Subject:

FW: October 2025 RRC Meeting

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Sent: Monday, October 20, 2025 11:30 AM

To: Baker, Denise < Denise.Baker@dhhs.nc.gov>; Rules, Oah < oah.rules@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: October 2025 RRC Meeting

Thank you, Ms. Baker.

Alex and Julie,

Attached are the final revised versions of these Rules and can be posted on the agenda for October.

Thanks,

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: Monday, October 20, 2025 11:26 AM **To:** Rules, Oah <<u>oah.rules@oah.nc.gov</u>>

Cc: Wiggs, Travis C < travis.wiggs@oah.nc.gov; Burgos, Alexander N alexander.burgos@oah.nc.gov

Subject: October 2025 RRC Meeting

Good morning –

Please see attached.

Thank you, Denise

Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

Email correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized state official.

1	Rule 10A NCAC 26E .0406 is amended with changes as published in 39:24 NCR 1605 as follows.
2	
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, including
10	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
11	Subpart C. which for any reason are unused shall be returned to the pharmacy from which they were received. The
12	pharmacist who receives these controlled substances shall return them to his stock or destroy them in accordance
13	with the procedure outlined by the director and The pharmacy shall keep a record of this the disposal and destruction
14	of unused controlled substances available for a minimum of two years. This record of disposal and destruction shall
15	be kept on the Division of Mental Health, Developmental Disabilities, and Substance Use Services (Division)
16	formForm entitled "Controlled Substances Destruction Record Nursing Homes." "Record of Controlled Substances
17	Destroyed Pursuant to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008
18	Mail Service Center Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock
19	must be in a hermetically sealed container or in an otherwise a pure uncontaminated condition and be
20	identifiable.identifiable with the original manufacturer's labelling legible. A pharmacy may outsource destruction o
21	the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the
22	pharmacy must first verify the reverse distributor is registered with the DEA as a reverse distributor and maintains
23	compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction
24	of unused controlled substances per 21 CFR 1317.15. Pharmacies that are authorized by the DEA as collectors may
25	install, [manage]manage, and maintain collection receptacles at nursing homes for the purpose of collection,
26	[disposal]disposal, and destruction of unused controlled substances from nursing homes, in accordance with 21 CFR
27	1317.05(c), 21 CFR [1317.40]1317.40, and other applicable federal regulations governing the use of collection
28	receptacles by authorized pharmacy collectors in nursing [homes, including 21 CFR 1301.51, 21 CFR
29	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
30	Rule is subject to audit by the Division Director or their designated representative.
31	
32	History Note: Authority G.S. 90-100; 143B-210(9); 143B-147;
33	Eff. June 30, 1978;
34	Amended Eff. September 15, 1980; May 15, 1979;
35	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2
36	2016. 2016;
37	Emergency Amendment Eff. September 30, 2024.2024;

1	Temporary Amendment	Eff. January 2, 2025;

2 <u>Amended Eff. November 1, 2025.</u>

1 2	Rule 10A NCAC 27G .3605 is adopted with changes as published in 39:24 NCR 1606 as follows.
3	10A NCAC 27G .3605 Medication Units and Mobile Units
4	(a) Definitions 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 t
7	facility license.
8	(3) "Opioid Treatment Program Medication Unit" (hereinafter OTP Medication Unit) means the san
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	(5) "Division" means the same as defined in G.S. 122C-3(13).
13	(b) The OTP Facility shall provide any medical, counseling, vocational, educational, and other assessment and
14	treatment services not provided by the OTP Medication Unit or OTP Mobile Unit.
15	(c) The OTP shall determine the type of services to be provided at the OTP Medication Units and OTP Mobile
16	Units. The OTP shall clearly specify which services are offered at the OTP Medication Units and OTP Mobile
17	Units. Any services not offered at the OTP Medication Unit or Mobile Unit shall be provided at the OTP
18	facility.Facility.
19	(d) Location and Service Capacity.
20	(1) The OTP shall ensure that each OTP Medication Unit and OTP Mobile Unit complies with all
21	applicable State and Federal laws and regulations, including without limitation, Substance Abuse
22	and Mental Health Services Administration regulations in 42 CFR Part 8 and Federal Drug
23	Enforcement Agency regulations in 21 CFR Parts 1300, 1301, and 1304, governing controlled
24	substances, dispensers of controlled substances, mobile narcotic treatment programs. governing
25	their operation. Each of these Codes is incorporated by reference, including subsequent
26	amendments. Copies are available free of charge at the Division 3001 Mail Service Center,
27	Raleigh, NC 27699-3001; electronic copies are available at no cost at www.ecfr.gov.
28	(2) An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall
29	maintain and provide the location of each unit associated with the OTP.
30	(3) The OTP Medication Units and OTP Mobile Units shall operate within a radius of 75 miles from
31	the Opioid Treatment Program facility. OTP Facility.
32	(4) The OTP shall maintain and provide schedules for the days and hours of operation to meet
33	patient needs.
34	(5) The OTP shall establish and implement an operating protocol identifying the number of patients
35	allowed per OTP Medication Unit and OTP Mobile Unit based on staffing ratios.
36	(6) The OTP shall establish and implement an operating protocol which includes predetermined
37	location(s) hours of operations, and a daily departure guide and business record of each OTP

