

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL032-412	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED R 06/14/2021
NAME OF PROVIDER OR SUPPLIER BAART COMMUNITY HEALTHCARE		STREET ADDRESS, CITY, STATE, ZIP CODE 800 NORTH MANGUM STREET, SUITE 300 & 400 DURHAM, NC 27701		
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V 000	<p>INITIAL COMMENTS</p> <p>An annual, follow-up and complaint survey was completed on June 14, 2021. One complaint was unsubstantiated (Intake #NC00172047). Two complaints were substantiated (Intake #NC00177554 & #NC00177316). Deficiencies were cited.</p> <p>This facility is licensed for the following service categories: 10A NCAC 27G .3600 Outpatient Opioid Treatment 10A NCAC 27G. 4400 Substance Abuse Intensive Outpatient Program 10A NCAC 27G. 4500 Substance Abuse Comprehensive Outpatient Treatment Program</p> <p>The client census was 476 at the time of this survey.</p>	V 000		
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. (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</p>	V 233		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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V 233	<p>Continued From page 1</p> <p>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 management 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, and failed to provide coordination of care with medical providers affecting 10 of 22 current audited clients (#2 #3 #4 #5 #6 #7 #9 #13 #18 #22) and 1 of 1 deceased client (DC #1). The findings are:</p> <p>Cross Reference: Tag V-235, 10A NCAC 27G .3603, STAFF. Based on interview and record review, the facility failed to have a minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients.</p> <p>Cross Reference: Tag V-237, 10A NCAC 27G .3604, OUTPATIENT OPIOID TREATMENT - OPERATIONS. Based on interview and record review, the facility management failed to ensure program compliance in the areas of Individual Counseling, Urine Drug Screen (UDS) frequency and dual enrollment requirements affecting 10 of 22 current audited clients (#2 #3 #4 #5 #6 #7 #9 #13</p>	V 233		

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V 233	Continued From page 2 #18 #22) and 1 of 1 deceased client (DC #1). 1. Review on 6/10/21 of DC #1's record revealed the following information; -- A 33-year-old female. -- Admitted to the program on 4/3/19. -- Date of death 7/8/20. -- Last documented face to face contact at the clinic: 7/7/20, dosed with 90 mg. of Methadone. -- "Married with three children 3, 5 & 7 years old." (This number changes in this report, depending on which staff she was speaking with.) -- Had been in Methadone Maintenance Treatment (MMT) 4 times previously. -- Diagnoses include Opioid Use Disorder-Severe, on Maintenance Therapy, Opioid Dependence, Low Income, Obesity (weight 374 pounds on 5/26/20), Hepatitis C, Hypertension, Asthma, Insomnia, Depression, Panic Attacks, Anxiety Disorder, ADHD (Attention Deficit Hyperactivity Disorder), PTSD (Post Traumatic Stress Disorder), History of a D & C (Dilation and Curettage procedure) for a perforated uterus and History of having Bell's Palsy and a stroke about 3 years ago (approximately 2016). -- Hospitalized for overdose 2 to 3 times from Percocets and Heroin. Last hospitalization 3 to 4 years ago. -- Began using Opioids (Oxycontin) at age 16, given to her by her mother. -- Had used IV (Intravenous) Heroin since she was 20 years old. "Reports she has utilized other Opioids on a daily basis via inhalation or IV as well." -- Reports use of Heroin for the last 15 to 16 years. Currently IV use in right upper breast. -- Using 2 grams of Heroin every day. -- Past use of Cocaine.	V 233		

