

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL044-062	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 11/15/2018
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NAME OF PROVIDER OR SUPPLIER BHG CLYDE TREATMENT CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 414 HOSPITAL DRIVE CLYDE, NC 28721
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V 000	<p>INITIAL COMMENTS</p> <p>An annual and follow up survey was completed on 11/15/18. Deficiencies were cited.</p> <p>This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment. The census at the time of survey was 163 clients.</p>	V 000		
V 111	<p>27G .0205 (A-B) Assessment/Treatment/Habilitation Plan</p> <p>10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN</p> <p>(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:</p> <ol style="list-style-type: none"> (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. <p>(b) When services are provided prior to the establishment and implementation of the treatment/habilitation or service plan, hereafter referred to as the "plan," strategies to address the client's presenting problem shall be documented.</p>	V 111		

Division of Health Service Regulation LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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V 111	<p>Continued From page 1</p> <p>This Rule is not met as evidenced by: Based upon record review and staff interview the facility failed to complete an assessment for clients prior to the delivery of services for 3 of 13 sampled clients. (Clients #3, #4 and #10). The findings are:</p> <p>Review on 11/7/18 of the record for Client #3 revealed: -Client was admitted 4/5/18 with a diagnosis of Opioid Use Disorder. -Client's Biopsychosocial Assessment dated 4/2/18 was blank. -The Program Director was asked to provide a copy but no paper records for client #3 were provided.</p> <p>Review on 11/7/18 of the record for Client #4 revealed: -Client was admitted on 4/18/18 with a diagnosis of Opioid Use Disorder. - Client's Biopsychosocial Assessment was not dated and was blank. -The Program Director was asked to provide a copy but no additional paper records for client #4 were provided.</p> <p>Review on 11/7/18 of the record for Client #10 revealed: -Client was originally admitted on 5/30/17 and readmitted on 12/27/18 with diagnosis of Opioid</p>	V 111		

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V 111	<p>Continued From page 2</p> <p>Dependence - Severe. -She was incarcerated from 9/30/17-12/25/17. -Physician physical dated 12/27/17 indicated she was re-admitted to the program. -No documentation in the record of a re-assessment or updated treatment plan after re-admission.</p> <p>Interview with the Program Director on 11/6/18 and 11/15/18 revealed that client records were kept in electronic health records. Access to electronic records was provided on 11/6/18, 11/7/18 and 11/15/18. On 11/15/18 the Program Director indicated that paper copies of client records were available for surveyor review.</p> <p>As of 11/15/18 no paper records were provided for Client #2 and #3. The survey findings were based upon both electronic and paper records provided.</p>	V 111		
V 112	<p>27G .0205 (C-D) Assessment/Treatment/Habilitation Plan</p> <p>10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN</p> <p>(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.</p> <p>(d) The plan shall include:</p> <p>(1) client outcome(s) that are anticipated to be achieved by provision of the service and a projected date of achievement;</p> <p>(2) strategies;</p>	V 112		

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V 112	<p>Continued From page 3</p> <p>(3) staff responsible; (4) a schedule for review of the plan at least annually in consultation with the client or legally responsible person or both; (5) basis for evaluation or assessment of outcome achievement; and (6) written consent or agreement by the client or responsible party, or a written statement by the provider stating why such consent could not be obtained.</p> <p>This Rule is not met as evidenced by: Based on record review and interviews, the facility failed to develop and implement a treatment plan (Clients #11 and #10), failed to update and review a plan at least annually (Clients #3, #4, #6, and #13) and failed to obtain written consent or agreement from the client or responsible party to their treatment plans (Clients #1, #2, #5 and #7) affecting 10 of 13 sampled clients. The findings are:</p> <p>Review on 11/7/18 of the record for Client #10 revealed: -Original admission date of 5/30/17 and discharged on 9/30/17. -Client #10 was incarcerated from 9/30/17-12/25/17. -Physician physical dated 12/27/18 indicated client was a re-admit to the program. -Treatment plan in the record was 5/30/17 admission with no update or new plan based on current need of the client.</p>	V 112		

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V 112	<p>Continued From page 4</p> <p>-A Treatment plan was dated 5/30/17. There was no treatment plan for the admission on 12/27/17. The Psychosocial Assessment indicated the client had a diagnosis of Opioid Use Disorder, severe.</p> <p>Review on 11/7/18 and 11/15/18 of the record for Client #11 revealed: -Admitted on 7/22/15 with a diagnosis of Opioid Use Disorder. -No treatment plan was found in either electronic or paper records.</p> <p>No signature: Review on 11/6/18 of the record for Client #1 revealed: - Admission date of 11/29/17 with a diagnosis of Opioid Use Disorder. -treatment plan dated 11/20/18 was not signed by the client.</p> <p>Review on 11/6/18 of the record for Client #2 revealed: -admitted 1/11/12 with diagnoses of Opioid Use Disorder, Obesity, Gastro-Esophageal Reflux Disease, Fibromyalgia, and Chronic Pain. -treatment plan dated 2/20/18 was not signed by the client.</p> <p>Review on 11/7/18 and on 11/15/18 of the record for Client #5 revealed: -admitted on 10/6/18 with a diagnosis of Opioid Use Disorder. -treatment plan 1/5/18 was not signed by the client.</p>	V 112		

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V 112	<p>Continued From page 5</p> <p>Review on 11/15/18 of the record for Client #7 revealed: -admitted on 1/9/18 with a diagnosis of Opioid Use Disorder. -treatment plan dated 10/9/18 was not signed by the client.</p> <p>No update: Review on 11/7/18 of the record for Client #3 revealed: -admitted 4/5/18 with a diagnosis of Opioid Use Disorder. -treatment plan dated 4/4/18 was not signed by the client. -from 8/7/18 through 11/7/18 the client tested positive for illicit substances in 8 out of 8 Urine Drug Screens (UDSs) -the treatment plan was not updated to address the client's continued drug use, type or frequency of use, or plans to address needed behavioral changes for recovery.</p> <p>Review on 11/7/18 of the record for Client #4 revealed: -admitted 4/18/18 with diagnoses of Opioid Use Disorder, severe; Asthma, and Acid Reflux. -treatment plan dated 4/17/18 was not signed by the client. -from 8/14/18 through 10/23/18 the client tested positive for illicit substances in 5 out of 10 UDSs -the treatment plan was not updated to address the client's continued drug use, type or frequency of use, or plans to address needed behavioral changes for recovery.</p> <p>Review on 11/7/18 and on 11/15/18 of the record for Client # 6 revealed:</p>	V 112		

