STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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CHANGING PATHS NC II	205 MARTHA LANE, UNITS 7 & 8 CLINTON, NC 28328

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 000	INITIAL COMMENTS An annual and complaint survey was completed on June 20, 2024. The complaint was substantiated (intake #NC00216805). Deficiencies were cited. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment. This facility has a current census of 16. The survey sample consisted of audits of 6 current clients.	V 000		
V 111	27G .0205 (A-B) Assessment/Treatment/Habilitation Plan 10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN (a) An assessment shall be completed for a client, according to governing body policy, prior to the delivery of services, and shall include, but not be limited to: (1) the client's presenting problem; (2) the client's needs and strengths; (3) a provisional or admitting diagnosis with an established diagnosis determined within 30 days of admission, except that a client admitted to a detoxification or other 24-hour medical program shall have an established diagnosis upon admission; (4) a pertinent social, family, and medical history; and (5) evaluations or assessments, such as psychiatric, substance abuse, medical, and vocational, as appropriate to the client's needs. (b) When services are provided prior to the establishment and implementation of the treatment/habilitation or service plan, hereafter	V 111		

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V 111	Continued From page 1 referred to as the "plan," strategies to address the client's presenting problem shall be documented. This Rule is not met as evidenced by: Based on record review and interviews the facility failed to ensure an admission assessment was completed prior to the delivery of services for 2 of 6 audited clients (#14 and #15) and failed to ensure the admission assessment had strategies to address the client's presenting problems prior to the delivery of services for 4 of 6 audited clients (#11, #13, #14 and #15) The findings are: Finding #1: Review on 06/18/24 and 06/19/24 of client #11's record revealed: - 46 year old male. - Admission date of 05/10/24. - An unconfirmed (due to no signature by author) diagnosis of Opioid Dependence Uncomplicated in the facility documentation software. - 05/10/24 Medical admission assessment diagnoses of Neurogenic bladder, History of Left Clavicle Fracture, Deep Vein Thrombosis, Hepatitis C, History of Sexually Transmitted Disease, Depression and Anxiety. - A psychosocial evaluation dated 05/14/24. - No strategies to address the client's presenting problem prior to the delivery of services.	V 111		

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V 111	Continued From page 2 Interview on 06/18/24 client #11 stated: - He had received services from the facility since 05/10/24. - He saw the counselor weekly. Finding #2: Review on 06/19/24 of client #13's record revealed: - 31 year old female. - Admission date of 03/20/24. - An unconfirmed (due to no signature by author) diagnosis of Opioid Use Disorder-Severe in the facility documentation software. - Admission assessment diagnoses of Bipolar Disorder; Depressive Disorder, Opioid Use Disorder-Severe; Cannabis Use-uncomplicated. - A psychosocial evaluation dated 03/20/24. - No strategies to address the client's presenting problem prior to delivery of services. Interview on 06/20/24 client #13 stated: - She had received services at the facility since March 2024. - The facility did extensive paperwork with her. - She met with the counselor on the first or second day. Finding #3: Review on 06/18/24 and 06/19/24 of client #14's record revealed: - 39 year old male. - Admission date of 06/05/24. - An unconfirmed (due to no signature by author) diagnosis of Opioid Dependence, Uncomplicated in the facility documentation software. - No documented admission assessment. - No strategies to address the client's presenting problem prior to delivery of services.	V 111		

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V 111	Continued From page 3	V 111		

Finding #4:
- Review on 06/18/24 of client #15's record revealed:
- 42 year old male.
- Admission date of 06/17/24.
- An unconfirmed (due to no signature by author) diagnosis of Opioid Use Disorder- Uncomplicated in the facility documentation software.
- No documented admission assessment.
- No strategies to address the client's presenting problem prior to delivery of services.

Interview on 06/18/24 client #15 stated:
- He started treatment at the facility on 06/17/24.
- He met with the counselor before he was administered his initial dose.

Interview on 06/19/24 and 06/20/24 the facility Counselor stated:
- Worked at the facility since April 2024.
- She was a Licensed Clinical Social Worker-Associate.
- Client #11 may have been admitted on a day when she was not at the facility.
- She was the only staff that completed psychosocial assessments and Comprehensive Clinical Assessments.
- She completed client #11's assessment on 05/14/24.
- Clients were in a hurry to leave and it was difficult to meet with them.
- She had not seen client #14 because he was incarcerated.
- The facility would be employing a second counselor soon.

