

1 Rule 10A NCAC 26E .0406 is amended as published in 39:24 NCR 1605 as follows.

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3 **10A NCAC 26E .0406 DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING**
4 **HOME**

5 A pharmacy that has dispensed controlled~~Controlled substances dispensed for inpatient administration to individuals~~
6 residing in to a licensed nursing home shall be responsible for either returning unused controlled substances to its
7 stock, or disposing of and destroying any unused controlled substances in accordance with 21 CFR 1317.05(a) or
8 (c), and other applicable federal regulations governing U.S. Drug Enforcement Administration (DEA) registrant
9 collection, disposal, and destruction of unused controlled substances in licensed nursing homes, which for any
10 reason are unused shall be returned to the pharmacy from which they were received. The pharmacist who receives
11 these controlled substances shall return them to his stock or destroy them in accordance with the procedure outlined
12 by the director and The pharmacy shall keep a record of this~~the disposal and destruction of unused controlled~~
13 substances available for a minimum of two years. This record of disposal and destruction shall be kept on the
14 Division of Mental Health, Developmental Disabilities, and Substance Use Services (Division) form entitled
15 "Controlled Substances Destruction Record Nursing Homes." "Record of Controlled Substances Destroyed Pursuant
16 to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008 Mail Service Center
17 Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock must be in a
18 hermetically sealed container or in an otherwise a pure uncontaminated condition and be identifiable. A pharmacy
19 may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR
20 1317.05(a)(2), provided the pharmacy must first verify the reverse distributor is registered with the DEA as a reverse
21 distributor and maintains compliance with all applicable federal and State laws and regulations governing reverse
22 distributors and destruction of unused controlled substances per 21 CFR 1317.15. Pharmacies that are authorized by
23 the DEA as collectors may install, manage and maintain collection receptacles at nursing homes for the purpose of
24 collection, disposal and destruction of unused controlled substances from nursing homes, in accordance with 21
25 CFR 1317.05(c), 21 CFR 1317.40 other applicable federal regulations governing the use of collection receptacles by
26 authorized pharmacy collectors in nursing homes. Compliance with this Rule is subject to audit by the Division
27 Director or their designated representative.

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29 *History Note: Authority G.S. 90-100; ~~143B-210(9); 143B-147;~~*

30 *Eff. June 30, 1978;*

31 *Amended Eff. September 15, 1980; May 15, 1979;*

32 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2,*
33 *~~2016-2016;~~*

34 *Emergency Amendment Eff. September 30, ~~2024-2024;~~*

35 *Temporary Amendment Eff. January 2, 2025;*

36 *Amended Eff. _____.*

1 **Rule 10A NCAC 27G .3605 is adopted as published in 39:24 NCR 1606 as follows.**

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

4 (a) Definitions

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

6 (2) “Opioid Treatment Program Facility” (hereinafter OTP Facility) means the primary location on the
7 facility license.

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

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

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

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

18 (d) Location and Service Capacity.

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

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

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

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

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

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

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

37 (1) The OTP shall have a 1.0 FTE Licensed Clinical Addiction Specialist (LCAS), or Licensed

- 1 Clinical Addiction Specialist-Associate (LCAS-A) per 50 patients. This position can be filled by
2 more than one LCAS or LCAS-A staff member (ratio 1:50); and
- 3 (2) The OTP shall have 1.0 FTE LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC),
4 Certified Alcohol and Drug Counselor Intern (CADC-I), Licensed Clinical Social Worker
5 (LCSW), Licensed Clinical Social Worker – Associate (LCSW-A), Licensed Clinical Mental
6 Health Counselor (LCMHC), Licensed Clinical Mental Health Counselor – Associate (LCMHC-
7 A), Licensed Marriage and Family Therapist (LMFT), Licensed Marriage and Family Therapist
8 – Associate (LMFT-A), Licensed Psychological Associate (LPA), or Licensed Psychologist (LP)
9 for each additional 50 patients in the program (ratio 1:50); and
- 10 (3) The OTP shall have a Medical Director who is a physician licensed to practice medicine in North
11 Carolina and who meets the standards and requirements outlined in 42 CFR § 8.2 and 42 CFR §
12 8.12(b).
- 13 (A) The Medical Director is responsible for ensuring all medical, psychiatric, nursing,
14 pharmacy, toxicology, and other services offered at the OTP and any associated OTP
15 Medication Units and OTP Mobile Units are conducted in compliance with State and
16 Federal laws and regulations, consistent with appropriate standards of care; and
- 17 (B) The Medical Director shall be physically present at the OTP a minimum of 4 hours per
18 month to assure regulatory compliance and to carry out those duties assigned to the
19 Medical Director in 42 CFR §8.2 and 42 CFR § 8.12(b)(2).
- 20 (C) The Medical Director shall be responsible for supervision of any physician extender(s)
21 and other medical staff.
- 22 (f) Each OTP shall develop and implement a policy regarding the maintenance, location, and retention of records
23 for its OTP Medication Units and OTP Mobile Units, in accordance with State and Federal laws and
24 regulations.
- 25 (g) Operations and Service Delivery
- 26 (1) Each OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and
27 shall be subject to inspections the Department deems necessary to validate compliance with all
28 applicable rules, and State and Federal laws and regulations.
- 29 (2) The OTP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State
30 and federal program requirements for Opioid Treatment Programs.
- 31 (3) Each OTP Medication Unit and OTP Mobile Unit shall establish and implement a written
32 policy and procedure for operations that meets the needs of its patients.
- 33 (4) The OTP shall establish and implement policies and procedures for a clinical and individualized
34 assessment of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that
35 considers medical and clinical appropriateness and accessibility to patients served.
- 36 (5) The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP
37 Mobile Unit receive a minimum of two counseling sessions per month during the first year of

1 continuous treatment and a minimum of one counseling session per month after the first year
2 and in all subsequent years of continuous treatment.

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

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

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

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

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20 *History Note:* Authority G.S. 122C-35; 42 C.F.R. § 8.12;
21 Emergency Eff. September 23, 2024;
22 Temporary Eff. January 2, 2025;
23 Eff. _____.