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V 112	<p>Continued From page 6</p> <ul style="list-style-type: none"> -The client had been in long term care at the facility, first admitted on 12/19/07 with a diagnosis of Opioid Use Disorder. -The current treatment plan and her signature was dated 1/5/17. -There was no update documentation completed that reflected at least an annual update of the treatment plan. <p>Review on 11/6/18 of the record for Client #13 revealed:</p> <ul style="list-style-type: none"> -admitted on 6/2/17 with diagnoses of Opioid Dependence, Post-Traumatic Stress Disorder, Severe Depression and Anxiety Disorder. -Treatment plan was dated 6/26/17 with no annual update. <p>Interview with Client #13 on 11/6/18 revealed:</p> <ul style="list-style-type: none"> -The counselor she was assigned recently left the clinic. -She was waiting to be re-assigned to a counselor. -She was currently attending group 2 times each month. <p>Interview and observation with Counselor #1 on 11/7/18 revealed:</p> <ul style="list-style-type: none"> -Counselor #1 reviewed the process of completing the treatment plan from scheduling through completion. -Counselor #1 stated that he asked the clients to sign their plan on paper and then had that document scanned into the electronic record. -An electronic signature device was observed on the desk but the Counselor stated they didn't believe he had ever used the device for a client to sign the plan. 	V 112		

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V 112	Continued From page 7 Interview with the Program Director on 11/15/18 revealed: -the clinic had lost several staff in the previous 3 or 4 months which may have accounted for plans being unsigned or incomplete. The clinic had just hired one new counselor. -Counseling sessions were currently being met with groups. This deficiency is cross referenced into 10A 27G .3601 Scope (V233) for a Type A1 rule violation and must be corrected within 23 days.	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; (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	V 113		

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V 113	<p>Continued From page 8</p> <p>and telephone number of the client's preferred physician;</p> <p>(6) a signed statement from the client or legally responsible person granting permission to seek emergency care from a hospital or physician;</p> <p>(7) documentation of services provided;</p> <p>(8) documentation of progress toward outcomes;</p> <p>(9) if applicable:</p> <p>(A) documentation of physical disorders diagnosis according to International Classification of Diseases (ICD-9-CM);</p> <p>(B) medication orders;</p> <p>(C) orders and copies of lab tests; and</p> <p>(D) documentation of medication and administration errors and adverse drug reactions.</p> <p>(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.</p> <p>This Rule is not met as evidenced by: Based on record review and interview the facility failed to obtain a signed statement from the client or legally responsible person granting permission to seek emergency care from a hospital or physician for 5 of 13 sampled clients (Clients #1, #2 #3, #4 and #5). The findings are:</p> <p>Review on 11/6/18 of the record for Client #1 revealed: -admission date of 11/29/17 with a diagnosis of Opioid Use Disorder. -permission to seek emergency care form was blank</p>	V 113		

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V 113	<p>Continued From page 9</p> <p>Review on 11/6/18 of the record for Client #2 revealed: -admitted 1/11/12 with diagnoses of Opioid Use Disorder, Obesity, Gastro-Esophageal Reflux Disease, Fibromyalgia, and Chronic Pain. -permission to seek emergency care form was blank.</p> <p>Review on 11/7/18 of the record for Client #3 revealed: -admitted 4/5/18 with a diagnosis of Opioid Use Disorder. -permission to seek emergency care form was blank.</p> <p>Review on 11/7/18 of the record for Client #4 revealed: -admitted 4/18/18 with diagnoses of Opioid Use Disorder, severe; Asthma, and Acid Reflux. -permission to seek emergency care form was blank.</p> <p>Review on 11/7/18 and on 11/15/18 of the record for Client #5 revealed: -admitted on 10/6/18 with a diagnosis of Opioid Use Disorder. -permission to seek emergency care form was unsigned by the client.</p> <p>Interview with Counselor #2 on 11/7/18 revealed that the permission to seek emergency treatment was addressed in the client's intake or annual update information. This information should be completed at those times. He revealed his process was to have releases scanned into the</p>	V 113		

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V 113	Continued From page 10 electronic record. He could not say why the permission for his client (Client #5) was not in the record. Interview with Counselor #1 on 11/15/18 revealed she had recently become responsible for the care of her caseload. Emergency care releases were done as a part of the intake process. These would have been the responsibility of prior staff who were no longer with the facility.	V 113		
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	V 118		

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V 118	<p>Continued From page 11</p> <p>drug.</p> <p>(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.</p> <p>This Rule is not met as evidenced by: Based on interview, and record review the facility failed to ensure prescription drugs were administered upon the written order of the physician for 7 of 13 sampled clients (#1, #3, #4, #8, #9, #10 and #13). The findings are:</p> <p>Finding #1: Review on 11/6/18 of the record for Client #1 revealed: -admission date of 11/29/17 with a diagnosis of Opioid Use Disorder. -physician order effective date of 7/15/18, increase from 120 mg to 125 mg due to COWS (Client Opiate Withdrawal Scale) of 15 and symptoms of withdrawal. -verbal order taken by the registered nurse on 7/14/18, no physician signature. -physician order effective date of 8/21/18, increase from 125 mg to 130 mg secondary to COWS of 15 and complaints of withdrawals. -verbal order taken by the registered nurse on 8/21/18, no physician signature.</p> <p>Review on 11/7/18 of the record for Client #3 revealed: -Client #3 was admitted 4/5/18 with a diagnosis of Opioid Use Disorder. -physician order effective date of 7/30/18,</p>	V 118		

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V 118	<p>Continued From page 12</p> <p>increase from 110 mg to 120 mg due to COWS of 12.</p> <p>-the same verbal order was taken by the registered nurse on 7/30/18, 7/31/18 and 8/2/18, each with no physician signature.</p> <p>-physician order effective date of 10/1/18, reduce to 100 mg due to on-going positive Urine Drug Screens</p> <p>-verbal order taken by the registered nurse on 10/1/18, no physician signature.</p> <p>Review on 11/7/18 of the record for Client #4 revealed:</p> <p>-Client #4 was admitted 4/18/18 with diagnoses of Opioid Use Disorder, severe; Asthma; and Acid Reflux.</p> <p>-physician order effective date of 10/15/18, decrease to 90 mg due to positive Urine Drug Screens (UDS).</p> <p>-verbal order taken by the registered nurse on 10/15/18, no physician signature.</p> <p>Rview on 11/7/18 of the record for Client #8 revealed:</p> <p>-Client #8 was admitted on 1/30/18 with a diagnosis of Severe Opioid Use Disorder.</p> <p>-Verbal order taken by the nurse to increase Methadone from 95 mg to 100mg on 5/2/18 with no physician signature.</p> <p>Review on 11/7/18 of the record for Client #10 revealed:</p> <p>-Client #10 was admitted on 5/30/17 and readmitted on 12/17/17 with a diagnosis of Severe Opioid Dependence.</p> <p>-Verbal order taken by the nurse for Methadone 50mg with no physician signature.</p>	V 118		