Interview 06/19/24 the Facility Registered Nurse (RN) stated:
- She had worked at the facility since 05/15/24.
- The admission process is lengthy and the

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V 111	Continued From page 4 admission process to included intake and assessments had been delayed if clients are not doing well or are complaining of withdrawal symptoms. Interview on 06/19/24 and 06/20/24 the Clinical Director stated: - She understood clients needed to have a full assessment prior to the delivery services. - Clients needed to have initial strategies to address issues prior to implementation of a treatment plan. - She would ensure the assessments were completed at admission.	V 111		
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	V 112		

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V 112	Continued From page 5 provider stating why such consent could not be obtained. This Rule is not met as evidenced by: Based on record review and interviews, the facility failed to develop and implement goals and strategies in the treatment/habilitation plan to address the client's needs within 30 days of admission affecting 3 of 6 clients (#11, #13, and #16). The findings are: Finding #1 Review on 06/18/24 and 06/19/24 of client #11's record revealed: - 46 year old male. - Admission date of 05/10/24. - An unconfirmed (due to no signature by author) diagnosis of Opioid Dependence Uncomplicated in the facility documentation software. - Admission assessment diagnoses of Neurogenic bladder, History of Left Clavicle Fracture, Deep Vein Thrombosis, Hepatitis C, History of Sexually Transmitted Disease, Depression and Anxiety. - No treatment/habilitation plan completed to address client #11's needs. Interview on 06/18/24 client #11 stated: - He had received services from the facility since 05/10/24. - He saw the counselor weekly.	V 112		

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V 112	Continued From page 6 - His goals included, "sobriety from crystal meth (methamphetamine), a driver's license & vehicle, job and his own place to live." Finding #2: Review on 06/19/24 of client #13's record revealed: - 31 year old female. - Admission date of 03/20/24. - An unconfirmed (due to no signature by author) diagnosis of Opioid Use Disorder-Severe in the facility documentation software. - Admission assessment diagnoses of Bipolar Disorder; Depressive Disorder, Opioid Use Disorder-Severe; Cannabis Use-uncomplicated. - No treatment/habilitation plan completed to address client #13's needs. Interview on 06/20/24 client #13 stated: - She had received services at the facility since March 2024. - The facility did extensive paperwork with her. - She met with the counselor on the first or second day. - She wanted to be off of methadone in 3-5 years, enroll in a university and open her own salon. Finding #3: Review on 06/18/24 and 06/19/24 of client #16's revealed: - 37 year old male. - Admission date of 05/03/24. - An unconfirmed (due to no signature by author) diagnosis of Opioid Dependence Uncomplicated in the facility documentation software. - Diagnoses of Current Heroin Use, Cannabis Use Disorder and Nicotine Use Disorder. - No treatment/habilitation plan completed to address client #16's needs.	V 112		

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V 112	Continued From page 7 Interview on 06/19/24 and 06/20/24 the facility Counselor stated: - She had worked at the facility since April 2024. - She was a Licensed Clinical Social Worker-Associate. - Client #11 may have been admitted on a day when she was not at the facility. - She had not completed client #11's treatment plan. - Client #16 did not come to the facility. - She did not have treatment plans completed. - Clients are in a hurry to leave and it is difficult to meet with them. - She had not seen client #14 because he was incarcerated. - The facility would be employing a second counselor soon. Interview 06/19/24 the Registered Nurse (RN) stated: - She had worked at the facility since 05/15/24. - She was the facility RN. - Sometimes the process is delayed if clients are not doing well or are complaining of withdrawal symptoms. - It's a lengthy process.	V 112		
V 113	27G .0206 Client Records 10A NCAC 27G .0206 CLIENT RECORDS (a) A client record shall be maintained for each individual admitted to the facility, which shall contain, but need not be limited to: (1) an identification face sheet which includes: (A) name (last, first, middle, maiden); (B) client record number; (C) date of birth; (D) race, gender and marital status;	V 113		

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V 113	Continued From page 8 (E) admission date; (F) discharge date; (2) documentation of mental illness, developmental disabilities or substance abuse diagnosis coded according to DSM IV; (3) documentation of the screening and assessment; (4) treatment/habilitation or service plan; (5) emergency information for each client which shall include the name, address and telephone number of the person to be contacted in case of sudden illness or accident and the name, address and telephone number of the client's preferred physician; (6) a signed statement from the client or legally responsible person granting permission to seek emergency care from a hospital or physician; (7) documentation of services provided; (8) documentation of progress toward outcomes; (9) if applicable: (A) documentation of physical disorders diagnosis according to International Classification of Diseases (ICD-9-CM); (B) medication orders; (C) orders and copies of lab tests; and (D) documentation of medication and administration errors and adverse drug reactions. (b) Each facility shall ensure that information relative to AIDS or related conditions is disclosed only in accordance with the communicable disease laws as specified in G.S. 130A-143. This Rule is not met as evidenced by: Based on record review and interview, the facility	V 113		