1		Mobile	Unit's location.
2	(e)	Staffing Requirement	s. The OTP shall develop and implement governing body policies in accordance with
3		Rule 10A NCAC 27C	6.0201, which is incorporated by reference, including subsequent amendments, and is
4		available free of charg	ge at the Division 3001 Mail Service Center Raleigh, NC 27699-3001; an electronic copy
5		is available at no cost	at www.oah.nc.gov. maintain standard operating and emergency staffing The OTP shall
6		maintain staffing to en	nsure service delivery at the OTP and any associated OTP Medication Units and OTP
7		Mobile Units. Units in	accordance with 42 CFR 8.12(b)(1). Staffing shall include, include but not be limited to
8		the following:	
9		(1) <u>The OT</u>	P shall have a 1.0 FTE Full-time employee (FTE) Licensed Clinical Addiction Specialist
10		(LCAS)	, or Licensed Clinical Addiction Specialist-Associate (LCAS-A) per 50 patients. This
11		position	can be filled by more than one LCAS or LCAS-A staff member (ratio 1:50); and
12		(2) The OT	P shall have 1.0 FTE LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC),
13		Certified	d Alcohol and Drug Counselor Intern (CADC-I), Licensed Clinical Social Worker
14		(LCSW)	, Licensed Clinical Social Worker – Associate (LCSW-A), Licensed Clinical Mental
15		Health (Counselor (LCMHC), Licensed Clinical Mental Health Counselor – Associate (LCMHC-
16		A), Lice	ensed Marriage and Family Therapist (LMFT), Licensed Marriage and Family Therapist
17		- Assoc	iate (LMFT-A), Licensed Psychological Associate (LPA), or Licensed Psychologist (LP)
18		for each	additional 50 patients in the program (ratio 1:50); and
19		(3) The OT	P shall have a Medical Director who is a physician licensed to practice medicine in North
20		Carolina	and who meets the standards and requirements outlined in 42 CFR 8.2 and 42 CFR
21		8.12(b).	
22		(A)	The Medical Director is responsible for ensuring all medical, psychiatric, nursing,
23			pharmacy, toxicology, and other services offered at the OTP and any associated OTP
24			Medication Units and OTP Mobile Units are conducted in compliance with <u>State and</u>
25			$\underline{Federal\ laws\ and}\ \underline{regulations}, \underline{eonsistent\ with\ appropriate\ standards\ of\ care;}\ \underline{regulations}$
26			pursuant to 42 CFR 8.2.
27		(B)	The Medical Director shall be physically present at the OTP a minimum of 4 hours per
28			month to assure regulatory compliance and to carry out those duties assigned to the
29			Medical Director in 42 CFR 8.2 and 42 CFR 8.12(b)(2).
30		(C)	The Medical Director shall be responsible for supervision of any physician
31			extender(s) practitioner(s), as defined in 42 CFR 8.2, and other medical staff.
32	(f)	Each OTP shall devel	op and implement a policy regarding the maintenance, location, and retention of records
33		for its OTP Medication	on Units and OTP Mobile Units, in accordance with State and Federal laws and
34		regulations. including	42 CFR 8.12(g), G.S. 90-104, Rule 10A NCAC 26E .0202, 21 CFR 1304.24 and 21
35		CFR 1304.25. G.S. 9	0-104 and 10A NCAC 26E .0202 are incorporated by reference, including subsequent
36		amendments, and are	available free of charge at the Division 3001 Mail Service Center, Raleigh, NC 27699-
37		3001. Electronic cop	ies of the statute are available at www.ncleg.gov; electronic copies of the Rule are

1	<u>available a</u>	t no cost at www.oah.nc.gov.
2	(g) Operations	and Service Delivery <u>Delivery.</u>
3	(1)	Each OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and
4		shall be subject to inspections the Department deems necessary to validate compliance with all
5		applicable rules, and State and Federal laws and regulations.referenced herein.
6	(2)	The OTP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State
7		and federal program requirements for Opioid Treatment Programs.
8	(3)	Each OTP Medication Unit and OTP Mobile Unit shall establish and implement a written
9		policy and procedure for operations that meets the needs of its patients.
10	(4)	The OTP shall establish and implement policies and procedures for a clinical and individualized
11		assessment of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that
12		considers medical and clinical appropriateness and accessibility to patients served.
13	(5)	The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP
14		Mobile Unit receive a minimum of two counseling sessions per month during the first year of
15		continuous treatment and a minimum of one counseling session per month after the first year
16		and in all subsequent years of continuous treatment.
17	(6)	Counseling staff shall be available, either in person and on-site or by telehealth, a minimum of
18		five days per week to offer and provide counseling in accordance with the patient's treatment
19		plan or person-centered plan.
20	(7)	The OTP shall establish and implement a policy and procedure to determine the appropriateness
21		of telehealth services for a patient that takes into consideration the patient's choice along with
22		the patient's behavior, physical, and cognitive abilities. The patient's verbal or written consent
23		shall be documented when telehealth services are provided.
24	(8)	The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP
25		Mobile Unit receive medical interventions, including naloxone, when medically necessary and
26		in compliance with the patient's treatment plan, person-centered plan, standing orders, or
27		emergency intervention protocols.
28	(9)	An OTP and its associated OTP Medication Units and OTP Mobile Units shall ensure that all
29		dosing of medication to patients on the site of the OTP and any associated OTP Medication
30		Units and OTP Mobile Units is directly observed by a Physician, Physician Assistant, Nurse
31		Practitioner, Pharmacist, Registered Nurse, or Licensed Practical Nurse, in accordance with
32		applicable State and Federal Law Law, including 42 CFR Part 8, and the OTP's Diversion
33		Control Plan.
34		
35	History Note:	Authority G.S. 122C-35; 42 C.F.R. 8.12;
36		Emergency Eff. September 23, 2024;
37		Temporary Eff. January 2. 2025:

1 2

Subject:

FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

From: Baker, Denise < Denise.Baker@dhhs.nc.gov>

Sent: Friday, October 17, 2025 11:27 AM **To:** Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Thanks so much Travis. I will.

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

Twitter | Facebook | YouTube | LinkedIn

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Sent: Friday, October 17, 2025 11:05 AM

To: Baker, Denise < Denise.Baker@dhhs.nc.gov >

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Good morning,

I'm satisfied with the changes to these rules. Please email both rules, with revisions, to oah.rules@oah.nc.gov by October 22, 2025 at 5pm for RRC review. Please copy me and alexander.burgos@oah.nc.gov to the email.

Thanks,

Travis C. Wiggs Rules Review Commission Counsel Office of Administrative Hearings

Telephone: 984-236-1929

Email: travis.wiggs@oah.nc.gov

Subject: FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Attachments: 10A NCAC 27G .3605.docx

From: Baker, Denise < Denise.Baker@dhhs.nc.gov>

Sent: Friday, October 17, 2025 9:56 AM

To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Thank you for your feedback; please see attached.

