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NJ Association for the Treatment of Opioid Dependence

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April 1, 2024

Sent via Email
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Dear Commissioner Baston and DOH/DHS Constituents:

I am writing on behalf of the New Jersey Association for the Treatment of Opioid Dependence (NJATOD), which represents 43 Opioid Treatment Programs (OTPs) in New Jersey. I am writing in response to the revised regulations under Part 8 of Title 42 of the Code of Federal Regulations (CFR) which includes the regulations that guide opioid treatment programs (OTPs). The final rule is effective April 2, 2024, and the compliance date is October 2, 2024, which allows a short period of time for OTPs to prepare and for states to review their regulations that impact how this rule is implemented.

We are providing supporting information in the attached report, describing the federal regulatory changes with the corresponding state regulation and impact that these changes will have on opioid treatment programs. Additionally, we are providing recommendations to support

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the smooth implementation of these changes. While the final rule provides more nuanced decision making in the OTP environment, it is critical that there be increased alignment of policymaking between SAMHSA/DEA and state regulatory authorities, which govern OTPs in New Jersey. This is a critical matter and one that will need greater coordination at all levels of federal and state government relations. In addition, there need to be revisions with the New Jersey Medicaid authorities and how OTP services are reimbursed given the flexibilities that have been provided. In other words, the only way that these rules will be effectively promulgated is if state authorities are better aligned with federal agencies and if third party reimbursors are also better aligned with the provisions of the final rule.

The reason we are writing with urgency is due to the fact that these changes will have significant positive impacts on OTPs and the patients we serve. NJATOD's guiding principles rely on the collaborative work with State and Local Authorities concerning opioid treatment policies, standards, and regulations to ensure the viability of a best-practice, evidenced-based opioid treatment system within the State of New Jersey.

We respectfully request either blanket waivers for regulations under Chapter 161B – Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities or the issuance of a joint memo from the Department of Health, Certificate of Need & Licensing-Behavioral Health and the Department of Human Services, Division of Mental Health and Addiction Services that authorizes New Jersey's concurrence with the 42 CFR Part 8 Final Rule for Opioid Treatment Programs (OTPs).

We strongly support and advocate for the state's recognition and immediate response for arriving to both short- and long-term solutions that will align with OTP 42 CFR Part 8 Final Rule which promotes practitioner autonomy, supports a patient-centered approach, reduces barriers to receiving care and improves quality outcomes for our patients rather than work against them. Additionally, we request an opportunity for stakeholder input concerning policies that directly impact our member providers and the patients we treat.

Thank you for your consideration and immediate response to this urgent matter.

Sincerely,

Maiysha Ware

Maiysha Ware
President, NJATOD

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Brief summary of why the waiver is needed.

1. Background. As of February 2024, there are 63 SAMHSA-certified OTPs in New Jersey[1], providing care to over 70,000 patients (43 of these sites are licensed in NJ as an ambulatory OTP). These are the only settings within which methadone, a schedule II opioid receptor agonist, can be legally provided to patients with OUD outside the context of hospital admission or certain other special circumstances.

2. The final rule draws on experience from the COVID-19 Public Health Emergency (PHE), as well as more than 20 years of practice-based research. The COVID-19 PHE necessitated changes to policy guidance and legal exemptions to protect the public's health, promote physical distancing and to preserve patient and OTP staff safety.[2]

3. This final rule not only makes these COVID-19-related flexibilities permanent, but also updates standards to reflect an accreditation and treatment environment that has evolved since part 8 went into effect in 2001. Accordingly, the Department is updating part 8 to promote practitioner autonomy; remove discriminatory or outdated language; create a patient-centered perspective; and reduce barriers to receiving care. These elements have been identified in the literature and in feedback as being essential to promoting effective treatment in OTPs.[3] [4] [5]

4. To this end, the definition of a practitioner has been modified to refer to a provider who is appropriately licensed by the State to prescribe (including dispense) medications. Admission criteria have been updated, as required by section 1252(b) of the 'Consolidated appropriations Act, 2023', to remove significant barriers to entry, such as the one-year

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[1] Data from the U.S. Department of Health and Human Services, Treatment Locator, at https://findtreatment.gov/

[2] *See* https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf and https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.

