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Memorandum

To: All BSAS Licensed and/or Approved Providers

From: Deirdre Calvert, LICSW, Director of the Bureau of Substance Addiction Services

Date: April 4, 2024, Revised on July 24, 2024, Revised on July 31, 2025, Revised on October 29, 2026

Re: Waiver from Certain Regulatory Requirements and Guidance – 42 CFR Part 8 and 105 CMR 164.000-OTP Revision

NOTE: This document is an update to guidance originally released on April 4, 2024, revised on July 24, 2024, and revised on July 31, 2025. This version provides new information about the following: Diversion Control - Random Callbacks – Pg. 11

On January 31, 2024, the U.S. Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) released the Final Rule to implement changes to the Opioid Treatment Program (OTP) regulations, Part 8 of Title 42 of the Code of Federal Regulations (42 CFR Part 8). The new federal OTP regulations took effect on April 2, 2024, and full compliance was expected by October 2, 2024.

This was the first substantial change to the regulations in 20 years and marked a historic step to increase access to medication for opioid use disorder. The new federal OTP regulations focus on patient- centered care, shared practitioner-patient decision-making, practitioners' clinical judgment, responsive, flexible OTP services, evidence-based practices, and non-stigmatizing language.

The Department of Public Health (DPH) Bureau of Substance Addiction Services (BSAS) commends SAMHSA for this important update to the federal OTP regulations and supports and encourages further efforts to modernize opioid use disorder treatment.

The purpose of this memo is to align the revisions to federal regulation 42 CFR Part 8 with Massachusetts regulation 105 CMR 164.000, by providing guidance and specific blanket waivers to BSAS Licensed or Approved Providers that are also a federally certified Opioid Treatment Provider, which may include Opioid Treatment Programs (OTPs), Intensive 24-Hour Diversionary

Medically Managed Withdrawal Management Services, 24-Hour Diversionary Medically Managed Withdrawal Management Services, Substance Use Disorder Treatment Programs Operated by Penal Facilities, and Outpatient Withdrawal Treatment Services.

The following section is intended to provide guidance to align 105 CMR 164.000 and changes to 42 CFR Part 8 Federal OTP regulations.

Medical Director, Physician, and Practitioner Definitions, Roles, and Responsibilities

The Department concurs and aligns with the new federal OTP regulatory definitions in 42 CFR § 8.2 regarding the Medical Director and Practitioner. The Medical Director (MD) must be a physician but can delegate specific responsibilities to authorized program physicians, appropriately licensed non-physician practitioners with prescriptive authority functioning under the MD's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP. Such delegations will not eliminate the Medical Director's responsibility for all medical and behavioral health services provided by the OTP.

A Practitioner is a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders, and as a result, is authorized to practice within an OTP.

164.305 (C): Assessment and 164.305 (D): Initial Medical Exam

In accordance with the updated federal OTP regulations 42 CFR § 8.12 (f)(2)(b)(ii), it is the Department's expectation that a "Practitioner," as defined in 42 CFR § 8.2, must see a patient prior to initiating an FDA-approved medication for the treatment of addiction. This replaces the current DPH BSAS regulatory language allowing for a "Qualified Healthcare Professional" as defined in 164.005.

In accordance with the new federal OTP regulations 42 CFR § 8.12 (f)(2), it is the Department's expectation that 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 the 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 as determined to be required by an appropriately licensed practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications.

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 as defined in 42 CFR § 8.2 and 164.005. 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.

A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP.

The full examination 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.

Serology testing and other testing 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.

Resource: Best Practice: Promoting Infectious Disease Testing in MA Opioid Treatment Programs (OTPs)

Initial Screening Conducted by RN or LPN (SAMHSA Clarification)

BSAS recently requested clarification from SAMHSA regarding whether the regulations allow trained licensed Registered Nurses (RNs) or Licensed Practical Nurses (LPNs) operating under the supervision of the OTP medical director to conduct the admission screening portion of the examination during the weekend, overnight shifts, or during an emergency when a practitioner is not physically available, and when OTP services are provided in an OTP licensed Mobile Unit or Medication Unit.