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V 118	<p>Continued From page 13</p> <p>Review on 11/6/18 of the record for Client #13 revealed: -Client #13 was admitted on 6/2/17 with diagnosis of Opioid Dependence, Post-Traumatic Stress Disorder, Severe Depression and Anxiety Disorder. -Verbal order taken by the nurse to increase Methadone to 115mg on 8/20/18 and 120mg on 8/28/18 with no physician signature.</p> <p>Interview with Counselor #1 on 11/7/18 revealed: -he reviewed the process of reviewing UDS from random scheduling through follow-up with the physician for positive screens. -he was notified electronically about each positive UDS and that nurses in the facility also kept him abreast of UDS results for his clients. -he had addressed positive drug screens in counseling with his clients several times. He also advised the previous medical Director of the issues and the client's doses were reduced in October. -physician availability had become a concern as the former medical director was only available a couple of times in October. Another routine physician left in September.</p> <p>Interview on 11/6/18 with Registered Nurse #2 revealed: -The nurse could take a verbal order from the physician. -When the order was taken a verbal read back was completed with the physician. -No other follow up was done by the nurse after the verbal order was taken.</p>	V 118		

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V 118	<p>Continued From page 14</p> <p>Finding 2: Review on 11/6/18 and 11/7/18 of the record for Client #9 revealed: -Admission date of 5/4/17 with diagnoses of Opioid Dependence - Severe and Hypertension. -Physician order effective date of 7/2/18, order 80 mg, and verbal order taken by registered nurse on 7/2/18, no physician signature. -Physician order effective date of 7/12/18, order 90mg, and verbal order taken by the registered nurse on 7/11/18, no physician signature. -Physician order effective date of 7/14/18, order 90mg, and verbal order taken by the registered nurse on 7/14/18, no physician signature and order note "increase dose to 80mg methadone liquid from 70mg, client has COWS of 11 and complaints of withdrawal. Client has advanced to code 4 due to compliance with program protocols. Verbal order Dr. [named physician] read back and verified." Current order was 90mg with this duplicate order in the record with inaccurate information.</p> <p>Review on 7/15/18 of the personnel record for Former Registered Nurse #3 (FRN#3) revealed: -Date of hire 10/20/17 and termination 8/1/18. -Note in record indicated last day of work was 7/29/18. -Current nursing license.</p> <p>Review on 11/6/18 and 11/15/18 of the facility incident reports revealed: -Incident occurred on 7/15/18 at 8:30am which involved Client #9 who was administered a wrong dose. "Client presented to the window to receive dose. I [[FRN#3] was transferring liquid methadone. I inadvertently gave client the "prime</p>	V 118		

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V 118	<p>Continued From page 15</p> <p>from the transfer a total of 300mg instead of client dose of 90mg. When I realized what had happened, I asked the administrative assistant [name] to call client. While she was calling client, I called [named former medical director] and explained what had occurred. I reached ached out tp patient after several attempts of calling, client answered the phone and according to the physician ... [Client #9] was directed to proceed to nearest ER (emergency room), he confirmed being approx. a mile away"</p> <p>"... [FRN#3] called me [former medical director] at approximately 8:35am to tell me she had accidentally given ... [Client #9] too much Methadone. She guessed it was about 270mg which was three times his dose. She had given him Methadone from the primer. I [former medical director] immediately called ... [Client #9] and was able to get him on the second attempt. He was driving home by himself. I told him that ... [FRN#3] had given him more Methadone than he usually received and wanted him to go to the emergency room. He [Client #9] said he felt fine but willingly went. I [former medical director] called the ER (emergency room) physician and told him what had happened. He said he would give him charcoal to absorb the Methadone and a narcan drip if necessary. ... [Client #9] later called me said he hated the charcoal but was doing fine. He was only kept for the day but it is my understanding the physician felt he was safe to go home. The next day he came in saying he wanted to get his dose because he felt like he was withdrawing. I gave him 50mg approximately half his dose that day and then his full dose the next day which he managed without side effects.</p> <p>"Resolution or Action Taken" - Section completed by Program Director on "7/18/18 12:00AM - Patient was given charcoal and a narcan drip while at the hospital and held for observation,</p>	V 118		

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V 118	<p>Continued From page 16</p> <p>released later that evening. Reported to the clinic the following day, was not dosed per MD (former medical director) appeared in good spirits with appropriate affect and demeanor. Following day re-evaluated via nurse administered COWS and consult with MD (former medical director), returned to regular dose of 90mg. Calibrating and priming of the pump is now being done with a different color cup other than what is used for patient administration. Dispensing nurse was given formal disciplinary corrective measures. Blue dispensing cups were purchased for calibration purposes."</p> <p>Review on 11/6/18 and 11/7/18 of the hospital emergency room record for Client #9 revealed: -"Triage Time: 8:19 7/15/18, Chief Complaint: ACCIDENTIAL INGESTION ...Arrived by private vehicle. ...This occurred just prior to arrival. (Pt [patient] treatment physician called to ED (emergency department) and reported that the nurse provided pt with 270mg of Methadone instead of 90mg dose.)" -"08:39 7/15/2018 CHARCOAL ACTIVATED (activated Charcoal) PO 50gm given ..." -"08:55 7/15/18 Zofran (ondansetron HCL) IVP 4 mg given" -"13:38 ...The patient was discharged home and accompanied by companion. He left the Emergency Department ambulatory and via private vehicle."</p> <p>Review on 11/7/18 of the July through November 2018 MAR for Client #9 revealed: -Client #9 dose was changed from 80mg to 90mg of Methadone on 7/12/18. -Client #9 was dosed 90mg on 7/15/18 at 7:47am, error in dose was not documented on</p>	V 118		

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V 118	<p>Continued From page 17</p> <p>the MAR.</p> <ul style="list-style-type: none"> - No dose was received on 7/16/18 and 50mg was dosed on 7/17/18. - Client #9 returned to regular dose of 90mg on 7/18/18. <p>Interview on 11/9/18 with Client #9 revealed:</p> <ul style="list-style-type: none"> -On the morning of 7/15/18 he went to the window at the clinic to dose. -Client #9 showed his identification, verified his dose of 90mg. - About 20-30 minutes after he left the clinic driving home when he was contacted by the doctor who informed him to "pull over immediately because I got an overdose." -The doctor informed him to wait for the sheriff and ambulance to transport to the hospital. -Client #9 waited a couple of minutes then drove to the hospital because it "scared me." -When he arrived at the hospital the staff rushed him back because the physician from the clinic had contacted the emergency room physician to make them aware of the overdose. -The hospital gave him charcoal and an intravenous medication for nausea. -The emergency room monitored him for about 7 hours. -The clinic physician told Client #9 if he had gone home and went to sleep he could have died. -The clinic would not provide him with the specific dose he received on 7/15/18, he thought the dose was around 290mg of Methadone. -The clinic held his Methadone dose for about "4 days for fear of an overdose" after the incident on 7/15/18. -Client #9 thought the nurse who dosed him and the physician were fired a couple of days later. 	V 118		

