



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

2. Rule citation & name: 10A NCAC 26E .0406

3. Action: ☐ Adoption ☒ Amendment ☐ Repeal

4. Was this an Emergency Rule: ☒ Yes ☐ No **Effective date:** September 25, 2024

5. Provide dates for the following actions as applicable:

- a. **Proposed Temporary Rule submitted to OAH:** September 17, 2024
- b. **Proposed Temporary Rule published on the OAH website:** September 23, 2024
- c. **Public Hearing date:** October 8, 2024
- d. **Comment Period:** September 30, 2024 – October 18, 2024
- e. **Notice pursuant to G.S. 150B-21.1(a3)(2):** September 17, 2024
- f. **Adoption by agency on:** November 21, 2024
- g. **Proposed effective date of temporary rule if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3:**

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

- ☒ **A serious and unforeseen threat to the public health, safety or welfare.**
- ☐ **The effective date of a recent act of the General Assembly or of the U.S. Congress.**
Cite:
Effective date:
- ☐ **A recent change in federal or state budgetary policy.**
Effective date of change:
- ☐ **A recent federal regulation.**
Cite:
Effective date:
- ☐ **A recent court order.**
Cite order:
- ☐ **Other:**

Explain: On July 26, 2024, Stericycle, the owners of the only incinerator in North Carolina that is capable of destroying controlled substances to the point that they are non-retrievable, notified long-term care pharmacies in North Carolina that they will no longer accept bookings for witnessed destruction of controlled substances. Stericycle's business decision to no longer provide long-term care pharmacies the option of destruction of unused controlled substances from nursing homes by an incinerator within the State was not foreseen by the Department. Rule 10A NCAC 26E .0406 is proposed for emergency, and simultaneously, temporary procedures to provide immediate clarity regarding the use of federally recognized options for disposing of and destroying unused controlled substances from nursing homes, including outsourcing the destruction to reverse distributors, in order to help ensure safe, secure, and timely disposal and destruction of unused controlled substances in North Carolina. The proposed emergency and temporary rules are in the public's best interest to avoid the threat of unused controlled substances accumulating at nursing homes or long-term care pharmacies, and the related diversion risks.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Stericycle's business decision to no longer provide long-term care pharmacies the option of destruction of unused controlled substances from nursing homes by an incinerator within the State was not foreseen by the Department. Amendment of Rule 10A NCAC 26E .0406, via emergency procedures, followed by temporary procedures, is to provide immediate clarity regarding the use of federally recognized options for disposing of and destroying unused controlled substances from nursing homes, including outsourcing the destruction to reverse distributors, in order to help ensure safe, secure, and timely disposal and destruction of unused controlled substances in North Carolina. The proposed temporary rule is in the public's best interest to avoid the threat of unused controlled substances accumulating at nursing homes or long-term care pharmacies, and the related diversion risks.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)
☐ Yes

Agency submitted request for consultation on:

Consultation not required. Cite authority:

☒ No

9. Rule-making Coordinator: Denise Baker

Phone: 984-236-5272

E-Mail: denise.baker@dhhs.nc.gov

Agency contact, if any:
Phone:
E-Mail:
10. Signature of Agency Head*:

 Signed by:

 01AA36FB62174A6...

*** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: I. Azell Reeves

Title: Chair, Commission for MH/DD/SAS

E-Mail: reev5205@bellsouth.net

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

☐ Date returned to agency:

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

AGENCY: Commission for Mental Health/DD/SAS

RULE CITATION: 10A NCAC 26E .0406 (Temporary)

DEADLINE FOR RECEIPT: December 13, 2024

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:

Lines 5-6: Add a comma after “home”, “which”, “reason”, and after “unused”.

Line 6: How shall the controlled substances be “returned”? Are the specific methods used for the return in a rule, law, or regulation?

Line 8: 21 CFR 1317.05(a) only applies to “practitioners”. Will the requirements in subsection (b) for “non-practitioners” ever apply?

Line 10: Is “a minimum” necessary since rules always set minimum standards? Also, which “Division” is being referred to? Please be specific.

Line 10: Where is the “form” located and how can it be obtained? Also, are the contents or substantive requirements in the form prescribed by rule or statute?

Line 12: Does your regulated public know what “hermetically” means or is it defined in another rule?

Line 12: Is “otherwise” necessary? If not, please delete it. Also, is the phrase “pure uncontaminated condition” defined? If so, please cite the definition. If not, how will your regulated public know how to interpret this phrase?

Line 15: Consider replacing “vendor” with “reverse distributor” for clarity. Please spell out “DEA” since it’s being used for the first time in this Rule.

Line 16: How will the pharmacy determine if the reverse distributor is maintaining “compliance with all applicable federal and State laws and regulations”?

Line 17: Please capitalize “rule”. Also, which “Director” are you referring to? Please be specific.

Line 26: Pursuant to G.S. 150B-21.1(b), the effective date will likely be January 2, 2025.

