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V 000	INITIAL COMMENTS An annual, complaint and follow up survey was completed on April 14, 2023. The complaints were substantiated intake (#NC00199675 and #NC00200191). Deficiencies were cited. This facility is licensed for the following service 10A NCAC 27G .3600 Outpatient Opioid Treatment. This facility has a current census of 278. The survey sample consisted of audits of 14 current clients.	V 000		
V 112	27G .0205 (C-D) Assessment/Treatment/Habilitation Plan 10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN (c) The plan shall be developed based on the assessment, and in partnership with the client or legally responsible person or both, within 30 days of admission for clients who are expected to receive services beyond 30 days. (d) The plan shall include: (1) client outcome(s) that are anticipated to be achieved by provision of the service and a projected date of achievement; (2) strategies; (3) staff responsible; (4) a schedule for review of the plan at least annually in consultation with the client or legally responsible person or both; (5) basis for evaluation or assessment of outcome achievement; and (6) written consent or agreement by the client or responsible party, or a written statement by the provider stating why such consent could not be obtained.	V 112	DHSR - Mental Health MAY 10 2023 Lic. & Cert. Section	

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

05/05/2023

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V 112	Continued From page 1 This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to schedule a review of a plan at least annually affecting one of fourteen clients (#2) and failed to have written consent or agreement by the client or responsible party affecting one of fourteen clients (#5). The findings are: Review on 4/12/23 of client #2's record revealed: -Admission date of 1/23/23. -Diagnosis of Opioid Use Disorder. -There was no documentation of a plan. Review on 4/12/23 of client #5's record revealed: -Admission date of 7/14/22. -Diagnosis of Opioid Use Disorder. -Person Centered Plan (PCP) dated 1/9/23. -There was no written consent or agreement by the client or responsible party. Interview on 4/13/23 with staff #1 revealed: -She had 88 clients on her caseload, however the caseload was constantly changing. -She was behind with completing treatment plans for clients. -She was behind with the treatment plans because she was also responsible for training other staff. -She also had other job-related issues.	V 112	Moving forward, counseling staff will be training annually on treatment planning and creating a PCP. All staff will be trained on PCP creation and treatment planning the week of May 8, 2023. PD and Clinical supervisor to monitor all PCPs on a weekly basis. All staff have been retrained on obtaining written consent and will utilize a checklist for intakes to assure that nothing is missed. Checklists will be turned into PD after completion of intake for audit.	05/03/2023 and ongoing

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V 112	Continued From page 2 -They are short staffed at the facility and more clients have been added to her caseload. Interview on 4/12/23 with the Clinical Director revealed: -She did a few PCPs for clients. -"They are grabbing clients as they can to get their PCPs completed." -"They are doing the best they can to get clients needs met, they are doing triage." -There is no PCP for client #2. -Client #2's Counselor was one of the staff who was just recently terminated for back dating PCPs. Interviews on 4/12/23 and 4/14/23 with the Regional Director revealed: -Some of the clients do not have a treatment plan. -They are in the process and trying to get clients records together. -Client #2's Counselor was terminated due to back dating plans for clients and that was the reason she had no plan. -Client #5's PCP was not signed because they were waiting for Medical Director to sign the plan. -She confirmed the facility failed to schedule a review of a plan at least annually for client #2. -She confirmed there was no written consent or agreement by the client or responsible party for client #5's PCP.	V 112		
V 233	27G .3601 Outpt. Opiod Tx. - Scope 10A NCAC 27G .3601 SCOPE (a) An outpatient opioid treatment facility provides periodic services designed to offer the individual an opportunity to effect constructive changes in his lifestyle by using methadone or	V 233		