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V 113	Continued From page 9 failed to maintain copies of lab test results affecting 1 of 6 audited clients (#11). The findings are: Review on 06/18/24 and 06/19/24 of client #11's record revealed: - 46 year old male. - Admission date of 05/10/24. - An unconfirmed (due to no signature by author) diagnosis of Opioid Dependence Uncomplicated in the facility documentation software. - Admission assessment diagnoses of Neurogenic bladder, History of Left Clavicle Fracture, Deep Vein Thrombosis, Hepatitis C, History of Sexually Transmitted Disease, Depression and Anxiety. - Point of care urine drug screen (UDS) positive for oxycodone and benzodiazepines on 05/10/24. - 05/10/24 UDS was to be sent to an outside lab for further testing. - No documentation of an outside lab result for client #11's UDS on 05/10/24. Interview on 06/18/24 client #11 stated: - He had been receiving treatment at the facility since 05/10/24. - He had a urine screen at his first appointment and had random screens afterwards. Interview on 06/20/24 the Clinical Director stated: - The facility had an outside agency to complete lab testing. - The lab technician was not currently at the facility. - Had requested the outside lab results from client #11's UDS on 05/10/24. - She was not currently able to access client #11's lab result from 05/10/24. - Understood all lab results should be maintained on the client record.	V 113		

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V 118	27G .0209 (C) Medication Requirements 10A NCAC 27G .0209 MEDICATION REQUIREMENTS (c) Medication administration: (1) Prescription or non-prescription drugs shall only be administered to a client on the written order of a person authorized by law to prescribe drugs. (2) Medications shall be self-administered by clients only when authorized in writing by the client's physician. (3) Medications, including injections, shall be administered only by licensed persons, or by unlicensed persons trained by a registered nurse, pharmacist or other legally qualified person and privileged to prepare and administer medications. (4) A Medication Administration Record (MAR) of all drugs administered to each client must be kept current. Medications administered shall be recorded immediately after administration. The MAR is to include the following: (A) client's name; (B) name, strength, and quantity of the drug; (C) instructions for administering the drug; (D) date and time the drug is administered; and (E) name or initials of person administering the drug. (5) Client requests for medication changes or checks shall be recorded and kept with the MAR file followed up by appointment or consultation with a physician. This Rule is not met as evidenced by:	V 118		

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V 118	Continued From page 11 Based on record review and interview, the facility failed to administer medications on the written order of a person authorized by law to prescribe drugs affecting 6 of 6 audited clients (#1, #11, #13, #14, #15 and #16). The findings are: Finding #1: Review on 06/18/24 of client #1's record revealed: - 47 year old female. - Admission date of 06/14/24. - An unconfirmed diagnosis (due to no signature by author) of Opioid Dependency-Moderate. - Admission assessment diagnoses of Opioid Use Disorder-Moderate, Alcohol Abuse-Uncomplicated, Tobacco Use-Moderate, Schizoaffective Disorder-Bipolar Type. Review on 06/19/24 of an unsigned "Assessment/Admission" note dated 06/14/24 revealed: - "...female presents at clinic for evaluation and treatment...report called in to [Medical Director] and awaiting orders/recommendations." - The Nurse's name was printed at the bottom. - No signature was noted. Interview on 06/18/24 client #1 stated: - She had received treatment from the facility for 2 weeks. - She was administered 30 milligrams (mg) Methadone (used in treatment of opioid addiction) Monday- Saturday and had a take home doses for Sundays due to the facility being closed. Finding #2: Review on 06/18/24 and 06/19/24 of client #11's record revealed: - 46 year old male. - Admission date of 05/10/24.	V 118		

