



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Mental Health, Developmental
Disabilities and Substance Use Services

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KODY H. KINSLEY • Secretary
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NC State Opioid Treatment Authority Guidance Document Re: OTP Federal Regulation Updates Effective 4/2/24

In light of recent updates to 42 CFR Part 8 effective April 2, 2024, this document is meant to inform OTP providers about how these changes can be implemented within the state of North Carolina, in accordance with our current statutes.

Admissions

- **Admission Criteria Change** - Patients no longer need to demonstrate 1 year of opioid addiction history prior to admission. No exception is needed to admit these patients.
- **Admissions for Minors** - Patients under 18 years of age no longer need to demonstrate two failed attempts at abstinence-based treatment prior to admission. *Consent in writing is still required by a parent or legal guardian.* No exception is needed to admit these patients.
- **Methadone Inductions** - Patients may be screened for the initiation of methadone via audio-visual telehealth.
 - The first dose of methadone is to be provided under direct supervision to ensure patient safety, that the medication is tolerated, and that the patient has connected with other members of the treatment team. This follows an initial screening appointment with the OTP practitioner who orders the medication to be dispensed after having established the nature, diagnosis, and severity of the person's opioid use disorder, any accompanying opioid withdrawal, and any contraindications to starting methadone. Additionally, the practitioner must ensure that the individual properly understands the safety aspects of methadone, including safe transportation and storage of any take-home doses, how the dose will safely be increased, and other precautions the person can take as they start treatment (e.g., having naloxone on hand).
 - Full in-person physical exam, including the results of serology and other tests that are considered to be clinically appropriate must be completed within 14 calendar days.
- **Initial Dose** - The first day's dose of methadone may be up to 50mg at the discretion of the medical provider. No exception is needed.

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

CSAT Exception/Exemptions No Longer Needed

- **Split Dosing** - Medical justification in line with clinical standards of practice for split dosing must be documented in the patient chart. There is not a need to complete an exception request for the take home doses needed to accommodate split dosing unless the amount of doses is more than would be allowed based on time in treatment.
- **Chain of Custody** - Medical justification for the use of chain of custody to provide a patient with take home medication must be documented in the patient chart. There is not a need to complete an exception request for the chain of custody process. *Chain of Custody is a DEA requirement and should be carefully documented and stored for DEA inspections.*
- **Methadone Metabolite Testing** - Drug tests must have received the FDA marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise impact treatment. There is not a need to complete an exception request if the method of testing cannot show methadone metabolite (EDDP) levels.
- **Advanced Practice Providers** - Physician Assistants and Nurse Practitioners employed with the OTP and under the supervision of the OTP Medical Director may complete program intakes and make take home determinations. There is not a need to complete a Mid-Level Exemption Request.

Medication Decisions are Person Centered

- Medication should not be contingent on patients participating in program requirements such as SAIOP or SACOT.

NC Rule Waiver and Monthly Blanket Exceptions

- Monthly exception requests for take homes will need to continue until our North Carolina rules have been updated to reflect the permanent flexibilities of the federal regulations. NC SOTA will continue to approve these monthly blanket exceptions. Providers should continue to submit individual patient exceptions via the Extranet for take homes that exceed what is written in the program's blanket exception.

**Please direct questions to:
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