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

Twitter | Facebook | YouTube | LinkedIn

1 2	Rule 10A NCAC 27G .3605 is adopted with changes as published in 39:24 NCR 1606 as follows.
3	10A NCAC 27G .3605 Medication Units and Mobile Units
4	(a) Definitions Definitions:
5	(1) "Opioid Treatment Program" (hereinafter, OTP) means the same as defined in G.S. 122C-3(25a)
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13	(b) The OTP Facility shall provide any medical, counseling, vocational, educational, and other assessment and
14	treatment services not provided by the OTP Medication Unit or OTP Mobile Unit.
15	(c) The OTP shall determine the type of services to be provided at the OTP Medication Units and OTP Mobile
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21	applicable State and Federal laws and regulations, including without limitation, Substance Abuse
22	and Mental Health Services Administration regulations in 42 CFR Part 8 and Federal Drug
23	Enforcement Agency regulations in 21 CFR Parts 1300, 1301, and 1304, governing controlled
24	substances, dispensers of controlled substances, mobile narcotic treatment programs. governing
25	their operation. Each of these Codes is incorporated by reference, including subsequent
26	amendments. Copies are available free of charge at the Division 3001 Mail Service Center,
27	Raleigh, NC 27699-3001; electronic copies are available at no cost at www.ecfr.gov.
28	(2) An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall
29	maintain and provide the location of each unit associated with the OTP.
30	(3) The OTP Medication Units and OTP Mobile Units shall operate within a radius of 75 miles from
31	the Opioid Treatment Program facility. OTP Facility.
32	(4) The OTP shall maintain and provide schedules for the days and hours of operation to meet
33	patient needs.
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9		(1) <u>The OT</u>	P shall have a 1.0 FTE Full-time employee (FTE) Licensed Clinical Addiction Specialist
10		(LCAS)	, or Licensed Clinical Addiction Specialist-Associate (LCAS-A) per 50 patients. This
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12		(2) The OT	P shall have 1.0 FTE LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC),
13		Certified	d Alcohol and Drug Counselor Intern (CADC-I), Licensed Clinical Social Worker
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17		- Assoc	iate (LMFT-A), Licensed Psychological Associate (LPA), or Licensed Psychologist (LP)
18		for each	additional 50 patients in the program (ratio 1:50); and
19		(3) The OT	P shall have a Medical Director who is a physician licensed to practice medicine in North
20		Carolina	and who meets the standards and requirements outlined in 42 CFR 8.2 and 42 CFR
21		8.12(b).	
22		(A)	The Medical Director is responsible for ensuring all medical, psychiatric, nursing,
23			pharmacy, toxicology, and other services offered at the OTP and any associated OTP
24			Medication Units and OTP Mobile Units are conducted in compliance with <u>State and</u>
25			$\underline{Federal\ laws\ and}\ \underline{regulations}, \underline{eonsistent\ with\ appropriate\ standards\ of\ care;}\ \underline{regulations}$
26			pursuant to 42 CFR 8.2.
27		(B)	The Medical Director shall be physically present at the OTP a minimum of 4 hours per
28			month to assure regulatory compliance and to carry out those duties assigned to the
29			Medical Director in 42 CFR 8.2 and 42 CFR 8.12(b)(2).
30		(C)	The Medical Director shall be responsible for supervision of any physician
31			extender(s) practitioner(s), as defined in 42 CFR 8.2, and other medical staff.
32	(f)	Each OTP shall devel	op and implement a policy regarding the maintenance, location, and retention of records
33		for its OTP Medication	on Units and OTP Mobile Units, in accordance with State and Federal laws and
34		regulations. including	42 CFR 8.12(g), G.S. 90-104, Rule 10A NCAC 26E .0202, 21 CFR 1304.24 and 21
35		CFR 1304.25. G.S. 9	0-104 and 10A NCAC 26E .0202 are incorporated by reference, including subsequent
36		amendments, and are	available free of charge at the Division 3001 Mail Service Center, Raleigh, NC 27699-
37		3001. Electronic cop	ies of the statute are available at www.ncleg.gov; electronic copies of the Rule are

1	<u>available a</u>	t no cost at www.oah.nc.gov.
2	(g) Operations	and Service Delivery <u>Delivery.</u>
3	(1)	Each OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and
4		shall be subject to inspections the Department deems necessary to validate compliance with all
5		applicable rules, and State and Federal laws and regulations.referenced herein.
6	(2)	The OTP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State
7		and federal program requirements for Opioid Treatment Programs.
8	(3)	Each OTP Medication Unit and OTP Mobile Unit shall establish and implement a written
9		policy and procedure for operations that meets the needs of its patients.
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16		and in all subsequent years of continuous treatment.
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18		five days per week to offer and provide counseling in accordance with the patient's treatment
19		plan or person-centered plan.
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27		emergency intervention protocols.
28	(9)	An OTP and its associated OTP Medication Units and OTP Mobile Units shall ensure that all
29		dosing of medication to patients on the site of the OTP and any associated OTP Medication
30		Units and OTP Mobile Units is directly observed by a Physician, Physician Assistant, Nurse
31		Practitioner, Pharmacist, Registered Nurse, or Licensed Practical Nurse, in accordance with
32		applicable State and Federal Law Law, including 42 CFR Part 8, and the OTP's Diversion
33		Control Plan.
34		
35	History Note:	Authority G.S. 122C-35; 42 C.F.R. 8.12;
36		Emergency Eff. September 23, 2024;
37		Temporary Eff. January 2. 2025:

1 2

Subject:

FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov> **Sent:** Wednesday, October 15, 2025 4:09 PM **To:** Baker, Denise <Denise.Baker@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Ms. Baker,

I have a few minor requests for changes:

р

- 1. Page 1, line 28, add "are available" after "copies".
- 2. Page 2, line 4, add a comma and "which" after ".0201". (.0201, which is ...)
- 3. Please remove all "§" within each G.S. or CFR referenced within the Rule.
- 4. Page 2, line 34, remove "and" at the end of the line.
- 5. Page 3, line 6, remove "and" after "laws".

Please complete these few changes and send to me for final review.

Thanks,

Travis C. Wiggs Rules Review Commission Counsel Office of Administrative Hearings Telephone: 984-236-1929

- " - - -

Email: travis.wiggs@oah.nc.gov

e all records of this email.

Subject:

FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>
Sent: Wednesday, October 15, 2025 1:44 PM
To: Baker, Denise <Denise.Baker@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Good afternoon,

When do you expect to make requested changes below and resend the rules to me for final review?

Thanks,

Travis C. Wiggs Rules Review Commission Counsel Office of Administrative Hearings

