



NC Department of Health and Human Services

Overview of 2023 Temporary Waiver

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Overview of the 2023 Licensure Waiver

- 2017: Centers for Medicare and Medicaid Services issued SMD #17-003
 - detailing strategies to address the opioid epidemic
 - pursuant to a Section 1115(a) demonstration waiver
 - to improve access to and quality treatment of Medicaid beneficiaries in an effort to combat the ongoing opioid crisis
 - This offered states the opportunity to demonstrate how to implement best practices for improving treatment for opioid and other substance use disorder in light of unique barriers to each
- 2019: NC Division of Health Benefits received approval of the 1115 SUD Demonstration Waiver

The “Why”

- OTP Clinical Coverage Policy & State Funded Service Definition are set to promulgate on October 15, 2023
- Changing the way that Opioid Treatment Program services are provided and supported within our service delivery system
- Need to update licensure rules accordingly
 - This is a temporary waiver of licensure rule, pending the adoption of emergency or permanent rule.

What the Waiver Accomplishes

- Increased flexibility
 - Examples: telehealth, expanding allowable treatment professionals, take home flexibilities
- Increased access to care
- Promotes more successful outcomes, through implementing best practice approaches
- Includes safeguards intended to ensure that the health safety and welfare of people served during these waivers will not be threatened

Rule: 10A NCAC 27G .3601 SCOPE (a)

Current Rule States:

An outpatient opioid treatment facility provides periodic services designed to offer the individual an opportunity to effect constructive changes in his lifestyle by using methadone or other medications approved for use in opioid treatment in conjunction with the provision of rehabilitation and medical services.

The Why:
Update language to reflect current definitions

Rule Waiver Revises the Language to State:

The Opioid Treatment Program (OTP) is an organized, outpatient treatment service for a patient with an opioid use disorder (OUD). The OTP service utilizes methadone, buprenorphine formulations, naltrexone or other drugs approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorders.

Rule: 10A NCAC 27G .3602 DEFINITIONS (8)

Current Rule States:

Counseling session in Outpatient Opioid Treatment is a **face-to-face** or **group** discussion of issues related to and of progress toward a client's treatment goals that is conducted by a person as specified in Rule .3603, Paragraph (a) of this Section.

The Why:

To improve access to care;
Current rule does not allow telehealth

Rule Waiver Revises the Language to the Following:

Clinical staff must be available, either on-site **or by telehealth**, a minimum five (5) days per week to offer and provide counseling in accordance with the patient's person-centered plan. The patient's choice to participate in telehealth services shall be considered in accordance with the patient's behavioral, physical and cognitive abilities. The patient's verbal or written consent must be documented when telehealth services are provided.

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule Requires:

A minimum of **one certified drug abuse counselor or certified substance abuse counselor to each 50 clients** and increment thereof shall be on the staff of the facility. If the facility falls below this prescribed ratio, and is unable to employ an individual who is certified because of the unavailability of certified persons in the facility's hiring area, then it may employ an uncertified person, provided that this employee meets the certification requirements within a maximum of 26 months from the date of employment.

The Why:

**To broaden available counseling staff;
Current rule only permits CSACs to serve in the role of counselor in the OTP setting**

Rule Waiver Revises this Language to Add:

Program must have a 1.0 FTE Licensed Clinical Addictions Specialist (**LCAS**), or Licensed Clinical Addictions Specialist-Associate (**LCAS-A**) per 50 individuals. Position can be filled by more than one **LCAS** or **LCAS-A** staff member (ratio 1:50).

AND...

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule (continued)

**The Why:
To broaden available
counseling staff and to update
language;
Current rule only permits
CSACs to serve in the role of
counselor in the OTP setting**

Rule Waiver Revises the Language to ALSO Include:

Program must have 1.0 FTE **LCAS, LCAS-A**, Certified Substance Abuse Counselor (**CSAC**), Certified Substance Abuse Counselor Intern (**CSAC-I**) or Certified Alcohol and Drug Counselor (**CADC**), Certified Alcohol and Drug Counselor Intern (**CADC-I**), Licensed Clinical Social Worker (**LCSW**), Licensed Clinical Social Worker - Associate (**LCSWA**), Licensed Clinical Mental Health Counselor (**LCMHC**), Licensed Clinical Mental Health Counselor Associate (**LCMHCA**), Licensed Marriage Family Therapist (**LMFT**), Licensed Marriage Family Therapist Associate (**LMFTA**), Licensed Psychological Associate (**LPA**) or Licensed Psychologist (**LP**) for each additional 50 individuals in the program (ratio 1:50).

