

**Note from the Codifier:** The OAH website includes notices and the text of proposed temporary rules as required by G.S. 150B-21.1(a1). Prior to the agency adopting the temporary rule, the agency must hold a public hearing no less than five days after the rule and notice have been published and must accept comments for at least 15 business days.  
For questions, you may contact the Office of Administrative Hearings at 984-236-1850 or email oah.postmaster@oah.nc.gov.

## TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Notice** is hereby given in accordance with G.S. 150B-21.1(a3) that the Commission for Mental Health/DD/SAS intends to adopt the rule cited as 10A NCAC 27G .3605.

**Codifier of Rules** approved this rule as an emergency rule effective September 23, 2024 and received for publication the following notice and proposed temporary rule on: September 13, 2024.

### Public Hearing:

**Date:** October 1, 2024

**Time:** 10:00 a.m.-11:30 a.m.

### Location:

Microsoft Teams Join the meeting now

Meeting ID: 280 457 754 276

Passcode DNLg3J

Dial in by phone +1 984-204-1487

630084139#

Phone conference ID: 630 084 139#

**Reason for Proposed Temporary Action:** A serious and unforeseen threat to the public health, safety or welfare. S.L. 2023-65 enacted G.S. 122C-35 which granted the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services authority to adopt emergency, temporary, and permanent rules for the licensure, inspection, and operation of opioid treatment program medication units and opioid treatment program mobile units, including rules concerning any of the following: (1) Compliance with all applicable Substance Abuse and Mental Health Services Administration and federal Drug Enforcement Agency regulations governing opioid treatment program mobile units and opioid treatment program medication units. (2) Identification of the location of opioid treatment program medication units and opioid treatment program mobile units. (3) Schedules for the days and hours of operation to meet client needs. (4) Maintenance and location of records. (5) Requisite clinical staff and staffing ratios to meet immediate client needs at each opioid treatment program medication unit or opioid treatment program mobile unit, including client needs for nursing, counseling, and medical care. (6) Emergency staffing requirements to ensure service delivery. (7) Criteria for policies and procedures for a clinical and individualized assessment of individuals to receive services at an opioid treatment medication unit or opioid treatment mobile unit that consider medical and clinical appropriateness and accessibility to individuals served. (8) Number of clients allowed per opioid treatment program medication unit and opioid treatment program mobile unit, based on staffing ratios. (9) Criteria to ensure the opioid treatment program facility is providing the required counseling to individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit. (10) Criteria for the opioid treatment program facility to ensure that individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit receive medical interventions when necessary.

**Comment Procedures:** Comments from the public shall be directed to: Denise Baker, 3001 Mail Service Center, Raleigh, NC 27699-3001; email dmhddsarules@dhhs.nc.gov. The comment period begins September 20, 2024 and ends October 10, 2024.

## CHAPTER 27 - MENTAL HEALTH, COMMUNITY FACILITIES AND SERVICES

### SUBCHAPTER 27G - RULES FOR MENTAL HEALTH, DEVELOPMENTAL DISABILITIES, AND SUBSTANCE ABUSE FACILITIES AND SERVICES

#### SECTION .3600 - OUTPATIENT OPIOID TREATMENT

##### 10A NCAC 27G .3605 MEDICATION UNITS AND MOBILE UNITS

###### (a) Definitions

- (1) "Opioid Treatment Program" (hereafter, OTP) means the same as defined in G.S. 122C-3(25a).
- (2) "OTP Facility" means the primary location on the facility license.
- (3) "Opioid Treatment Program Medication Unit" (hereafter OTP Medication Unit) means the same as defined in G.S. 122C-3(25b).
- (4) "Opioid Treatment Program Mobile Unit" (hereafter OTP Mobile Unit) means the same as defined in G.S. 122C-3(25c).

(b) The OTP Facility shall provide any medical, counseling, vocational, educational, and other assessment and treatment services not provided by the OTP Medication Unit or OTP Mobile Unit.

(c) The OTP shall determine the type of services to be provided at the OTP Medication Units and OTP Mobile Units. The OTP shall clearly specify which services are offered at the OTP Medication Units and OTP Mobile Units. Any services not offered at the OTP Medication Unit or Mobile Unit shall be provided at the OTP facility.

(d) Location and Service Capacity.