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V 118	<p>Continued From page 18</p> <p>Unable to interview FRN#3 due to termination and no current phone number.</p> <p>Interview on 11/7/18 with Registered Nurse #1 (RN#1) revealed:</p> <ul style="list-style-type: none"> -Priming the pump was the exchange of the bottles of Methadone. -The computer system would prompt you through each stage of the process involved with the prime/exchange. -When you exchange the bottle the tube from the bottle goes into a cup, you then put the new bottle in and click open, the system will then say "do you wish to prime?" -The nurse will then click on yes and the system then tells you to put the liquid back in the bottle. -90 milligrams of Methadone would be visibly different than a 270 milligram dose. -A client standing at the window when the nurse was exchanging the bottles was the only way they could receive a prime dose. -The protocol was to close the window when doing a bottle exchange. -The clinic now used a different color of cup for the exchange of bottles. <p>Interview on 11/13/18 with the current Medical Director revealed:</p> <ul style="list-style-type: none"> -If a client was on 90mg and received 270mg of Methadone there was a potential for overdose. <p>Interview on 11/7/18 and 11/15/18 with the Program Director revealed:</p> <ul style="list-style-type: none"> -FRN#3 contacted him on 7/15/18 which was a Sunday and reported she had made a dosing error with Client #9. -The nurse realized a couple of minutes after 	V 118		

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V 118	<p>Continued From page 19</p> <p>Client #9 had left the clinic. -FRN#3 reported she accidentally administered the prime dose of methadone instead of Client #9's prescribed amount of Methadone. -The nurse also notified the physician and the sheriff department. -The physician got in contact with the client and coordinated care with the hospital. -Client #9 went to the emergency room and was monitored for the day. -Client #9 presented at the clinic the following day and was doing fine. -He spoke with FRN#3 about the incident and advised to not have clients at the window when they are exchanging the bottles. -The nurse realized it was a serious mistake and was very upset. -The nurse was no longer employed by the clinic. -The clinic had changed the cups that were used for prime of Methadone. -FRN#3 was formally written up but resigned prior to the review and part of her plan was going to be re-training.</p> <p>This deficiency is cross referenced into 10A 27G .3601 Scope (V233) for a Type A1 rule violation and must be corrected within 23 days.</p>	V 118		
V 233	<p>27G .3601 Outpt. Opioid Tx. - Scope</p> <p>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.</p>	V 233		

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V 233	<p>Continued From page 20</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>This Rule is not met as evidenced by: Based on interviews and record review the facility failed to provide medical and rehabilitation services designed to effect changes in the lives of 12 of 13 sampled clients (Clients #1, #2, #3 #4, #5, #6, #7, #8, #9, #10, #11 and #13). The findings are:</p> <p>Cross Reference: 10A NCAC 27G.0208(c)(1) Medication Requirements (V118). Based on interview, and record review the facility failed to ensure prescription drugs were administered upon the written order of the physician for 7 of 13 sampled clients (#1, #3, #4, #8, #9, #10 and #13).</p> <p>Cross Reference: 10A NCAC 27G.0205</p>	V 233		

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V 233	<p>Continued From page 21</p> <p>Assessment and Treatment/Habilitation or Service Plan(c) (d) (V112). Based on record review and interviews, the facility failed to develop and implement a treatment plan (Clients #11 and #10), failed to update and review a plan at least annually (Clients #3, #4, #6, and #13) and failed to obtain written consent or agreement from the client or responsible party to their treatment plans (Clients #1, #2, #5 and #7) affecting 10 of 13 sampled clients.</p> <p>Cross Reference 10A NCAC 27G .3604 (F) (V238) Based upon record reviews and interviews the facility failed to assure that during the first year of continuous treatment each client attended a minimum of two counseling sessions per month for 2 of 13 sampled clients (Clients #9, #10) and failed to assure that 2 of 13 sampled clients met the time in continuous treatment requirements for take home medication. (Client #8, #10).</p> <p>Findings #1:</p> <p>Review on 11/7/18 of the facility policy and procedure dated June 2013 titled "Urine Drug Screen Procedure" revealed: --" ...12. If the UDS [Urine Drug Screen] is positive, the counselor will discuss the reasons for the drug use, type of drug being used and amount and frequency of use with the patient. The counselor and the patient will update the treatment plan to reflect the behavioral changes needed to provide a negative UDS. The counselor will write a progress note to document the results of the UDS and the follow-up counseling session." -"13. The program physician will sign off on all positive UDSs and ensure the counselor</p>	V 233		

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V 233	<p>Continued From page 22</p> <p>completes a clinical interview with the patient within ten (10) days of a positive drug screen."</p> <p>Review on 11/7/18 of Client #3's record revealed: -admission date of 4/5/18 with a diagnosis of Opioid Use Disorder. -there was no approved prescription for amphetamines, benzodiazepines or methamphetamines. -treatment plan dated 4/4/18 indicated a goal of getting off all street drugs and presenting with negative UDS.</p> <p>Review on 11/7/18 of Client 3's UDS from 8/7/18 - 11/7/18 revealed: -8/7/18 positive for amphetamine, benzodiazepine and fentanyl -8/16/18 positive for amphetamine and fentanyl -8/21/18 positive for amphetamine and fentanyl -8/28/18 positive for benzodiazepine -9/6/18 positive for amphetamine, benzodiazepine, cocaine, and fentanyl -9/11/18 positive for amphetamine and benzodiazepine -9/19/18 positive for alcohol -9/24/18 positive for amphetamine, benzodiazepine and alcohol -there was no physician signature or note to indicate the physician was aware of the above UDSs</p> <p>Review on 11/7/18 of Client #3's Medication Administration Records (MARs) dated August 2018 - September 2018 revealed: -8/1/18 - 9/30/18 daily dose of methadone 120 mg</p>	V 233		

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V 233	<p>Continued From page 23</p> <p>Review on 11/7/18 of "General Notes" written by Counselor #1 revealed: -8/17/18 - admitted to relapse - next UDS should be clean - goals discussed -8/31/18 - admitted to Adderall and Xanax use - goals discussed -9/11/18 - admitted to Adderall and Xanax use - goals discussed -9/28/18 - admitted to relapse - next UDS should be clean - goals discussed</p> <p>Attempted interview on 11/7/18 with Client #3 - he refused.</p> <p>Review on 11/7/18 of Client #4's record revealed: -admission date of 4/18/18 with diagnoses of Opioid Use Disorder, severe; Asthma, and Acid Reflux. -there was no approved prescription for amphetamines, benzodiazepines or methamphetamines. -treatment plan dated 4/17/18 indicated a goal of earning level II privileges and presenting with negative UDS.</p> <p>Review on 11/7/18 of Client 4's UDS from 8/14/18 - 10/23/18 revealed: -8/14/18 positive for amphetamine and fentanyl -9/5/18 positive for amphetamine, benzodiazepine, and cocaine -9/11/18 positive for amphetamine -10/15/18 positive for benzodiazepine -10/23/18 positive for benzodiazepine (level was down) -there was no physician signature or note to indicate the physician was aware of the above</p>	V 233		

