Methadone Take-Home Flexibilities Extension Guidance

On March 16, 2020, SAMHSA issued an exemption to Opioid Treatment Programs (OTPs) whereby a state could request "a blanket exception for all stable patients in an OTP to receive up to 28 days of Take-Home doses of the patient's medication for opioid use disorder."[1] States could also request an exemption for an OTP to "request up to 14 days of Take-Home medication for those patients who are less stable but whom the OTP believes can safely handle this level of Take-Home medication." In the three years since this exemption was granted, states, OTPs, and other stakeholders report that it has resulted in increased treatment engagement, improved patient satisfaction with care, with relatively few incidents of misuse or medication diversion.[2] SAMHSA has concluded that there is sufficient evidence[3,4,5] that this exemption has enhanced and encouraged use of OTP services at a time of significant fentanyl-related overdose mortality.

SAMHSA published Methadone Take-Home Flexibilities Extension Guidance in November 2021. SAMHSA is updating this November 2021 Guidance in full by revising the standards applicable to OTP provision of methadone for unsupervised use. **This newly revised April 2023 Guidance (hereinafter "the Guidance") will be effective upon the expiration of the COVID-19 Public Health Emergency, and will remain in effect for the period of one year from the end of the COVID-19 Public Health Emergency, or until such time that the U.S. Department of Health and Human Services publishes final rules revising 42 C.F.R part 8, whichever occurs sooner**. A notice of proposed rulemaking has been published that proposes revisions to 42 C.F.R. part 8 entitled 'Medications for the Treatment of Opioid Use Disorder' (87 FR 77330), which SAMHSA is working to finalize.

Subject to the conditions identified below, this Guidance will offer an exemption from the unsupervised take-home medication requirements of 42 C.F.R. § 8.12(i). Specifically, OTPs taking advantage of this exemption, may provide unsupervised take-home doses of methadone in accordance with the following time in treatment standards:

- In treatment 0-14 days, up to 7 unsupervised take-home doses of methadone may be provided to the patient
- Treatment days 15-30, up to 14 unsupervised take-home doses of methadone may be provided to the patient
- From 31 days in treatment, up to 28 unsupervised take-home doses of methadone may be provided to the patient

In all instances, it is within the clinical judgement of the OTP practitioner to determine the actual number of take-home doses within these ranges. OTP decisions regarding dispensing methadone for unsupervised use

---

[1] https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf

[2] Amram O, Amiri S, Panwala V, Lutz R, Joudrey PJ, Socias E. The impact of relaxation of methadone take-home protocols on treatment outcomes in the COVID-19 era. Am J Drug Alcohol Abuse. 2021 Oct 20:1-8. doi: 10.1080/00952990.2021.1979991. Epub ahead of print. PMID: 34670453.

[3] 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.

[4] 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.

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

under this exemption shall be determined by an appropriately licensed OTP medical practitioner or the medical director. In determining which patients may receive unsupervised doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate whether the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

(a) 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;

(b) Regularity of attendance for supervised medication administration;

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

(d) Absence of known recent diversion activity; and

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

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

Such determinations and the basis for such determinations consistent with the criteria outlined in **a – f**, above, 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 in accordance with the time in treatment standards outlined above, the following dispensing restrictions apply:

- During the first 14 days of treatment, the take home supply 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 a-f listed above. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

- From 15 days of treatment, the take home supply 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 decisions must be based on the criteria a-f listed above. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

- From 31 days of treatment, the take home supply 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 decisions must be based on the criteria a-f listed above. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

This exemption only applies to OTPs whose states concur with the exercise of this exemption and its conditions within their states. The duration of this exemption shall be for the period of one year from the end of the COVID-19 Public Health Emergency, or until such time that final rules revising 42 C.F.R. part 8 are published by the U.S. Department of Health and Human Services, whichever occurs sooner. To be clear, this exemption will replace and supersede the exemption provided in the guidance published in November 2021, and the exemption announced in SAMHSA's OTP guidance issued on March 16, 2020 (LINK TO: https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf). All other requirements of 42 C.F.R. § 8.12(i) that are not in direct conflict with the exercise of this exemption will remain in force. SAMHSA will

publish a list of States that have concurred with this exemption on the SAMHSA's website at https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines.