[3] Suen LW, Coe WH, Wyatt JP, Adams ZM, Gandhi M, Batchelor HM, Castellanos S, Joshi N, Satterwhite S, Pérez-Rodríguez R, Rodríguez-Guerra E, Albizu-Garcia CE, Knight KR, Jordan A. Structural Adaptations to Methadone Maintenance Treatment and Take-Home Dosing for Opioid Use Disorder in the Era of COVID-19. Am J Public Health. 2022 Apr;112(S2):S112-S116. doi: 10.2105/AJPH.2021.306654. PMID: 35349324; PMCID: PMC8965183.

[4] Kleinman MB, Felton JW, Johnson A, Magidson JF. "I have to be around people that are doing what I'm doing": The importance of expanding the peer recovery coach role in treatment of opioid use disorder in the face of COVID-19 health disparities. J Subst Abuse Treat. 2021 Mar;122:108182. doi: 10.1016/j.jsat.2020.108182. Epub 2020 Oct 21. PMID: 33160763; PMCID: PMC7577312.

[5] Suen LW, Castellanos S, Joshi N, Satterwhite S, Knight KR. "The idea is to help people achieve greater success and liberty": A qualitative study of expanded methadone take-home access in opioid use disorder treatment. Subst Abus. 2022;43(1):1143-1150. doi: 10.1080/08897077.2022.2060438. PMID: 35499469.

requirement for opioid use disorder (OUD),[6] while also defining the scope and purpose of the 'initial' and 'periodic' medical examinations. The final rule also includes new definitions to expand access to evidence-based practices such as split dosing, telehealth and harm reduction activities.

5. The Department promotes practitioner autonomy and individualized care by finalizing the provision containing the criteria for unsupervised doses of methadone. This includes removal from sole consideration the length of time an individual has been in treatment and requirements for rigid reliance on toxicology testing results that demonstrate complete and sustained abstinence from all substances prone to misuse. Based on the clinical judgment of the treating provider, patients may be eligible for unsupervised, take-home doses of methadone upon entry into treatment. This change recognizes the importance of the practitioner-patient relationship and is consistent with modern substance use disorder treatment standards.[7] It also allows for greater flexibility in creating plans of care that promote recovery activities such as employment or education, while also eliminating the barrier of frequent OTP visits for individuals without access to reliable transportation.[8]

6. While the COVID-19 public health emergency expired as of May 11, 2023, the lessons learned from the COVID-19 pandemic remain relevant for ensuring access to safe and effective substance use disorder treatment. The changes created by this final rule are expansive but are focused on permanently implementing the existing flexibilities and updating policies and practices that are based on evidence. In this way, SAMHSA believes that much of what is contained in the rule will not represent a significant burden for OTPs and, in fact, will reduce burdens and confer many benefits to providers and patients. The final rule, therefore, supports OTPs in their ongoing provision of equitable and evidence-based care to often marginalized patients with OUD. The final rule also is consistent with the HHS Overdose Prevention Strategy and the National Drug Control Strategy, both of which call for

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[6] *See* 42 CFR 8.12(e)(1).

[7] Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63 Publication No. PEP21-02-01-002. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2021.

[8] Ware OD, Frey JJ, Cloeren M, Mosby A, Imboden R, Bazell AT, Huffman M, Hochheimer M, Greenblatt AD, Sherman SA. Examining Employment and Employment Barriers Among a Sample of Patients in Medication-Assisted Treatment in the United States, Addictive Disorders & Their Treatment: December 2021 - Volume 20 - Issue 4 - p 578-586 doi: 10.1097/ADT.0000000000000295.

increasing access to and the uptake of evidence-based treatments for substance use disorders.[9]

7. Regulatory Background – On January 17, 2001 (66 FR 4075), the Department issued final regulations which shifted administrative responsibility and oversight from the FDA to SAMHSA. This rulemaking initiative followed a 1995 study, 'Federal Regulation of Methadone Treatment'[10] by the Institute of Medicine (IOM, now known as the National Academy of Medicine) and reflected recommendations by the IOM and several other entities to improve the treatment of OUD by allowing for increased medical judgment in the care of patients with OUD. The IOM report recommended that the FDA process-oriented regulations should be reduced in scope to allow more clinical judgment in treatment and greater reliance on guidelines. The IOM report also recommended designing a single inspection format, having multiple elements, that would (1) provide for consolidated, comprehensive inspections conducted by one agency (under a delegation of Federal authority, if necessary), which serves all agencies (Federal, State, local) and (2) improve the efficiency of the provision of methadone services by reducing the number of inspections and consolidating their purposes.

