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V 000	INITIAL COMMENTS An annual survey was completed on October 8, 2019. Deficiencies were cited. The census at the time of the survey was 118. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment	V 000		
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	V 118		

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V 118	Continued From page 1 with a physician. This Rule is not met as evidenced by: Based on record review and interviews the facility failed to ensure medications were administered as ordered and failed to ensure MARs were current for 1 of 12 audited clients (#1). The findings are: Record review on 9/30/19 for Client #1 revealed: -Admitted on 6/26/19 with diagnosis of Opioid Use Disorder. -Transferred from a Methadone clinic in a neighboring state. -Physician's order dated 6/26/19 (transfer) was 75mg. The initial order did not indicate a level for take home doses. -Physician's order dated 10/2/19 was for Level 5, dosing one day per week at the clinic. -Transfer paperwork from the prior clinic indicated " ...Pt (patient) is currently level 4 attending the clinic once a week ..." Review on 9/30/19 of the 7/2019-9/30/19 MARs for Client #1 revealed: -Client #1 had been receiving 6 take homes per week since 7/3/19. -The MARs indicated Level 4 although Client #1 was considered a level 5, attending the clinic once per week. Interview on 10/8/19 with the Program Director revealed: -She was unaware that the initial order failed to include the level of take homes. -Client #1 came from a clinic in a neighboring	V 118		

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V 118	Continued From page 2 state and at that clinic level 4 only required clinic dosing once per week. -She indicated that when they entered the information into the computer for Client #1 the nurses had seen level 4 indicated in her transfer documentation. She stated that the level 4 was an error on the MAR. -Client #1 continued to dose at the clinic once per week following her admission.	V 118		
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 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.	V 233		

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This Rule is not met as evidenced by:
Based on interviews and record review the facility failed to provide services designed to affect constructive changes in the client's lifestyle by using methadone in conjunction with the provision of medical services affecting 6 of 11 current clients (#2, #3, #6, #8, #9, #11) and 1 of 1 deceased client (DC #12). The findings are:

Record review on 9/30/19, 10/1/19 and 10/4/19 for Client #2 revealed:
-Admitted on 7/26/19 with diagnoses of Opioid Use Disorder, Anxiety Disorder, Depression, Traumatic Brain Injury and Seizure Disorder.
-Client #2 was admitted with a Methadone dose of 20mg (milligram) and it was increased incrementally to 70mg. The Medical Director ordered the current dose of Methadone at 70mg on 9/25/19.
-Psychosocial Assessment dated 7/26/19 indicated that Client #2 was being treated by another medical provider for seizures that were the result of a head injury at age 21. The assessment further indicated that she had been diagnosed with emotional problems and that she was on medication for this condition. This assessment did not indicate any prescribed medication for Client #2.
-Physician's admission assessment on 7/26/19 indicated the medications for Client #2 were Xanax (anxiety) 1mg twice daily, Tegretol (anti-convulsant) 200mg twice daily, Keppra (seizures) 900mg twice daily, and Gabapentin (anti-convulsant) 300mg three times daily. The name of the PCP (Primary Care Physician) for Client #2 was indicated in this assessment.

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V 233	Continued From page 4 -Physician's progress note dated 10/2/19 indicated that in addition to Methadone Client #2 was taking Lipitor (cholesterol) (no dose or frequency indicated, and it was noted that the medication had not started yet) and daily Aspirin (325mg daily) were added to her medication regimen. -Coordination of Care Notification sent to the PCP on 9/6/19, 5 weeks following admission. No records had been received and no follow up with the PCP was documented. Record review on 10/1/19 for Client #3 revealed: -Admitted on 10/3/18 with Opioid Use Disorder, Alcohol Use Disorder and Bi Polar Disorder. -Client #3 transferred from another methadone clinic at a dose of 82 mg. The Methadone dose incrementally increased since that time. The Medical Director ordered current dose of 105mg on 8/20/19. -Bio-Psychosocial dated 10/15/18 indicated prescribed medications of Gabapentin and Wellbutrin. The assessment indicated " ...he does report some medical concern including diabetes and having his toes amputated ...." No other prescribed medications were indicated for Client #3. -Physician's progress note dated 11/14/18 indicated " ...He stopped the cholesterol medication because it was making him dizzy ...Medication: gabapentin (anti-convulsant), glipizide (Diabetes), Wellbutrin (anti-depressant), insulin injections, sliding scale and Lantus (insulin) ..." No doses or frequency indicated for any medication. -Physician's note dated 12/26/18 indicated " ...further surgical intervention for osteomyelitis of the right foot due to vascular disease, diabetes, and foot trauma ...currently taking an oral antibiotic but does not recall the name ..."	V 233		

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V 233	Continued From page 5 -No physician notes between December 2018 and June 27, 2019. -Physician's progress note dated 6/28/19 indicated a Gabapentin dose of 900mg daily. -Physician's progress note dated 8/28/19 indicated a recent hospitalization for partial foot amputation. Vitamins and PRN (as needed) Benadryl were added as medications. -Physicians' progress note dated 9/18/19 indicated a recent hospitalization for right foot osteomyelitis related to Diabetes and " ...started on an oral antibiotic Bactrim + ?..." -Physician progress notes did not reflect a consistent record of medications prescribed for Client #3. -Records for a hospitalization from 8/2/19-8/6/19 and another hospitalization from 9/12/19-9/17/19 indicated the discharge medications for Client #3 were Aspirin 81mg daily, Bupropion (Wellbutrin) 450mg daily, Gabapentin 300mg 3 capsule 3 times daily, Glipizide 10mg twice daily, Novolog (insulin) 10 units three times daily sliding scale, and Levemir (insulin) 68 units twice daily. When discharged from the second hospitalization on 9/17/19 the discharge record indicated the addition of Bactrim (antibiotic) 800mg-160mg tablet twice daily. -Coordination of Care Notification to the PCP for Client #3 was sent on 9/23/19, almost 12 months following admission. Review on 10-1-19 of Client #6's record revealed: -Date of admission: 10-19-18 -Diagnoses: Insomnia, Chronic Pain related to Osteoarthritis, Degenerative Disc Disease, Sciatica, Depression, Asthma, Chronic Obstructive Pulmonary Disease, Opioid Use Disorder-Severe, History of Kidney Stones; -Her initial dose of Methadone was 86 milligrams (mg);	V 233		