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V 233	<p>Continued From page 24</p> <p>UDSs</p> <p>Review on 11/7/18 of Client #4's MARs dated August 2018 - October 2018 revealed: -8/1/18 - 10/13/18 daily dose of methadone 100 mg -10/14/18 - missed dosage -10/15/18 - dosed methadone 90 mg</p> <p>Review on 11/7/18 of Client #4's physician order revealed: -physician order effective date of 10/15/18, decrease to 90 mg due to positive Urine Drug Screens. -verbal order taken by the registered nurse on 10/15/18, no physician signature.</p> <p>Review on 11/7/18 of "General Notes" written by Counselor #2 revealed: -8/13/18 - positive UDS - disclosed Adderall and Ativan - goals discussed -8/23/18 - positive UDS - disclosed Adderall - goals discussed -8/31/18 - positive UDS - discussed dangers - goals discussed -9/7/18 - positive UDS - acknowledged use with brother - see per week counselor/group -9/13/18 - psychoeducational - goals discussed -10/8/18 - close friend died of overdose -10/9/18 - positive UDS - recommended behavioral health</p> <p>Attempted interview on 11/7/18 with Client #4 - he refused.</p> <p>Interview with Counselor #1 on 11/7/18 revealed:</p>	V 233		

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V 233	<p>Continued From page 25</p> <p>-he reviewed the process of reviewing UDS from random scheduling through follow-up with the physician for positive screens. -he was notified electronically about each positive UDS and that nurses in the facility also kept him abreast of UDS results for his clients. -he had addressed positive drug screens in counseling with his clients several times. He also advised the previous medical Director of the issues and the client's doses were reduced in October. -physician availability had become a concern as the former medical director was only available a couple of times in October. Another routine physician left in September.</p> <p>Interview on 11/6/18 with Registered Nurse #2 revealed: -she was responsible to review the UDSs once the results were received -she would identify the positive results and have the doctor sign off on all positives -if the UDS was positive specifically for benzodiazepine she would call the doctor -today was the first day for their new doctor -their previous doctor was at the clinic 2 times in October.</p> <p>Findings #2:</p> <p>Review on 11/7/18 of the facility policy and procedure dated December 2012 titled "Substance Intoxication/Impaired Patient Policy" revealed: -"Procedure: 1. Team member observes a patient who appears to be impaired ..." -" ...4. The patient meets with a nurse or nurse</p>	V 233		

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V 233	<p>Continued From page 26</p> <p>supervisor for physical assessment of signs of impairment, including assessment of patient's pupils, temperature, pulse, respirations, and blood pressure." -"5. The patient submits to the collection of an observed urine sample for a rapid Urine Drug Screen (UDS)" -" ...9. When the rapid UDS result is known and the nurse supervisor, counselor, and program director agree that the patient seems to be impaired: a. The nurse supervisor relates the information to the medical director ..."</p> <p>Review on 11/6/18 of the record for Client #2 revealed: -admitted 1/11/12 with diagnoses of Opioid Use Disorder, Obesity, Gastro-Esophageal Reflux Disease, Fibromyalgia, and Chronic Pain. -there was no approved prescription for amphetamines, benzodiazepines or methamphetamines. -treatment plan dated 3/5/18 indicated a goal of finding a stable methadone dose, finding a mental health counselor, overdose prevention education and meet criteria to earn level II privileges.</p> <p>Review on 11/7/18 of "General Notes" written by Counselor #2 dated 9/11/18 revealed: -observed Client #2 falling over, slurred speech, difficulty communicating and falling asleep during session. -alerted nursing staff</p> <p>Review on 11/7/18 of Client #2's MAR dated 9/11/18 revealed: -dosed methadone 100 mg</p>	V 233		

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V 233	<p>Continued From page 27</p> <p>Review on 11/7/18 of a medical note signed by the physician and dated 9/19/18 revealed: -positive UDS, continue to taper 10 mg decrease every 2 weeks -encouraged in-patient, does not want to leave her kids. -there were no medical notes to indicate the doctor was notified of suspected impairment on 9/11/18</p> <p>Review on 11/7/18 of nurse's notes for Client #2 on 9/11/18 revealed: -there was no nursing documentation of notification of suspicion Client #2 was impaired, no assessment, and no notification to the doctor.</p> <p>Attempted interview on 11/7/18 with Client #2 - she refused.</p> <p>Interview on 11/7/18 with Counselor #2 revealed: -she was alerted by RN #1 that Client #2 appeared intoxicated on 9/11/18 -she asked the client to come to her office and agreed she appeared to be "high" -she had slurred speech, she kept nodding off, and could barely sign her name -the client was open about her illicit methamphetamine use -she did not think the client was dosed on 9/11/18 and that RN #1 called the doctor -she reviewed Client #2's record and stated she could not find a nurse or medical note regarding this.</p> <p>Interview on 11/7/18 with RN #1 revealed:</p>	V 233		

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V 233	<p>Continued From page 28</p> <ul style="list-style-type: none"> -signs of a client being impaired included grogginess, and/or slurred speech -she would do a "Reditest" in order to get results immediately -if the Reditest was positive she would inquire with the client about what they took and notify the doctor -she would hold dosing until further instruction from the doctor -Client #2 came in "a lot like that"; she laid her head on the dosing window, gave poor eye contact - this was her normal -She was not aware of Client #2 being suspected of impairment on 9/11/18 - "at all." <p>Review on 11/7/18 of Client 2's UDS from 9/12/18 through 11/7/18 revealed: -9/12/18 positive for amphetamine and fentanyl</p> <p>Interview on 11/13/18 with the new facility physician revealed: -if a client was thought to be impaired he would expect staff to notify him immediately -he would not want the client to be dosed until they were seen by a physician</p> <p>Review on 11/15/18 of a Plan of Protection provided by the Program Director and licensee Corporate Compliance Officer dated 11/15/18 revealed:</p> <p>"PLAN OF PROTECTION BHG Clyde Treatment Center November 15, 2018 Please find following the Plan of Protection for the identified deficiencies during the State visit to the</p>	V 233		