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V 233	<p>Continued From page 3</p> <p>-- Reports history of "being molested" from age 7 to 11.</p> <p>Interview on 6/8/21 with the Counselor Supervisor revealed that DC #1's Counselor is no longer employed by BAART.</p> <p>Review on 6/10/21 of DC #1's record revealed the following information; An Admission History and Physical dated 4/3/19 done by the former Medical Director: -- "Plan: Methadone 30 mg. today and increase 10 mg. tomorrow and 5 mg. Q (every) other day to 60 mg. Pt (Patient-DC #1) commits to safety-no other drug use ... Commits to no other meds (medications) and to get Psych (Psychiatry) follow up-no benzo (no use of benzodiazepines)."</p> <p>Review on 6/10/21 of DC #1's record revealed the following information; An Intake Assessment dated 4/3/19: -- Reports Mother with mental health issues, including Bipolar, Schizophrenia and panic attacks. -- Mother and brother have substance abuse issues. -- Mother addicted to Opioids, Cannabis and Alcohol. -- Brother is addicted to Cannabis and Alcohol. -- "Reports that she is living apart from her child, due to her addiction. Her child lives with the father in Florida." -- "Reports being arrested/convicted/incarcerated for probation violation, assault and misdemeanor larceny (theft)." -- "Housing Problems: Must move. Currently living in a hotel." -- "Mental Health:" no mental health diagnoses documented. Categories listed under this heading: "Anxiety DO, ADHD, Panic DO,</p>	V 233		

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V 233	<p>Continued From page 4</p> <p>Persistent/Major Depressive DO, PTSD..." (none of these categories were addressed indicating a need). -- "Medical Diagnoses:" no medical health diagnoses documented.</p> <p>Review on 6/10/21 of DC #1's record revealed the following information; A Treatment Plan dated 3/17/20: Goal: Opiate Use Disorder: "[DC #1] will participate with treatment by, attending all individual sessions... Service and frequency: individual counseling 1-4 times per month. To address core issues that led to her addictive behaviors...</p> <p>Reviewed (this treatment plan) 3/17/20: random UDS (urine drug screen) on a monthly basis. "Patient last 3 UA (urinalysis = UDS) screens consist of 3/12/20 (-) (negative), 2/3/20 (-) and 1/10/20 (+) (positive for) Opiates. Patient denies use of Opioids, showing in UA provided 1/10/20... Currently dosing at 130 mg. of Methadone, Patient currently has level two take home status... Patient reports stable housing..."</p> <p>"GOAL: Mental Health "I am not working on this goal at the moment. Patient denies mental health symptoms at this time... Patient reports that she is prescribed Seroquel 100 mg. (an Antipsychotic) 1X (one time) nightly for Insomnia. Patient reports 'it helps me sleep.' Documentation from provider linked to patient chart ..." (No documentation from any other providers could be found in this client's chart).</p> <p>Review on 6/10/21 of DC #1's record revealed the following information; An "Individual Counseling" note dated 3/17/20 (the same date as this Treatment Plan was reviewed - see above): "Patient reports stable housing... Patient reports</p>	V 233		

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V 233	<p>Continued From page 5</p> <p>the following prescriptions: Albuterol 90 mcg. (Micrograms) (an inhaler used for Asthma) as needed, and Seroquel 100 mg. nightly for insomnia."</p> <p>1. Review on 6/10/21 and 6/14/21 of DC #1's record revealed the following information regarding a hospitalization occurring from 2/13/20 through 2/18/20 (the 1st of 2 hospitalizations that occurred while in active treatment): A Hospital Discharge Summary dated 2/18/20 -- "...Patient admitted with acute (severe) resp (respiratory) failure likely related to exacerbation (an acute increase of the severity of a problem) of Asthma and Bronchitis. Improved with abx (antibiotics), steroids and supportive care. No O2 (oxygen) requirement at discharge... Sponsored (paid for) refill of Quetiapine (Seroquel) (dosed as recommended by Psychiatry). Will need refills provided by PCP (Primary Care Physician) at follow up (appointment)." -- CONTINUE taking these medications which have CHANGED: Seroquel 100 mg. take 1 tablet nightly. May take an additional tablet at night for Insomnia. Quantity: 50 tablets, No refills. Seroquel 50 mg. take 1 tablet twice a day as needed for Anxiety. Quantity: 30 tablets, No refills. -- CONTINUE taking these medications which have NOT changed: Methadone 130 mg. daily. -- STOP taking these medications: Klonopin 2 mg. tablet (for Anxiety, a benzodiazepine). -- Brief History of Present Illness: "[DC #1] is a 32 Y.O. (year old) female, PMH (past medical history) of Polysubstance Abuse (benzodiazepine, tobacco), Migraines, Panic</p>	V 233			

