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Methadone Take-Home Flexibilities Extension Guidance

Main page content

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 28 days of Take-Home doses of the patient’s medication for opioid use disorder.” States could also “request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.” Almost two 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, and few incidents of misuse or medication diversion¹. There is sufficient evidence to conclude that this exemption has enhanced and encouraged use of OTP services.

Therefore, SAMHSA is pre-emptively granting OTPs an exemption, effective upon the expiration of the COVID-19 Public Health Emergency, and subject to the conditions identified below, from the unsupervised take-home medication requirements of 42 C.F.R. § 8.12(i) that are necessary to (1) dispense up to 28 days of take-home doses of opioid use disorder medication to stable patients if the OTP believes the patient can safely handle this amount of take-home medication and (2) dispense up to 14 days of take-home doses of opioid use disorder medication to less stable patients if the OTP believes the patient can

Pharmacist Verification of Buprenorphine Providers	safely handle this amount of take-home medication. SAMHSA is also considering mechanisms to make this flexibility permanent. “Stable patients” within the meaning of this exemption are defined as patients who have completed a minimum of 60 days in treatment, and whose medical record fully documents the following:
Become an Accredited and Certified Opioid Treatment Program (OTP)	(a) that the benefits of providing unsupervised doses to an individual outweigh the risks; (b) that the individual demonstrates total adherence per the OTP’s discretion with their treatment plan for at least 60 days;
OTP Resources and Information	(c) negative toxicology tests for 60 calendar days; (d) an absence of serious behavioral problems;
State Opioid Treatment Authority (SOTA)	(e) stability in their living arrangements and social relationships; (f) an absence of substance misuse-related behaviors; (g) an absence recent diversion activity; and
Statutes, Regulations, and Guidelines	(h) assurance that the medication can be safely stored. Patients who do not meet all 8 criteria, listed above, are not eligible for treatment as “stable” patients under this exemption.
Methadone Extension Guidance	“Less stable” patients within the meaning of this exemption are defined as patients who have completed a minimum of 30 days in treatment, and whose medical record fully documents the following:
Special Circumstances for Providing Buprenorphine	(a) that the benefits of providing unsupervised doses of methadone to the individual outweigh the risks; (b) that the patient demonstrates partial adherence with their treatment plan for at least 30 days;
Training Materials and Resources	(c) 30 days of negative toxicology tests; (d) an absence recent diversion activity; and
About SAMHSA’s Division of Pharmacologic Therapies (DPT)	(e) assurance that that the medication can be safely stored. Patients who do not meet all 5 criteria, listed above, are not eligible for treatment as “less stable” patients under this exemption. It remains within the OTP provider’s discretion to determine the number of take-home doses within each category of ‘stable’ or ‘less stable’. 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. Once in effect, the exemption will replace and supersede the exemption announced in SAMHSA’s OTP guidance issued on

[March 16, 2020 \(PDF | 216 KB\)](#). Definitions of 'stable' and 'less stable' patients should be applied when this exemption comes into effect. 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.

When determining take-home medication schedules under this exemption, SAMHSA recommends that the best interest of each patient and the public's health should be taken into consideration. Although the exemption allows for up to 14 or 28 take home doses depending on the stability of the patient, 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. 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, be required to take further 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 this exemption once it takes effect. 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, 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 the exemption announced in this document, states are encouraged to register their concurrence with this exemption before the COVID-19 PHE expires.

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. 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?

New OTP patients will not be eligible to receive a 14- or 28-day supply of take-home medication in the first 30 or 60 days (as applicable) following admission as it would be impossible to achieve the above-mentioned requirements for stability. The time in treatment requirement is intended to assure that OTP patients achieve a medication dose that is sufficient to block both the withdrawal symptoms and the craving for illicit opioids, and to determine the most appropriate combination of services and therapies that will support their recovery

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

At the program level, 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

¹ 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.

Last Updated

Last Updated: 11/18/2021

MAT RR - Medications to Treat OPIOID ADDICTION

Medications to Treat OPIOID ADDICTION

[Methadone](#)

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MAT Opioid Overdose banner



MAT RR - Contact Us

Contact Us

For information on buprenorphine waiver processing, contact the SAMHSA Center for Substance Abuse Treatment (CSAT) at [866-BUP-CSAT](tel:866-287-2728) [☎](tel:866-287-2728) (866-287-2728) or infobuprenorphine@samhsa.hhs.gov.

For information about other medication-assisted treatment (MAT) or the certification of opioid treatment programs (OTPs), contact the SAMHSA Division of Pharmacologic Therapies at [240-276-2700](tel:240-276-2700) [☎](mailto:DPT@SAMHSA.HHS.Gov). DPT@SAMHSA.HHS.Gov.

For assistance with the Opioid Treatment Program Extranet, contact the OTP helpdesk at OTP-Help@jbsinternational.com [☎](mailto:OTP-Help@jbsinternational.com) or [1-866-348-5741](tel:1-866-348-5741) [☎](tel:1-866-348-5741).

Contact SAMHSA's regional [OTP Compliance Officers](#) to determine if an OTP is qualified to provide treatment for substance use disorders.

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SAMHSA's mission is to reduce the impact of substance abuse and mental illness on

America's communities.

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