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V 118	Continued From page 12 - An unconfirmed diagnosis (due to no signature by author) of Opioid Dependence Uncomplicated in the facility documentation software. - Admission assessment diagnoses of Neurogenic bladder, History of Left Clavicle Fracture, Deep Vein Thrombosis, Hepatitis C, History of Sexually Transmitted Disease, Depression and Anxiety. Review on 06/19/24 of an unsigned "Assessment/Admission" note dated 05/10/24 revealed: - "...In consultation with [Medical Director] will administer Methadone 30 mg today..." - The Clinical Director's name was printed at the bottom. - No signature was noted. Review on 06/19/24 of client #11's dosing history and medication orders revealed: - Methadone 30mg administered from 05/10/24 thru 05/26/24 with no written medication order. - Increase of Methadone from 30mg to 35mg on 05/27/24. - No signed order to authorize the increase in the Methadone dosage. Interview on 06/18/24 client #11 stated: - He had received services from the facility since 05/10/24. - He saw the doctor 2 weeks ago. - He was administered 35mg Methadone Monday- Saturday, with take home doses on Sundays due to the facility's closure schedule. Finding #3: Review on 06/19/24 of client #13's record revealed: - 31 year old female. - Admission date of 03/20/24.	V 118		

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- An unconfirmed diagnosis (due to no signature by author) of Opioid Use Disorder-Severe in the facility documentation software.
- Admission assessment diagnoses of Bipolar Disorder; Depressive Disorder, Opioid Use Disorder-Severe; Cannabis Use-uncomplicated.
- No order to administer Methadone.

Review on 06/19/24 of client #13's dosing history and medication orders revealed:
- Methadone 35mg administered from 05/25/24 thru 06/5/24 with no written medication order.
-Increases of Methadone from 5mg to 10mg on 03/27/24; 10mg to 15mg on 04/5/24; 15mg to 20mg on 04/17/24; 20mg to 25mg on 05/8/24; 25mg to 30mg on 05/25/24; 30mg to 35mg on 06/5/24.
- No written or electronic order to authorize the increase in the Methadone dosage.

Interview on 06/20/24 client #13 stated:
- She had received services at the facility since March 2024.
- She was being administered 35mg Methadone Monday- Saturday with take home dose on Sundays due to the facility being closed.

Finding #4:
Review on 06/18/24 and 06/19/24 of client #14's record revealed:
- 39 year old male.
- Admission date of 06/5/24.
- An unconfirmed diagnosis (due to no signature by author) of Opioid Dependence, Uncomplicated in the facility documentation software.
- No admission assessment.
- No written or electronic order to administer Methadone.

Review on 06/19/24 of client #14's written orders

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 118	Continued From page 14 revealed: - Written order dated 06/12/24 to taper Methadone dosage from 30mg to 25mg- not signed authorizing the tapering of the Methadone dosage.. - Written order dated 06/17/24 to taper Methadone from 25mg to 20mg- not signed authorizing the tapering of the Methadone dosage. - Written order dated 06/19/24 to taper Methadone from 15mg to 10mg- not signed authorizing the tapering of the Methadone dosage. Finding #5: - Review on 06/18/24 of client #15's record revealed: - 42 year old male. - Admission date of 06/17/24. - An unconfirmed diagnosis (due to no signature by author) of Opioid Use Disorder-Uncomplicated in the facility documentation software. - No documented admission assessment. - A printed copy of an order to administer 30mg Methadone that was not signed by the prescribing physician. - No electronic signature noted in the facility documentation software. Interview on 06/18/24 client #15 stated: - He started treatment at the facility on 06/17/24. - He started 30mg of Methadone on 06/18/24. Finding #6: Review on 06/18/24 and 06/19/24 of client #16's revealed: - 37 year old male. - Admission date of 05/03/24.	V 118		

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V 118	Continued From page 15 - An unconfirmed diagnosis (due to no signature by author) of Opioid Dependence Uncomplicated in the facility documentation software. - Diagnoses of Current Heroin Use, Cannabis Use Disorder and Nicotine Use Disorder. Review on 06/19/24 of an unsigned "Assessment/Admission" note dated 05/03/24 revealed: - "...Received buprenorphine 8mg/Naloxone 2mg SL tablet and tolerated well..." - The Clinical Director's name was printed at the bottom. - No signature or date was noted. Review on 06/19/24 of client #16's dosing history revealed: - He was administered buprenorphine 8mg on 05/03/24, 05/07/24, 05/08/24, 05/09/24 and 05/13/24 at the facility. - He was also provided with take 3 take home doses of buprenorphine 8mg/Naloxone 2mg on 05/09/24 and 05/13/24. - No written order or electronic signature to administer or dispense the buprenorphine 8mg on the above dates. Interview on 06/19/24 and 06/20/24 the Clinical Director stated: - She was a Doctor of Nursing Practice. - She had spoken with a State Opioid Treatment Authority representative on 06/18/24 about Methadone Assisted Treatment requirements. - She would ensure going forward there are written or electronic signatures in the record for Methadone Assisted Treatment.	V 118		
V 233	27G .3601 Outpt. Opiod Tx. - Scope	V 233		