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V 233	Continued From page 6 -Her current Methadone dose was 91 mg daily as ordered by the Medical Director on 7-2-19; -Counselor #1 listed Client #6's medications on the Bio-Psychosocial Assessment form as follows: -gabapentin (Neurontin) (anti-convulsant) 300mg three times per day; -meloxicam (Mobic) (anti-inflammatory) 7.5 mg twice per day; -trazodone (anti-depressant) 300 mg at bedtime; -Proair Inhaler; -The medications listed by Counselor #1 were not consistent with the medications reported by Client #6 during survey interview on 10-1-19; -A Physician Progress Note was completed by the Medical Director on 6-28-19 and Methadone was the only listed medication; -The Physician Progress Note from 6-28-19 had written documentation to follow up monthly and as needed; -There was only one Physician Progress note in Client #6's record; -A written Coordination of Care Notification form dated 10-19-18 was in Client #6's chart with no indication that the form had been submitted to her provider and no documentation that the records were ever received; -There was no additional information in Client #6's record that specified what her current prescribed medications were, or if she had been scheduled for a follow up medical appointment. Review on 9-30-19 of Client #8's record revealed: -Date of admission: 10-5-18; -Diagnoses: Neuropathy, Bi-Polar, Hyperlipidemia, GERD (Gastroesophageal reflux disease), Diabetes Type II, Mitral Valve Prolapse, PTSD (Post-Traumatic Stress Disorder), Opioid Use Disorder-Severe;	V 233		

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-Her initial dose of Methadone was 30 milligrams (mg) daily;
-Her current Methadone dose was 95 mg daily as ordered by the Medical Director on 9-25-19;
-The Medical Director listed Client #8's medications on the Intake/Admission Medical & Mental Health History form as follows:
-Lyrica (pain) 150 mg by mouth three times per day;
-topical cream with gabapentin (Neurontin), ketoprofen (anti-inflammatory) (Orudis) and lidocaine;
-Lamictal (anti-convulsant/mood disorders) 100 mg by mouth twice daily;
-Zantac (reflux) 150 mg by mouth twice daily;
-Zyrtec (allergies) 10 mg PO at bedtime;
-Counselor #1 listed Client #8's medications on the Bio-Psychosocial Assessment form as follows:
-Lyrica 150 mg three times per day;
-Lipitor (cholesterol) 20 mg at bedtime;
-Zantac 150 mg twice per day;
-cetirizine (Zyrtec) 10 mg at bedtime;
-The medications listed by the Medical Director were not consistent with the medications listed by Counselor #1;
-Written Physician Progress notes completed by the Medical Director listed the following prescribed medications for Client #8:
-On 2-15-19 Methadone, Lamictal, Zantac, Zyrtec, Lyrica and a statin drug were documented;
-On 3-8-19 Lamictal, Zantac, Zyrtec, Lyrica and a statin drug were documented;
-On 4-12-19 only Methadone was documented;
-On 5-3-19 only Methadone was documented;
-On 6-26-19 Lamictal, Zantac, Lyrica, atorvastatin, lisinopril (blood pressure), vitamin D,

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V 233	Continued From page 8 and acyclovir were documented; -On 7-31-19 Methadone, Lamictal, Zantac, Zyrtec, Lyrica, statin, lisinopril, vitamin D were documented; -9-25-19 only Methadone was documented; -A Prescription Monitoring Program (PMP) summary dated 9-17-19 indicated that Client #8 received 90 capsules of Lyrica 150 mg on 4-30-18, 5-31-18, 6-29-18, 7-25-18, 8-23-18, 9-24-18, 10-23-18, 11-20-18, 12-18-18, 1-17-19, 3-18-19, 4-22-19, 5-22-19, 6-18-19, 7-17-19 and 8-20-19; -A written Coordination of Care Notification form dated 10-10-18 was in Client #8's chart with no indication that the form had been submitted to her provider and no documentation that the records were ever received; -There was no additional information in Client #8's record that specified what her current prescribed medications were, or if she had been scheduled for a follow up medical appointment. Review on 9-30-19 of Client #9's record revealed: -Date of admission: 7-26-19; -Diagnoses: Opioid Use Disorder-Severe, Anxiety Disorder, Depression, Chronic Benzodiazepine Use, Hepatitis C; -His initial dose of Methadone was 20 milligrams (mg) daily; -His current Methadone dose was 75 mg daily as ordered by the Medical Director on 9-27-19; -The Physician's Admission Assessment form completed by the Medical Director on 7-26-19 lists the following medications for Client #9: -Xanax (anxiety) 1 milligrams (mg) three times per day; -Prozac (anti-depressant) 20 mg daily; -Seroquel (anti-psychotic) 100mg at bedtime; -tizanidine (muscle relaxer) (Zanaflex) 1 tablet twice per day;	V 233		

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-No dose amount for the tizanidine (Zanaflex) was documented;
-A written Coordination of Care Notification form dated 7-26-19 was in Client #9's chart with no indication that the form had been submitted to his provider and no documentation that the records were ever received;
-There was no additional information in Client #9's record that specified what his current medications were.