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule (continued)

The Why:
Current rule does not define the minimum qualifications of the Medical Director

Rule Waiver Revises the Language to Define:

a. The **Medical Director** shall be licensed as a physician in North Carolina and meet the standards outlined in the Federal Guidelines for Opioid Treatment Programs Refer to:
<https://store.samhsa.gov/product/Federal-Guidelines-for-Opioid-Treatment-Programs/PEP15-FEDGUIDEOTP>;

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule (continued)

The Why:
Current rule does not define the responsibilities of the Medical Director

Rule Waiver Revises the Language to Define

- b. The **medical director** is responsible for ensuring all medical, psychiatric, nursing, pharmacy, toxicology, and other services offered at the OTP are conducted in compliance with federal and state regulations, consistent within appropriate standards of care;
- and
- c. In addition to the above, the **Medical Director** is responsible for supervision of the physician extender and other medical staff.

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule (continued)

The Why:
Current rule does not define the minimum qualifications of the program physician(s) or OTP medical provider(s).

Rule Waiver Revises the Language to Define:

An OTP program physician must be either:

a. An **M.D** or **D.O.** who is actively licensed with the NC Medical Board;

OR

b. a **Physician Assistant (PA)** who is licensed and in good standing with the NC Medical Board and certified and in good standing with the National Commission on Certification of Physician Assistants (NCCPA), with appropriate federal waiver of 42 CFR Part 8.12(h)

OR

c. a **Nurse Practitioner (NP)** who is licensed and in good standing with the NC Board of Nursing (NCBON), with appropriate federal waiver of 42 CFR Part 8.12(h).

AND...

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule (continued)

The Why:
Current rule does not define the minimum qualifications of the program physician(s) or OTP medical provider(s).

Rule Waiver Revises the Language to Define:

...AND

d. Have at least **1 year of experience** in the provision of substance use disorder treatment services **OR be supervised by** the OTP medical director **OR be supervised by** the OTP program physician who holds current certification in addiction medicine by the American Society of Addiction Medicine (ASAM) or the American Board of Preventive Medicine (ABPM), or in addiction psychiatry by the American Board of Psychiatry and Neurology.

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule (continued)

The Why:
Current rule does not define the minimum qualifications of nursing staff in the OTP setting.

Rule Waiver Revises the Language to define:

The **Supervising Registered Nurse (RN)** shall have at a minimum, one year of experience working with adults with a substance use disorder.

The **Supervising RN** must hold active licensure as an RN and be in good standing with the NC Board of Nursing (NCBON).

Additional nurses can be **Licensed Practical Nurses (LPNs)** or **RNs** working within their scope of practice, holding an active licensure and be in good standing with the NCBON.

Rule: 10A NCAC 27G .3603 STAFFING (a)

Current Rule (continued)

**The Why:
Current rule does not
define the minimum
qualifications of the
Program Director**

Rule Waiver Revises the Language to Define:

The **Program Director** must have minimum of a bachelor's degree in a human services field from an accredited college or university

AND

one year of work experience providing direct care services to individuals with substance use disorders;

OR

be a Licensed Clinical Addiction Specialist (LCAS), Licensed Clinical Addiction Specialist- Associate (LCAS-A), Certified Substance Abuse Counselor (CSAC), Certified Substance Abuse Counselor Intern (CSAC-I) or Certified Alcohol and Drug Counselor (CADC), Certified Alcohol and Drug Counselor Intern (CADC-I), or be an individual who is a **Registrant with the NCASPPB and who shall be designated as a CADC-I by March 31, 2024.**

OR

be an RN or LPN

AND

one year of work experience providing direct care services to individuals with substance use disorders;

AND

in all cases one year of work experience in administration or programmatic supervision in human services.