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V 233	Continued From page 16 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 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 reviews and interviews, the facility failed to provide services designed to affect constructive changes in the client's lifestyle	V 233		

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V 233	Continued From page 17	V 233		

by using methadone in conjunction with the provision of rehabilitation and medical services affecting 4 of 6 audited clients (#11, #13, #14 and #16). The findings are

Finding #1
Review on 06/18/24 and 06/19/24 of client #11's record revealed:
- 46 year old male.
- Admission date of 05/10/24.
- An unconfirmed diagnosis (due to no signature by author) of Opioid Dependence Uncomplicated in the facility documentation software.
- Admission assessment diagnoses of Neurogenic bladder, History of Left Clavicle Fracture, Deep Vein Thrombosis, Hepatitis C, History of Sexually Transmitted Disease, Depression and Anxiety.
- Prescription list as of 06/07/24: Lactulose (constipation), Gabapentin (seizures), Olmesartan (high blood pressure), Trazodone (antidepressant), Diazepam (anti-anxiety), Methadone (long lasting opioid), Baclofen (muscle relaxer), Sertraline (antidepressant), Hydroxyzine (anti-anxiety) and Polyethylene Glycol (constipation).
- No documentation of a release of information for client #11's primary care provider (PCP).
- No documentation of coordination of care with client #11's PCP regarding Medication Assisted Treatment.

Interview on 06/18/24 client #11 stated:
- He had received services from the facility since 05/10/24.
- The primary physician prescribed him Gabapentin, Olmesartan, Lactulose, Diazepam, Baclofen, Sertraline, Hydroxyzine and Polyethylene Glycol.
- He also saw a doctor for urology concerns.

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V 233	Continued From page 18	V 233		

- The primary physician was aware he was being administered Methadone at the facility but he was not sure if his urologist was aware of his attendance in an OTP.

Finding #2
Review on 06/19/24 of client #13's record revealed:
- 31 year old female.
- Admission date of 03/20/24.
- An unconfirmed diagnosis (due to no signature by author) of Opioid Use Disorder-Severe in the facility documentation software.
- Admission assessment diagnoses of Bipolar Disorder; Depressive Disorder, Opioid Use Disorder-Severe; Cannabis Use-uncomplicated.
- Prescription list as of 03/20/24: Buspirone 5mg (anxiety), Fluoxetine 20mg (depression).
- No documentation of a release of information for client #13's PCP.
- No documentation of coordination of care with client #13's PCP regarding Medication Assisted Treatment.

Interview on 06/20/24 client #13 stated:
- She had received services at the facility since March 2024.
- She took Buspirone and Effexor and she informed her prescribing physician.
- She was not sure if the facility had informed her physician of her OTP admission.

Finding #3
Review on 06/18/24 and 06/19/24 of client #14's record revealed:
- 39 year old male.
- Admission date of 06/5/24.
- An unconfirmed diagnosis of Opioid Dependence, Uncomplicated in the facility

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documentation software.
- Client #14 was incarcerated at the local detention center.
- Referral letter dated 06/3/24 for client #14 to receive evaluation and treatment from facility.
- No documentation of a release of information for the local detention center that client #14 was being housed at.
- No documentation of a release of information for the primary physician that referred client #14 to the facility.
- No coordination of care documented with the local detention center.

Finding #4:
Review on 06/18/24 and 06/19/24 of client #16's revealed:
- 37 year old male.
- Admission date of 05/03/24.
- An unconfirmed diagnosis of Opioid Dependence Uncomplicated in the facility documentation software.
- Diagnoses of Current Heroin Use, Cannabis Use Disorder and Nicotine Use Disorder.
- A local hospital Emergency Department report dated 04/30/24.
- No signed release of information from the client for local hospital records.
- No coordination of care documented with the local hospital.