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V 233	Continued From page 3 other medications approved for use in opioid treatment in conjunction with the provision of rehabilitation and medical services. (b) Methadone and other medications approved for use in opioid treatment are also tools in the detoxification and rehabilitation process of an opioid dependent individual. (c) For the purpose of detoxification, methadone and other medications approved for use in opioid treatment shall be administered in decreasing doses for a period not to exceed 180 days. (d) For individuals with a history of being physiologically addicted to an opioid drug for at least one year before admission to the service, methadone and other medications approved for use in opioid treatment may also be used in maintenance treatment. In these cases, methadone and other medications approved for use in opioid treatment may be administered or dispensed in excess of 180 days and shall be administered in stable and clinically established dosage levels. This Rule is not met as evidenced by: Based on record review and interviews, the facility failed to coordinate services with other prescribing physicians for 1 of 14 audited clients (#8). The findings are: Review on 4/12/23 of client #8's record revealed: -Admission date of 11/30/21. -Diagnosis of Opioid Use Disorder.	V 233		

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V 233	Continued From page 4 -Admission physical completed 11/30/21 listed client #8 was prescribed medications Zofran and Phenergan. -There was no evidence of an initial or updated coordination with the physician to verify medications and updated diagnosis. Interview on 4/13/23 with client #8 revealed: -During the intake she was asked to share her current physicians and any prescribed medications. -She did not recall signing documentation to coordinate with the physicians during her intake process. -She recently brought in a letter from a physician about her recent updated diagnosis. -She provided the letter to the Clinical Supervisor. Interview on 4/13/23 with the Clinical Supervisor revealed: -Client #8 brought in a letter from a physician of a current health diagnosis March 2023. -She just recently saw the letter in client #8's chart. -The documentation was initially reviewed by the facility physician. -She confirmed the documentation had not been reviewed by the facility physician at this time. -She confirmed the facility failed to coordinate services with other physicians in a timely manner.	V 233	Patients will see the provider for quarterly appointments. During quarterly, MD will notify medical staff and clinician to obtain ROI and conduct coordination of care with all providers. Medical and Mental Health concerns/diagnosis to be added to all PCPs and CPs. Lead nurse in combination with PD will work to ensure that all medical records are requested in a timely manner by utilizing a COC spreadsheet.	In place as of 04/01/2023 and ongoing 05/15/2023
V 235	27G .3603 (A-C) Outpt. Opiod Tx. - Staff 10A NCAC 27G .3603 STAFF (a) A minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients and increment thereof shall be on the staff of the facility. If the facility falls below this prescribed ratio, and is unable to employ an	V 235		

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V 235	Continued From page 5 individual who is certified because of the unavailability of certified persons in the facility's hiring area, then it may employ an uncertified person, provided that this employee meets the certification requirements within a maximum of 26 months from the date of employment. (b) Each facility shall have at least one staff member on duty trained in the following areas: (1) drug abuse withdrawal symptoms; and (2) symptoms of secondary complications to drug addiction. (c) Each direct care staff member shall receive continuing education to include understanding of the following: (1) nature of addiction; (2) the withdrawal syndrome; (3) group and family therapy; and (4) infectious diseases including HIV, sexually transmitted diseases and TB. This Rule is not met as evidenced by: Based on record review and interviews, the facility failed to ensure a minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients. The findings are: Review on 4/12/23 of facility records revealed: -The facility had a census of 278 clients. -The facility had three full time substance abuse counselors listed. -Staff #1 had a caseload of 88 clients. -Staff #2 had a caseload of 97 clients.	V 235	The Parent Company andTalent Acquisit on Team along with New Season Durham Program Director, Regional Director will work simultaneously to recruit certified and licensed counselors to fulfill the requirements for counselor to patient ratio of 1:50. There is one counselor starting on 5/8/23 and another one in background that is scheduled to start in 2 weeks.	05/08/2023

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V 235	Continued From page 6 -Staff #5 had a caseload of 93 clients. Interview on 4/13/23 with staff #1 revealed: -She was the Lead Counselor at the facility. -She had 88 clients on her caseload, however the caseload was "constantly changing." -She confirmed the facility failed to ensure there was a ratio of one counselor to every 50 or less clients. Interview on 4/13/23 with staff #2 revealed: -She was a Counselor with the facility. -She has been employed with the agency since November 2021. -She worked at a facility in another city. -She just started at Durham Treatment Center on 4/12/23. -She was only helping out at this facility until more Counselors are hired. -She will be working at this facility 2 days a week. -There are 96 people on her caseload, however she will be sharing the caseload with the Clinical Supervisor. -She confirmed the facility failed to ensure there was a ratio of one counselor to every 50 or less clients. Interview on 4/12/23 with the Clinical Supervisor revealed: -She started around January 2023. -She was at the facility just to help until they get more Counselors hired. -"I don't officially have a caseload." -She confirmed the facility failed to ensure there was a ratio of one counselor to every 50 or less clients. Interview on 4/12/23 with the Regional Director revealed: -There are 4 counselors at the facility including	V 235		