10A NCAC 27G .3603 STAFFING (b)

Current Rule Requires:

(b) Each facility shall have at least one staff member on duty trained in the following areas: (1) drug abuse withdrawal symptoms; and (2) symptoms of secondary complications to drug addiction.

(c) Each direct care staff member shall receive continuing education to include understanding of the following: (1) nature of addiction; (2) the withdrawal syndrome; (3) group and family therapy; and (4) infectious diseases including HIV, sexually transmitted diseases and TB.

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

The waiver **additionally requires** the following training for the specified OTP positions (including contract staff): OTP services must be provided by an interdisciplinary team of individuals who have strong clinical skills, professional qualifications, experience, and competency to provide the range of practices. All OTP team members are expected to receive initial and ongoing training in core and evidence-based practices that support the implementation of ethical, person-centered, high-fidelity OTP practices.

10A NCAC 27G .3603 STAFFING (b)

Current Rule (continued)

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

Prior to Service Delivery: All Direct Care Staff

- Crisis Response
- Opioid Antagonist Administration (Administering Naloxone or other Federal Food and Drug Administration approved opioid antagonist for drug overdose)
- Harm Reduction

10A NCAC 27G .3603 STAFFING (b)

Current Rule (continued)

The Why:
To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

Within 90 calendar days of hire to provide service:

- **All Licensed professional staff under .3603 above and Certified Alcohol & Drug Counselor and Certified Alcohol & Drug Counselor Interns:**
 - PCP Instructional Elements
- **RN, LPNs MDs, DOs, all extenders & Program Director:**
 - NC State Opioid Treatment Authority (SOTA) Webinar Series <https://addiction-medicine.org/training/otp/>

10A NCAC 27G .3603 STAFFING (b)

Current Rule (continued)

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

Within 180 calendar days of hire to provide this service: Medical Staff, including Medical Director, Program Physician, Nursing Supervisor, Registered Nurses, and Licensed Practical Nurses

- ASAM Criteria**
- Pregnancy and Opioid Use Disorder Treatment

10A NCAC 27G .3603 STAFFING (b)

Current Rule (continued)

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

Within 180 calendar days of hire to provide this service: Counseling Staff, consisting of the **Program Director** and **all other Counselors** (LCAS, LCAS-A, CADC, CADCI, **Registrants** (Alcohol and Drug Counselor), LCSW, LCSW-A, LCMHC, LCMHC-A, LMFT, LMFT-A, LPA, or LP), and **any non-licensed staff providing clinical services under supervision.**

- Introductory Motivational Interviewing**
- ASAM Criteria**
- Co-Occurring Treatment**
- Trauma Informed Care**
- Pregnancy and Opioid Use Disorder Treatment

10A NCAC 27G .3603 STAFFING (b)

Current Rule (continued)

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

Within 180 calendar days of hire to provide this service: All staff except MDs, DOs, and all extenders

- Medication Assisted Treatment

10A NCAC 27G .3603 STAFFING (b)

Current Rule (continued)

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

Annually: All direct care staff

- Continuing education in evidence-based treatment practices including crisis response**

10A NCAC 27G .3603 STAFFING (b)

Current Rule (continued)

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

- The initial training requirements may be waived by the hiring agency if the employee can produce documentation certifying that training appropriate for the population being served was completed no more than 48-months prior to hire date.
- Staff hired prior to October 15, 2023 shall complete all the required training within one (1) year.

10A NCAC 27G .3603 STAFFING (b)

Current Rule Requires:

The Why:

To ensure that services are provided by a team of individuals who have the qualifications, knowledge, skills, and abilities to serve this population.

Rule Waiver Revises the Training to Add:

** Training must be approved and certified by a nationally recognized program that issues continuing education for licensed or clinical professionals. Approved programs are the North Carolina Addictions Specialist Professional Practice Board (**NCASPPB**), National Association of Addiction Professionals (**NAADAC**), National Board for Certified Counselors (**NBCC**), Approved Continuing Education Provider (**ACEP**), National Association of Social Workers (**NASW**), and Motivational Interviewing Network of Trainers (**MINT**).