- (1) The OTP shall ensure that each OTP Medication Unit and OTP Mobile Unit complies with all applicable State and Federal laws and regulations, including without limitation, Substance Abuse and Mental Health Services Administration and Federal Drug Enforcement Agency regulations governing their operation.
- (2) An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall maintain and provide the location of each unit associated with the OTP.
- (3) The OTP Medication Units and Mobile Units shall operate within a radius of 75 miles from the Opioid Treatment Program facility.
- (4) The OTP shall maintain and provide schedules for the days and hours of operation to meet patient needs.
- (5) The OTP shall establish and implement an operating protocol identifying the number of patients allowed per OTP Medication Unit and OTP Mobile Unit based on staffing ratios.
- (6) The OTP shall establish and implement an operating protocol which includes predetermined location(s), hours of operations, and a daily departure guide and business record of each OTP Mobile Unit's location.

(e) Staffing Requirements. The OTP and any associated OTP Medication Units and OTP Mobile Units shall maintain standard operating and emergency staffing to ensure service delivery at the OTP and any associated OTP Medication Units and OTP Mobile Units. Staffing shall include, but not be limited to the following:

- (1) The OTP and any associated OTP Medication Units and OTP Mobile Units shall have a 1.0 FTE Licensed Clinical Addiction Specialist (LCAS), or Licensed Clinical Addiction Specialist-Associate (LCAS-A) per 50 patients. This position can be filled by more than one LCAS or LCAS-A staff member (ratio 1:50); and
- (2) The OTP and any associated OTP Medication Units and OTP Mobile Units shall have 1.0 FTE LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC), Certified Alcohol and Drug Counselor Intern (CADC-I), Licensed Clinical Social Worker (LCSW), Licensed Clinical Social Worker – Associate (LCSW-A), Licensed Clinical Mental Health Counselor (LCMHC), Licensed Clinical Mental Health Counselor – Associate (LCMHC-A), Licensed Marriage and Family Therapist (LMFT), Licensed Marriage and Family Therapist – Associate (LMFT-A), Licensed Psychological Associate (LPA), or Licensed Psychologist (LP) for each additional 50 patients in the program (ratio 1:50); and
- (3) The OTP and any associated OTP Medication Units and OTP Mobile Units shall have a Medical Director who is a physician licensed to practice medicine in North Carolina and who meets the standards and requirements outlined in 42 CFR 8.2 and 42 CFR 8.12(b).
  - (A) The Medical Director is responsible for ensuring all medical, psychiatric, nursing, pharmacy, toxicology, and other services offered at the OTP and any associated OTP Medication Units and OTP Mobile Units are conducted in compliance with State and Federal laws and regulations, consistent with appropriate standards of care; and
  - (B) The Medical Director shall be physically present at the OTP a minimum of four hours per month to assure regulatory compliance and to carry out those duties assigned to the Medical Director in 42 CFR 8.2 and 42 CFR 8.12(b)(2).
  - (C) The Medical Director shall be responsible for supervision of any physician extender(s) and other medical staff.

(f) Each OTP shall develop and implement a policy regarding the maintenance, location, and retention of records for its OTP Medication Units and OTP Mobile Units, in accordance with State and Federal laws and regulations.

(g) Operations and Service Delivery

- (1) Each OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and shall be subject to inspections the Department deems necessary to validate compliance with all applicable rules, and State and Federal laws and regulations.
- (2) The OTP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State and federal program requirements for Opioid Treatment Programs.
- (3) Each OTP Medication Unit and OTP Mobile Unit shall establish and implement a written policy and procedure for operations that meets the needs of its patients.
- (4) The OTP shall establish and implement policies and procedures for a clinical and individualized assessment of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that considers medical and clinical appropriateness and accessibility to patients served.
- (5) The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP Mobile Unit receive a minimum of two counseling sessions per month during the first year of continuous treatment and a minimum of one counseling session per month after the first year and in all subsequent years of continuous treatment.
- (6) Counseling staff shall be available, either in person and on-site or by telehealth, a minimum of five days per week to offer and provide counseling in accordance with the patient's treatment plan or person-centered plan.
- (7) The OTP shall establish and implement a policy and procedure to determine the appropriateness of telehealth services for a patient that takes into consideration the patient's choice along with the patient's behavior, physical, and cognitive abilities. The patient's verbal or written consent shall be documented when telehealth services are provided.
- (8) The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP Mobile Unit receive medical interventions, including naloxone, when medically necessary and in compliance with the patient's treatment plan, person-centered plan, standing orders, or emergency intervention protocols.

- (9) An OTP and its associated OTP Medication Units and OTP Mobile Units shall ensure that all dosing of medication to patients on the site of the OTP and any associated OTP Medication Units and OTP Mobile Units is directly observed by a Physician, Physician Assistant, Nurse Practitioner, Registered Nurse, or Licensed Practical Nurse, in accordance with applicable State and Federal Law and the OTP's Diversion Control Plan.

*Authority G.S. 122C-35; 42 C.F.R. 8.12.*