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

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

A pharmacy that has dispensed controlled~~Controlled~~ substances ~~dispensed~~ for inpatient administration to individuals residing in ~~to~~ a licensed nursing home shall be responsible for either returning unused controlled substances to its stock, or disposing of and destroying any unused controlled substances in accordance with 21 CFR 1317.05(a) or (c), and other applicable federal regulations governing U.S. Drug Enforcement Administration (DEA) registrant collection, disposal, and destruction of unused controlled substances in licensed nursing [~~homes.~~]homes, including 21 U.S.C. 822(g), 21 CFR 1317.10, 21 CFR 1317.15, 21 CFR 1317.80, 21 CFR 1304.22, and 21 CFR Part 1317 Subpart C. ~~which for any reason are unused shall be returned to the pharmacy from which they were received. The pharmacist who receives these controlled substances shall return them to his stock or destroy them in accordance with the procedure outlined by the director and~~ The pharmacy shall keep a record of ~~this~~the disposal and destruction of unused controlled substances available for a minimum of two years. This record of disposal and destruction shall be kept on the Division of Mental Health, Developmental Disabilities, and Substance Use Services (Division) ~~form~~Form entitled ~~"Controlled Substances Destruction Record Nursing Homes."~~ "Record of Controlled Substances Destroyed Pursuant to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008 Mail Service Center Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock must be in a hermetically sealed container or in ~~an otherwise~~ a pure uncontaminated condition and be ~~identifiable.~~identifiable with the original manufacturer's labelling legible. A pharmacy may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the pharmacy must first verify the reverse distributor is registered with the DEA as a reverse distributor and maintains compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction of unused controlled substances per 21 CFR 1317.15. Pharmacies that are authorized by the DEA as collectors may install, [~~manage~~]manage, and maintain collection receptacles at nursing homes for the purpose of collection, [~~disposal~~]disposal, and destruction of unused controlled substances from nursing homes, in accordance with 21 CFR 1317.05(c), 21 CFR [~~1317.40~~]1317.40, and other applicable federal regulations governing the use of collection receptacles by authorized pharmacy collectors in nursing [~~homes.~~]homes, including 21 CFR 1301.51, 21 CFR 1316.02, 21 CFR 1317.05(c)(2)(iv), 21 CFR 1317.60, 21 CFR 1317.75, and 21 CFR 1317.80. Compliance with this Rule is subject to audit by the Division Director or their designated representative.

History Note: *Authority G.S. 90-100; ~~143B-210(9);~~143B-147;*
Eff. June 30, 1978;
Amended Eff. September 15, 1980; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, ~~2016.~~2016;
Emergency Amendment Eff. September 30, ~~2024.~~2024;

Temporary Amendment Eff. January 2, 2025;
Amended Eff. November 1, 2025.

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

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

(a) ~~Definitions~~Definitions:

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

(2) "Opioid Treatment Program Facility" (hereinafter OTP Facility) means the primary location on the facility license.

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

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

(5) "Division" means the same as defined in G.S. 122C-3(13).

(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.~~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 regulations in 42 CFR Part 8 and Federal Drug Enforcement Agency regulations in 21 CFR Parts 1300, 1301, and 1304, governing controlled substances, dispensers of controlled substances, mobile narcotic treatment programs. ~~governing their operation.~~ Each of these Codes is incorporated by reference, including subsequent amendments. Copies are available free of charge at the Division 3001 Mail Service Center, Raleigh, NC 27699-3001; electronic copies are available at no cost at www.ecfr.gov.

(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 OTP Mobile Units shall operate within a radius of 75 miles from the ~~Opioid Treatment Program facility~~.OTP 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 shall develop and implement governing body policies in accordance with Rule 10A NCAC 27G .0201, which is incorporated by reference, including subsequent amendments, and is available free of charge at the Division 3001 Mail Service Center Raleigh, NC 27699-3001; an electronic copy is available at no cost at www.oah.nc.gov. ~~maintain standard operating and emergency staffing~~ The OTP shall maintain staffing to ensure service delivery at the OTP and any associated OTP Medication Units and OTP Mobile ~~Units.~~Units in accordance with 42 CFR 8.12(b)(1). Staffing shall ~~include,~~include ~~but not be limited to~~ the following:

(1) The OTP shall have a 1.0 ~~FTE~~Full-time employee (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 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 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;~~ regulations pursuant to 42 CFR 8.2.

(B) The Medical Director shall be physically present at the OTP a minimum of 4 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)~~practitioner(s), as defined in 42 CFR 8.2, 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.~~ including 42 CFR 8.12(g), G.S. 90-104, Rule 10A NCAC 26E .0202, 21 CFR 1304.24 and 21 CFR 1304.25. G.S. 90-104 and 10A NCAC 26E .0202 are incorporated by reference, including subsequent amendments, and are available free of charge at the Division 3001 Mail Service Center, Raleigh, NC 27699-3001. Electronic copies of the statute are available at www.ncleg.gov; electronic copies of the Rule are

available at no cost at www.oah.nc.gov.

(g) Operations and Service ~~Delivery~~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.~~referenced herein.

(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, Pharmacist, Registered Nurse, or Licensed Practical Nurse, in accordance with applicable State and Federal ~~Law~~Law, including 42 CFR Part 8, and the OTP's Diversion Control Plan.

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

Eff. November 1, 2025.