Interview on 06/19/24 and 06/20/24 the Clinical Director stated:
- She had spoken with a State Opioid Treatment Authority representative on 06/18/24 about Medication Assisted Treatment requirements.
- Facility staff had obtained one consent for release of information from clients.
- She understood the facility needed to coordinate with the medical professionals responsible for a

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V 233	Continued From page 20 clients' care.	V 233		
V 237	27G .3604 (A-D) Outpt. Opiod - Operations 10A NCAC 27G .3604 OPERATIONS (a) Hours. Each facility shall operate at least six days per week, 12 months per year. Daily, weekend and holiday medication dispensing hours shall be scheduled to meet the needs of the client. (b) Compliance with The Substance Abuse and Mental Health Services Administration (SAMHSA) or The Center for Substance Abuse Treatment (CSAT) Regulations. Each facility shall be certified by a private non-profit entity or a State agency, that has been approved by the SAMHSA of the United State Department of Health and Human Services and shall be in compliance with all SAMHSA Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction regulations in 42 CFR Part 8, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the CSAT, SAMHSA, Rockwall II, 5600 Fishers Lane, Rockville, Maryland 20857 at no cost. (c) Compliance With DEA Regulations. Each facility shall be currently registered with the Federal Drug Enforcement Administration and shall be in compliance with all Drug Enforcement Administration regulations pertaining to opioid treatment programs codified in 21 C.F.R., Food and Drugs, Part 1300 to end, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the United States Government Printing Office, Washington, D.C. 20402 at the published rate. (d) Compliance With State Authority Regulations.	V 237		

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V 237	Continued From page 21 Each facility shall be approved by the North Carolina State Authority for Opioid Treatment, DMH/DD/SAS, which is the person designated by the Secretary of Health and Human Services to exercise the responsibility and authority within the state for governing the treatment of addiction with an opioid drug, including program approval, for monitoring compliance with the regulations related to scope, staff, and operations, and for monitoring compliance with Section 1923 of P.L. 102-321. The referenced material may be obtained from the Substance Abuse Services Section of DMH/DD/SAS. This Rule is not met as evidenced by: Based on record reviews and interviews, the facility management failed to assure compliance with regulations in 42 CFR (Code of Federal Regulations) Part 8 which require the person is currently addicted to an opioid drug affecting 4 of 6 audited current clients (#11, #14, #15 and #16) and failed to access the Prescription drug monitoring programs (PDMPs) for new admissions for 6 of 6 audited clients (#1, #11, #13, #14, #15 and #16). The findings are: Review on 06/20/24 of SAMHSA regulations and guidelines revealed: "42 CFR 8.12(e) Patient admission criteria. (1) Maintenance treatment. An OTP (Opioid Treatment Program) shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the	V 237		

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V 237	Continued From page 22 Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment...The regulations specify that accepted medical criteria such as those described in the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) be used. New criteria in DSM-V, the current version, use language that is consistent with the current understanding of substance use disorders, departing somewhat from the familiar terms of "abuse" and "dependence." The diagnostic criteria described in the DSM-V, however, are substantially the same as those used in earlier versions of the DSM. Based on the number of criteria identified for an individual patient, the substance use disorder is now classified as mild, moderate, or severe. Because there is no basis for concluding that medication-assisted treatment is only for those persons with severe disease, careful consideration and patient-center decision making must be used when considering the most appropriate pharmacotherapy for patients at all stages of opioid use disorder." Review on 06/20/24 of SAMHSA regulations and guidelines revealed: "42 CFR 8.12(c) (2). An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP. While state programs may vary from one another, all OTP physicians and other healthcare	V 237		

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providers, as permitted, should register to use their respective state's PDMP and query it for each newly admitted patient prior to initiating dosing. The PDMP should be checked periodically (for example, quarterly) through the course of each individual's treatment and, in particular, before ordering take-home doses as well as at other important clinical decision points. Querying the PDMP will result in a range of possible results. In some cases, no use of scheduled prescription medications will be identified ...The program should develop detailed policies and procedures to govern the use of and response to PDMP information for diversion control. Every effort, including full psychiatric assessment, higher levels of substance use disorder treatment, detoxification services, and intensive counseling, should be made to address the addictive behaviors underlying the individual's polysubstance use."

Review on 06/18/24 of client #1's record revealed:
- 47 year old female.
- Admission date of 06/14/24.
- An unconfirmed diagnosis (due to no signature by author) of Opioid Dependency-Moderate.
- 06/14/24 Admission assessment diagnoses of Opioid Use Disorder-Moderate, Alcohol Abuse-Uncomplicated, Tobacco Use-Moderate, Schizoaffective Disorder-Bipolar Type.
- No documentation the facility accessed the PDMP at admission.