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

1 Rule 10A NCAC 26E .0406 is amended via temporary procedures with changes as follows'

2
3 **10A NCAC 26E .0406 DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING**
4 **HOME**

5 Controlled substances dispensed for inpatient administration to individuals residing in ~~to~~ a licensed nursing home
6 which for any reason are unused shall be returned to the pharmacy from which they were received. The
7 ~~pharmacist~~pharmacy ~~who~~that receives these controlled substances shall return them to ~~his~~their ~~its~~ stock or dispose
8 of and destroy them in accordance with ~~the procedure outlined by the director and~~ 21 CFR 1317.05(a). The
9 ~~pharmacist~~pharmacy shall keep a record of ~~this~~the disposal and destruction of unused controlled substances
10 available for a minimum of two years. This record of disposal and destruction shall be kept on the Division form
11 entitled "~~Controlled~~ Record of Ultimate User Controlled Substances Destroyed" ~~.Destruction Record Nursing~~
12 ~~Homes.~~" Controlled substances returned to stock must be in a hermetically sealed container or in an otherwise pure
13 uncontaminated condition and be identifiable. A ~~pharmacist~~pharmacy may outsource destruction of the unused
14 controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the
15 ~~pharmacist~~pharmacy must first verify the vendor is registered with the DEA as a reverse distributor and maintains
16 compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction
17 of unused controlled substances. Compliance with this rule is subject to audit by the Director or their designated
18 representative.

19
20 *History Note: Authority G.S. 90-100; ~~143B-210(9)~~; 143B-147;*

21 *Eff. June 30, 1978;*

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

23 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2,*
24 *~~2016-2016~~;*

25 *Emergency Amendment Eff. September 25, 2024;*

26 *Temporary Amendment Eff. _____.*



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

2. Rule citation & name: 10A NCAC 27G .3605

3. Action: ☒ Adoption ☐ Amendment ☐ Repeal

4. Was this an Emergency Rule: ☒ Yes ☐ No **Effective date:** September 23, 2024

5. Provide dates for the following actions as applicable:

- a. **Proposed Temporary Rule submitted to OAH:** September 13, 2024
- b. **Proposed Temporary Rule published on the OAH website:** September 19, 2024
- c. **Public Hearing date:** October 1, 2024
- d. **Comment Period:** September 20, 2024 – October 10, 2024
- e. **Notice pursuant to G.S. 150B-21.1(a3)(2):** September 13, 2024
- f. **Adoption by agency on:** November 21, 2024
- g. **Proposed effective date of temporary rule if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3:**

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

- ☒ **A serious and unforeseen threat to the public health, safety or welfare.**
- ☐ **The effective date of a recent act of the General Assembly or of the U.S. Congress.**
Cite:
Effective date:
- ☐ **A recent change in federal or state budgetary policy.**
Effective date of change:
- ☐ **A recent federal regulation.**
Cite:
Effective date:
- ☐ **A recent court order.**
Cite order:
- ☐ **Other:**

Explain: 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.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

Adoption of this emergency, and now temporary, rule adhered to the mandate in S.L. 2023-65 and aligns North Carolina with the recently updated federal rules in 21 C.F.R., which allow OTPs to add and operate a mobile unit under their existing Drug Enforcement Agency (DEA) license. Without this change, the rules would direct OTPs to comply with an outdated version of federal regulations that did not include the ability to operate a mobile OTP component thereby creating a discrepancy between NC rules and federal regulation. Furthermore, this has become an emergent issue as a result of the ongoing opioid crisis in North Carolina. These efforts will increase access to treatment for individuals who suffer from opioid use disorder, while maintaining regulatory oversight to ensure client and public safety

8. Rule establishes or increases a fee? (See G.S. 12-3.1)
☐ Yes

Agency submitted request for consultation on:

Consultation not required. Cite authority:

☒ No
9. Rule-making Coordinator: Denise Baker

Phone: 984-236-5272

E-Mail: denise.baker@dhhs.nc.gov

Agency contact, if any:

Phone:

E-Mail:

10. Signature of Agency Head*:

Signed by:

 01AA36FB62174A6...

*** If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.**

Typed Name: I. Azell Reeves

Title: Chair, Commission for MH/DD/SAS

E-Mail: reev5205@bellsouth.net

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

☐ Date returned to agency:

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

AGENCY: Commission for Mental Health/DD/SAS

RULE CITATION: 10A NCAC 27G .3605 (Temporary)

DEADLINE FOR RECEIPT: December 13, 2024

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" appears unnecessary. Please delete it.

Line 35: Please spell out "FTE" for clarity. Also, on page 2, line 3.

Page 2, line 25: Add a period after "Delivery".

Line 21: What is the definition of "physician extender" and where can it be found?

Page 3, line 22: Pursuant to G.S. 150B-21.1(b), the effective date will likely be January 2, 2025.

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

RULE 10A NCAC 27G .3605 is adopted via temporary procedures as follows.

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

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

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

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

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

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

19
20 *History Note:* Authority G.S. 122C-35; 42 C.F.R. 8.12;

21 Emergency Adoption Eff. September 17, 2024;

22 Temporary Adoption Eff. _____.