Telephone: 984-236-1929

Email: travis.wiggs@oah.nc.gov

1	Rule 10A NCAC	27G .3605 is adopted with changes as published in 39:24 NCR 1606 as follows.
2		
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4	(a) Definitions Def	<u>finitions:</u>
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	f	facility license.
8	(3) "	'Opioid Treatment Program Medication Unit' (hereinafter OTP Medication Unit) means the same
9	а	as defined in G.S. § 122C-3(25b).
10	(4) "	'Opioid Treatment Program Mobile Unit" (hereinafter OTP Mobile Unit) means the same as
11	Ċ	defined in G.S.§ 122C-3(25c).
12	<u>(5)</u> "	'Division" means the same as defined in G.S. § 122C-3(13).
13	(b) The OTP Faci	lity shall provide any medical, counseling, vocational, educational, and other assessment and
14	treatment serv	rices not provided by the OTP Medication Unit or OTP Mobile Unit.
15	(c) The OTP shall	l determine the type of services to be provided at the OTP Medication Units and OTP Mobile
16	Units. The OT	CP shall clearly specify which services are offered at the OTP Medication Units and OTP Mobile
17	Units. Any ser	rvices not offered at the OTP Medication Unit or Mobile Unit shall be provided at the OTP
18	facility.Facilit	<u>y.</u>
19	(d) Location and S	Service Capacity.
20	(1)	The OTP shall ensure that each OTP Medication Unit and OTP Mobile Unit complies with all
21	а	applicable State and Federal laws and regulations, including without limitation, Substance Abuse
22	а	and Mental Health Services Administration and Federal Drug Enforcement Agency regulations
23	<u>i</u>	in 42 CFR Part 8 and federal Drug Enforcement Agency regulations in 21 CFR Parts 1300, 1301,
24	<u>a</u>	and 1304, governing controlled substances, dispensers of controlled substances, mobile narcotic
25	<u>t</u>	treatment programs, and federal Drug Enforcement Agency restraints. governing their operation.
26	<u>I</u>	Each of these Codes is incorporated by reference, including subsequent amendments. Copies are
27	<u>a</u>	available free of charge at the Division 3001 Mail Service Center, Raleigh, NC 27699-3001;
28	<u>e</u>	electronic copies at no cost at www.ecfr.gov.
29	(2) A	An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall
30	r	maintain and provide the location of each unit associated with the OTP.
31	(3)	The OTP Medication Units and Mobile Units shall operate within a radius of 75 miles from the
32	(Opioid Treatment Program facility. OTP Facility.
33	(4)	The OTP shall maintain and provide schedules for the days and hours of operation to meet
34	r	patient needs.
35	(5)	The OTP shall establish and implement an operating protocol identifying the number of patients
36	а	allowed per OTP Medication Unit and OTP Mobile Unit based on staffing ratios.
37	(6)	The OTP shall establish and implement an operating protocol which includes predetermined

1		location	n(s), hours of operations, and a daily departure guide and business record of each OTP
2		Mobile	Unit's location.
3	(e)	Staffing Requirement	ts. The OTP shall develop and implement governing body policies in accordance with
4		Rule 10A NCAC 270	6.0201 is incorporated by reference, including subsequent amendments, and is available
5		free of charge at the l	Division 3001 Mail Service Center Raleigh, NC 27699-3001; an electronic copy is
6		available at no cost a	t www.oah.nc.gov. standard operating and emergency staffing The OTP shall maintain
7		staffing to ensure ser	vice delivery at the OTP and any associated OTP Medication Units and OTP Mobile
8		Units.Units in accord	ance with 42 CFR § 8.12(b)(1). Staffing shall include, include but not be limited to the
9		following:	
10		(1) <u>The OT</u>	P shall have a 1.0 FTE Full-time employee (FTE) Licensed Clinical Addiction Specialist
11		(LCAS)	, or Licensed Clinical Addiction Specialist-Associate (LCAS-A) per 50 patients. This
12		position	can be filled by more than one LCAS or LCAS-A staff member (ratio 1:50); and
13		(2) The OT	P shall have 1.0 FTE LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC),
14		Certifie	d Alcohol and Drug Counselor Intern (CADC-I), Licensed Clinical Social Worker
15		(LCSW), Licensed Clinical Social Worker – Associate (LCSW-A), Licensed Clinical Mental
16		Health	Counselor (LCMHC), Licensed Clinical Mental Health Counselor – Associate (LCMHC-
17		A), Lice	ensed Marriage and Family Therapist (LMFT), Licensed Marriage and Family Therapist
18		- Assoc	tiate (LMFT-A), Licensed Psychological Associate (LPA), or Licensed Psychologist (LP)
19		for each	additional 50 patients in the program (ratio 1:50); and
20		(3) The OT	P shall have a Medical Director who is a physician licensed to practice medicine in North
21		Carolin	a and who meets the standards and requirements outlined in 42 CFR \S 8.2 and 42 CFR \S
22		8.12(b).	
23		(A)	The Medical Director is responsible for ensuring all medical, psychiatric, nursing,
24			pharmacy, toxicology, and other services offered at the OTP and any associated OTP
25			Medication Units and OTP Mobile Units are conducted in compliance with <u>State and</u>
26			$\underline{Federal\ laws\ and\ regulations,}\ consistent\ with\ appropriate\ standards\ of\ care; \underline{regulations}$
27			pursuant to 42 CFR 8.2; and
28		(B)	The Medical Director shall be physically present at the OTP a minimum of 4 hours per
29			month to assure regulatory compliance and to carry out those duties assigned to the
30			Medical Director in 42 CFR § 8.2 and 42 CFR § 8.12(b)(2).
31		(C)	The Medical Director shall be responsible for supervision of any physician
32			extender(s)practitioner(s), as defined in 42 CFR § 8.2, and other medical staff.
33	(f)	Each OTP shall deve	lop and implement a policy regarding the maintenance, location, and retention of records
34		for its OTP Medication	on Units and OTP Mobile Units, in accordance with State and Federal laws and
35		regulations. including	g 42 CFR 8.12(g), G.S. § 90-104, Rule 10A NCAC 26E .0202, 21 CFR 1304.24 and 21
36		CFR 1304.25. G.S. §	§ 90-104 and 10A NCAC 26E .0202 are incorporated by reference, including subsequent
37		amendments, and are	available free of charge at the Division 3001 Mail Service Center, Raleigh, NC 27699-

1	3001. Elec	3001. Electronic copies of the statute are available at www.ncleg.gov; electronic copies of the Rule are		
2	available a	t no cost at www.oah.nc.gov.		
3	(g) Operations	s and Service Delivery Delivery.		
4	(1)	Each OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and		
5		shall be subject to inspections the Department deems necessary to validate compliance with all		
6		applicable rules, and State and Federal laws and regulations.referenced herein.		
7	(2)	The OTP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State		
8		and federal program requirements for Opioid Treatment Programs.		
9	(3)	Each OTP Medication Unit and OTP Mobile Unit shall establish and implement a written		
10		policy and procedure for operations that meets the needs of its patients.		
11	(4)	The OTP shall establish and implement policies and procedures for a clinical and individualized		
12		assessment of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that		
13		considers medical and clinical appropriateness and accessibility to patients served.		
14	(5)	The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP		
15		Mobile Unit receive a minimum of two counseling sessions per month during the first year of		
16		continuous treatment and a minimum of one counseling session per month after the first year		
17		and in all subsequent years of continuous treatment.		
18	(6)	Counseling staff shall be available, either in person and on-site or by telehealth, a minimum of		
19		five days per week to offer and provide counseling in accordance with the patient's treatment		
20		plan or person-centered plan.		
21	(7)	The OTP shall establish and implement a policy and procedure to determine the appropriateness		
22		of telehealth services for a patient that takes into consideration the patient's choice along with		
23		the patient's behavior, physical, and cognitive abilities. The patient's verbal or written consent		
24		shall be documented when telehealth services are provided.		
25	(8)	The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP		
26		Mobile Unit receive medical interventions, including naloxone, when medically necessary and		
27		in compliance with the patient's treatment plan, person-centered plan, standing orders, or		
28		emergency intervention protocols.		
29	(9)	An OTP and its associated OTP Medication Units and OTP Mobile Units shall ensure that all		
30		dosing of medication to patients on the site of the OTP and any associated OTP Medication		
31		Units and OTP Mobile Units is directly observed by a Physician, Physician Assistant, Nurse		
32		Practitioner, Pharmacist, Registered Nurse, or Licensed Practical Nurse, in accordance with		
33		applicable State and Federal Law Law, including 42 CFR Part 8, and the OTP's Diversion		
34		Control Plan.		
35				
36	History Note:	Authority G.S. 122C-35; 42 C.F.R. § 8.12;		
37		Emergency Eff. September 23, 2024;		