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V 235	Continued From page 7 the Clinical Supervisor. -She hired 2 new counselors, however they have not started. -They are over the one counselor to 50 clients ratio. -The Clinical Supervisor had a caseload as well. -The Clinical Supervisor was just added to the system last week. -The Clinical Supervisor has not officially taken her caseload yet. -The Clinical Supervisor was just filling in as a counselor as needed. -She confirmed the facility failed to ensure there was a ratio of one counselor to every 50 or less clients.	V 235		
V 238	27G .3604 (E-K) Outpt. Opiod - Operations 10A NCAC 27G .3604 OUTPATIENT OPIOD TREATMENT, OPERATIONS. (e) The State Authority shall base program approval on the following criteria: (1) compliance with all state and federal law and regulations; (2) compliance with all applicable standards of practice; (3) program structure for successful service delivery; and (4) impact on the delivery of opioid treatment services in the applicable population. (f) Take-Home Eligibility. Any client in comprehensive maintenance treatment who requests unsupervised or take-home use of methadone or other medications approved for treatment of opioid addiction must meet the specified requirements for time in continuous treatment. The client must also meet all the requirements for continuous program compliance and must demonstrate such compliance during	V 238		

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the specified time periods immediately preceding any level increase. In addition, during the first year of continuous treatment a patient must attend a minimum of two counseling sessions per month. After the first year and in all subsequent years of continuous treatment a patient must attend a minimum of one counseling session per month.

(1) Levels of Eligibility are subject to the following conditions:

(A) Level 1. During the first 90 days of continuous treatment, the take-home supply is limited to a single dose each week and the client shall ingest all other doses under supervision at the clinic;

(B) Level 2. After a minimum of 90 days of continuous program compliance, a client may be granted for a maximum of three take-home doses and shall ingest all other doses under supervision at the clinic each week;

(C) Level 3. After 180 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 2, a client may be granted for a maximum of four take-home doses and shall ingest all other doses under supervision at the clinic each week;

(D) Level 4. After 270 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 3, a client may be granted for a maximum of five take-home doses and shall ingest all other doses under supervision at the clinic each week;

(E) Level 5. After 364 days of continuous treatment and a minimum of 180 days of continuous program compliance, a client may be granted for a maximum of six take-home doses and shall ingest at least one dose under supervision at the clinic each week;

(F) Level 6. After two years of continuous

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treatment and a minimum of one year of continuous program compliance at level 5, a client may be granted for a maximum of 13 take-home doses and shall ingest at least one dose under supervision at the clinic every 14 days; and

(G) Level 7. After four years of continuous treatment and a minimum of three years of continuous program compliance, a client may be granted for a maximum of 30 take-home doses and shall ingest at least one dose under supervision at the clinic every month.

(2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility:

(A) A client's take-home eligibility is reduced or suspended for evidence of recent drug abuse. A client who tests positive on two drug screens within a 90-day period shall have an immediate reduction of eligibility by one level of eligibility;

(B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and

(C) The reinstatement of take-home eligibility shall be determined by each Outpatient Opioid Treatment Program.

(3) Exceptions to Take-Home Eligibility:

(A) A client in the first two years of continuous treatment who is unable to conform to the applicable mandatory schedule because of exceptional circumstances such as illness, personal or family crisis, travel or other hardship may be permitted a temporarily reduced schedule by the State authority, provided she or he is also found to be responsible in handling opioid drugs. Except in instances involving a client with a verifiable physical disability, there is a maximum of 13 take-home doses allowable in any two-week period during the first two years of continuous treatment.