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V 233	<p>Continued From page 6</p> <p>Attacks... Asthma and chronic Bronchitis and Morbid Obesity (BMI (body mass index) of 57) who presents with DOE (dyspnea on exertion-shortness of breath) and boils (a painful, pus filled bump that forms under skin when bacteria infect and inflame hair follicles) under her arms and breast...</p> <p>Coming in with increased dyspnea on exertion which has been ongoing for several months, worse over the past few weeks. She describes it as inability to catch her breath, with minimal ambulation (walking). She feels she can't even make it down a full grocery aisle. She gets short of breath walking to the car... Her husband has seen her stop breathing while she sleeps. She wakes up feeling unrested... She reports she has been very depressed and spending most of the day at home, not moving around very much. She lives with her husband and 2 kids... She reports she has severe Anxiety... reports that she was kidnapped. She indicates she has an Anxiety attack 2 - 3 times per day ...She also has had multiple axillary (armpit area) boils that drain intermittently as well as one under her right breast that she burst herself. She reports that they are painful at times. She had one lanced in the past..."</p> <p>2. Review on 6/10/21 and 6/14/21 of DC #1's record revealed the following information regarding a hospitalization occurring from 5/7/20 through 5/26/20 (the 2nd hospitalization while in active treatment. Her current take home bottles of Methadone: 13 bottles, 120 mg. each.) -- A Hospital Discharge Summary dated 5/26/20: "Admission Diagnoses: Shortness of breath. Discharge Diagnoses: Aspiration Pneumonia (aspiration occurs when food, drink, or foreign objects are breathed into the lungs - going down the wrong tube. It might happen during choking,</p>	V 233		

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V 233	<p>Continued From page 7</p> <p>but aspiration can also be silent, meaning that there is no outward sign) (Pneumonia is an infection in the lungs causing them to fill with phlegm or puss, making breathing difficult), Hypoxic (not enough Oxygen in the blood) Hypercarbic (an increase in carbon dioxide in the blood stream) Respiratory Failure, Acute Respiratory Distress Syndrome (ARDS), Substance Use Disorder, Chronic Methadone Use."</p> <p>-- Was brought into the emergency department on 5/7/20 by EMS (emergency medical services) requiring intubation and mechanical ventilation on admission (intubation places a tube in the throat to help move air in and out of the lungs, mechanical ventilation is the use of a machine to move air in and out of the lungs).</p> <p>-- Was placed on the medical intensive care unit.</p> <p>-- Had a Bronchoscopy (a procedure where a thin lighted tube is put down the nose or mouth in order to look directly at the airways in the lungs) on 5/14/20.</p> <p>-- A negative COVID test.</p> <p>-- A feeding tube was placed into her stomach to provide nutrition.</p> <p>-- DC #1 was not able to breathe on her own and could not be weaned off the ventilator until 5/20/20, despite multiple attempts to do so.</p> <p>-- "Overall, it was felt that her respiratory decompensation (worsening of breathing) was secondary to (due to) poorly controlled chronic lung disease and ARDS resulting from aspiration event. Her aspiration event was felt to be triggered by polypharmacy (the simultaneous use of multiple medications at the same time) (Clonazepam, Methadone and Seroquel)."</p> <p>-- "Patient has a history of tobacco and benzodiazepine and opioid abuse, currently on Methadone per BAART clinic and husband collateral. Patient on substantial amounts of</p>	V 233			