1	Temporary Eff. January 2, 2025;
2	Eff. November 1, 2025.
3	

Subject:

FW: Periodic Review 10A NCAC 27, 28

From: Baker, Denise < Denise.Baker@dhhs.nc.gov>

Sent: Tuesday, October 14, 2025 10:28 AM **To:** Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: Periodic Review 10A NCAC 27, 28

Thanks Travis -

I'll get it to you before the end of the week.

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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Subject:

FW: Periodic Review 10A NCAC 27, 28

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Sent: Tuesday, October 14, 2025 10:01 AM **To:** Baker, Denise <Denise.Baker@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: Periodic Review 10A NCAC 27, 28

Good morning,

I will need the requested information by October 24 for the RRC to vote on the readoption deadline at the October meeting.

Thanks,

Travis C. Wiggs Rules Review Commission Counsel Office of Administrative Hearings

Telephone: 984-236-1929

Email: travis.wiggs@oah.nc.gov

Subject:

FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

From: Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Sent: Monday, October 13, 2025 9:17 PM **To:** Baker, Denise < Denise.Baker@dhhs.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Ms. Baker,

Thank you for the reply and changes. Specific materials only need to be incorporated by reference once within each rule. Please remove all duplicative incorporations of the same information (e.g., 42 C.F.R. § 8.12) and send me the Rule for review.

Thanks,

Travis C. Wiggs Rules Review Commission Counsel Office of Administrative Hearings

Telephone: 984-236-1929

Email: travis.wiggs@oah.nc.gov

Subject: FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Attachments: 10A NCAC 27G .3605.docx

From: Baker, Denise < Denise.Baker@dhhs.nc.gov>

Sent: Monday, October 13, 2025 2:42 PM **To:** Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Hi Travis -

It seems I inadvertently attached the rule with the corrections you had requested for the temporary rule.

Please forgive the oversight and see the attached instead.

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

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

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

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1	Rule 10A NCAC	27G .3605 is adopted with changes as published in 39:24 NCR 1606 as follows.
2		
3	10A NCAC 27G	.3605 Medication Units and Mobile Units
4	(a) Definitions D	efinitions:
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	<u>(5)</u>	"Division" means the same as defined in G.S. § 122C-3(13).
13	(b) The OTP Fac	cility shall provide any medical, counseling, vocational, educational, and other assessment and
14	treatment ser	vices not provided by the OTP Medication Unit or OTP Mobile Unit.
15	(c) The OTP sha	all determine the type of services to be provided at the OTP Medication Units and OTP Mobile
16	Units. The O	TP shall clearly specify which services are offered at the OTP Medication Units and OTP Mobile
17	Units. Any s	ervices not offered at the OTP Medication Unit or Mobile Unit shall be provided at the OTP
18	facility.Facil	ity.
19	(d) Location and	Service Capacity.
20	(1)	The OTP shall ensure that each OTP Medication Unit and OTP Mobile Unit complies with all
21		applicable State and Federal laws and regulations, including without limitation, Substance Abuse
22		and Mental Health Services Administration and Federal Drug Enforcement Agency regulations
23		in 42 CFR Part 8 and federal Drug Enforcement Agency regulations in 21 CFR Parts 1300, 1301,
24		and 1304, and 21 CFR 1301.13 governing controlled substances, dispensers of controlled
25		substances, mobile narcotic treatment programs, and federal Drug Enforcement Agency
26		restraints. governing their operation. Each of these Codes is incorporated by reference, including
27		subsequent amendments. Copies are available free of charge at the Division 3001 Mail Service
28		Center, Raleigh, NC 27699-3001; electronic copies at no cost at www.ecfr.gov.
29	(2)	An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall
30		maintain and provide the location of each unit associated with the OTP.
31	(3)	The OTP Medication Units and Mobile Units shall operate within a radius of 75 miles from the
32		Opioid Treatment Program facility. OTP Facility.
33	(4)	The OTP shall maintain and provide schedules for the days and hours of operation to meet
34		patient needs.
35	(5)	The OTP shall establish and implement an operating protocol identifying the number of patients
36		allowed per OTP Medication Unit and OTP Mobile Unit based on staffing ratios.
37	(6)	The OTP shall establish and implement an operating protocol which includes predetermined