    a. To address these recommendations, SAMHSA proposed a "certification" system based on accreditation. Under the system, an applicant organization who intended to dispense opioid agonist medications in the treatment of OUD must first obtain from SAMHSA, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification depended upon the applicant organization obtaining accreditation from a private nonprofit entity, or from a State agency, which had been approved by SAMHSA to accredit OTPs.

    b. Accreditation Requirements: Accreditation Bodies were directed to base accreditation decisions on a review of an application for accreditation and on surveys (onsite inspections) conducted every three years by OUD treatment experts. In addition, Accreditation Bodies must apply specific opioid treatment accreditation elements that reflect "state-of-the-art" opioid treatment guidelines. Further to this, accreditation standards required that OTPs have quality assurance systems that consider patient outcomes.

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[9] *See* https://www.hhs.gov/overdose-prevention/. *See also* https://www.whitehouse.gov/briefing-room/statementsreleases/
2022/04/21/fact-sheet-white-house-releases-2022-national-drug-control-strategy-that-outlinescomprehensive-path-forward-to-address-addiction-and-the-overdose-epidemic/

[10] For full text, see: https://www.ncbi.nlm.nih.gov/books/NBK232108/

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Additional Blanket Waiver Flexibility Requested. In addition to the OTP Take Home Guidance Memo announced by Division of Mental Health and Addiction Services (DMHAS) and the Division of Certificate of Need and Licensing–Behavioral Health (CN&LBH) dated May 12, 2023, New Jersey's OTPs are requesting the following blanket waivers: *(NOTE: Take-home Guidelines and Mobile Unit changes are not included in this document as they have already been addressed by NJ waivers and/or regulations. However, request to make permanent to align with §8.12(i)(1)-(4) Unsupervised or "take-home" medication doses[11] and §8.11(h)(1)-(3) Medication units, long-term care facilities and hospitals[12])*

Request for Immediate Blanket Waiver – Effective 4/2/2024. Request immediate blanket waivers for items #1 – 6 below that authorizes New Jersey's concurrence with the following 42 CFR Part 8 Final Rule for Opioid Treatment Programs (OTPs).

1. **Admission criteria.**

   The final rule eliminates the 1-year opioid addiction history requirement and promotes priority treatment for pregnant individuals. Patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: the person 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. Such decisions must be appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.[13]

   It also removes the requirement for two documented instances of unsuccessful treatment for people under age 18.[14]

   Allows consent to be obtained electronically. In addition, medication access is no longer contingent on receipt of counseling. This has been a significant barrier.

   REQUEST FOR WAIVER:

[11] https://www.federalregister.gov/d/2024-01693/p-509
[12] https://www.federalregister.gov/d/2024-01693/p-467
[13] https://www.federalregister.gov/d/2024-01693/p-478
[14] https://www.federalregister.gov/d/2024-01693/p-479

- **§10:161B-6.3 - Standards for preadmission, admission, and retention of clients**
- **§Section 10:161B-11.5 - Minimum standards for admission to an opioid treatment program**

2. **Acknowledging the Skill and Understanding of Practitioners**

   The final rule expands the definition of practitioners to include a health care professional who is appropriately licensed by a State to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner.[15] [16]

   Further, the rule does not specify that a director of nursing or RN must be "on-site" whenever medications are being administered. The final rule also pointed out that not all states allow for the expanded definition of practitioners. It includes specific language where NPs and PAs are defined as practitioners able to order and manage methadone.[17] [18]

   Medical Director still must be a physician (MD/DO), however the final rule does not require ASAM certification.[19] [20]

   REQUEST FOR WAIVER:

   - **§10:161B-1.4 - Qualifications and responsibilities of the medical director**
   - **§10:161B-1.6 - Qualifications of pharmacists**
   - **§10:161B-7.2 - Designation of medical director**
   - **§10:161B-8.1.(a).2 - Provision of nursing services**
   - **§10:161B-11.2 – Staffing**
   - **§10:161B-18.4 - Requirements for clinical record entries**

3. **OTPs Increasing the Initial Dose of Methadone**

   In recognition of the fact that most of the patients being admitted to OTPs are using fentanyl, the final regulations make an important change. "The regulation of an initial dose of methadone has been increased to 50 milligrams on first day, with the clarification

[15] https://www.federalregister.gov/d/2024-01693/p-339
[16] https://www.federalregister.gov/d/2024-01693/p-500
[17] https://www.federalregister.gov/d/2024-01693/p-489
[18] https://www.federalregister.gov/d/2024-01693/p-490
[19] https://www.federalregister.gov/d/2024-01693/p-329
[20] https://www.federalregister.gov/d/2024-01693/p-474

left of allowance for higher doses if clinically indicated and documented in the person's record."[21] As OTP practitioners know, the maximum initial dosage of 30 milligrams on the first day of medication has been in place for many years. While there have always been opportunities for clinical judgment to increase the initial dose as needed by the patient, the final rule provides greater clarity.