SAMHSA reiterates that although the exemption allows for up to 28 take home doses, the exercise of this exemption remains subject to the clinical judgement of the provider that the patient can manage take home medication without incident. The exemption is meant to support recovery and eliminate a barrier to care. Therefore, it is expected that OTP providers use clinical judgment in determining the number of unsupervised doses an individual can safely manage, keeping in mind that the input of the multi-disciplinary OTP clinical team can help provide important information about the patient, their progress in treatment, and ability to safely handle take home medication. The risks of a patient losing access to medication continuity should also be considered, as well as the medical provider's own assessment of the patient to make the final decision to approve or resume a patient's use of take-home medication. Such decision-making and discussions must be documented in the individual's medical record consistent with 42 C.F.R. § 8.12(i)(3).

Frequently Asked Questions:

1. Will states that are currently operating under the exemption announced on March 16, 2020[1] (and furthered in November 2021), be required to take additional action in order to utilize this exemption when the COVID-19 public health emergency officially ends?

Yes. States will need to affirmatively register their concurrence with this specific exemption in order for OTPs within the state to utilize it. States that have already authorized its OTPs to operate under the exemption announced on March 16, 2020, do not need to take any immediate action while the COVID-19 public health emergency is in effect. Please note, however, that if a state has not registered its concurrence with this exemption before the COVID-19 PHE expires, or has removed its concurrence, OTPs within the state will have to comply with all unsupervised use requirements under 42 C.F.R. § 8.12(i). Therefore, in order to facilitate a seamless transition from operations under the March 16, 2020, exemption to this April 2023 exemption, states are encouraged to register their concurrence with this exemption by May 10, 2023 so that it can be in effect as of the expiration of the COVID-19 PHE on May 11, 2023.

2. What is the procedure for State Opioid Treatment Authorities to register their concurrence with this exemption?

State Opioid Treatment Authorities may, at any time following the issuance of this FAQ, register their concurrence with this exemption by submitting a written concurrence to the Division of Pharmacological Therapies mailbox. To ensure a seamless transition from the methadone take home flexibility issued during the COVID-19 public health emergency to this guidance, states are encouraged to do this no later than May 10, 2023. If a state previously did not utilize the exemption announced on March 16, 2020, then the state may still submit a written concurrence.

3. How soon after beginning treatment can an individual be considered for take-home doses of unsupervised medication under this exemption?

It is up to the OTP practitioner to determine the actual number of take-homes for patients, but the allowable range is as follows:

- In treatment 0-14 days, up to 7 unsupervised take-home doses of methadone may be provided to the patient

- Treatment days 15-30, up to 14 unsupervised take-home doses of methadone may be provided to the patient
- From 31 days in treatment, up to 28 unsupervised take-home doses of methadone may be provided to the patient

When a patient first starts taking methadone to treat OUD, they may need to be seen more frequently at the OTP, to safeguard against the dose causing undue or adverse effects, and that the individual's treatment is responding as anticipated. For the majority of patients new to methadone, this may require multiple visits to the OTP during the first and second weeks of treatment, to ensure appropriate and safe medication titration and response.

4. What additional safeguards are in place to prevent diversion or other misuse of medication?

At the program level, adherence to the above recommendations and requirements will ensure safeguards are in place to prevent diversion or other misuse of medication. The following activities provide additional safeguards:

- Accreditation Standards
- OTP Diversion Control Plans
- Routine Prescriber Activities
    - Regular checks of state PDMPs
    - Regular client follow-up early in treatment and as needed as treatment progresses

5. What is meant by an 'absence of active substance use disorders that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely'?

SAMHSA recognizes that individuals in treatment with methadone may intermittently use substances that do not necessarily impact the efficacy or safety of methadone or increase the risk of overdose above that which may occur in the absence of methadone. In other cases, individuals in treatment with methadone may misuse central nervous system depressants or other substances, including alcohol, that, in combination with methadone, potentially increase the risk of adverse effects.[6] Practitioners should consider how a patient's use of additional substances might impact overdose risk, and make methadone take-home dosing decisions based on their knowledge of the patient, their patterns of risk-taking behavior, stage of change, and need for engagement with OTP team members. Such consideration includes an honest dialogue with the patient about the risks associated with the other use of substances, assessment and interventions for any other identified SUDs, and how this might impact methadone take-home dosing decisions. It is also important to consider ways to mitigate risk, including ensuring access to naloxone. A practitioner's determination of risk and safety, and decisions around access to take home doses of methadone, should be documented, along with the underlying rationale, in the clinical record.

[6] Liu S, O'Donnell J, Gladden RM, McGlone L, Chowdhury F. Trends in Nonfatal and Fatal Overdoses Involving Benzodiazepines — 38 States and the District of Columbia, 2019–2020. MMWR Morb Mortal Wkly Rep 2021;70:1136–1141. DOI: http://dx.doi.org/10.15585/mmwr.mm7034a2