR § 8.11(f)(2)(iv) (The OTP practitioner must “consider on-going and patient-centered treatment needs, which are to be documented in the patient record, while awaiting transfer to a comprehensive treatment program.”)

<sup>65</sup> 89 Fed. Reg. 7536 (“Language pertaining to public and not for-profit OTPs has been removed from the final rule in order to expand access to interim treatment among all OTPs”)

<sup>66</sup> 42 CFR § 8.11(f)(1).

<sup>67</sup> 42 CFR § 8.12(h)(3)(ii).

<sup>68</sup> 42 CFR § 8.12(h)(3)(ii).

<sup>69</sup> “Split dosing means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent



pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.” 42 CFR 8.2.

<sup>70</sup> 42 CFR § 8.2 (“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.”) See also 42 CFR § 8.12(f)(3) (“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.”)

<sup>71</sup> 89 Fed. Reg. 7538 (“The final rule does not specify requirements of any additional testing or documentation beyond that of routine clinical practice. There is nothing in the final rule that precludes provision of split doses for take-home doses of methadone.”)

<sup>72</sup> 42 CFR § 8.12(g)(2) (“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.”)

<sup>73</sup> 42 CFR § 8.12(g)(2).

<sup>74</sup> “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.” 42 CFR § 8.2.

<sup>75</sup> 42 CFR § 8.11(h)(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.”)

<sup>76</sup> 42 CFR § 8.11(h)(1) (“Medication units include both mobile and brick and mortar facilities.”)

<sup>77</sup> The Final Rule specifically defines “long-term care facilities” as “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.” 42 CFR § 8.2. Prior federal regulations deferred to definitions in state law.

<sup>78</sup> 42 CFR § 8.11(h)(3). See also 42 CFR § 8.11(i) (“Nothing in this section is intended to relieve hospitals, or long-term care facilities and correctional facilities that are registered with the Drug Enforcement Administration as a hospital/clinic, from their obligations to obtain appropriate registration from the Attorney General, under section 303(g) of the Controlled Substances Act. Treatment provided under this section should always comply with applicable Federal laws.”)

<sup>79</sup> “Rules regarding controlled substance dispensing that is outside the context of OTPs, such as waiver language that specifies the OUD diagnosis be secondary to another condition, is beyond the scope of this rulemaking.” 89 Fed. Reg. 7536.

<sup>80</sup> 89 Fed. Reg. 7534.

<sup>81</sup> 42 CFR § 8.3(a).