1			location	(s), hours of operations, and a daily departure guide and business record of each OTP
2			Mobile	Unit's location.
3	(e)	Staffing Req	uirement	s. The OTP shall develop and implement governing body policies in accordance with
4		Rule 10A NO	CAC 270	6.0201 which is incorporated by reference, including subsequent amendments, and is
5		available free	e of char	ge at the Division 3001 Mail Service Center Raleigh, NC 27699-3001; an electronic copy
6		is available a	t no cost	at www.oah.nc.gov. standard operating and emergency staffing The OTP shall maintain
7		staffing to en	sure serv	vice delivery at the OTP and any associated OTP Medication Units and OTP Mobile
8		Units.Units i	n accord	ance with 42 CFR § 8.12(b)(1) which is incorporated by reference, including subsequent
9		amendments	, and is a	vailable free of charge at the Division 3001 Mail Service Center Raleigh, NC 27699-
10		3001; an elec	etronic co	opy is available at no cost at www.ecfr.gov. Staffing shall include, include but not be
11		limited to the	followi	ng:
12		(1)	The OT	P shall have a 1.0 FTEFull-time employee (FTE) Licensed Clinical Addiction Specialist
13			(LCAS)	, or Licensed Clinical Addiction Specialist-Associate (LCAS-A) per 50 patients. This
14			position	can be filled by more than one LCAS or LCAS-A staff member (ratio 1:50); and
15		(2)	The OT	P shall have 1.0 FTE LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC),
16			Certifie	d Alcohol and Drug Counselor Intern (CADC-I), Licensed Clinical Social Worker
17			(LCSW)), Licensed Clinical Social Worker – Associate (LCSW-A), Licensed Clinical Mental
18			Health (Counselor (LCMHC), Licensed Clinical Mental Health Counselor – Associate (LCMHC-
19			A), Lice	ensed Marriage and Family Therapist (LMFT), Licensed Marriage and Family Therapist
20			- Assoc	iate (LMFT-A), Licensed Psychological Associate (LPA), or Licensed Psychologist (LP)
21			for each	additional 50 patients in the program (ratio 1:50); and
22		(3)	The OT	P shall have a Medical Director who is a physician licensed to practice medicine in North
23			Carolina	a and who meets the standards and requirements outlined in 42 CFR § 8.2 and 42 CFR §
24			8.12(b).	8.12(b) which are incorporated by reference, including subsequent amendments. Copies
25			of these	Codes are available free of charge at the Division 3001 Mail Service Center, Raleigh,
26			NC 276	99-3001; electronic copies of the Code of Federal Regulations are available at no cost at
27			www.ec	fr.gov.
28			(A)	The Medical Director is responsible for ensuring all medical, psychiatric, nursing,
29				pharmacy, toxicology, and other services offered at the OTP and any associated OTP
30				Medication Units and OTP Mobile Units are conducted in compliance with <u>State and</u>
31				Federal laws and regulations, consistent with appropriate standards of care; regulations
32				pursuant to 42 CFR 8.2 which is incorporated by reference, including all subsequent
33				amendments, a copy of which is available free of charge at the Division 3001 Mail
34				Service Center, Raleigh, NC 27699-3001; an electronic copy is available at
35				www.ecfr.gov; and
36			(B)	The Medical Director shall be physically present at the OTP a minimum of 4 hours per
37				month to assure regulatory compliance and to carry out those duties assigned to the

1				Medical Director in 42 CFR §8.2 and 42 CFR § 8.12(b)(2).
2			(C)	The Medical Director shall be responsible for supervision of any physician
3				extender(s)practitioner(s), as defined in 42 CFR § 8.2, incorporated by reference,
4				including subsequent amendments, available free of charge at the Division 3001 Mail
5				Service Center, Raleigh, NC 27699-3001; electronic copies of the Code of Federal
6				Regulations are available at no cost at www.ecfr.gov; and other medical staff.
7	(f)	Each OTP s	hall deve	lop and implement a policy regarding the maintenance, location, and retention of records
8		for its OTP	Medication	on Units and OTP Mobile Units, in accordance with State and Federal laws and
9		regulations.	including	g 42 CFR 8.12(g), G.S. § 90-104, Rule 10A NCAC 26E .0202, 21 CFR 1304.24 and 21
10		CFR 1304.2	5 incorpo	prated by reference including subsequent amendments. Copies of the statute, rule, and
11		Codes are av	vailable f	ree of charge at the Division 3001 Mail Service Center, Raleigh, NC 27699-3001;
12		electronic co	opies of the	he Code of Federal Regulations are available at no cost at www.ecfr.gov while copies of
13		NC General	Statutes	are available at www.ncleg.gov.
14	(g)	Operations a	and Servi	<u>ce</u> Delivery Delivery.
15		(1)	Each C	OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and
16			shall b	e subject to inspections the Department deems necessary to validate compliance with all
17			applica	able rules, and State and Federal laws and regulations.referenced herein.
18		(2)	The O	TP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State
19			and fee	deral program requirements for Opioid Treatment Programs.
20		(3)	Each C	OTP Medication Unit and OTP Mobile Unit shall establish and implement a written
21			policy	and procedure for operations that meets the needs of its patients.
22		(4)	The O	TP shall establish and implement policies and procedures for a clinical and individualized
23			assessi	ment of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that
24			consid	ers medical and clinical appropriateness and accessibility to patients served.
25		(5)	The O	TP shall ensure that patients receiving services at an OTP Medication Unit or OTP
26			Mobile	e Unit receive a minimum of two counseling sessions per month during the first year of
27			contin	uous treatment and a minimum of one counseling session per month after the first year
28			and in	all subsequent years of continuous treatment.
29		(6)	Couns	eling staff shall be available, either in person and on-site or by telehealth, a minimum of
30			five da	sys per week to offer and provide counseling in accordance with the patient's treatment
31			plan o	r person-centered plan.
32		(7)	The O	TP shall establish and implement a policy and procedure to determine the appropriateness
33			of tele	health services for a patient that takes into consideration the patient's choice along with
34			the pat	cient's behavior, physical, and cognitive abilities. The patient's verbal or written consent
35			shall b	e documented when telehealth services are provided.
36		(8)	The O	TP shall ensure that patients receiving services at an OTP Medication Unit or OTP
37			Mobile	e Unit receive medical interventions, including naloxone, when medically necessary and

1		in compliance with the patient's treatment plan, person-centered plan, standing orders, or
2		emergency intervention protocols.
3	(9)	An OTP and its associated OTP Medication Units and OTP Mobile Units shall ensure that all
4		dosing of medication to patients on the site of the OTP and any associated OTP Medication
5		Units and OTP Mobile Units is directly observed by a Physician, Physician Assistant, Nurse
6		Practitioner, Pharmacist, Registered Nurse, or Licensed Practical Nurse, in accordance with
7		applicable State and Federal Law Law, including 42 CFR Part 8 incorporated by reference,
8		including subsequent amendments, copies of which are available free of charge at the Division
9		3001 Mail Service Center, Raleigh, NC 27699-3001; electronic copies of the Code of Federal
10		Regulations are available at no cost at www.ecfr.gov, and the OTP's Diversion Control Plan.
11		
12	History Note:	Authority G.S. 122C-35; 42 C.F.R. § 8.12;
13		Emergency Eff. September 23, 2024;
14		Temporary Eff. January 2, 2025;
15		Eff. November 1, 2025.
16		

Subject: Attachments:

FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025 Responses to Request for Technical Corrections 10A NCAC 27G .3605.docx; 10A NCAC 27G .3605.docx; Responses to RRC Counsel Oct2025 10A NCAC 26E .0406.docx; 10A NCAC 26E .0406 .docx

From: Baker, Denise < Denise.Baker@dhhs.nc.gov>

Sent: Friday, October 10, 2025 4:59 PM

To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Please see attached.