Review on 9/30/19 of Client #11's record revealed:
-Date of admission: 7/13/18;
-Diagnoses: Opioid Use Disorder, Sedative Use Disorder, Methamphetamine Abuse;
-Her initial and ongoing dose of Methadone was 40 milligrams (mg) daily;
-A review of her written physician progress note dated 7/31/19 showed her with one medication as Methadone 40 mg daily while her 8/28/19 written physician progress note showed her medications as Methadone 40 mg and "OCPs" (oral contraceptives);
-The written physician progress notes for clients were completed by the Medical Director;
-On 9/18/19, a fax records request was sent by Counselor #2 to Client #11's primary care physician (PCP) with the request to include a past and current medication list;
-On 9/20/19, the facility received a faxed report from Client #11's PCP which included 3 separate visits Client #11 made to outside medical providers on 7/20/19, 9/11/19, and 9/17/19 with prescribed medications that included:
  -albuterol (ProAir HFA) inhaler 90 microgram (mcg), "See Instructions", used to treat or prevent bronchospasm;
  -Amitiza 8 mcg, twice daily (BID) to treat constipation;

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V 233	Continued From page 10 -fluticasone (Flonase) nasal spray 50 mcg, BID to treat allergy symptoms; -Macrobid 100 mg, BID, used to treat urinary tract infections; -sulfamethoxazole-trimethoprim (Bactrim) 800 mg-160 mg, BID, used to treat bacterial infections; -Tri-Previfem oral tablet, once daily to prevent pregnancy; -Chantix Starter Pack 0.5.mg-1 mg oral tablet, BID, used as tobacco cessation method; -There appeared to be medication changes during each of these medical visit dates as new medications were added and Client #11 stopped her prescribed OCPs on or about 9/17/19 due to concerns about skin lesions; -The Medical Director initialed the faxed medical reports which indicated she had reviewed the information on Client #11; -There was no additional information in Client #11's record that indicated what her current prescribed medications were or if she had been scheduled for a follow up medical appointment. Record review on 9/30/19 for Deceased Client #12 (DC #12) revealed: -Admitted on 10/19/18 with diagnoses of Opioid Dependence, Bi Polar Disorder, Depression, and Anxiety Disorder. DC #12 transferred from another methadone clinic. -Date of Death 6/16/19. The facility was notified of her death on 6/19/19. -Methadone dose at admission was 90mg (transfer from another clinic). The dose was incrementally increased and her dose prior to her death was 119mg (ordered on 4/18/19). -She was a level 3 and received 4 take homes per week. -She last dosed at the clinic on 6/13/19 and received 4 take homes.	V 233		

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V 233	Continued From page 11 -Psychosocial assessment dated 9/4/18 from the prior program indicated " ...Patient is currently prescribed haloperidol (anti-psychotic), hydroxyzine (anxiety), lithium (mania/Bi Polar Disorder), gabapentin (anti-convulsant), HCTZ (Hydrochlorothiazide) (diuretic), and meloxicam (anti-inflammatory); Patient has a diagnosis of bipolar, manic depression and is currently being treated at [behavioral health agency] in [town] ..." -History and Physical from the prior program indicated medications were " ...Lithium 300mg TID (three times daily), prazosin (high blood pressure) 2mg daily, HCTZ 25mg daily, hydroxyzine 50mg TID/PRN (as needed), omeprazole (reflux) 40mg daily, gabapentin 600mg QID (four times daily), haloperidol 10mg daily to BID (twice daily), celecoxib (anti-inflammatory) 15mg daily ..." -Biopsychosocial dated 10/18/18 indicated current medications were " ...Omeprazole 40mg daily ... (HCTZ) 25 mg daily ...voltaren gel lotion 1% 4 times daily ...Gabapentin 300mg 2 cap 4 times a day ...". Primary Care Physician (PCP) was indicated as the prescriber. -Intake assessment by the Medical Director indicated " ...Medical History ...Bi Polar Disorder, Borderline Personality Disorder, PTSD (post-traumatic Stress Disorder), obesity, HTN (hypertension) ..." The medications were consistent with those indicated in the transfer information except for Hydroxyzine which was not indicated as a PRN medication. The assessment further indicated that DC #12 was under the care of a psychiatrist with a behavioral health program and had a physician for primary care. -Physician progress note dated 12/19/18 indicated an increase in the Gabapentin to 800mg four times daily and the addition of Rexulti (anti-depressant) 2mg daily to her medication regimen.	V 233		

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V 233	Continued From page 12 -Monthly Physician progress notes from February through June 2019 were inconsistent in documentation of the medications that DC #12 was prescribed in addition to her Methadone. Physician progress notes did not reflect a consistent record of medications prescribed for DC #12. -There was no documentation to indicate coordination of care was completed with either Physician for DC #12. Neither physician was notified about her Methadone dose and no records were obtained to confirm her medication regimen. Review on 10/3/19 of DC #12's written autopsy report revealed: -Her autopsy was performed on 6/19/19 by a physician with the Office of the Chief Medical Examiner's Office (OCME); -Cause of death was determined by the OCME on or about 8/22/19 as Methadone and Gabapentin toxicity. Interview on 10/1/19 with Client #2 revealed: -She had been in treatment for approximately 4 months at the facility; -This was her first time in Methadone treatment; -Her initial Methadone dose was 25 milligrams (mg) and her current dose was 70 mg; -Her dose was increased 3 days ago from 65 mg to 70 mg due to withdrawal symptoms from having used Opana; -She stated she was recently hospitalized due to a stroke and was on prescribed medications that included Tegretol and Keppra to treat her seizures, Xanax for her anxiety, and Lipitor and Aspirin to treat her stroke; -She stated the doctor at the facility had all her records from where she was hospitalized for her stroke;	V 233		