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V 238	Continued From page 10 (B) A client who is unable to conform to the applicable mandatory schedule because of a verifiable physical disability may be permitted additional take-home eligibility by the State authority. Clients who are granted additional take-home eligibility due to a verifiable physical disability may be granted up to a maximum 30-day supply of take-home medication and shall make monthly clinic visits. (4) Take-Home Dosages For Holidays: Take-home dosages of methadone or other medications approved for the treatment of opioid addiction shall be authorized by the facility physician on an individual client basis according to the following: (A) An additional one-day supply of methadone or other medications approved for the treatment of opioid addiction may be dispensed to each eligible client (regardless of time in treatment) for each state holiday. (B) No more than a three-day supply of methadone or other medications approved for the treatment of opicid addiction may be dispensed to any eligible client because of holidays. This restriction shall not apply to clients who are receiving take-home medications at Level 4 or above. (g) Withdrawal From Medications For Use In Opioid Treatment. The risks and benefits of withdrawal from methadone or other medications approved for use in opioid treatment shall be discussed with each client at the initiation of treatment and annually thereafter. (h) Random Testing. Random testing for alcohol and other drugs shall be conducted on each active opioid treatment client with a minimum of one random drug test each month of continuous treatment. Additionally, in two out of each three-month period of a client's continuous	V 238		

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treatment episode, at least one random drug test will be observed by program staff. Drug testing is to include at least the following: opioids, methadone, cocaine, barbiturates, amphetamines, THC, benzodiazepines and alcohol. Alcohol testing results can be gathered by either urinalysis, breathalyzer or other alternate scientifically valid method.

(i) Client Discharge Restrictions. No client shall be discharged from the facility while physically dependent upon methadone or other medications approved for use in opioid treatment unless the client is provided the opportunity to detoxify from the drug.

(j) Dual Enrollment Prevention. All licensed outpatient opioid addiction treatment facilities which dispense Methadone, Levo-Alpha-Acetyl-Methadol (LAAM) or any other pharmacological agent approved by the Food and Drug Administration for the treatment of opioid addiction subsequent to November 1, 1998, are required to participate in a computerized Central Registry or ensure that clients are not dually enrolled by means of direct contact or a list exchange with all opioid treatment programs within at least a 75-mile radius of the admitting program. Programs are also required to participate in a computerized Capacity Management and Waiting List Management System as established by the North Carolina State Authority for Opioid Treatment.

(k) Diversion Control Plan. Outpatient Addiction Opioid Treatment Programs in North Carolina are required to establish and maintain a diversion control plan as part of program operations and shall document the plan in their policies and procedures. A diversion control plan shall include the following elements:

(1) dual enrollment prevention measures

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V 238	Continued From page 12 that consist of client consents, and either program contacts, participation in the central registry or list exchanges; (2) call-in's for bottle checks, bottle returns or solid dosage form call-in's; (3) call-in's for drug testing; (4) drug testing results that include a review of the levels of methadone or other medications approved for the treatment of opioid addiction; (5) client attendance minimums; and (6) procedures to ensure that clients properly ingest medication. This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to ensure after the first year and in all subsequent years of continuous treatment a client attended at least one counseling session per month affecting thirteen of fourteen audited current clients (#1, #2, #3, #4, #5, #6, #8, #9, #10, #11, #12, #13 and #14) and failed to ensure counseling sessions were completed after a positive Urine Drug Screen (UDS) affecting thirteen of fourteen audited current clients ((#1, #2, #3, #4, #5, #6, #8, #9, #10, #11, #12, #13 and #14). The findings are: The following is evidence the facility staff failed to ensure clients attended at least one counseling session per month.	V 238		