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V 233	<p>Continued From page 29</p> <p>clinic on November 6, 7, and 15, 2018.</p> <p>1. Acknowledging and addressing nontherapeutic urine drug screens (UDS): It is recognized that previously-implemented procedures for addressing nontherapeutic UDS have not been consistently maintained as they relate to treatment planning and recommended clinical interventions. It should be pointed out, however, that this deficiency has not created a patient-safety issue. Specifically, nontherapeutic UDS results have been consistently reviewed by the clinical team at the weekly treatment-team meetings, with patients referred to see the medical director or program physician when necessary. It is the goal of BHG to provide safe patient care and to follow all appropriate state regulations in the delivery of such care. The procedure for addressing nontherapeutic drugs screens involves the results being reported by the receiving medical team member to the nurse on duty, the patient's counselor, and the medical director. This may consist of face-to-face communication, email, or a telephone call. The counselor is to then place a hold in the electronic medical record so that the patient is directed to their counselor on the next present day to the clinic. The visit details are to be documented in a specific Positive UDS and Follow-Up service note in the patient record. As previously stated, all nontherapeutic urine drug screens are to be reviewed at the weekly treatment team meeting, where the medical director will make any required decisions about dosing, level status, or any other treatment-related topics. At this time, the following tasks have been undertaken to ensure all processes are being completed correctly and appropriately:</p> <p>A. A review of all nontherapeutic urine drug screens from September 1, 2018, through November 7, 2018 has been completed. The</p>	V 233		
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V 233	<p>Continued From page 30</p> <p>review consisted of determining if an appropriate counseling visit occurred to address the nontherapeutic urine drug screen and if a proper service note detailing the visit is in place in the patient record. The program director held a meeting with the counseling staff on November 9, 2018, to review the deficiencies and to reinforce the need to visit with each of the indicated patients as soon as possible.</p> <p>B. A review of patients with nontherapeutic urine drug screens from September 1, 2018, through November 7, 2018, also consisted of ensuring that patients with nontherapeutic urine drug screens were participating in weekly urine drug screens until there are two therapeutic results.</p> <p>This information will be tracked by the medical team and counseling staff.</p> <p>C. Beginning 11-15-18, the program director will oversee an audit of 100% of the charts of patients being who have nontherapeutic UDS for the next three months, done on a weekly basis, to ensure the processes are followed. After the three-month period, if it is determined the processes are being followed properly, the program director will be responsible for doing random checks of charts on a monthly basis, as well as ensuring peer chart audits are done per policy.</p> <p>D. A staff meeting was held on Friday, November 9, 2018, to review the proper processes and procedures for addressing nontherapeutic urine drug screens. The training material consisted of the previous plans of correction and protection related to site visits in early 2018. The documentation of training is housed in the local treatment center.</p>	V 233		

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V 233	<p>Continued From page 31</p> <p>2. Safe administration of medication: One of the most important obligations we have to our patients is to ensure the provision of safe and appropriate care. All BHG team members are provided education about medication-assisted treatment at the time of hire and on an annual basis. All nurses are provided education related to medication-room-specific topics, based on BHG policy. Regarding the July 15th medication error, the nurse who made the medication error is no longer with the company, but it should be noted that she was provided one-on-one training at the time of hire by (name), Compliance Specialist. We recognize that human error is always a factor in any healthcare setting, but we strive to keep our error rates low and to provide proper re-education and examination of medication-room processes when errors occur. With regard to the medication error that occurred on July 15, 2018, it should be noted that immediate action was taken in the form of notifying the medical director, a phone call between the nurse and a compliance specialist, discussions between the program director and nurse regarding safe medication administration and BHG medication-room policies, submission of an internal incident report with subsequent requests for corrections, directives to the program director to complete a root cause analysis, and creation of a disciplinary action plan prior to the nurse terminating. Regarding the September 11th incident where there is confusion regarding a possibly-impaired patient being dosed, an investigation of this incident is currently underway but will be addressed specifically below. Based on recent medication errors that have occurred at the treatment center, the following has occurred: A. A specific medication-room training was completed on November 9, 2018, with the</p>	V 233		
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V 233	<p>Continued From page 32</p> <p>program director and nurses in attendance. The training was conducted by (name of licensee authorized trainer). The documentation of training is housed in the local treatment center.</p> <p>B. The program director and nursing staff have reviewed BHG policies related to medication safety, security, and administration. These policies have been signed and dated and are housed at the local treatment center.</p> <p>C. The program director has been re-educated on proper disciplinary action and training topics related to medication errors. The disciplinary action form created for the nurse making the July 15 medication error is available for review at the treatment center. It is recognized that (compliance staff name) had a phone conversation with the nurse on the day of the incident, and this information is reflected in the incident report, also available for review at the treatment center. In addition, the program director had several conversations with the nurse about the need for process changes and individual accountability. The processes changed immediately after the event included bottles would not be changed out with patients at the window, and new priming cups of a different color than the dispensing cups would be used, both in attempts to reduce the likelihood of a future similar occurrence.</p> <p>D. A root cause analysis for the July 2018 medication error has been completed and is available for review at the treatment center.</p> <p>E. The program director will conduct a training</p>	V 233		

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V 233	<p>Continued From page 33</p> <p>regarding proper processes to undertake when there is any suspicion of impairment. This training will include a review of appropriate team communication, patient assessment when impairment is suspected or evident, and provider notification when a patient is found to be impaired. This training will take place on or before November 19, 2018. A rough draft of that SOP is included.</p> <p>3. Advances in treatment phases: BHG utilizes level justification forms and appropriate state regulations in determining when a patient may advance in phase of treatment. It is recognized that these processes were not followed properly, and the following plan has been established to address this:</p> <p>A. The program director will conduct a training regarding time in treatment and phase increase policy and procedures. This training will take place on or before November 21st, 2018.</p> <p>B. The program director will review with the new medical director and all other providers the requirement to sign all orders within the 72-hour time requirement. This review will occur by Wednesday, November 14, 2018.</p> <p>C. For the existing unsigned orders entered by Dr. (named physician), who is no longer employed by BHG, the program director will work with the new medical director to review these orders to ensure they were safe and do not present any danger to patients. The program director will enter a service note for each reviewed order to reflect what occurred and that the order is deemed safe and appropriate for the individual patient. This project will be completed by November 30, 2018, due to the medical director only being at the treatment center two days per week.</p> <p>D. Beginning 11-15-18, the program director will</p>	V 233		