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V 233	Continued From page 13 -She was scheduled to be seen by her physician on 10/7/19 for the clogged arteries in her neck; -She was scheduled to be seen by the Medical Director on this date, 10/1/19; -While she was hospitalized for 5 nights, she was dosed with Percocet and other pain medications so she knew she would fail her urine drug screen on this date because of the pain medications. Interview on 10/2/19 with Counselor #1 revealed: -When a client indicated they were taking prescribed medications at the time of admission, the counselor was responsible for the documentation of the medication on the client's assessment and informing the medical staff of the client's medications; -A counselor was responsible for getting a release of information (ROI) and coordination of care (COC) signed by the client at the time of their admission to obtain copies of their medical and mental health information as part of their treatment; -Once a faxed request for client information was sent to their medical provider, staff checked the fax machine periodically to see if the information had been received; -If the client information requested had not been received, a counselor gave "it a few days" and then called the medical provider about the faxed request for records; -There was no set procedure, but he documented the status of whether the information was received in the client's record. -There were a lot of systems at the facility with client medications and the electronic client record that were still being worked on and corrected. -DC #12's prescribed medications would have been indicated on her admission assessment; -There should have been a written ROI and written consent for COC completed and signed	V 233		

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V 233	Continued From page 14 by her (DC #12) at the time of her admission; -He did not have access to the prior electronic client record to confirm whether an admission ROI and COC was completed for DC #12; -He stated he thought these processes were done; -As DC #12's counselor, he was responsible for ensuring the ROI and COC were completed and the medical staff were made aware of her prescribed medications. Interview on 10/8/19 with Counselor #2 revealed: -Client #11 typically went to a local walk-in medical clinic when she had medical concerns; -She had faxed a coordination of care request to Client #11's doctor in 9/2019 for a copy of her records; -She did not know whether Client #11 was an established patient of the local primary care physician where she was seen on 9/17/19; -She was uncertain about Client #11's current medications; -The Medical Director had not scheduled a follow up appointment with Client #11 after copies of her medical records were received into the facility on 9/20/19. -There was no prior request of medical records from the primary care physician for Client #3. She discussed his medications with him on 10/7/19. Interview on 10/2/19 with the Clinical Supervisor revealed: -She began work as the Clinical Supervisor on 8/16/19; -She indicated that there had been a learning curve and there are a lot of projects to make some corrections; -When she started her position, coordination of care "wasn't much of anything" and	V 233		

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communication was difficult;
-The Medical Director would request information about a client, but it was never communicated;
-The only release of information that was being done was the emergency contact and requesting transfer paperwork;
-Her responsibilities included overseeing program compliance of the counseling staff with client counseling sessions, completing counseling notes, updating treatment plans, conducting weekly client record audits, evaluating the treatment progress of "high risk" clients, and she carried a caseload of 38 clients;
-She was not familiar with Deceased Client (DC #12);
-At the time of the bio-psychosocial assessment, each client was asked by a counselor about their prescribed medications and specific physical and mental health conditions;
-Now the Counselors documented client responses about their medications and diagnoses and were responsible for getting the ROIs and COC consents signed by client;
-The counselors faxed the ROIs and COCs to client medical and mental health providers in attempt to get information back as soon as possible about the clients served by the facility;
-The outside medical and mental health providers were informed as part of the client's COC about their Methadone treatment and dose amount;
-She was aware there had been past difficulty with staff coordination of client care with outside medical providers due to no information being uploaded into the client electronic system or communicated in team staffing about physician-recommended COC and referrals needed for clients;
-This problem began to get worked on when the former Director left her position and she and the current facility Director began communicating

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directly about the need for client COC information to be obtained and reviewed;
-There were continued issues with the facility not receiving client information from medical providers although written requests were faxed multiple times and with staff having placed "flags" in the client record for a 2-week follow-up;
-Weekly team meeting between nursing and the counselors to discuss client situations occurred every Thursday, were led by the Program Director after review of recommendations made by the Medical Director on Wednesdays;
-She reviewed the Medical Director's recommendations to the counselors and was responsible for "flagging" a client's record based on a recommendation, such as mental health referral might be needed for a client as an example;
-She did not think there was a central location in the client's record where client prescribed medications were kept current and updated;
-If there was a central medication list in the client record, she had never been shown the location;
-Her assessment of the communication between the facility physician and counselors was "better" although the physician was present at the facility for 2-3 hours on Wednesdays and does not answer her telephone if called.

Interviews on 10/1/19 and 10/2/19 with the Registered Nurse (RN) revealed:
10/1/19, she was the primary dosing nurse and had been employed at the facility since 11/2018;
-Her job duties included an initial client assessment that involved collecting vital signs, urine drug screen (UDS) and breathalyzer, a list of medications prescribed by other doctors, daily client dosing of liquid Methadone based on the Medical Director's signed written orders for each client, and review of client post hospitalization

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and post incarceration paperwork;
-For new client admissions, the Medical Director provided nursing with new orders written and signed in paper prescriptions which were later scanned into the client record;
-Existing clients had a physician-ordered maximum limit on the amount of their Methadone dose;
-Weekly team meetings were held between staff to discuss client phases (levels) and client concerns (pregnancies);
-The Medical Director did not attend or participate in the weekly team meetings;
-Sometimes, she and counselors discussed client situations on an individual basis if there were questions and/or concerns between the weekly team meetings;
-New client medications which were made known to her by a client or through a review of a client's post hospitalization paperwork. That information was documented in a nurse's note and located in the client's individual record;
-Client initial assessments were done by the nursing staff and client medications were reviewed at the same time;
-Clients were asked about their medications and they printed a PMP (Prescription Monitoring Program) of controlled medications;
-Clients were not always forthcoming about their medications and sometimes they forgot to bring in their medication bottles;
-The facility switched to a new client electronic record program within the year and she would have to access the former electronic system to find client medication for clients who were admitted in 2018;
-The counselors were responsible for the clients' coordination of care by faxing client signed consents and releases of information to obtain their medical information from other

