

1 **Rule 10A NCAC 27G .3605 is proposed for adoption via temporary procedures as follows.**

2
3 **10A NCAC 27G .3605 Medication Units and Mobile Units**

4 (a) Definitions

5 (1) “Opioid Treatment Program” (hereafter, OTP) means the same as defined in G.S. §122C-3(25a).

6 (2) “OTP Facility” means the primary location on the facility license.

7 (3) “Opioid Treatment Program Medication Unit” (hereafter OTP Medication Unit) means the same
8 as defined in G.S. § 122C-3(25b).

9 (4) “Opioid Treatment Program Mobile Unit” (hereafter OTP Mobile Unit) means the same as defined
10 in G.S. § 122C-3(25c).

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

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

17 (d) Location and Service Capacity.

18 (1) The OTP shall ensure that each OTP Medication Unit and OTP Mobile Unit complies with all
19 applicable State and Federal laws and regulations, including without limitation, Substance
20 Abuse and Mental Health Services Administration and Federal Drug Enforcement Agency
21 regulations governing their operation.

22 (2) An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall
23 maintain and provide the location of each unit associated with the OTP.

24 (3) The OTP Medication Units and Mobile Units shall operate within a radius of 75 miles from the
25 Opioid Treatment Program facility.

26 (4) The OTP shall maintain and provide schedules for the days and hours of operation to meet
27 patient needs.

28 (5) The OTP shall establish and implement an operating protocol identifying the number of patients
29 allowed per OTP Medication Unit and OTP Mobile Unit based on staffing ratios.

30 (6) The OTP shall establish and implement an operating protocol which includes predetermined
31 location(s), hours of operations, and a daily departure guide and business record of each OTP
32 Mobile Unit’s location.

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

36 (1) The OTP and any associated OTP Medication Units and OTP Mobile Units shall have a 1.0
37 FTE Licensed Clinical Addiction Specialist (LCAS), or Licensed Clinical Addiction Specialist-

1 Associate (LCAS-A) per 50 patients. This position can be filled by more than one LCAS or
2 LCAS-A staff member (ratio 1:50); and

3 (2) The OTP and any associated OTP Medication Units and OTP Mobile Units shall have 1.0 FTE
4 LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC), Certified Alcohol and Drug
5 Counselor Intern (CADC-I), Licensed Clinical Social Worker (LCSW), Licensed Clinical
6 Social Worker – Associate (LCSW-A), Licensed Clinical Mental Health Counselor (LCMHC),
7 Licensed Clinical Mental Health Counselor – Associate (LCMHC-A), Licensed Marriage and
8 Family Therapist (LMFT), Licensed Marriage and Family Therapist – Associate (LMFT-A),
9 Licensed Psychological Associate (LPA), or Licensed Psychologist (LP) for each additional 50
10 patients in the program (ratio 1:50); and

11 (3) The OTP and any associated OTP Medication Units and OTP Mobile Units shall have a
12 Medical Director who is a physician licensed to practice medicine in North Carolina and who
13 meets the standards and requirements outlined in 42 CFR § 8.2 and 42 CFR § 8.12(b).

14 (A) The Medical Director is responsible for ensuring all medical, psychiatric, nursing,
15 pharmacy, toxicology, and other services offered at the OTP and any associated OTP
16 Medication Units and OTP Mobile Units are conducted in compliance with State and
17 Federal laws and regulations, consistent with appropriate standards of care; and

18 (B) The Medical Director shall be physically present at the OTP a minimum of 4 hours per
19 month to assure regulatory compliance and to carry out those duties assigned to the
20 Medical Director in 42 CFR §8.2 and 42 CFR § 8.12(b)(2).

21 (C) The Medical Director shall be responsible for supervision of any physician extender(s)
22 and other medical staff.

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

26 (g) Operations and Service Delivery

27 (1) Each OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and
28 shall be subject to inspections the Department deems necessary to validate compliance with all
29 applicable rules, and State and Federal laws and regulations.

30 (2) The OTP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State
31 and federal program requirements for Opioid Treatment Programs.

32 (3) Each OTP Medication Unit and OTP Mobile Unit shall establish and implement a written
33 policy and procedure for operations that meets the needs of its patients.

34 (4) The OTP shall establish and implement policies and procedures for a clinical and individualized
35 assessment of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that
36 considers medical and clinical appropriateness and accessibility to patients served.

37 (5) The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP

1 Mobile Unit receive a minimum of two counseling sessions per month during the first year of
2 continuous treatment and a minimum of one counseling session per month after the first year
3 and in all subsequent years of continuous treatment.

4 (6) Counseling staff shall be available, either in person and on-site or by telehealth, a minimum of
5 five days per week to offer and provide counseling in accordance with the patient’s treatment
6 plan or person-centered plan.

7 (7) The OTP shall establish and implement a policy and procedure to determine the appropriateness
8 of telehealth services for a patient that takes into consideration the patient’s choice along with
9 the patient’s behavior, physical, and cognitive abilities. The patient’s verbal or written consent
10 shall be documented when telehealth services are provided.

11 (8) The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP
12 Mobile Unit receive medical interventions, including naloxone, when medically necessary and
13 in compliance with the patient’s treatment plan, person-centered plan, standing orders, or
14 emergency intervention protocols.

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

20
21 History Note: Authority G.S. 122C-35; 42 C.F.R. §8.12;
22 Emergency Adoption Eff. September 17, 2024;
23 Temporary Adoption Eff. _____.