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V 233	<p>Continued From page 34</p> <p>take control of monitoring the unsigned orders on a weekly basis, or he will delegate this task to another qualified team member.</p> <p>4. Completion of all required documentation: As previously stated, BHG utilizes an electronic health record. All patient-related information is housed electronically in the SAMMS software system. The BHG Clyde Treatment Center does also have paper charts from prior to the conversion to SAMMS software system. The expectation is that 100% of patient charts comply and contain all required documentation as per state and federal regulations and BHG policy.</p> <p>A. The program director conducted a staff training on November 9, 2018, about chart audits, using BHG policy and the BHG chart audit form as training materials. The documentation of training is housed at the treatment center.</p> <p>B. The program director will take control of monitoring chart audits and ensuring resolution of all deficiencies within the prescribed timeline, or he will delegate this task to another qualified team member.</p> <p>The Program Director will compile appropriate related documentation of any and all reviews and monitoring to have available upon demand.</p> <p>Established facility protocol was to have the physician sign off within 10 days of a positive UDS, and to have the counselor discuss reasons for the drug use, update the treatment plan and write progress notes addressing the counseling sessions and follow-up. Client #3 tested positive for illicit drugs in 8 out of 8 drug screens, from August through September, 2018. Client #3's dose of methadone remained the same while testing positive for illicit substances continued.</p>	V 233		

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V 233	<p>Continued From page 35</p> <p>Client #4 tested positive for illicit drugs in 5 out of 10 drug screens from July through September, 2018. The methadone dose for Client #4 remained the same until the October 15, 2018, the third month testing positive for illicit substances. The counselors and nurses did not address the continual positive UDSs, did not consult with the physician after continuous illicit use, and did not update the treatment plan to address actions the client was willing to take to ensure a safe recovery. No changes were made to address the clients' risk of using illicit drugs while in active treatment.</p> <p>Established facility protocol was to physically assess a client when they were suspected of impairment, do an immediate drug test, and notify the physician. On 9/11/18, Client #2 was suspected of impairment, the nurse was not notified and did not conduct an assessment. The doctor was not notified. The client was given her daily dose of methadone. The following day a UDS result tested positive for amphetamines and fentanyl.</p> <p>Established facility protocol was to dose clients according to physician's orders. FRN#3 provided Client #9 with a potentially life threatening overdose on 7/15/18 that required the client to seek and receive treatment at a local emergency room. In addition, staff failed to administer medication based upon signed, written orders.</p> <p>This deficiency constitutes a Type A1 rule violation for serious neglect and must be corrected within 23 days. An administrative penalty of \$6,000.00 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</p>	V 233		

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V 233	Continued From page 36 compliance beyond the 23rd day.	V 233		
V 235	<p>27G .3603 (A-C) Outpt. Opiod Tx. - Staff</p> <p>10A NCAC 27G .3603 STAFF</p> <p>(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.</p> <p>(b) Each facility shall have at least one staff member on duty trained in the following areas:</p> <p>(1) drug abuse withdrawal symptoms; and</p> <p>(2) symptoms of secondary complications to drug addiction.</p> <p>(c) Each direct care staff member shall receive continuing education to include understanding of the following:</p> <p>(1) nature of addiction;</p> <p>(2) the withdrawal syndrome;</p> <p>(3) group and family therapy; and</p> <p>(4) infectious diseases including HIV, sexually transmitted diseases and TB.</p> <p>This Rule is not met as evidenced by: Based upon record review and interview the facility failed to assure that the prescribed ratio of a minimum of one certified staff to each 50 clients was maintained for 1 of 3 counselor caseloads (Counselors #2): The findings are:</p>	V 235		

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V 235	<p>Continued From page 37</p> <p>Review on 11/6/18 of the Active Client Report provided by the Program Director containing the names of Counselors and their caseloads revealed:</p> <ul style="list-style-type: none"> -Counselor #1 had a caseload of 45 clients. -Counselor #2 had a caseload of 58 clients. -Former Counselor #1 had been assigned 60 clients prior to her leaving employment. A caseload for Former Counselor #1 of 60 clients was listed in Active Client Report provided. <p>Interview on 11/15/18 with Counselor #2 revealed she had a caseload of 58 clients.</p> <p>Interview on 11/6/18 and 11/15/18 with the Program Director revealed:</p> <ul style="list-style-type: none"> -Former Counselor #1 had left the facility approximately the week before the start of the survey. Her position was posted for applicants but she had not been replaced. - In the interim clients had not been specifically assigned a counselor and were being covered by the remaining 2 counselors in group counseling. -A third new counselor had started on 11/6/18 but was not assigned a caseload at the time of survey. 	V 235		
V 238	<p>27G .3604 (E-K) Outpt. Opioid - Operations</p> <p>10A NCAC 27G .3604 OUTPATIENT OPIOD TREATMENT. OPERATIONS.</p> <p>(e) The State Authority shall base program approval on the following criteria:</p> <p>(1) compliance with all state and federal law and regulations;</p>	V 238		

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V 238	<p>Continued From page 38</p> <p>(2) compliance with all applicable standards of practice;</p> <p>(3) program structure for successful service delivery; and</p> <p>(4) impact on the delivery of opioid treatment services in the applicable population.</p> <p>(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.</p> <p>(1) Levels of Eligibility are subject to the following conditions:</p> <p>(A) Level 1. During the first 90 days of continuous treatment, the take-home supply is limited to a single dose each week and the client shall ingest all other doses under supervision at the clinic;</p> <p>(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;</p> <p>(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</p>	V 238		

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V 238	<p>Continued From page 39</p> <p>take-home doses and shall ingest all other doses under supervision at the clinic each week;</p> <p>(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;</p> <p>(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;</p> <p>(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</p> <p>(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.</p> <p>(2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility:</p> <p>(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;</p> <p>(B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and</p> <p>(C) The reinstatement of take-home eligibility shall be determined by each Outpatient</p>	V 238		

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V 238	<p>Continued From page 40</p> <p>Opioid Treatment Program.</p> <p>(3) Exceptions to Take-Home Eligibility:</p> <p>(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.</p> <p>(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.</p> <p>(4) Take-Home Dosages For Holidays:</p> <p>Take-home dosages of methadone or other medications approved for the treatment of opioid addiction shall be authorized by the facility physician on an individual client basis according to the following:</p> <p>(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.</p> <p>(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</p>	V 238		

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V 238	<p>Continued From page 41</p> <p>restriction shall not apply to clients who are receiving take-home medications at Level 4 or above.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(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</p>	V 238		

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V 238	<p>Continued From page 42</p> <p>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.</p> <p>(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:</p> <ul style="list-style-type: none"> (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. <p>This Rule is not met as evidenced by: Based upon record reviews and interviews the facility failed to assure that during the first year of continuous treatment each client attended a minimum of two counseling sessions per month for 2 of 13 sampled clients (Clients #9, #10) and failed to assure that 2 of 13 sampled clients met</p>	V 238		