The program director shall maintain documentation of both supervision and training activities.

10A NCAC 27G .3604 OPERATIONS (f)(1)(A)-(G)...

Current Rule

(1) Levels of Eligibility are subject to the following conditions:

(A) Level 1. During the first 90 days of continuous treatment, the take-home supply is limited to a single dose each week and the client shall ingest all other doses under supervision at the clinic;

(B) Level 2. After a minimum of 90 days of continuous program compliance, a client may be granted for a maximum of three take-home doses and shall ingest all other doses under supervision at the clinic each week;

(C) Level 3. After 180 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 2, a client may be granted for a maximum of four take-home doses and shall ingest all other doses under supervision at the clinic each week;

(D) Level 4. After 270 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 3, a client may be granted for a maximum of five take-home doses and shall ingest all other doses under supervision at the clinic each week;

(E) Level 5. After 364 days of continuous treatment and a minimum of 180 days of continuous program compliance, a client may be granted for a maximum of six take-home doses and shall ingest at least one dose under supervision at the clinic each week;

(F) Level 6. After two years of continuous treatment and a minimum of one year of continuous program compliance at level 5, a client may be granted for a maximum of 13 take-home doses and shall ingest at least one dose under supervision at the clinic every 14 days; and

(G) Level 7. After four years of continuous treatment and a minimum of three years of continuous program compliance, a client may be granted for a maximum of 30 take-home doses and shall ingest at least one dose under supervision at the clinic every month.

The Why:

To align with SAMHSA and have a single waiver.

Rule Waiver Combines Current Waiver with Past Waiver for Take-Home Eligibility

In order for the facility to render care to its clients most effectively, facility is requesting DHSR to waive 10A NCAC 27G .3604 (f)(1)(A)-(G), (f)(2)(A)-(C) and (3)(A) in exchange for facility agreeing to comply with SAMHSA's temporary exemption, subject to applicable conditions, from the unsupervised take-home medication requirements of 42 C.F.R. § 8.12(i) that are necessary to: Provide unsupervised take home doses of opioid use disorder medication with the following time in treatment standards:

- In treatment 0-14 days, up to 7 unsupervised take-home doses may be provided to the patient. During the first 14 days of treatment, the take home supply is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take home doses up to 7 days, but decisions must be based on the criteria a-f listed below. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record
- Treatment days 15-30, up to 14 unsupervised take-home doses may be provided to the patient. From 15 days of treatment, the take home supply is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take home doses up to 14 days, but decisions must be based on the criteria a-f listed below. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.
- From 31 days in treatment, up to 28 unsupervised take-home doses may be provided to the patient. From 31 days of treatment, the take home supply provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take home doses up to 28 days, but decisions must be based on the criteria a-f listed below. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record.

10A NCAC 27G .3604 OPERATIONS (f)(1)(A)-(G)...

Current Rule (continued)

**The Why:
To align with SAMHSA and
have a single waiver.**

Rule Waiver Combines Current Waiver with Past Waiver for Take-Home Eligibility

In all instances, it is within the clinical judgement 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. In determining which patients may receive unsupervised doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate whether the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

- (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;
- (b) Regularity of attendance for supervised medication administration;
- (c) Absence of serious behavioral problems that endanger the patient, the public or others;
- (d) Absence of known recent diversion activity; and
- (e) Whether take home medication can be safely transported and stored; and
- (f) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

Such determinations and the basis for such determinations consistent with the criteria outlined in a – f, above, shall be documented in the patient's medical record consistent with 42 C.F.R. § 8.12(i)(3).

10A NCAC 27G .3604 OPERATIONS

...(f)(2)(A)-(C)...