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medical providers;
-The counselors made the follow-up contacts with medical providers if there were no responses from providers about the clients;
-She reviewed client hospital records and client records from local medical walk-in clinics to make sure they had not been prescribed new medications or may not have reported they were on Methadone;
-There were times the medical information was not provided to her by the counselor for review which could be problematic if the client was placed on new medication and the medical staff was not made aware;
-The counselors would let her know if she needed to be involved in a client's coordination of care;
-10/2/19, she asked clients about their medication changes when they came to dose and if they indicated they had been to a local walk-in medical clinic or at a local hospital;
-Client dosing post-hospitalization and post-incarceration were verified by nursing staff through telephone calls to the appropriate facilities and by reviewing client discharge paperwork;
-She communicated with the Medical Director about a client's hospitalization or incarceration by completing a nurse's note in the client's record which included changes in client medications;
- "We try to keep track of their medicines;"
-Recommendations by the Medical Director were usually taken care of by the Counselor;
-There was a place in the client record to pull up, review and update a client's list of medications but the system for managing the medication list was not "user-friendly;"
-Because of this difficulty, client medications were found in the written physician progress notes or nurses notes;

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V 233	Continued From page 19 -She did not know Client #11 was on prescribed medications other than her Methadone 40 mg. once daily; -She was aware that Client #3 had 2 hospitalizations for surgery on his feet because his hospital paperwork had come across her desk for her review. Interviews on 10/2/19 and 10/4/19 with the Medical Director revealed: 10/2/19, she had been the facility's physician since it opened in 6/2018; -In 9/2019, she reduced seeing clients from twice a week, on Wednesdays and Fridays, to once a week, on Wednesdays; -Her last work day as the Medical Director, was planned for 10/16/19; -The majority of the clients were seen by her once a month; -At each physician visit, she pulled up the client's Prescription Monitoring Program (PMP) report or Controlled Substance Report (CSR), which contained narcotic medications and was the "most important" report for her review of client medications; -She asked each time she saw a client about whether they had any medication changes; -She relied on client self-reports of their prescribed medications and medication changes for a medication list in addition to the PMP report; -She knew that the PMP did not capture all medications prescribed for clients; -A paper physician progress note was used to document each client contact visit; -The progress note was scanned by staff into the client's electronic record; -Not all of a client's prescribed medications were written down by her at each visit; -She varied whether she wrote all the medications on the progress note;	V 233		

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V 233	Continued From page 20 -Sometimes a client reported no change in their medications; - "They (clients) don't keep good records; they will usually say 'no change';" - "Patients are trained to let us know if they go to the ER (Emergency Room) and have new medicines or changes;" -A lot of the clients served by the facility were homeless, seen by different doctors, and when they had changes in medications, they were likely to tell the dosing nurse because of their more frequent interaction with the nurse; -She was not aware of one location in the client's record where client prescribed medications were recorded and updated; -The counseling staff was responsible for working with the clients to obtain consent for their coordination of care; -She believed the counseling staff were reaching out to the clients' medical providers by faxing the clients' written and signed coordination of care requests; -She believed the systems of care coordination and communication could be improved as there was not a "good mechanism" in place for having client information returned from other medical providers with the exception of post client hospitalizations; 10/4/19, she acknowledged the responsibility was hers, as the facility physician, to: -question if clients need to be on certain medications; -to review the prescribed narcotics, report each time; -to collect all the medication at the time the client is seen by her; -to discuss the prescribed medications and illicit substances with the clients that they were taking; -She stated that with medication changes, the clients had responsibility to let their medication	V 233		

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prescriber know they were on Methadone and let her and the other facility staff know what other medications they were taking;
-"It is up to the clients to tell us if they have new medicines but they don't always remember to tell us;"
-She was uncertain how often nursing staff collected and updated client medications.
-She indicated it was very important to know all medications that clients were taking. The most concerning medications were gabapentin, anti-psychotics, benzodiazepines and Lyrica.
-She indicated that the medication list was not updated or reviewed regularly due to time constraints or a client not knowing their own medications.
-She felt that the system to track medications was not optimal and that the staff may know of medications changes that she doesn't.
-She was aware of the serious interactions between Methadone and other medications.
-Use of methadone with benzodiazepines, Neurontin (Gapapentin), barbiturates, antibiotics, and psychotropics medications could result in a "deadly combination;"
-Gabapentin, like benzodiazepines, had a depressant effect on the central nervous system and could result in loss of consciousness or an overdose if too much of the medication was taken;
-Lyrica and Trazadone had a "sedating" effect in their interactions with other drugs;
-Psychotropics could cause cardiac issues like prolonged QT syndrome;
-The point at which methadone combined with prescribed medications could become harmful to an individual were varied and depended on a person's gene composition and liver enzyme processing;
-Because of the individualized variance, it was

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important for a client on methadone and other prescribed medications be monitored daily and "individual clinical judgement" used;
-She had no recollection of DC #12's prescribing physician having increased her gabapentin to 3200 mg a day;
-When DC #12 transferred to the facility, she was admitted at a 90 mg Methadone dose;
-She determined her to be stable with "no huge risk" for an overdose for her to have increased her Methadone to 119 mg;
-Signs and symptoms that her body would have not coped with the increase would have included increased sleepiness during the day and DC #12 did not report this symptom;
-She talked extensively with DC #12 about her medicine list and told her to talk with her primary care doctor about her medicines;
-DC #12 was taking Neurontin (gabapentin) which was her "least favorite drug" for a client;
-If she had been the "sole prescriber," DC #12 would have not been on the gabapentin. She indicated that she had to make a clinical decision when DC #12 came to the clinic. "I didn't want to de-stabilize her and have her die of an opiate overdose." She stated that she had a serious talk with DC #12 about the high doses of Gabapentin but "patients make their own decisions." DC #12 was not sedated even though taking the high dose of Gabapentin with the Methadone;
-There would have been warning signs such as getting sleepy during the day and DC #12 did not report that;
-She indicated that she talked to her patients about the risks of combining medications and encouraged the clients to talk to their physicians;
-She (DC #12) was at "high risk" because she was morbidly obese and on multiple psychotropic medications with an underlying mental illness;
-Anyone who used opioids was at "high risk" for