SAMHSA clarified that licensed nurses who have patient assessment within their scope of practice, and authority as established by the state board of nursing, may conduct the information gathering and assessment portion of the initial screening examinations required by 42 CFR 8.12(f)(2)(i)(A) and relay information to practitioners for decision-making. Because the practitioner reviews the information, makes the admission determination, and orders the methadone or buprenorphine medication, this workflow satisfies the requirement that the examination be "completed by" a practitioner. The trained and licensed RN or LPN transmits screening exam information to the OTP practitioner consistent with applicable privacy laws. The practitioner must clearly document their review of and involvement in completing each screening examination in the patients' records.

In accordance with regulations and guidance from the Massachusetts Board of Registration in Nursing (BORN), RNs may conduct systematic assessments, which include gathering information concerning the patient's individual physiological, psychological, sociological, and spiritual needs. Part of the assessment includes data collection by obtaining vital signs such as temperature, respiratory rate, heart rate, blood pressure, and pain level using an age or condition appropriate pain scale. The assessment identifies current and future care needs of the patient by allowing the formation of a nursing diagnosis. The nurse recognizes normal and abnormal patient physiology and helps prioritize interventions and care.

Licensed Practical Nurses (LPNs) may conduct a basic health assessment by collecting and performing focused assessments, which may include collection of vital signs such as temperature, respiratory rate, heart rate, blood pressure, and pain level. LPNs must be competent to perform the focused assessments associated with the initial screening, taking into consideration the complexity, urgency, and acuity of the patient's presentation. It is not within an LPN's scope of practice to complete a systemic assessment that formulates a plan of care;

however, an RN may review an LPN's assessment data to determine the patient's nursing care needs and develop the plan of care.

Under no circumstances should an RN or LPN make admission or treatment decisions outside the scope of their practice. A practitioner reviewing assessments conducted by RNs and/or LPNs must clearly document their review of and involvement in completing each initial screening exam in the patient's record.

For more information about LPN/RN scope of practice, please see the Massachusetts Board of Registration in Nursing Advisory Ruling on Nursing Practice 25-01 "Registered Nurse and Licensed Practical Nurse Scope of Practice." Additional resources are available on BORN's website.

Other Assessments

Initial and periodic physical and behavioral health assessment services must be provided in accordance with 42 CFR § 8.12(f) and 105 CMR 164.000.

Each patient must be given a physical and behavioral health assessment within 14 days of admission. The Care Plan (referred to as the "Treatment Plan" in 105 CMR 164.000) created as a result must include psychosocial needs, harm reduction interventions, legal, housing, and other recovery support services. This plan must be updated, reviewed with the patient, and amended as necessary.

164.307(H): Annual Medical Exam

In accordance with the new federal OTP regulation 8.12 (f)(4)(ii), it is the Department's expectation that each patient has an annual medical examination by a Practitioner as defined in 42 CFR § 8.2.

Mid-level Exemption Requirement

The new federal OTP regulations 42 CFR § 8.12 permit Practitioners in addition to Physicians to initiate and make dosing decisions in OTPs. Therefore, Mid-level Exemption (MLE) applications will no longer need to be submitted to SAMHSA and BSAS. SAMHSA and BSAS stopped accepting new MLEs in the Extranet starting April 2, 2024.

Medication and Dosing

In accordance with 42 CFR § 8.12(h)(3)(ii), the initial dose of methadone should be individually determined, and the total dose for the first day should not exceed 50mg (up from 40mg in previous regulations) unless the OTP practitioner finds sufficient medical rationale (e.g., transfer of a patient from another OTP, dose did not alleviate withdrawal symptoms). This decision must be made by the OTP practitioner, and their assessment and justification must be clearly documented in the patient record.

Telehealth

Federal OTP regulations 42 CFR § 8.12 allow for the screening examination to be completed via telehealth for patients admitted for treatment at the OTP with either buprenorphine or methadone, if

the practitioner or primary care provider determines that an adequate evaluation of the patient can be accomplished via telehealth. A screening examination ensures that the patient meets the criteria for admission and there are no contraindications to treatment with medications for opioid use disorder. The use of audio-visual telehealth may only be used for the screening exam to treat with methadone. Thus, a patient may undergo a screening exam via audio-visual telehealth prior to initiating treatment with methadone to assess the patient's appropriateness for methadone. The full physical exam must be performed in person to treat a patient with methadone. To treat with buprenorphine, the screening and full exam may be conducted using audio-visual or audio-only platforms.