Current Rule

(2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility:

(A) A client's take-home eligibility is reduced or suspended for evidence of recent drug abuse. A client who tests positive on two drug screens within a 90-day period shall have an immediate reduction of eligibility by one level of eligibility;

(B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and

(C) The reinstatement of take-home eligibility shall be determined by each Outpatient Opioid Treatment Program.

The Why:

To update the existing waiver to include (f)(2); to align with SAMHSA and have a single waiver.

Rule Waiver Revision

(waived)

10A NCAC 27G .3604 OPERATIONS ...and (f)(3)(A)

Current Rule

(3) Exceptions to Take-Home Eligibility:
(A) A client in the first two years of continuous treatment who is unable to conform to the applicable mandatory schedule because of exceptional circumstances such as illness, personal or family crisis, travel or other hardship may be permitted a temporarily reduced schedule by the State authority, provided she or he is also found to be responsible in handling opioid drugs. Except in instances involving a client with a verifiable physical disability, there is a maximum of 13 take-home doses allowable in any two-week period during the first two years of continuous treatment.

The Why:
To align with SAMHSA and have a single waiver.

Rule Waiver Revision

(waived)

Next Steps and Logistics!

- DHSR will send letters and waiver request forms to OTP contacts.
- DHHS has met with and informed LME/MCOs, who are prepared to respond quickly
- Programs should contact each LME/MCO that they contract with and request a letter of support
- Programs should complete the Waiver Request Form and submit it to DHSR
 - Make sure that all boxes are initialed
 - Make sure that form is signed, includes printed name, and date signed
 - Attach letter of support from each LME/MCO that you contract with (or from your Governing Body, if you do not contract with any LME/MCO)
- Programs should continue to submit monthly blanket exception plan requests to SOTA (Smith)

Sample Letter

October XX, 2023

Robin Sulfridge, Chief Division of Health Service Regulation
Mental Health Licensure & Certification Section
2718 Mail Service Center
Raleigh, NC 27699-2718

RE: Letter of Support - Request for Temporary Waiver of 10A NCAC 27G .3601 SCOPE (a); 10A NCAC 27G .3602 DEFINITIONS (8); 10A NCAC 27G .3603 STAFFING (a); 10A NCAC 27G .3603 STAFFING (b); and 10A NCAC 27G .3604 OPERATIONS (f)(1)(A)-(G), (f)(2)(A)-(C) and (f)(3)(A).

Dear Ms. Sulfridge,

(LME/MCO) has reviewed a request from (OTP name), located at (address), to support a temporary waiver of 10A NCAC 27G .3601 SCOPE (a); 10A NCAC 27G .3602 DEFINITIONS (8); 10A NCAC 27G .3603 STAFFING (a); 10A NCAC 27G .3603 STAFFING (b); and 10A NCAC 27G .3604 OPERATIONS (f)(1)(A)-(G), (f)(2)(A)-(C) and (f)(3)(A) to operate under the Substance Abuse and Mental Health Services Administration's (SAMHSA) temporary exemptions, subject to outlined conditions, from the unsupervised take-home medication requirement of 42 CFR § 8.12(i).

The named provider above has submitted a satisfactory process related to additional safeguards in place to prevent diversion or other misuse of medication. To (LME/MCO's) knowledge, there are no current sanctions or health and safety concerns related to this facility.

Based on a review of the provider's submitted safeguards and the provider's completed NCDHHS Opioid Treatment Program (OTP) Waiver Request Form, (LME/MCO) is supportive of this waiver request of 10A NCAC 27G .3601 SCOPE (a); 10A NCAC 27G .3602 DEFINITIONS (8); 10A NCAC 27G .3603 STAFFING (a); 10A NCAC 27G .3603 STAFFING (b); and 10A NCAC 27G .3604 OPERATIONS (f)(1)(A)-(G), (f)(2)(A)-(C), and (f)(3)(A).

Should you have any further questions regarding this letter, please do not hesitate to contact me.

Sincerely,

(signature)

LME/MCO Contact Information

Contact Us!

For submission of the waiver, contact DHSR

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For general questions, contact SOTA

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Contact Us!

For questions about the Medicaid Clinical Coverage Policy and State-Funded Service Definition, Contact:

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AND

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