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To: Massachusetts Opioid Treatment Programs

From: Jen Babich, State Opioid Treatment Authority

Subject: Updated Post-PHE Take-Home Guidance & Criteria

Date: May 1, 2023

SAMHSA has released updated take-home guidance which will go into effect at the expiration of the federal COVID-19 Public Health Emergency on May 11, 2023 (<https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance>). This updated guidance provides patients the opportunity to access take homes earlier in their treatment, receive more take homes than existing regulations allow, and allows for individualized treatment.

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 judgment of the OTP practitioner to determine the actual number of take-home doses within these ranges.

OTP decisions regarding dispensing methadone for unsupervised use under this exemption shall be determined by an appropriately licensed OTP medical practitioner or the medical director. This exemption only applies to OTPs whose states concur with the exercise of this exemption and its conditions within their states. Massachusetts concurred with the exercise of this exemption and has communicated this concurrence with SAMHSA. DPH BSAS OTP regulations align with SAMHSA’s

federal OTP regulations and guidance. Exception Requests must only be submitted to SAMHSA’s extranet if the request falls outside of the newly released April 2023 Take Home Guidance.

The table below shows the most current state and federal OTP take-home requirements effective May 11, 2023.

Requirements	April 2023 Methadone Take-Home Flexibilities Extension Guidance
Factors to be Considered	<p>Appropriately licensed OTP medical practitioner or medical director must consider six factors (and other pertinent factors) that indicate whether therapeutic benefits of unsupervised doses outweigh the risks:</p> <p>(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;</p> <p>(b) Regularity of attendance for supervised medication administration;</p> <p>(c) Absence of serious behavioral problems that endanger the patient, the public or others;</p> <p>(d) Absence of known recent diversion activity; and</p> <p>(e) Whether take-home medication can be safely transported and stored; and</p> <p>(f) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.</p>
Time Restrictions	<p>During the first 14 days, take-home limited to 7 days.</p> <p>From 15 days, take-home is limited to 14 days.</p> <p>From 31 days, take-home is limited to 28 days.</p>

Please contact Jen Babich, SOTA at Jennifer.Babich@Mass.Gov or Mike Gurney, Opioid Services Coordinator at Michael.Gurney@Mass.Gov with any questions.