Review on 06/18/24 and 06/19/24 of client #11's record revealed:
- 46 year old male.
- Admission date of 05/10/24.
- An unconfirmed diagnoses (due to no signature by author) of Opioid Dependence Uncomplicated

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in the facility documentation software.
- 05/10/24 Admission assessment diagnoses of Neurogenic bladder, History of Left Clavicle Fracture, Deep Vein Thrombosis, Hepatitis C, History of Sexually Transmitted Disease, Depression and Anxiety.
- No Opioid Use Disorder diagnosis documented on the admission assessment.
- No documentation the facility accessed the PDMP at admission.

Review on 06/19/24 of client #13's record revealed:
- 31 year old female.
- Admission date of 3/20/24.
- An unconfirmed diagnosis (due to no signature by author) of Opioid Use Disorder-Severe in the facility documentation software.
- 03/20/24 Admission assessment diagnoses of Bipolar Disorder; Depressive Disorder, Opioid Use Disorder-Severe; Cannabis Use-uncomplicated.
- No documentation the facility accessed the PDMP at admission.

Review on 06/18/24 and 06/19/24 of client #14's record revealed.
- 39 year old male.
- Admission date of 06/5/24.
- An unconfirmed diagnoses (due to no signature by author) of Opioid Dependence, Uncomplicated in the facility documentation software.
- No documented admission assessment.
- No documentation the facility accessed the PDMP at admission.

Review on 06/18/24 of client #15's record revealed:
- 42 year old male.
- Admission date of 06/17/24.

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V 237	Continued From page 25 - An unconfirmed diagnosis (due to no signature by author) of Opioid Use Disorder-Uncomplicated in the facility documentation software. - No documented admission assessment. - No documentation the facility accessed the PDMP at admission. Review on 06/18/24 and 06/19/24 of client #16's revealed: - 37 year old male. - Admission date of 05/03/24. - An unconfirmed diagnosis (due to no signature by author) of Opioid Dependence Uncomplicated in the facility documentation software. - Diagnoses of Current Heroin Use, Cannabis Use Disorder and Nicotine Use Disorder. - No Opioid Use Disorder diagnosis documented on the admission assessment. - No documentation the facility accessed the PDMP at admission. Interview on 06/19/24 and 06/20/24 the Clinical Director stated: - She was a Doctor of Nursing Practice. - She had spoken with a State Opioid Treatment Authority representative on 06/18/24 about Medication Assisted Treatment requirements. - She assessed new clients as well as the Medical Director. - She was aware all clients admitted needed a diagnosis of opioid addiction for treatment. - She would ensure all assessments moving forward had a specific diagnosis for Medication Assisted Treatment. - She had accessed the PDMP on each new admission. - She did not document she had accessed the PDMP or printed the report for the client record. - She would ensure the documentation of all	V 237		

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V 237	Continued From page 26 PDMPs.	V 237		
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 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	V 238		

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V 238	Continued From page 27 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 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:	V 238		

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V 238	Continued From page 28 (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. (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	V 238		

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V 238	Continued From page 29 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 opioid 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 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.	V 238		

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V 238	Continued From page 30 (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 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.	V 238		

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This Rule is not met as evidenced by:
Based on record reviews and interviews, the facility failed to follow the take-home eligibility for 1 of 6 audited clients (#16) and failed to ensure the risks and benefits of withdrawal from methadone or other medications approved for use in opioid treatment were discussed with each client at the initiation of treatment for 2 of 6 audited clients (#15 and #16). The findings are

Review on 06/18/24 and 06/19/24 of client #16's revealed:
- 37 year old male.
- Admission date of 05/03/24.
- An unconfirmed diagnosis (due to no signature by author) of Opioid Dependence Uncomplicated in the facility documentation software.
- Diagnoses of Current Heroin Use, Cannabis Use Disorder and Nicotine Use Disorder.
- No documentation client #16 met the criteria for take home doses.
- No acknowledgement was documented that the client was provided with 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.