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V 233	<p>Continued From page 8</p> <p>Klonopin at home (3 mg. BID (twice a day)) per patient and sometimes takes more per husband... Review of outside records are concerning for abuse behavior as well as likely purchasing benzos (benzodiazepines) on the street... At discharge she was continued on Seroquel 50 mg. Q HS and Methadone 80 mg. daily. The BAART clinic providers and her community psychiatric provider were updated on her new reduced doses (of Seroquel and Methadone)."</p> <p>-- Discharge Anxiety plan: "Seroquel 50 mg. every night..."</p> <p>-- "Methadone dosing reduced to 80 mg. daily. Discussed with BAART clinic and they will continue to prescribe. Of note, Psychiatrist [Physician's name] was not aware that patient was prescribed Methadone. The BAART Methadone Clinic did not know she was receiving Clonazepam (Klonopin) from Psychiatry..."</p> <p>-- "New Adverse Drug Effects: admission diagnosis of Acute Hypoxic Respiratory Failure thought to be secondary to polypharmacy (Clonazepam, Methadone, Seroquel) - all prior to hospitalization."</p> <p>-- START taking these medications: Melatonin 6 mg. every night for sleep. Quantity: 30 tablets, No refill.</p> <p>-- CONTINUE taking these medications which have CHANGED: Methadone 80 mg. every day. "DO NOT FILL. PROVIDED BY BAART CLINIC." Seroquel 50 mg. every night as needed. Quantity: 30 tablets, No refill.</p> <p>-- STOP taking these medications: Klonopin, Adderal (a stimulant prescribed for ADHD), Lyrica (prescribed for nerve pain). "Follow-up: [name of Psychiatrist and phone number] - Appointment on 6/2/20 at 8:30 am."</p> <p>3. Review on 6/14/21 of DC Client #1's record</p>	V 233		

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V 233	<p>Continued From page 9</p> <p>revealed the following documentation regarding her treatment in the BAART program;</p> <p>-- A "DOCTOR NOTE" dated 5/26/20 completed by a temporary Physician following her 2nd hospitalization (5/7/20 - 5/26/20):</p> <p>"Coordination of care patient was admitted to [name of hospital] for Respiratory failure secondary to aspiration. Received a call from [name of Physician]. During her admission (to the hospital), patient had her dose reduced from 130 mg. to 80 mg. of Methadone, as well as having Clonazepam, Adderal and Gabapentin discontinued. Patient placed on Seroquel 50 mg. at night. Patient has take home doses of Methadone, she will need to bring them back to BAART, along with any discharge paperwork. Per BAART Lead Nurse [Nurse's name], patient is aware she has to bring back her take home doses. Plan to meet with patient when she returns to BAART."</p> <p>-- A "DOCTOR NOTE" dated 6/1/20 (completed by the same temporary Physician as above, following her 2nd hospitalization (5/7/20 - 5/26/20)):</p> <p>"Received call from patient. Patient states she 'was in the hospital at [name of hospital], they put me to sleep for a month.' Patient states she was discharged last Tuesday 5/26/20 and has been 'dosing off my bottles (of take home doses of Methadone).' Patient states 'I did not know I was supposed to bring in my bottles.' BAART staff reports that this patient has been in the hospital before and knows she has to report back to BAART and bring in her bottles with in 24 hours of being discharged from the hospital. Requested patient return to the clinic as soon as possible and bring in her Methadone bottles and well as her discharge summary from [name of</p>	V 233		

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V 233	<p>Continued From page 10</p> <p>hospital]. Patient verbalized she understood and agreed to this plan. Discussed with her Counselor [Counselor's name]."</p> <p>-- A "DOCTOR VISIT" note dated 6/3/20 (completed by the same temporary Physician as above following her 2nd hospitalization (5/7/20 - 5/26/20)):</p> <p>"Patient present for follow up from her hospital admission at [name of hospital] from 5/7/20 - 5/26/27 (2020). Admitted due to Acute Hypoxic respiratory failure secondary to aspiration. ARDS - SEVERE, possible multi focal PNA (Pneumonia) for respiratory failure from possible aspiration secondary to poly substance use. Patient was given Methadone 5/8-05/26/2020 at 80 mg. verified by a phone call from [name of Physician] to BAART-also noted in hospital discharge summary. Patient last dosed at BAART on 5/6/20 at 5:54 am. Patient was discharged (from the hospital) on 5/26/20. Diagnosed also with Bipolar Disorder on Seroquel 50 mg. PO Q HS (by mouth every night), also has an MDI (multidose Inhaler). Taken off Clonazepam, Lyrica, etc... which was not showing up on previous drug screen - was prescribed by [name of Psychiatrist]...</p> <p>Patient denies withdrawal symptoms and or any illicit drug use. Patient has a current hospital dose of 80 mg. of Methadone during admission. Patient had take 12 take home dose bottles containing 130 mg. each, states she was dosing from discharge until yesterday. If patient had taken a bottle each day, she should have unopened 5 bottles left today (for a total of 650 mg.).</p> <p>Patient presents with 12 empty bottles. Patient states I am weak and can not remember anything. Patient denies being called by BAART staff she states she has a new phone....</p> <p>UDS instant from today is positive for Methadone</p>	V 233			