The Department adopts the Telehealth option for completing the screening exam in 105 CMR 164.000. It is the Department's expectation that programs will develop Telehealth policies and protocols, provide appropriate training to staff, and abide by all relevant privacy laws in implementing this feature of the new regulations.

Telehealth for Full Examinations (SAMHSA Clarification)

SAMHSA recently clarified with DPH that, in accordance with 42 CFR § 8.12(f)(2)(iii-v), the full examination may be completed via telehealth prior to treatment with methadone. Such an examination must utilize audio-visual telehealth platforms, 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.[1] The full examination can be conducted via telehealth if the OTP practitioner or primary care provider determines and documents that an adequate evaluation that would provide a comprehensive assessment of potential physical health impacts of a patient's opioid use disorder can be accomplished this way. It is best practice to ensure that appropriate technology is used for these services and meets the requirements for HIPAA, 42 CFR Part 2, and the medical board telehealth practices.

Take-Home Medication

The Department adopts the new federal OTP regulations and guidance regarding take-home medication in accordance with 42 CFR § 8.12(i). Additionally, it is the Department's expectation that licensed or approved OTPs will assess each patient's eligibility for take-home medication upon admission and monthly throughout the duration of treatment. Program policies must include a take-home eligibility assessment for each patient to occur at a minimum monthly, and at a mutually convenient time for the patient and the program. The assessment and outcome must be documented including the rationale for not providing take-homes or an increase in the number of take-homes. Documentation in the patient record should include the individualized education guidance and support that was given to the patient to be eligible for initial or increases in take-homes.

Special Services for Pregnant Patients

In accordance with 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. Evidence-based treatment protocols for pregnant

[1] 42 CFR § 8.12(f)(2)(v)(A-B).

patients, 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.

Consent to Treatment

Written consent to treatment requirements are now updated: consent may be provided verbally or electronically and documented as such. The Department supports this provision of the updated federal OTP regulations, and it is the Department's expectation that programs include this in their Consent to Treatment policies and protocols. The program shall ensure that there are clear procedures in place to educate patients about their consent options and for program staff to clearly record when consent is given.

Interim Treatment

In accordance with 42 CFR § 8.12(j), OTPs may provide interim treatment, and the maximum time for interim treatment has increased from 120 days to 180 days.
All comprehensive treatment requirements apply, except that

- A primary counselor is not required, but crisis services, including shelter support, must be available;
- Interim treatment cannot be provided for more than 180 days in any 12 -month period;
- By day 120, a plan for continuing treatment beyond 180 days must be created; and
- Formal counseling, vocational training, employment, economic, legal education, and other recovery support services not required, but information pertaining to locally available community-based resources should be made available to the patient.

Treatment Plans/Care Plans

Treatment Plans are referred to as "Care Plans" within the Final Rule and the use of "shared decision-making" is incorporated. In accordance with 42 CFR § 8.12(f) and aligning with the Department's vision of individualized treatment, the Department supports the requirement that OTPs provide adequate medical, counseling, vocational, educational, other screening, assessment, and treatment services to meet patient needs, with the combination and frequency of services tailored to each 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.

It is the Department's expectation that programs will integrate the new language into their daily practice and policies. OTPs must offer counseling services, however, the frequency and extent should be individualized based on the patient's needs and ability to engage in counseling. Patients should not be discharged from treatment for not attending counseling.

Part Two Waivers:

In order to align with the new federal OTP regulations, The Department is issuing the following blanket waivers pursuant to 105 CMR 164.023 in the event that: (1) the provider is in substantial compliance with the spirit of the requirement and has instituted compensating features that are acceptable to the Department; (2) that the program's non-compliance does not jeopardize the health or safety of its clients; and (3) it does not limit the program's capacity to provide the services for which it is licensed.

The following waivers are in effect until rescinded by the Department. No further action or requests for approvals are required by programs to implement these waivers at this time.

Definitions

The Department is waiving the following definitions under 105 CMR 164.005 and replacing these terms with the 42 CFR § Part 8.2 definitions.

105 CMR 164.005 Medical Director:

A physician licensed to practice medicine in the Commonwealth of Massachusetts, with specialized training in addiction medicine, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and qualified healthcare professionals functioning under the medical director's direct supervision.

42 CFR § Part 8.2 Medical Director:

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.