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V 233	Continued From page 23 death when accompanied by high-risk behaviors; -She would not be shocked if other clients died as they too were going to doctors for other prescribed medications and she had "no control over that;" -Clients made their own decisions what they were going to do; -She reviewed DC #12's treatment record with the company's Medical Director and completed paperwork as a part of DC #12's supplemental death review, which was completed on 6/20/19; -DC #12's autopsy showed her cause of death was cardiac-related and not due to an overdose situation; -She saw the autopsy report earlier than on 8/22/19; -The concern she and the staff discussed related to DC #12's course of treatment was her having been a high-risk patient. -"I think there is always risk when you don't have all the information." Interview on 10/4/19 with the Program Director revealed: -The facility used to only track the controlled medications that clients were prescribed; -They only knew about other medications prescribed if a client reported it; -There was no coordination of care completed in the past; -She indicated that she had seen the coordination of care form filled out but never any information coming back from other medical providers; -She felt it was a concern not knowing what other medications a client might be taking; -She transitioned from a dosing nurse to the Facility Director on 9/16/19; -Since becoming the Director, she was aware that if a client had medications prescribed by another	V 233		

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physician, a coordination of care (COC) document was signed by the client and sent to the prescribing physician by the client's counselor to obtain a list of their medications and diagnoses;
-Each completed (successful) faxed COC request for a client was scanned into the client's record by staff;
-If a follow up was needed with the medical provider to obtain the client medical information, a call was made by the counselor about 3 days after a faxed request was made and documented in a case manager note;
-This was not a written policy but instead, it was a process "talked about" at a staff meeting;
-When client's medical information was received , the information was placed on the Medical Director's desk for her review and she determined the next time the client would be seen for a physician visit;
-In 9/2019, a COC request was faxed to Client #11's physician and a copy of her medical records were received into the facility by fax and placed on the Medical Director's desk for review;
-Her medical records were reviewed by the Medical Director as indicated by the Medical Director's initials on the medical paperwork;
-Other than Methadone 40 mg, Client #11 had a prescribed medication for an oral contraceptive that was listed in her record;
-She was uncertain who the prescribing physician was for Client #11's oral contraceptive;
-The Medical Director made the decision whether to have a follow up appointment scheduled with Client #11 after review of her medical information;
-She was not aware of a central location in the client record for client medications to be maintained and updated;
-They had clients who were on prescribed medications that could not be verified by staff

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V 233	Continued From page 25 because not all clients wanted their Methadone treatment disclosed to their medical providers; -They had clients who knew their medical providers would "drop" them from medical care if it were known they were receiving Methadone treatment. -She was aware the Medical Director was concerned about clients who took gabapentin and methadone; -There were studies conducted where gabapentin uses by persons produced a "euphoric feeling;" -There was never a conversation between her and the Medical Director about the effects of a gabapentin and methadone combination; -The Medical Director did not prescribe gabapentin; she prescribed methadone; -The Medical Director was at the facility one day a week to see clients and was unavailable other days of the week due to having her own private practice; -She was not aware of conversations the Medical Director may have had with outside prescribers of client medications; -She had not had conversations with outside prescribers of client medications; -She had not been a part of a client death review process since she became the Program Director; -She was not aware of DC #12's cause of death; -She had not seen the written results of her autopsy report; -There had been no changes in facility processes she knew of as a result of the death of DC #12. Review on 10/4/19 of an initial Plan of Protection which was completed, dated and signed on 10/4/19 by the Program Director revealed: What will you immediately do to correct the above rule violations in order to protect clients from further risk or additional harm?	V 233		

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V 233	Continued From page 26 "Every patient will be staffed and the need for a Coordination of Care will be determined and processed at that time. " Describe your plans to make sure the above happens. "A step by step process of completing a Coordination of Care (COC) will be reviewed with all staff members by the Regional Nurse and Program Director. Coordination of Care will be implemented on the day of admission for patients who have initial documentation of conditions or behaviors that require a COC. Current clients will be staffed and COCs will be implemented as needed. Once a COC is implemented, the counselor will fax the COC to the patient's provider. The COC and fax confirmation will be linked to patient's Electronic Medical Record. The patient will be flagged for the counselor to follow up with prescribing office within 72 hours if records have not been obtained and will document encounter in a case manager note. If the records have not been obtained within 72 hours, the program nurse will consult the prescribing physician's nurse for records and document encounter in a nurse's note. If records are still not received, the Medical Director will contact the prescribing physician for a consult. COCs will be updated with any change in medications as reported by the patient, the controlled substance report, and when required by the Medical Director or program physician. High Risk patients will be staffed weekly at treatment team and monthly with the Medical Director or program physician." Review on 10/7/19 of an amended Plan of Protection dated 10/7/19 and completed by President of Clinical Operations revealed: What will you immediately do to correct the above rule violations in order to protect clients from	V 233		

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further risk or additional harm? "[The Facility] trained staff on step by step process of completing Coordination of Care (COC) which will include identification of client's current medications on 10/7/19. The training was completed by [the Regional Nurse] and [the Program Director]. [The Clinical Supervisor] will review each intake chart to ensure that an appropriate coordination of care has been completed. New admissions, readmissions, patients with documented medical conditions and/or patients with changes in medications as reported by the patient or controlled substance report will be staffed with the Medical Director weekly during treatment team and the proper coordination of care completed."
Describe your plans to make sure the above happens. "Coordination of Care will be implemented on the day of admission for patients who have initial documentation of medical conditions and/or an active prescription that require a COC. Current clients will be staffed by 10/11/19 with the Program Director, Director of Nursing and Clinical Supervisor and COCs will be implemented as deemed appropriate.
COCs will be updated with any change in medications as reported by the patient or the controlled substance report in consultation with other Providers and when required by the Medical Director or program physician. High Risk patients will be staffed weekly at treatment team and monthly with the Medical Director or program physician. All Coordination of Care will be tracked in the patient's chart in the Electronic Medical Record, filed under Medication tab, and will be monitored by the Clinical Supervisor and Director of Regional Compliance monthly. The Medical Director and/or Program Physician will staff all cases with [the Chief Medical Officer] when there are concerns regarding coordination of care,

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prescribed medications, patient admissions and/or methadone dose increase protocols."