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V 238	Continued From page 13 Review on 4/12/23 of client #1's record revealed: -Admission date of 8/20/18. -Diagnoses of Opioid Use Disorder, Diabetes and Hypertension. -Staff #2 was his current Counselor. -There were no counseling sessions completed for January and February 2023. Review on 4/12/23 of client #2's record revealed: -Admission date of 1/23/23. -Diagnosis of Opioid Use Disorder. -Staff #2 was her current Counselor. -There were no counseling session completed for March 2023. Review on 4/12/23 of client #3's record revealed: -Admission date of 9/24/14. -Diagnoses of Opioid Use Disorder and Endocarditis -Staff #5 was her current Counselor. -There were no counseling session completed for February 2023. Review on 4/12/23 of client #4's record revealed: -Admission date of 10/15/18. -Diagnosis of Opioid Use Disorder. -Staff #1 was his current Counselor. -There was no counseling sessions completed for March 2023. Review on 4/12/23 of client #5's record revealed: -Admission date of 7/14/22. -Diagnosis of Opioid Use Disorder. -Staff #1 was his current Counselor. -There was no counseling sessions completed for March 2023. Review on 4/12/23 of client #6's record revealed: -Admission date of 11/8/22. -Diagnosis of Opioid Use Disorder.	V 238	PD and CCS will monitor caseloads by running reports and reviewing counselors scheduling calendar. Clinician will meet with all patients per state requirements. PD to meet with counselors bi-weekly and send out weekly reminders of patients that still need a session. All staff will be retrained on documentation and use of scheduling calendar. All patient's will be placed on hold to see their by CDT or PD as positive results come in to assure that all drug screens are reviewed with patients. PD and CCS to audit charts each week to assure that all drug screens are being addressed.	05/01/2023 05/31/2023 05/01/2023

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	MHL032-233	A. BUILDING: _____ B. WING _____	R 04/14/2023

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V 238	Continued From page 14 -Staff #5 was his current Counselor. -There was no counseling session completed for March 2023. Review on 4/12/23 of client #8's record revealed: -Admission date of 11/30/21. -Diagnosis of Opioid Use Disorder. -Staff #2 was her current Counselor. -There was no counseling session completed for March 2023. Review on 4/12/23 of client #9's record revealed: -Admission date of 8/2/22. -Diagnosis of Opioid Use Disorder. -Staff #5 was her current Counselor. -There was no counseling session completed for March 2023. Review on 4/12/23 of client #10's record revealed: -Admission date of 8/16/22. -Diagnosis of Opioid Use Disorder. -Staff #1 was her current Counselor. -There was no counseling session completed for March 2023. Review on 4/13/23 of client #11's record revealed: -Admission date of 4/14/21. -Diagnosis of Opioid Use Disorder. -Staff #1 was his current Counselor. -There was no counseling sessions completed for February 2023. Review on 4/13/23 of client #12's record revealed: -Admission date of 2/2/22. -Diagnosis of Opioid Use Disorder. -Staff #5 was her current Counselor. -Her last documented counseling session was 9/15/22.	V 238		

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V 238	Continued From page 15 -There was no counseling sessions completed for January, February and March 2023. Review on 4/13/23 of client #13's record revealed: -Admission date of 10/21/21. -Diagnosis of Opioid Use Disorder. -Staff #2 was her current Counselor. -There was no counseling sessions completed for March 2023. Review on 4/13/23 of client #14's record revealed: -Admission date of 12/23/22. -Diagnosis of Opioid Use Disorder. -Staff #2 was her current Counselor. -There was no counseling sessions completed for March 2023. The following is evidence the facility staff failed to ensure counseling sessions were completed after a positive urine drug screen. Review on 4/12/23 of client #1's record revealed: -UDS completed on 3/1/23 and 2/24/23-client #1 tested positive for Cocaine. -There was no documentation of a counseling session completed by client #1's Counselor to address the positive UDS results. Review on 4/12/23 of client #2's record revealed: -UDS completed on 2/17/23-client #2 tested positive for Fentanyl. -There was no documentation of a counseling session completed by client #2's Counselor to address the positive UDS results. Review on 4/12/23 of client #3's record revealed: -UDS completed on 2/11/23 and 1/30/23-client #3 tested positive for Fentanyl, Amphetamines and	V 238		

