REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Mental Health/DD/SAS

RULE CITATION: 10A NCAC 26E .0406

DEADLINE FOR RECEIPT: October 10, 2025

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Line 7: 21 CFR 1317.05(a) only applies to "practitioners". Will the requirements in subsection (b) for "non-practitioners" ever apply?

Lines 7-8: The cited CFR will need to be incorporated by reference, in accordance with 150B-21.6, if your agency intends to enforce the provisions within the CFR. You can simply reference it, as you've done, if the intent is to simply set a standard for the regulated public to follow.

Line 8: What are the "other applicable federal regulations governing U.S. DEA registrant collection, disposal, and destruction of …" that are being referenced for the regulated public to follow? Again, you will need to specify the regulations and incorporate them by reference if your agency intends to enforce them.

Line 13: Is "a minimum" necessary since rules always set minimum standards?

Line 14-16: Capitalize "form" since you're identifying a specific form. Are the contents or substantive requirements in the Form prescribed by rule or statute?

Line 18: Is the phrase "pure uncontaminated condition" defined? If so, please cite the definition. If not, how should your regulated public interpret this phrase?

Line 18: How should the regulated public make the controlled substances "identifiable"? Please make this clear in the Rule.

Lines 20-22: How will the pharmacy determine if the reverse distributor is maintaining "compliance with all applicable federal and State laws and regulations"? Also, where is this requirement specifically mentioned within 21 CFR 1317.15?

Travis C. Wiggs
Commission Counsel
Submitted to agency: September 24, 2025

Line 22: 21 CFR 1317.15 will need to be incorporated by reference, in accordance with 150B-21.6, if your agency intends to enforce the provisions within the CFR. You can simply reference it, as you've done, if the intent is to simply set a standard for the regulated public to follow.

Line 23: Add a comma after "manage".

Line 24: Add a comma after "disposal".

Line 25: Add a comma after "21 CFR 1317.40". Add "and" before "other".

Line 25: What are the "other applicable federal regulations governing the use of collection receptacles by…" that are being referenced for the regulated public to follow? Again, you will need to specify the regulations and incorporate them by reference if your agency intends to enforce them.

Line 36: Please add intended date after "Eff.". The effective date will likely be October 1, 2025, unless you indicate otherwise.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Travis C. Wiggs
Commission Counsel
Submitted to agency: September 24, 2025

Rule 10A NCAC 26E .0406 is amended 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. ~~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 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. 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 and maintain collection receptacles at nursing homes for the purpose of collection, disposal and destruction of unused controlled substances from nursing homes, in accordance with 21 CFR 1317.05(c), 21 CFR 1317.40 other applicable federal regulations governing the use of collection receptacles by authorized pharmacy collectors in nursing homes. 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. .

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Mental Health/DD/SAS

RULE CITATION: 10A NCAC 27G .3605

DEADLINE FOR RECEIPT: October 10, 2025

***PLEASE NOTE:* This request may extend to several pages. Please be sure you have reached the end of the document.**

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Line 4: Add a colon at the end of "Definitions".

Line 14: The use of "clearly" is ambiguous and unnecessary. Please delete it or use different language.

Line 17: Capitalize "facility".

Line 20: What are "all applicable State and federal laws and regulations…" that are being referenced for the regulated public to follow? You will need to specify the regulations and incorporate them by reference if your agency intends to enforce them.

Line 21: Why is "including without limitation" necessary? I interpret that to be a "catchall" provision that is unclear and ambiguous.

Line 26: Did you intend to use "OTP" as an abbreviation? Please capitalize "facility" if it's part of a specific title.

Line 34: Is there a definition or policy that can be referenced for "standard operating and emergency staffing"?

Line 36: Is the phrase "but not limited to" necessary? I interpret that to be a "catchall" provision that is unclear and ambiguous.

Line 37: Please spell out "FTE" and add "(FTE)" for clarity.

Page 2, lines 11-12: 42 CFR 8.2 and CFR 8.12(b) will need to be incorporated by reference, in accordance with 150B-21.6, if your agency intends to enforce the provisions within the CFR. You can simply reference it, as you've done, if the intent is to simply set a standard for the regulated public to follow.

Travis C. Wiggs
Commission Counsel
Submitted to agency: September 24, 2025

Lines 15-16: What are the "State and federal laws and regulations" that are being referenced for the regulated public to follow? Please specify the regulations and incorporate them by reference if your agency intends to enforce them.

Line 20: What is the definition of "physician extender" and where can it be found?

Lines 23-24: What are the "State and federal laws and regulations" that are being referenced for the regulated public to follow? Specify the regulations and incorporate them by reference if your agency intends to enforce them.

Line 25: Add a period after "Delivery".

Lines 26-27: What are "all applicable State and federal laws and regulations…" that are being referenced for the regulated public to follow? Specify the regulations and incorporate them by reference if your agency intends to enforce them.

Page 3, lines 17-18: What are the "State and federal laws and regulations" that are being referenced for the regulated public to follow? Again, you will need to specify the regulations and incorporate them by reference if your agency intends to enforce them.

Line 23: Please add intended date after "Eff.". The effective date will likely be October 1, 2025, unless you indicate otherwise.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Travis C. Wiggs
Commission Counsel
Submitted to agency: September 24, 2025

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

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

(a) 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).

(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 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 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 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; and

(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) 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, Pharmacist, Registered Nurse, or Licensed Practical Nurse, in accordance with applicable State and Federal Law 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. _____.