105 CMR 164.005 Practitioner:

A Physician, Physician Assistant, or Advanced Practice Registered Nurse as those terms are defined in 105 CMR 164.005, acting within the applicable scope of service and pursuant to state and federal law.

42 CFR § Part 8.2 Practitioner:

A health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.

The Department is waiving the following regulations under 105 CMR 164.300.

164.305 (B)(1)

The Department issues a blanket waiver from the requirement that, prior to admitting a patient into treatment, the Licensed or Approved Provider must determine that the patient has a current physiologic dependence on opioids for at least a 12-month duration. It is the expectation of the Department that patient admission criteria align with 42 CFR § 8.12(e)(1). Specifically, prior to admission, the person meets the diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or an OUD in remission, or is at high risk for recurrence or overdose.

Providers shall revise any admission policies and update program admission criteria, as well as ensure appropriate documentation in the patient record. Program staff shall be trained on the new policies.

164.305 (D)(4)

The Department issues a blanket waiver from the requirement that the Medical Director review any relevant laboratory findings. It is the Department's expectation that any relevant laboratory findings shall be reviewed with the patient by a program practitioner or physician as defined in 42 CFR § 8.2. A practitioner is defined as a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.

The patient record shall include documentation of this review, the laboratory findings, and evidence of direct referrals made to address findings. The Licensed or Approved Provider shall ensure that such laboratory tests are completed by licensed facilities that comply with all applicable federal and state laboratory licensure and certification requirements.

164.305 (E)(1)

The Department is issuing a blanket waiver from the requirement that only the Medical Director shall ensure all dosing of an opioid agonist treatment medication is ordered. It is the expectation of the Department that the Medical Director is responsible for overall medical oversight of the OTP, however, a program practitioner or physician as defined in 42 CFR § 8.2 may ensure that all dosing of an opioid agonist treatment medication is ordered in accordance with federal requirements.

Additional Opioid Treatment Provider Requirements: Medically Supervised Withdrawal

164.306 (A)(4)

The Department is issuing a blanket waiver from the prohibition on admission of patients with two or more unsuccessful episodes of supervised withdrawal within a 12 -month period to opioid medically supervised withdrawal management treatment. This aligns with the new 42 CFR § 8.12(e)(3). Accordingly, providers shall determine if admission is clinically appropriate and document the information in the patient record.

164.306 (A)(5)

In accordance with 42 CFR § Part 8.12, the Department is issuing a blanket waiver from the requirement that a waiting period of at least one week is required between withdrawal attempts. Providers shall utilize clinical judgment in collaboration with the patient when making decisions about supervised withdrawal, and the basis for the determination should be documented in the patient record.

164.306 (B)(1)

The Department is issuing a blanket waiver from the requirement that a program physician determine for each patient the rate at which the opioid drug is to be decreased.

It is the Department's expectation that a program physician or practitioner determine for each patient the rate at which is to be decreased.

164.306 (B)(2)

The Department is issuing a blanket waiver from the requirement that if the withdrawal management period exceeds 30 calendar days, the Licensed or Approved Provider shall obtain at least one drug screen per month for the duration of medically supervised withdrawal treatment. In accordance with 42 CFR § Part 8.12(f)(6) it is the Department's expectation that a program physician or practitioner determine for each patient in medically supervised withdrawal the frequency of drug screens based on clinical discretion as long as the minimum number of random drug screens is met.

164.306 (B)(4)

The Department is issuing a blanket waiver from the requirement that the Licensed or Approved Provider shall dispense opioid agonist treatment medications to the patient daily at the facility under the direct supervision of a physician or other qualified medical person. The Department aligns with the new federal OTP regulations regarding take-homes at 42 CFR § 8.12(i).

Additionally, it is the Department's expectation that licensed or approved OTPs will assess each patient's eligibility for take-home medication upon admission and monthly throughout the duration of treatment. The Department also expects that the rationale underlying the decision to provide take-home doses to be documented in the patient's clinical record, as required by 42 CFR § 8.12(i).

164.306 (B)(5)

The Department is issuing a blanket waiver from the requirement that the Licensed or Approved Provider shall not provide take-home medication for withdrawal management. The Department aligns with the new federal OTP regulations regarding take-homes at 42 CFR § 8.12(i). Additionally, it is the Department's expectation that licensed or approved OTPs will assess each patient's eligibility for take-home medication upon admission and monthly throughout the duration of treatment.