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

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Subject:

FW: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

From: Baker, Denise < Denise.Baker@dhhs.nc.gov>

Sent: Friday, October 10, 2025 3:48 PM

To: Wiggs, Travis C <travis.wiggs@oah.nc.gov>

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: Re: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Hi I had something come up unexpectedly but I hope to meet that deadline.

Get Outlook for iOS

From: Wiggs, Travis C < travis.wiggs@oah.nc.gov>

Sent: Friday, October 10, 2025 3:40 PM

To: Baker, Denise < Denise.Baker@dhhs.nc.gov>

Cc: Burgos, Alexander N < alexander.burgos@oah.nc.gov >

Subject: RE: MH/DD/SA Services Commission-Request for Technical Changes-October 2025

Good afternoon,

Is your agency going to comply with the deadline of 5pm today?

Thanks,

Travis C. Wiggs
Rules Review Commission Counsel
Office of Administrative Hearings

Telephone: 984-236-1929

Email: travis.wiggs@oah.nc.gov

lete all records of this email.

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

<u>PLEASE NOTE:</u> 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". Completed.

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

Completed.

Line 17: Capitalize "facility". Completed.

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. Added.

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

Deleted "without limitation".

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

Completed

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

Rule 10A NCAC 27G .0201 requires all facilities to develop and implement governing body policies which govern its operation, management, staff qualifications, etc.; it has been added to the rule. Also, added "in accordance with 42 CFR § 8.12(b)(1)"

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

Deleted.

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

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.

Added.

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.

Added.

Line 20: What is the definition of "physician extender" and where can it be found? 42 C.F.R. § 8.2 uses the term "practitioner," stating, "Practitioner, for purposes of this part, means a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorder and, as a result, is authorized to practice within an OTP."

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.

Added.

Line 25: Add a period after "Delivery". Completed.

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.

Added.

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. Added 42 C.F.R., Part 8

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

Added

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

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

<u>PLEASE NOTE:</u> 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?

No. 10A NCAC 26E .0406 addresses the disposal of controlled substances from Nursing Homes, the requirements in subsection (b) for non-practitioner registrants would not apply because all Nursing Home registrants would be destroying controlled substances in the practitioner registrants' inventory that would need to follow the standards within 21 CFR 1317.05(a).

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.

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.

There are other applicable federal regulations governing nursing homes and long-term care facilities registered with the U.S. DEA and the State of NC, these rules provide guidance to the regulated public but would not be enforced by our agency. Some of these rules include 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.

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

The Rule requires the record to be kept a minimum of two years while permitting the pharmacy to maintain them longer. The language is consistent with that in These standards align with the Federal requirements set forth in <u>21 U.S.C. 827</u>.

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? Done. The contents and requirements of the form provide documentation of the substances prescribed that are now subject to destruction. The contents of the form are outlined in 21 CFR 1304.22 and the state form is similarly aligned with Form DEA-41.

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? Pure uncontaminated condition is not directly defined by a federal agency; however, 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. In this context, the reference is to pharmacies returning controlled substances to stock, itself an extreme rarity, given the risk of contamination.

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

Language added to the rule "with the original manufacturer's labeling fully legible" to define identifiable for the regulated public.

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?

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. In 21 CFR 1317.15 (a) is the requirement for the reverse distributor to be registered with the Administration (DEA) and 21 CFR 1317.15 (b)-(d) are the federal regulatory requirements reverse distributors must operate in compliance with.

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.

The intent is to set a standard for the regulated public to follow.

Line 23: Add a comma after "manage". This change has been made.

Line 24: Add a comma after "disposal".

This change has been made.

Line 25: Add a comma after "21 CFR 1317.40". Add "and" before "other". This change has been made.

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.

There are other applicable federal regulations governing the use of collection receptables such as 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. These rules provide guidance to the regulated public but would not be enforced by our agency.

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

An effective date has been added.

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 with changes as published in 39:24 NCR 1605 as follows.				
2					
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, including				
10	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				
11	Subpart C. which for any reason are unused shall be returned to the pharmacy from which they were received. The				
12	pharmacist who receives these controlled substances shall return them to his stock or destroy them in accordance				
13	with the procedure outlined by the director and The pharmacy shall keep a record of this the disposal and destruction				
14	of unused controlled substances available for a minimum of two years. This record of disposal and destruction shall				
15	be kept on the Division of Mental Health, Developmental Disabilities, and Substance Use Services (Division)				
16	formForm entitled "Controlled Substances Destruction Record Nursing Homes." "Record of Controlled Substances				
17	Destroyed Pursuant to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008				
18	Mail Service Center Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock				
19	must be in a hermetically sealed container or in an otherwise a pure uncontaminated condition and be				
20	identifiable.identifiable with the original manufacturer's labelling legible. A pharmacy may outsource destruction o				
21	the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the				
22	pharmacy must first verify the reverse distributor is registered with the DEA as a reverse distributor and maintains				
23	compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction				
24	of unused controlled substances per 21 CFR 1317.15. Pharmacies that are authorized by the DEA as collectors may				
25	install, [manage]manage, and maintain collection receptacles at nursing homes for the purpose of collection,				
26	[disposal]disposal, and destruction of unused controlled substances from nursing homes, in accordance with 21 CFR				
27	1317.05(c), 21 CFR [1317.40]1317.40, and other applicable federal regulations governing the use of collection				
28	receptacles by authorized pharmacy collectors in nursing [homes, including 21 CFR 1301.51, 21 CFR				
29	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				
30	Rule is subject to audit by the Division Director or their designated representative.				
31					
32	History Note: Authority G.S. 90-100; 143B-210(9); 143B-147;				
33	Eff. June 30, 1978;				
34	Amended Eff. September 15, 1980; May 15, 1979;				
35	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2				
36	2016. 2016;				
37	Emergency Amendment Eff. September 30, 2024.2024;				