Clients #2, #3, #6, #8, #9, #11 and DC #12 were admitted into treatment with various medical and/or mental health diagnoses in addition to Opioid Use Disorder. These diagnoses included Diabetes, Chronic Obstruction Pulmonary Disease, Depression, Anxiety, Bi Polar Disorder, Seizure Disorder and Post-Traumatic Stress Disorder. The clients had medication regimens that included a wide range of medications to treat these conditions. The medications prescribed included Gabapentin, Lyrica, psychotropic and anti-psychotic medications which were identified by the Medical Director to be the most concerning due to the risks they pose in combination with Methadone. The facility failed to coordinate care with the prescribers of these medications. There was no evidence to indicate that the primary care physicians or psychiatrists treating the clients were fully informed about the Methadone being dosed to their clients. The facility had conflicting or incomplete information about medications. Furthermore, there was no system to update medications for clients as changes occurred. DC #12 was in treatment for 8 months and there was no coordination of care with the psychiatrist who prescribed her Gabapentin. During her treatment the Gabapentin dose increased to 3200 mg daily as her Methadone also increased to 119mg. On 6/16/19 DC #12 died from Methadone and Gabapentin toxicity. In combination with Methadone, medications prescribed for these clients can cause increased sedation, suppression to the central nervous system and fatal overdose. Failure to coordinate care regarding co-occurring medical conditions and medications associated with those conditions constitutes a Type A1 rule violation for serious

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V 233	Continued From page 29 neglect and must be corrected within 23 days. An administrative penalty of $12,000.00 is imposed. If the violation is not corrected within 23 days an additional administrative penalty of $500.00 per day will be imposed for each day the facility is out of compliance beyond the 23rd day.	V 233		
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 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.	V 235		

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V 235	Continued From page 30 This Rule is not met as evidenced by: Based on record review and interview the facility failed to ensure 1 of 4 audited staff (Registered Nurse) was trained in group and family therapy. The findings are: Review on 10/1/19 of the personnel record for RN (Registered Nurse) revealed: -Date of hire was 3/3/18. -Current Permanent RN license. -No training documented Group and Family therapy. Interview on 10/1/19 with the Program Director revealed: -The Nursing staff had not been required to complete training in group and family therapy. -She had not been aware that the training requirement was for all direct care staff.	V 235		
V 367	27G .0604 Incident Reporting Requirements 10A NCAC 27G .0604 INCIDENT REPORTING REQUIREMENTS FOR CATEGORY A AND B PROVIDERS (a) Category A and B providers shall report all level II incidents, except deaths, that occur during the provision of billable services or while the consumer is on the providers premises or level III incidents and level II deaths involving the clients to whom the provider rendered any service within 90 days prior to the incident to the LME responsible for the catchment area where services are provided within 72 hours of becoming aware of the incident. The report shall be submitted on a form provided by the Secretary. The report may be submitted via mail, in person, facsimile or encrypted electronic means. The report shall include the following	V 367		

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V 367	Continued From page 31 information: (1) reporting provider contact and identification information; (2) client identification information; (3) type of incident; (4) description of incident; (5) status of the effort to determine the cause of the incident; and (6) other individuals or authorities notified or responding. (b) Category A and B providers shall explain any missing or incomplete information. The provider shall submit an updated report to all required report recipients by the end of the next business day whenever: (1) the provider has reason to believe that information provided in the report may be erroneous, misleading or otherwise unreliable; or (2) the provider obtains information required on the incident form that was previously unavailable. (c) Category A and B providers shall submit, upon request by the LME, other information obtained regarding the incident, including: (1) hospital records including confidential information; (2) reports by other authorities; and (3) the provider's response to the incident. (d) Category A and B providers shall send a copy of all level III incident reports to the Division of Mental Health, Developmental Disabilities and Substance Abuse Services within 72 hours of becoming aware of the incident. Category A providers shall send a copy of all level III incidents involving a client death to the Division of Health Service Regulation within 72 hours of becoming aware of the incident. In cases of client death within seven days of use of seclusion or restraint, the provider shall report the death	V 367		

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V 367	Continued From page 32 immediately, as required by 10A NCAC 26C .0300 and 10A NCAC 27E .0104(e)(18). (e) Category A and B providers shall send a report quarterly to the LME responsible for the catchment area where services are provided. The report shall be submitted on a form provided by the Secretary via electronic means and shall include summary information as follows: (1) medication errors that do not meet the definition of a level II or level III incident; (2) restrictive interventions that do not meet the definition of a level II or level III incident; (3) searches of a client or his living area; (4) seizures of client property or property in the possession of a client; (5) the total number of level II and level III incidents that occurred; and (6) a statement indicating that there have been no reportable incidents whenever no incidents have occurred during the quarter that meet any of the criteria as set forth in Paragraphs (a) and (d) of this Rule and Subparagraphs (1) through (4) of this Paragraph. This Rule is not met as evidenced by: Based on record review and interview the facility failed to ensure Level III incidents were reported to the Local Management Entity (LME) within 72 hours of becoming aware of the incident effecting 1 of 1 deceased client (DC#12). The findings are: Review on 9/30/19 of the incident reports in IRIS (Incident Response Improvement System) revealed: -Date of incident was 6/16/19. The incident was the death of DC #12.	V 367		