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V 238	<p>Continued From page 43</p> <p>the time in continuous treatment requirements for take home medication. (Client #8, #10) The findings are:</p> <p>Review on 11/6/18 and 11/7/18 of the record for Client #9 revealed: -Client #9 was admitted on 5/4/17 with diagnoses of Severe Opioid Dependence and Hypertension. -No documentation of counseling sessions in September and October 2018.</p> <p>Review on 11/6/18 and 11/7/18 of the record for Client #10 revealed: -Admission date of 12/27/18 and re-admitted to the clinic on 12/27/18. -Counseling sessions were conducted 1 time each month.</p> <p>Interview on 11/13/18 with Client #9 revealed: -He was assigned a new counselor and had not met with her yet.</p> <p>Client #10 refused the interview on 11/7/18.</p> <p>Interview on 11/15/18 with Counselor #2 revealed: -Client #9 was recently transferred to her caseload. -She could not locate any documentation for the September session with the previous counselor. -Client #9 canceled the October session with her. -Based on review of the record for Client #10 she should have been receiving 2 counseling sessions each month.</p>	V 238		

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V 238	<p>Continued From page 44</p> <p>This deficiency constitutes a re-cited deficiency and must be corrected within 30 days.</p> <p>Part 2</p> <p>Review on 11/7/18 of the record for Client #8 revealed: -Admission date of 1/30/18 with a diagnosis of Opioid Use Disorder. -Facility "Level Justification and 90 day Review" dated 9/26/18 proposed Code 4 with 5 take homes. Time in treatment checked as 6-9 months. -September 2018 MAR indicated level change took place on 9/30/18 with only 8 months in treatment.</p> <p>Review on 11/6/18 and 11/7/18 of the record for Client #10 revealed: -Admission date of 12/27/17 and re-admitted to the clinic on 12/27/18. -She was incarcerated from 9/30/17 until 12/25/17. -Physician re-admitted on 12/27/17. -Client #10 was currently being given Take Homes at Level 4- with 5 doses at home per week. -Based on the re-admission to the facility client was not eligible due to only receiving one counseling session per month.</p> <p>Interview on 11/6/18 with Client #8 revealed: -He dosed 2 days a week in the clinic. -He received 5 take homes each week.</p> <p>Client #10 refused the interview on 11/7/18.</p>	V 238		

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V 238	<p>Continued From page 45</p> <p>Interview on 11/15/18 with Counselor #2 revealed: -Take homes were approved after the first 90 days in treatment. -Approval of take homes was based on program compliance. -Take homes were initiated by the counselor and staffed with the team for approval. -After reviewing the increase in levels for Client #8 she acknowledged the increase should have occurred in October. -The increase in level for Client #8 was an error on her part. -Client #10's counselor recently left the clinic and she was not familiar with the status of takes homes for this client.</p> <p>Interview with the Program Director on 11/15/18 revealed he was aware of the prescribed levels of take homes that could be earned based upon time in treatment. He was not aware that Client #10 had take-home doses based upon inaccurate time in continuous treatment.</p> <p>This deficiency is cross referenced into 10A 27G .3601 Scope (V233) for a Type A1 rule violation and must be corrected within 23 days</p>	V 238		
V 536	<p>27E .0107 Client Rights - Training on Alt to Rest. Int.</p> <p>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</p>	V 536		

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V 536	<p>Continued From page 46</p> <p>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 or injury to a person with disabilities or others or property damage is prevented.</p> <p>(c) Provider agencies shall establish training based on state competencies, monitor for internal compliance and demonstrate they acted on data gathered.</p> <p>(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.</p> <p>(e) Formal refresher training must be completed by each service provider periodically (minimum annually).</p> <p>(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.</p> <p>(g) Staff shall demonstrate competence in the following core areas:</p> <ol style="list-style-type: none"> (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; 	V 536		

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V 536	<p>Continued From page 47</p> <p>(6) recognizing the importance of and assisting in the person's involvement in making decisions about their life;</p> <p>(7) skills in assessing individual risk for escalating behavior;</p> <p>(8) communication strategies for defusing and de-escalating potentially dangerous behavior; and</p> <p>(9) positive behavioral supports (providing means for people with disabilities to choose activities which directly oppose or replace behaviors which are unsafe).</p> <p>(h) Service providers shall maintain documentation of initial and refresher training for at least three years.</p> <p>(1) Documentation shall include:</p> <p>(A) who participated in the training and the outcomes (pass/fail);</p> <p>(B) when and where they attended; and</p> <p>(C) instructor's name;</p> <p>(2) The Division of MH/DD/SAS may review/request this documentation at any time.</p> <p>(i) Instructor Qualifications and Training Requirements:</p> <p>(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.</p> <p>(2) Trainers shall demonstrate competence by scoring a passing grade on testing in an instructor training program.</p> <p>(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.</p> <p>(4) The content of the instructor training the service provider plans to employ shall be</p>	V 536		

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V 536	<p>Continued From page 48</p> <p>approved by the Division of MH/DD/SAS pursuant to Subparagraph (i)(5) of this Rule.</p> <p>(5) Acceptable instructor training programs shall include but are not limited to presentation of:</p> <p>(A) understanding the adult learner;</p> <p>(B) methods for teaching content of the course;</p> <p>(C) methods for evaluating trainee performance; and</p> <p>(D) documentation procedures.</p> <p>(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.</p> <p>(7) Trainers shall teach a training program aimed at preventing, reducing and eliminating the need for restrictive interventions at least once annually.</p> <p>(8) Trainers shall complete a refresher instructor training at least every two years.</p> <p>(j) Service providers shall maintain documentation of initial and refresher instructor training for at least three years.</p> <p>(1) Documentation shall include:</p> <p>(A) who participated in the training and the outcomes (pass/fail);</p> <p>(B) when and where attended; and</p> <p>(C) instructor's name.</p> <p>(2) The Division of MH/DD/SAS may request and review this documentation any time.</p> <p>(k) Qualifications of Coaches:</p> <p>(1) Coaches shall meet all preparation requirements as a trainer.</p> <p>(2) Coaches shall teach at least three times the course which is being coached.</p> <p>(3) Coaches shall demonstrate competence by completion of coaching or train-the-trainer instruction.</p>	V 536		

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V 536	<p>Continued From page 49</p> <p>(I) Documentation shall be the same preparation as for trainers.</p> <p>This Rule is not met as evidenced by: Based on record review and staff interview, the facility failed to ensure all staff completed training in alternatives to restrictive intervention training from an approved curriculum annually for 3 of 4 sampled staff (Counselor # 2, The Program Director and Registered Nurse #1). The findings are:</p> <p>Review of the Personnel Records for the Program Director, Counselor #2 and Registered Nurse #1 on 11/7/18 revealed that none of the files for these three staff contained documentation of training in alternatives to restrictive interventions.</p> <p>Review on 11/15/18 of a Training Attendance Roster provided by the Program Director for the last training done in the area of alternatives to restrictive interventions revealed that 1/31/17 was the last date of training.</p> <p>Interview with the Program Director 11/15/18 revealed that when asked to provide documentation on training in alternatives to restrictive interventions he confirmed the staff training had not been renewed since the 1/31/17 training.</p>	V 536		

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