Additional Service Requirements for Opioid Maintenance

164.307 (A)

The Department issues a blanket waiver from the requirement that patients under 18 have two documented unsuccessful attempts at short-term withdrawal or drug-free treatment within a 12-month period before getting care at an OTP, as provided in the new 42 CFR § 8.12(e)(2). Providers shall revise any admission policies and update program admission criteria, as well as ensure appropriate documentation in the patient record. Program staff shall be trained on the new policies.

164.307 (C)

The Department is issuing a blanket waiver from the requirement that the Medical Director may reduce the number of times patients must present themselves for observed ingestion of medication by providing take-home doses. It is the Department's expectation that the program physician or practitioner may reduce and determine the number of times patients may present themselves daily for observed ingestion of medication by providing take-home doses.

Additionally, it is the Department's expectation that licensed or approved OTPs will assess each patient's eligibility for take-home medication upon admission and monthly throughout the duration of treatment.

164.307 (C)(5): Take-home Doses Locked Container

The Department is issuing a blanket waiver from the requirement under 105 CMR 164.307(C)(5) that take-home doses be dispensed to patients in locked containers. It is the Department's expectation that OTPs must maintain current procedures adequate to mitigate the theft or diversion of take-home medications, including labeling bottles or containers with the OTP's name, address, and telephone number. Programs 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.).

Requirements under 105 CMR 164. 307(C)(6) remain in place for programs to provide each patient with education on safely transporting medication from the OTP to their place of residence and include the safe storage of take-home medication 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.

Additionally, under 105 CMR 164.310, OTPs are required to maintain a current "Diversion Control Plan" or "DCP" as part of their quality assurance program. The DCP contains specific measures to reduce the possibility of diversion of dispensed medication for opioid use disorder and assigns specific responsibility to the OTP Medical Director for carrying out the diversion control measures and functions listed in the plan.

OTPs are not prohibited from utilizing locked containers for take-home doses, provided that such use does not inhibit access to receiving take-home doses. The Department recommends that the determination regarding whether a locked container is utilized should be made in collaboration with the patient, maximize safety and minimize disruption in receiving take-homes, and should be individualized. If an OTP determines that the use of locked containers is an appropriate practice,

the OTP must have policies that describe the use, including the circumstances in which use of locked containers is indicated and expectations of patients regarding their use. Evidence of patient education and orientation to the program's locked container policy shall be included in the patient record.

OTPs that provide patient-specific doses to Correctional Facilities and Skilled/Long Term Care Facilities must comply with applicable Federal and State regulations regarding locked container requirements. Please see the DEA Narcotic Treatment Manual (2022) Section 12.2 regarding locked container requirements when correctional facility or skilled nursing facility staff take custody of patient-specific medications.

164.310 (A): Diversion Control - Random Callbacks

The Department is issuing a blanket waiver from the requirement under 105 CMR 164.310 (A) that OTPs must include Random Callbacks as part of its Diversion Control Plan. It is the Department's expectation that OTPs must maintain current procedures adequate to mitigate diversion of take-home medications. Requirements under 105 CMR 164.310 (B-E) remain in place for programs to maintain a Diversion Control Plan in alignment with 42 CFR § 8.12(c)(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.

BSAS aligns with the following recommendations from SAMHSA's Federal Guidelines for Opioid Treatment Programs Fall 2024 (See Pg. 85) and "***strongly encourages OTPs to consider the disruptive nature of random callbacks for patients, as callbacks may require patients to secure unplanned transportation and childcare and can affect employment, causing patients to not respond as expected. SAMHSA therefore recommends that callbacks, if done, be considered only when clinically indicated and as part of a broader assessment to clarify concerns around clinical stability. SAMHSA also recommends implementing any callbacks in a manner that supports patient safety, reduces interference in the patient's life, and does not discourage engagement with treatment or willingness to continue medication. If OTPs do callbacks, they may consider virtual callbacks. OTPs and practitioners considering callbacks may identify clinical rationale for when callbacks are appropriate".***

It is the Department's expectation that policies should be updated to include how random callbacks are utilized should the program continue to use them. In addition, program staff should receive training on a person-centered approach towards random callbacks based on the program policy,

For any questions, please contact:

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