Once again, it is important for admitting personnel to carefully document in the patient's medical record the need for a more rapid increase of methadone maintenance dosage during the initial stabilization period. This must be balanced against objective findings in toxicology reports in addition to observations in dispensing by the OTP personnel.

This new final rulemaking is intended to more rapidly engage the patient to achieve stability at the earliest possible opportunity, also keeping in mind the ultimate safety of individual patients.

REQUEST FOR WAIVER:

- **§10:161B-7.1 - Provision of medical services**

4. **Physical Exams and Admission**

The final rule allows patients to begin treatment with MOUD after the screening examination has been completed.[22] [23] [24] [25]

Examination may be completed by practitioners external to the OTP and accepts examination results of non-OTP practitioners, if the exam is verified by an OTP practitioner (e.g., MD, NP, or PA). Completion of physical and behavioral health assessment is required within 14 calendar days following admission and periodically thereafter.[26] [27] [28]

Allows the full assessment to be completed via telehealth.[29]

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[21] https://www.federalregister.gov/d/2024-01693/p-507
[22] https://www.federalregister.gov/d/2024-01693/p-478
[23] https://www.federalregister.gov/d/2024-01693/p-482
[24] https://www.federalregister.gov/d/2024-01693/p-483
[25] https://www.federalregister.gov/d/2024-01693/p-485
[26] https://www.federalregister.gov/d/2024-01693/p-486
[27] https://www.federalregister.gov/d/2024-01693/p-492
[28] https://www.federalregister.gov/d/2024-01693/p-493
[29] https://www.federalregister.gov/d/2024-01693/p-488

Serology testing and other testing as 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.[30]

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 potential to negatively impact treatment with medications.

REQUEST FOR WAIVER:

- **§10:161B-7.1.(a).4. - Provision of medical services**
- **§10:161B-9.1 - Provision of nursing services**
- **§10:161B-9.2 - Client treatment planning**
- **§10:161B-11.6. - Admissions and assessment**
- **§10:161B-10.4 - Co-occurring services**
- **§10:161B-11.7 - Medical assessments**
- **§10:161B-18.3.(a).5. - Contents of clinical records**

5. **Removing the prior requirement of minors having two documented unsuccessful attempts at short term withdrawal management or drug free treatment within a 12-month period before entering an OTP.**

   This has been a long-standing barrier in admitting minors into OTPs especially with the use of methadone maintenance treatment.

   The final rule removes the requirement, previously at 8.12(e)(2), that minors are required to have had two documented unsuccessful attempts at short-term "detoxification", or withdrawal management, or drug-free treatment within a 12-month period to be eligible for maintenance treatment, and that those seeking withdrawal management, previously under 8.12(e)(4), cannot initiate methadone treatment more than twice per year.[31] Instead, OTPs shall ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: the person meets diagnostic criteria for

[30] https://www.federalregister.gov/d/2024-01693/p-487
[31] https://www.federalregister.gov/d/2024-01693/p-479

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.[32]

The issue here is that OTP admitting personnel need to exercise good clinical judgment in determining if such an individual (minor) meets the criteria to be admitted to an OTP. It is important for OTPs to understand that they could be adapting their services to accommodate a younger population.

6. **Initiation of Buprenorphine and Methadone Induction Through Telehealth Allows for Audio only for Buprenorphine and Audio-Visual for Methadone**

The final rule responds to our concerns stated over the course of the past several years, through the beginning of COVID-19 and its impact on the patients we treat.

SAMHSA believes that evidence underlying the initiation of buprenorphine using telehealth also is applicable to the treatment of OUD with methadone, and warrants expanding access to methadone therapy by applying some of the buprenorphine in person examination flexibilities to treatment with methadone in OTPs. [33]

However, SAMHSA also acknowledges that there are differences between these two medications.