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V 367	Continued From page 33 -Date provider learned of the incident was 6/19/19. -Date submitted to IRIS was 6/24/19. Interview on 10/4/19 with the Program Director revealed: -The prior Program Director had been responsible for reporting at the time of DC #12's death. -She remembered having received a State call that it had been 5 days and a report was not in the NC Incident Response Improvement System (IRIS) on the death of DC #12 and the facility "could be shut down because of this." Interview on 10/8/19 with the President of Clinical Operations revealed: -The death of DC #12 had been reviewed. -She was not aware that the IRIS report had not been submitted within the 72-hour timeframe. -The prior Director had been responsible for submitting the IRIS reports.	V 367		
V 536	27E .0107 Client Rights - Training on Alt to Rest. Int. 10A NCAC 27E .0107 TRAINING ON ALTERNATIVES TO RESTRICTIVE INTERVENTIONS (a) Facilities shall implement policies and practices that emphasize the use of alternatives to restrictive interventions. (b) Prior to providing services to people with disabilities, staff including service providers, employees, students or volunteers, shall demonstrate competence by successfully completing training in communication skills and other strategies for creating an environment in which the likelihood of imminent danger of abuse	V 536		

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V 536	Continued From page 34 or injury to a person with disabilities or others or property damage is prevented. (c) Provider agencies shall establish training based on state competencies, monitor for internal compliance and demonstrate they acted on data gathered. (d) The training shall be competency-based, include measurable learning objectives, measurable testing (written and by observation of behavior) on those objectives and measurable methods to determine passing or failing the course. (e) Formal refresher training must be completed by each service provider periodically (minimum annually). (f) Content of the training that the service provider wishes to employ must be approved by the Division of MH/DD/SAS pursuant to Paragraph (g) of this Rule. (g) Staff shall demonstrate competence in the following core areas: (1) knowledge and understanding of the people being served; (2) recognizing and interpreting human behavior; (3) recognizing the effect of internal and external stressors that may affect people with disabilities; (4) strategies for building positive relationships with persons with disabilities; (5) recognizing cultural, environmental and organizational factors that may affect people with disabilities; (6) recognizing the importance of and assisting in the person's involvement in making decisions about their life; (7) skills in assessing individual risk for escalating behavior; (8) communication strategies for defusing	V 536		

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and de-escalating potentially dangerous behavior; and
(9) positive behavioral supports (providing means for people with disabilities to choose activities which directly oppose or replace behaviors which are unsafe).
(h) Service providers shall maintain documentation of initial and refresher training for at least three years.
(1) Documentation shall include:
(A) who participated in the training and the outcomes (pass/fail);
(B) when and where they attended; and
(C) instructor's name;
(2) The Division of MH/DD/SAS may review/request this documentation at any time.
(i) Instructor Qualifications and Training Requirements:
(1) Trainers shall demonstrate competence by scoring 100% on testing in a training program aimed at preventing, reducing and eliminating the need for restrictive interventions.
(2) Trainers shall demonstrate competence by scoring a passing grade on testing in an instructor training program.
(3) The training shall be competency-based, include measurable learning objectives, measurable testing (written and by observation of behavior) on those objectives and measurable methods to determine passing or failing the course.
(4) The content of the instructor training the service provider plans to employ shall be approved by the Division of MH/DD/SAS pursuant to Subparagraph (i)(5) of this Rule.
(5) Acceptable instructor training programs shall include but are not limited to presentation of:
(A) understanding the adult learner;
(B) methods for teaching content of the

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course;
(C) methods for evaluating trainee performance; and
(D) documentation procedures.
(6) Trainers shall have coached experience teaching a training program aimed at preventing, reducing and eliminating the need for restrictive interventions at least one time, with positive review by the coach.
(7) Trainers shall teach a training program aimed at preventing, reducing and eliminating the need for restrictive interventions at least once annually.
(8) Trainers shall complete a refresher instructor training at least every two years.
(j) Service providers shall maintain documentation of initial and refresher instructor training for at least three years.
(1) Documentation shall include:
(A) who participated in the training and the outcomes (pass/fail);
(B) when and where attended; and
(C) instructor's name.
(2) The Division of MH/DD/SAS may request and review this documentation any time.
(k) Qualifications of Coaches:
(1) Coaches shall meet all preparation requirements as a trainer.
(2) Coaches shall teach at least three times the course which is being coached.
(3) Coaches shall demonstrate competence by completion of coaching or train-the-trainer instruction.
(l) Documentation shall be the same preparation as for trainers.

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This Rule is not met as evidenced by:
Based on record review and interviews the facility failed to ensure 3 of 3 audited staff (Registered Nurse, Counselor #1, and the Clinical Director) had been trained in alternatives to restrictive interventions. The findings are:

Review on 10/1/19 of the personnel record for Registered Nurse revealed:
-Hired on 3/3/18.
-Current Permanent RN license.
-No documentation of training in alternatives to restrictive interventions.

Review on 10/1/19 of the personnel record for Counselor #1 revealed:
-Hired on 9/27/18.
-Licensed Clinical Addictions Specialist.
-No documentation of training in alternatives to restrictive interventions.

Review on 10/1/19 of the personnel record for the Clinical Supervisor revealed:
-Hired on 5/6/19.
-Licensed Clinical Addictions Specialist and Certified Clinical Supervisor-Intern.
-No documentation of training in alternatives to restrictive interventions.

Interview on 10/8/19 with the President of Clinical Operations revealed:
-Training in alternatives to restrictive interventions was usually done. In the past the training was NCI (North Carolina Interventions). This training was usually part of their orientation process.
-The Program Director and Regional Director were ultimately responsible for ensuring all staff

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V 536	Continued From page 38 training was provided. -There had been turn over of management in the facility. -She was unsure why this training had not been done.	V 536		