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V 238	Continued From page 16 Tetrahydrocannabinol (THC). -There was no documentation of a counseling session completed by client #3's Counselor to address the positive UDS results. Review on 4/12/23 of client #4's record revealed: -UDS completed on 3/13/23-client #4 tested positive for Fentanyl, Cocaine and Opiates. -There was no documentation of a counseling session completed by client #4's Counselor to address the positive UDS results. Review on 4/12/23 of client #5's record revealed: -UDS completed on 3/15/23-client #5 tested positive for Benzodiazepines. -There was no documentation of a counseling session completed by client #5's Counselor to address the positive UDS results. Review on 4/12/23 of client #6's record revealed: -UDS completed on 2/24/23- client #6 tested positive for THC. -There was no documentation of a counseling session completed by client #6's Counselor to address the positive UDS results. Review on 4/12/23 of client #8's record revealed: -UDS completed on 3/24/23- client #8 tested positive for THC. -There was no documentation of a counseling session completed by client #8's Counselor to address the positive UDS results. Review on 4/12/23 of client #9's record revealed: -UDS completed on 2/10/23- client #9 tested positive for Fentanyl. -There was no documentation of a counseling session completed by client #9's Counselor to address the positive UDS results.	V 238		

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V 238	Continued From page 17 Review on 4/12/23 of client #10's record revealed: -UDS completed on 3/10/23 and 3/7/23- client #10 tested positive for Fentanyl and THC. -UDS completed on 3/24/23- client #10 tested positive for Opiates and THC. -There was no documentation of a counseling session completed by client #10's Counselor to address the positive UDS results. Review on 4/13/23 of client #11's record revealed: -UDS completed on 3/20/23-client #11 tested positive for THC. -There was no documentation of a counseling session completed by client #11's Counselor to address the positive UDS results. Review on 4/13/23 of client #12's record revealed: -UDS completed on 3/13/23, 3/8/23, 2/18/23, 2/10/23, 2/4/23 and 1/17/23-client #12 tested positive for Amphetamines, Fentanyl, THC and Opiates. -There was no documentation of a counseling session completed by client #12's Counselor to address the positive UDS results. Review on 4/13/23 of client #13's record revealed: -UDS completed on 2/27/23-client #13 tested positive for Cocaine, Fentanyl and THC. -There was no documentation of a counseling session completed by client #13's Counselor to address the positive UDS results. Review on 4/13/23 of client #14's record revealed: -UDS completed on 3/15/23, 3/7/23, 3/1/23 and 2/1/23-client #14 tested positive for Benzodiazepines, Cocaine and Fentanyl.	V 238		

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V 238	Continued From page 18 -There was no documentation of a counseling session completed by client #14's Counselor to address the positive UDS results. Interview on 4/13/23 with staff #1 revealed: -She was the Lead Counselor at the facility. -She had 88 clients on her caseload, however the caseload was "constantly changing". -She was behind doing counseling sessions for the clients on her caseload on a monthly basis. -She knew some of the clients on her caseload were testing positive for illicit substances. -"It can be a little more challenging to meet with that client to address the positive Urine Drug Screens and monthly counseling sessions because they are so short staffed." Interview on 4/13/23 with staff #2 revealed: -She was a Counselor with the facility. -She has been employed with the agency since November 2021. -She worked at a facility in another city. -She just started at Durham Treatment Center on 4/12/23. -She was only helping out at this facility until more Counselors are hired. -She will be working at this facility 2 days a week. -She had not done any counseling sessions with any of the clients on her caseload. Interview on 4/14/22 with the Regional Director revealed: -They are in the process and trying to get clients records together. -She was aware that some of the Counselors were not completing their counseling sessions with clients. -She was aware counseling sessions were not being completed by counselors if a clients test positive for illicit substances.	V 238		

Division of Health Service Regulation

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V 238	Continued From page 19 -A former Counselor was documenting counseling sessions that were not held with clients. The clients were not at the facility on those days. -She confirmed facility staff failed to ensure counseling sessions were completed for clients #1, #2, #3, #4, #5, #6, #8, #9, #10, #11, #12, #13 and #14. -She confirmed facility staff failed to ensure counseling sessions were completed after a positive urine drug screen for clients #1, #2, #3, #4, #5, #6, #8, #9, #10, #11, #12, #13 and #14. This deficiency constitutes a re-cited deficiency and must be corrected within 30 days.	V 238		