Accordingly, this final rule allows for the use of audio-visual telehealth for any new patient who will be treated by the OTP with methadone if a program physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via audio or audio-visual platform. [34]

The striking issue here is that the only way that a methadone-maintained patient can be inducted with methadone through an OTP will be through an audio-visual experience. Once again, SAMHSA will provide training webinars with references to how OTPs may interpret this audio-visual related methadone induction particularly when significant barriers exist for in person or audiovisual induction.

REQUEST FOR WAIVER:

[32] https://www.federalregister.gov/d/2024-01693/p-478
[33] https://www.federalregister.gov/d/2024-01693/p-490
[34] https://www.federalregister.gov/d/2024-01693/p-489

- **§10:161B-11.6 - Admissions and assessment**

Request for Future Blanket Waiver or Amendment to Regulations – Effective no later than 10/2/2024. Request for future blanket waivers or amendment to regulations for items #7 - 10 below that authorizes New Jersey's concurrence with the following 42 CFR Part 8 Final Rule for Opioid Treatment Programs (OTPs).

7. **Expanding Access to MOUD through Mobile Units and Medication Units**

   Certified OTPs may establish medication units that are authorized to dispense MOUD.[35] A Medication units is defined as 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.[36] Medication units can be a brick-and-mortar location or mobile unit.

   - **§10:161B-2.3 - Application requirements**
   - **§10:161B-2.4 - Newly constructed, renovated, expanded or relocated facilities**

8. **Promoting Cultural Shifts in Care and Service Deliver – Fostering trust and recovery in a Patient-centered environment**

   Administrative and organizational structure

   An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth under the rule[37].

   - **§10:161B-11.2 – Staffing**
   - **§10:161B-18.2 - Assignment of responsibility**

[35] https://www.federalregister.gov/d/2024-01693/p-467
[36] https://www.federalregister.gov/d/2024-01693/p-468
[37] https://www.federalregister.gov/d/2024-01693/p-473

Incorporates harm reduction and recovery principles.

Revises the language for drug testing from identifying misuse to a strengths-based approach, such as "allowing for extenuating circumstances."[38]

Allows for distribution of supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose. [39]

Incorporates overdose education and distribution of opioid overdose reversal medications.

- **§10:161B-11.4.(a).2. – Drug Screening procedures**
- **§10:161B-11.4.(a).4.iv. – Referral and discharge**
- **§10:161B-11.9 - Drug screening**
- **§10:161B-17.1 - Discharge/continuum of care planning**
- **§10:161B-17.3 - Client and family education**

9. **Changes to Certification and Accreditation Content.**

The final rule extends the time allotted for corrective action to 180 days (following receipt of the survey report) and distinguishes between "minor" and "significant" non-compliance.

The rule introduces a three-year accreditation for OTPs that are required to correct minor non-compliant conditions and one-year accreditation for those required to correct significant non-compliant conditions. Corrections must be made within one year and adds rules detailing procedures for severe non-compliance.[40]

- **§10:161B-11.1 – Authority**
- **§10:161B-2.8 - Periodic surveys following licensure**

10. **Counseling and psychoeducational services.**

The final rule removes participation in counseling as a contingency for medication access.[41] [42] Counseling must be offered but is not required. Engagement, Patient Care

[38] https://www.federalregister.gov/d/2024-01693/p-497
[39] https://www.federalregister.gov/d/2024-01693/p-497
[40] https://www.federalregister.gov/d/2024-01693/p-433
[41] https://www.federalregister.gov/d/2024-01693/p-494
[42] https://www.federalregister.gov/d/2024-01693/p-495

Plan (not Treatment Plan) and recovery person-centered approaches to recovery will drive counseling needs and wants of the patient. [43] [44] Understanding that this impacts the NJ Phase System, caseload/staffing ratios and billing, this area will need greater discussion.

REQUEST FOR WAIVER:

- **§10:161B-3.1 - Provision of services**
- **§10:161B-9.2 - Client treatment planning**
- **§10:161B-10.1 - Provision of substance abuse counseling**
- **§10:161B-11.3 - Multidisciplinary team**
- **§10:161B-11.8 - Counseling services**
- **§10:161B-18.3.(a).6.,9. - Contents of clinical records**

[43] https://www.federalregister.gov/d/2024-01693/p-481
[44] https://www.federalregister.gov/d/2024-01693/p-494