Review on 06/19/24 of an unsigned "Assessment/Admission" note for client #16 dated 05/03/24 revealed:
- "Assessment/Admission - 38 year old

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V 238	Continued From page 32 Caucasian male presents for evaluation and treatment. He is recently separated from his wife and has no children. He runs a tree cutting service. Appears fatigued and disheveled. He is oriented and pleasant. Released from [Local Regional Medical Center] on 3/28/24 after overdosing. He then spent several days in jail. He presents with withdrawal symptoms after abstinence from Fentanyl. He has experiencing insomnia, irritability, vomiting, anorexia, diaphoresis, tremors and body aches for the last 5 days...Exam unremarkable. He states he would like to stop using drugs and resume his tree business. He requests Suboxone. Examined by [Medical Director]. EKG (electrocardiogram) obtained and reviewed. POC (point of care) urine + (positive) for Morphine and Benzodiazepines. Received buprenorphine 8mg (milligrams) /Naloxone 2mg SL (sublingual) tablet tolerated well. Buprenorphine 8mg/Naloxone 2mg SL film #3 sent to [Local] pharmacy of [local town] for . Client will be out of town for two days and is scheduled for counseling on Monday, May 6." - The Clinical Director's name was printed at the bottom. - No signature was noted. - No documentation the client was provided with 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. Review on 06/19/24 of client #16's dosing history revealed: - He was administered buprenorphine 8mg on 05/03/24, 05/07/24, 05/08/24, 05/09/24 and 05/13/24 at the facility. - He was also provided with take 3 take home doses of buprenorphine 8mg on 05/09/24 and 05/13/24.	V 238		

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- No written order or electronic signature to administer or dispense the buprenorphine 8mg on the above dates.

- Review on 06/18/24 of client #15's record revealed:
- 42 year old male.
- Admission date of 06/17/24.
- An unconfirmed diagnosis (due to no signature by author) of Opioid Use Disorder-Uncomplicated in the facility documentation software.
- No acknowledgement was documented that the client was provided with 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.

Review on 06/19/24 of an unsigned "Assessment/Admission" note for client #15 dated 05/03/24 revealed:
- "Assessment/Admission - 42 year old Caucasian male presents for evaluation an treatment of a 3 year addiction to heroin and fentanyl. He presently uses 1 gram of fentanyl daily by IV (intravenous), snorting and smoking. He last used on yesterday, 6/16/24. States he usually begins to have cravings 6 hours after using. Reports having asthma as a child and yearly bronchitis. Had positive PPD (purified protein derivative) in 2013 while incarcerated and has been treated with INH (isonicotinic acid hydrazide) & B12 (vitamin) for 1 year. . Tested positive for Hepatitis C in 2018 for which he has not been treated. Surgeries include removal of tumor from the right buttock, tonsillectomy, repair of a dislocated shoulder, ORIF (open reduction and internal fixation) of legs to fracture after a MVA (motor vehicle accident). Surgical repair of

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an extensive laceration to the right wrist. States he has had seizures after Cocaine use. Has been diagnosed with Schizophrenia but does not take medication. Was hit by a car in 1995 and sustained head injury. Last dental visit 2 months ago for multiple caries. Currently being treated with Cipro for a UTI (urinary tract infection). Allergic to penicillin (rash), and aspirin (palpitations). Reports allergy to ultram as well. Complains of withdrawal symptoms to include nausea, backache, abdominal cramping, rhinorrhea, yawning and insomnia and headache. Thinks he may have thyroid concerns because of fluctuation in weight, hair loss and heat intolerance. T (temperature)-98, P (pulse)-73, R (respirations)-16, BP (blood pressure) 117/77, SPO2 (oxygen saturation) -99%, Weighs 161lb and is 6'1" tall. PERRLA (pupils equal, round, reactive to light). Nares (opening of the nose) erythematous. Lungs clear to auscultation. Abdomen tender to palpation. No hepatomegaly noted. Bowel sounds positive, Extremities warm with equal strength. Urine positive for Fentanyl, MDMA (methylenedioxy methamphetamine), methamphetamines and amphetamines. EKG (electrocardiogram) obtained. QT (heart electrical activity graphed on electrocardiogram) interval 406.
- The Clinical Director's name was printed at the bottom.
- No signature was noted.
- No documentation the client was provided with 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.

Interview on 06/18/24 client #15 stated:
- He started treatment at the facility on 06/17/24.
- He started 30mg of Methadone on 06/18/24.

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V 238	Continued From page 35 - It was his first time on Methadone. Interview on 06/19/24 and 06/20/24 the Clinical Director stated: - She was a Doctor of Nursing Practice. - She had spoken with a State Opioid Treatment Authority representative on 6/18/24 about Medication Assisted Treatment requirements. - It was her "oversight" on client #16 getting take home doses. - Client #16 was having difficulty getting medications from the pharmacy. - Clients at the facility have to meet specific requirements for take home doses. - Client #16 did not meet the criteria for take home doses. - Client #16 is no longer receiving services at the facility but had not been officially discharged.	V 238		