Burgos, Alexander N

Subject: FW: RRC December 2024-Request for Changes

From: Baker, Denise <Denise.Baker@dhhs.nc.gov>
Sent: Friday, December 13, 2024 3:12 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: RRC December 2024-Request for Changes

Thanks so much Travis.

I'll let you know to whom, in addition to me, the invitation to the meeting should be sent.

W. Denise Baker, M.A., L.P.A., J.D.
Team Leader, Legislative and Regulatory Affairs
Division of MH/DD/SAS
NC Department of Health and Human Services

Office: 984-236-5272
Mobile: 919-437-6517
Fax: 919-508-0973
denise.baker@dhhs.nc.gov

Anderson Building
695 Palmer Dr
3004 Mail Service Center
Raleigh NC 27699-3004

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From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Friday, December 13, 2024 3:10 PM
To: Baker, Denise <Denise.Baker@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: RRC December 2024-Request for Changes

Good afternoon,

I intend to recommend to the RRC that both final revised rules be approved at the December 19th meeting. Please submit the revised rules via email to oah.rules@oah.nc.gov no later than 5pm on December 17, 2024. The electronic copy must be saved as the official rule name (XX NCAC XXXX). Please include me on the email.

Thank you.

Travis C. Wiggs
Rules Review Commission Counsel

Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov

From: Baker, Denise <Denise.Baker@dhhs.nc.gov>
Sent: Friday, December 13, 2024 12:44 PM
To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: RE: RRC December 2024-Request for Changes

Hi Travis –

Attached please find Rules 10A NCAC 27G .3605 and 10A NCAC 26E .0406 as revised in response to the feedback provided.

Otherwise, please see attached for further explanation regarding Rule 10A NCAC 26E .0406.

Please let me know if you have questions or need additional information.

Thank you,
Denise

W. Denise Baker, M.A., L.P.A., J.D.
Team Leader, Legislative and Regulatory Affairs
Division of MH/DD/SAS
NC Department of Health and Human Services

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Mobile: 919-437-6517
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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".
This has been completed.

Line 6: How shall the controlled substances be "returned"? Are the specific methods used for the return in a rule, law, or regulation?
Rule 10A NCAC 26E .0406 does not define a specific method required for the return of controlled substances to the long-term care pharmacies. However, by practice, controlled substances are returned from nursing homes to long-term care pharmacies by pharmacy couriers.

Line 8: 21 CFR 1317.05(a) only applies to "practitioners". Will the requirements in subsection (b) for "non-practitioners" ever apply?
The emergency and temporary rules were adopted to meet the urgent need created by the termination of incineration services in North Carolina for controlled substance destruction by the only company that was providing that service. Given the urgency of this response, the proposed rule changes are intended to result in minimal disruption of existing processes by clarifying existing options available under federal law which already have been approved for use in North Carolina. While the original rule specified the destruction be accomplished in accordance with a procedure outlined by the Director, the amendment requires the destruction be accomplished in accordance with federal regulation 21 CFR 1317.05(a). The temporary rule makes clear the options available to long term care pharmacies for the destruction of returned controlled substances from nursing homes to meet the immediate need for appropriate and secure destruction of such controlled substances. The applicability of the requirements in subsection (b) will likely be considered during the permanent rulemaking process.

Line 10: Is "a minimum" necessary since rules always set minimum standards?
This Rule requires the record be kept a minimum of two years without while permitting the pharmacy to maintain them longer.

Also, which "Division" is being referred to? Please be specific.

Director of the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services (DMH/DD/SAS) has been added for clarity.

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?
The form is available upon request by contacting the Drug Control Unit; the contact information has been added to the Rule. The contents and requirements of the form provide documentation of the substances prescribed that are now subject to destruction.

Line 12: Does your regulated public know what "hermetically" means or is it defined in another rule?
While not defined in rule, the regulated public is aware of this concept as it has existed in this rule for many years and refers to an airtight seal that prevents the passage of gases, liquids, and solids.

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?

In this context, the reference is to pharmacies returning controlled substances to stock, itself a extreme rarity, given the risk of contamination. Yes, our regulated public is familiar with this phrase as this practice has been in place for many years and refers to controlled substances that are in their original manufacturer packaging, with all seals intact, all original labels legible, without signs of damage or tampering.

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.
This change has been completed.

Line 16: How will the pharmacy determine if the reverse distributor is maintaining "compliance with all applicable federal and State laws and regulations"?
The pharmacy would need to ensure that the reverse distributor is registered with the DEA and operating in accordance with 21 CFR 1317.15. A list of reverse distributors is maintained by the DEA and is available upon request.

Line 17: Please capitalize "rule". Also, which "Director" are you referring to? Please be specific.
This has been clarified in the Rule.

Line 26: Pursuant to G.S. 150B-21.1(b), the effective date will likely be January 2, 2025.
This date has been added to the Rule. Please let me know if this changes.

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 with changes via temporary procedures as follows.

10A NCAC 27G .3605 MEDICATION UNITS AND MOBILE UNITS

(a) [~~Definitions~~]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 Full Time Employee (FTE) [~~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~~]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, 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 Adoption Eff. September 17, 2024;
Temporary Adoption Eff. January 2, 2025.

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

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

Controlled substances dispensed for inpatient administration to individuals residing in ~~to~~ a licensed nursing ~~home~~home, ~~which~~which, for any ~~reason~~reason, are ~~unused~~unused, shall be returned to the pharmacy from which they were received. The ~~pharmacist~~pharmacy ~~who~~that receives these controlled substances shall return them to ~~his~~[~~their~~]its stock or dispose of and destroy them in accordance with ~~the procedure outlined by the director and~~21 CFR 1317.05(a). The [~~pharmacist~~]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~~ "Record of [~~Ultimate User~~"]Controlled Substances Destroyed pursuant to Rule 10A NCAC 26E .0406".~~Destruction Record Nursing Homes."~~ 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 a~~an otherwise~~ pure uncontaminated condition and be identifiable. A [~~pharmacist~~]pharmacy may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the [~~pharmacist~~]pharmacy must first verify the [~~vendor~~]reverse distributor is registered with the federal Drug Enforcement Agency (DEA) [~~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.~~] substances per 21 CFR 1317.15. Compliance with this [~~rule~~]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 25, 2024;
Temporary Amendment Eff. January 2, 2025.

Burgos, Alexander N

From: Wiggs, Travis C
Sent: Tuesday, December 3, 2024 2:38 PM
To: Baker, Denise
Cc: Burgos, Alexander N
Subject: RRC December 2024-Request for Changes
Attachments: 12_2024_Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services.docx

Good afternoon,

I'm the attorney who reviewed the temporary rules submitted by the Division of MH/DD/SAS for the December 2024 RRC meeting. The RRC will formally review these rules at its meeting on Thursday, December 19, 2024, at 10:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get close to the meeting. If there are any other representatives from your agency who want to attend virtually, please let me know prior to the meeting, and we will get evites out to them as well.

Attached is the Request for Changes Pursuant to G.S. 150B-21.10. Please submit the revised rules and forms to me via email, no later than 5 p.m. on December 13, 2024. Let me know if you have any questions.

Thank you.

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings
Telephone: 984-236-1929
Email: travis.wiggs@oah.nc.gov