1	Temporary Amendment	Eff. January 2, 2025;

2 <u>Amended Eff. November 1, 2025.</u>

1	RULE 10A NCAC 27G .3605 is adopted with changes via temporary procedures as follows.		
2			
3	10A NCAC 27	G .3605 MEDICATION UNITS AND MOBILE UNITS	
4	(a) Definition	s]Definitions:	
5	<u>(1)</u>	"Opioid Treatment Program" (hereafter, OTP) means the same as defined in G.S. 122C-3(25a).	
6	<u>(2)</u>	"OTP Facility" means the primary location on the facility license.	
7	<u>(3)</u>	"Opioid Treatment Program Medication Unit" (hereafter OTP Medication Unit) means the same as	
8		defined in G.S. 122C-3(25b).	
9	<u>(4)</u>	"Opioid Treatment Program Mobile Unit" (hereafter OTP Mobile Unit) means the same as defined	
10		in G.S. 122C-3(25c).	
11	(b) The OTP	Facility shall provide any medical, counseling, vocational, educational, and other assessment and	
12	treatment service	ces not provided by the OTP Medication Unit or OTP Mobile Unit.	
13	(c) The OTP sh	nall determine the type of services to be provided at the OTP Medication Units and OTP Mobile Units.	
14	The OTP shall	[elearly] specify which services are offered at the OTP Medication Units and OTP Mobile Units. Any	
15	services not off	ered at the OTP Medication Unit or Mobile Unit shall be provided at the OTP facility.	
16	(d) Location as	nd Service Capacity.	
17	<u>(1)</u>	The OTP shall ensure that each OTP Medication Unit and OTP Mobile Unit complies with all	
18		applicable State and Federal laws and regulations, including without limitation, Substance Abuse	
19		and Mental Health Services Administration and Federal Drug Enforcement Agency regulations	
20		governing their operation.	
21	<u>(2)</u>	An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall maintain	
22		and provide the location of each unit associated with the OTP.	
23	<u>(3)</u>	The OTP Medication Units and Mobile Units shall operate within a radius of 75 miles from the	
24		Opioid Treatment Program facility.	
25	<u>(4)</u>	The OTP shall maintain and provide schedules for the days and hours of operation to meet patient	
26		needs.	
27	<u>(5)</u>	The OTP shall establish and implement an operating protocol identifying the number of patients	
28		allowed per OTP Medication Unit and OTP Mobile Unit based on staffing ratios.	
29	<u>(6)</u>	The OTP shall establish and implement an operating protocol which includes predetermined	
30		location(s), hours of operations, and a daily departure guide and business record of each OTP Mobile	
31		Unit's location.	
32	(e) Staffing Re	quirements. The OTP and any associated OTP Medication Units and OTP Mobile Units shall maintain	
33	standard operat	ing and emergency staffing to ensure service delivery at the OTP and any associated OTP Medication	
34	Units and OTP	Mobile Units. Staffing shall include, but not be limited to the following:	
35	<u>(1)</u>	The OTP and any associated OTP Medication Units and OTP Mobile Units shall have a 1.0 Full	
36		Time Employee (FTE) [FTE] Licensed Clinical Addiction Specialist (LCAS), or Licensed Clinical	

1		Addicti	ion Specialist-Associate (LCAS-A) per 50 patients. This position can be filled by more than
2		one LC	AS or LCAS-A staff member (ratio 1:50); and
3	<u>(2)</u>	The O	TP and any associated OTP Medication Units and OTP Mobile Units shall have 1.0 FTE
4		LCAS,	LCAS-A, Certified Alcohol and Drug Counselor (CADC), Certified Alcohol and Drug
5		Counse	elor Intern (CADC-I), Licensed Clinical Social Worker (LCSW), Licensed Clinical Social
6		Worker	r - Associate (LCSW-A), Licensed Clinical Mental Health Counselor (LCMHC), Licensed
7		Clinica	l Mental Health Counselor - Associate (LCMHC-A), Licensed Marriage and Family
8		Therap	ist (LMFT), Licensed Marriage and Family Therapist - Associate (LMFT-A), Licensed
9		<u>Psycho</u>	logical Associate (LPA), or Licensed Psychologist (LP) for each additional 50 patients in the
10		progran	m (ratio 1:50); and
11	<u>(3)</u>	The O	TP and any associated OTP Medication Units and OTP Mobile Units shall have a Medical
12		Directo	or who is a physician licensed to practice medicine in North Carolina and who meets the
13		standar	ds and requirements outlined in 42 CFR 8.2 and 42 CFR 8.12(b).
14		<u>(A)</u>	The Medical Director is responsible for ensuring all medical, psychiatric, nursing,
15			pharmacy, toxicology, and other services offered at the OTP and any associated OTP
16			Medication Units and OTP Mobile Units are conducted in compliance with State and
17			Federal laws and regulations, consistent with appropriate standards of care; and
18		<u>(B)</u>	The Medical Director shall be physically present at the OTP a minimum of four hours per
19			month to assure regulatory compliance and to carry out those duties assigned to the Medical
20			Director in 42 CFR 8.2 and 42 CFR 8.12(b)(2).
21		<u>(C)</u>	The Medical Director shall be responsible for supervision of any physician extender(s) and
22			other medical staff.
23	(f) Each OTP sh	all devel	op and implement a policy regarding the maintenance, location, and retention of records for
24	its OTP Medicat	ion Units	s and OTP Mobile Units, in accordance with State and Federal laws and regulations.
25	(g) Operations a	ınd Servi	<u>ce <mark>[Delivery]Delivery.</mark></u>
26	<u>(1)</u>	Each O	TP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and shall
27		be subj	ect to inspections the Department deems necessary to validate compliance with all applicable
28		rules, a	nd State and Federal laws and regulations.
29	<u>(2)</u>	The OT	TP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State and
30		<u>federal</u>	program requirements for Opioid Treatment Programs.
31	<u>(3)</u>	Each C	OTP Medication Unit and OTP Mobile Unit shall establish and implement a written policy
32		and pro	ocedure for operations that meets the needs of its patients.
33	<u>(4)</u>	The O	TP shall establish and implement policies and procedures for a clinical and individualized
34		assessn	nent of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that
35		conside	ers medical and clinical appropriateness and accessibility to patients served.
36	<u>(5)</u>	The O	TP shall ensure that patients receiving services at an OTP Medication Unit or OTP Mobile
37		Unit re	ceive 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	<u>(6)</u>	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	<u>(7)</u>	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	<u>(8)</u>	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	<u>(9)</u>	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	<u>History Note:</u>	Authority G.S. 122C-35; 42 C.F.R. 8.12;
21		Emergency Adoption Eff. September 17, 2024;
22		<u>Temporary Adoption Eff. <mark>January 2, 2025.</mark></u>

From: Wiggs, Travis C

Sent: Wednesday, September 24, 2025 9:32 PM

To: Baker, Denise

Cc: Burgos, Alexander N

Subject: MH/DD/SA Services Commission-Request for Technical Changes-October 2025 **Attachments:** 10_2025_Commission for Mental Health, Developmental Disabilities, and Substance

Abuse Services.docx

Good evening,

I'm the attorney who reviewed the rules submitted by the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services for the October 2025 RRC meeting. The RRC will formally review these rules at its meeting on Thursday, October 30, 2025, 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 to me via email, no later than 5 p.m. on October 10, 2025. Let me know if you have any questions.

Thanks,

Travis C. Wiggs Rules Review Commission Counsel Office of Administrative Hearings

Telephone: 984-236-1929

Email: travis.wiggs@oah.nc.gov

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