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V 233	<p>Continued From page 11</p> <p>only...</p> <p>A (Assessment): Methadone Dependence, OUD (Opioid Use Disorder), Diversion of take home doses of Methadone ...</p> <p>P (Plan): Patient will continue on 80 mg. of Methadone. Take home doses of Methadone will be revoked ..."</p> <p>-- A "DOCTOR NOTE" dated 6/19/20 (completed by the same temporary Physician as above following her 2nd hospitalization (5/7/20 - 5/26/20)):</p> <p>"Patient presents for a medication review and possible dose adjustment. Current dose is 80 mg. of Methadone. Patient reports that she has followed current recommendations of abstaining from benzodiazepines. States she is having withdrawal symptoms reported as flu like symptoms and drug cravings. Denies use of any illicit drugs. Denies chest pain, SOB (shortness of breath), DOE. Denies SI, HI (suicidal ideation, homicidal ideation), intent or plans. Last UDS 6/30/2020 was positive for Opiates, no benzodiazepines noted... History of poly substance use with benzodiazepines.</p> <p>P (Plan): Increase (Methadone dose) by 5 mg. today and 5 mg. on 6/22/2020 days (see orders) for a total of 90 mg. Follow up in 2 weeks."</p> <p>(This follow up Physician visit should have occurred on 7/3/20, prior to her death on 7/8/20)</p> <p>-- A "Case Management" note dated 6/30/20 written by the Counselor:</p> <p>"Patient (DC #1) presented to Counselor office due to flag on patient account. Counselor followed up with patient regarding her recent contact with BAART PA (Physician's Assistant) and TCD (Temporary Clinical Director) regarding patient request for take homes. Patient reports, 'I just shouldn't have to mess with it because it is</p>	V 233		

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V 233	<p>Continued From page 12</p> <p>ridiculous because I should already have my take homes.' Patient reports that she is requesting documentation from her PCP (Primary Care Physician) regarding patient need for take home doses. Patient reports, 'I will bring Y'all the letter from my Doctor when I get it.' Counselor informs patient that if she is exhibiting symptoms related to COVID19, that she needs to request curbside dosing before coming into the clinic for daily dosing."</p> <p>-- A letter from a Physician at the hospital DC #1 was hospitalized at, addressed to the former Clinic Director dated 6/30/20 (after her 2nd hospitalization 5/7/20 - 5/26/20):</p> <p>"[DC #1] requested that I reach out to you to inform you that she has a medical condition that makes her high risk for complications should she contract Coronavirus.</p> <p>She also recently had a prolonged and traumatic hospitalization in the intensive care unit due to combined effects of Methadone and benzodiazepines. She has a history of misuse of Opioids and benzodiazepines so she would be high risk for recurrence if given a large supply of Methadone to take home. I would therefore recommend not providing greater than a three-day supply at any time."</p> <p>Review on 6/8/21 of a Medical Examiner report dated 7/9/20 revealed the following information regarding DC #1;</p> <p>"Medical Examiner Preliminary Summary Of Circumstances Surrounding Death:</p> <p>[DC #1] is a 33 year old African American female who resided at the [name of motel] on [name of street] in [room number] with her husband. Per decedent's (DC #1's) husband, [DC #1] was last seen on 7/2/20 at approximately 19:30 (7:30 pm) prior to him leaving for work.</p>	V 233		

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V 233	<p>Continued From page 13</p> <p>Per law enforcement the husband states that he arrived home (back to the motel) from work on the morning of 7/8/2020 around 05:30 (5:30 am) to find the room door locked. Husband stated that this was not unusual as they only had one key to the room. The husband knocked on the door multiple times with no response. He then states that he entered the room via the window to find [DC #1] laying face down in the bed, cradling her head with her arms. He attempted to wake [DC #1] however, upon rolling her over found her to be unresponsive with mucous and phlegm (respiratory mucus expelled by coughing) around her mouth. Husband then called 911 and they instructed him to start CPR (Cardiopulmonary Resuscitation). Upon EMS arriving rigor mortis (the stiffness of the body after death) was noted and no life saving measures were performed. Per the decedent's primary care provider [DC #1] was admitted to [name of hospital] approximately two months prior with Acute Respiratory Distress and aspiration pneumonia. Both were thought to be related to over-sedation from prescribed medication.</p> <p>The decedent's medical history included an extensive substance abuse history including recent Methadone use, depression, chronic bronchitis, hypertension, asthma and obesity. Per the husband the decedent was non-compliant with taking her prescribed medications. She would often not take prescribed medications without assistance. If she did she would take multiple pills not paying attention to what they were or the prescribed dosage.</p> <p>At the scene medications were found including the following: Amlodipine, Prazosin, Lyrica (Pregabalin), Trazadone, Seroquel, D-Amphetamine, and two inhalers. Lyrica was the only medication with an empty bottle. Upon brief visual examination at the scene, no</p>	V 233		

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V 233	<p>Continued From page 14</p> <p>trauma was apparent nor were there any concerns for foul play as the LEO (law enforcement officer) confirms the husband's story via video surveillance..."</p> <p>"Toxicology Report" dated 8/13/20: (Substances found in DC #1's body) "Present:... Amlodipine, Benzodiazepines, Diphenhydramine, Gabapentin/Pregabalin, Opiates/Opioids, Promethazine, Trazadone, 7- Amonoclonazepam, Clonazepam, Citalopram, Methadone, Pregabalin."</p> <p>"Report of Investigation" dated 7/9/20 "Probable Cause of Death: Multidrug Toxicity involving Methadone, Clonazepam, Pregabalin and Citalopram." "Manner of death: Accident."</p> <p>Review on 6/14/21 of the Plan of Protection dated 6/14/21 written by the Temporary Clinical Director revealed the following information; "What immediate action will the facility take to ensure the safety of the consumers in your care? V233 All patients testing positive for illicit Benzodiazepines are to meet with the Medical Director of the clinic(s), or designee with prescribing authority, within seven (7) days of the results. Patients will meet monthly with the physician until they no longer test positive for Benzodiazepines. Patients testing positive for illicit Benzodiazepines will have a minimum of twice per month documented counseling sessions until they no longer test positive for Benzodiazepines. V238 Care of patients at increased risk due to continued illicit drug use will at a minimum consist of: a) Reduced take home, if applicable, in order to</p>	V 233			

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V 233	<p>Continued From page 15</p> <p>ensure the patient is seen by dispensing staff at least once per week;</p> <p>b) Increased counseling to at least twice per month;</p> <p>c) Obtain a signed release of information to coordinate care with outside providers; and,</p> <p>d) Increased access to a provider as needed</p> <p>Describe your plans to make sure the above happens:</p> <p>V233</p> <p>In order to ensure that patients testing positive for illicit benzodiazepines are seen at a greater frequency, the drug screen results will be reviewed daily by the Medical Assistant who will notify the counselors and place the patient on a hold to schedule an appointment with the Medical Provider within 7 days. Upon notification from the Medical Assistant, the counselor will place the patient on a treatment hold to address the positive drug screen and set up recurring individual counseling sessions of at least twice per month. The Medical Assistant will utilize (a) SAMMS (Substance Abuse Methadone Maintenance System - the computer program the clinic uses to document in client records) report called 'benzo positive or Methadone Metabolite Negative' in order to identify patients testing positive for benzodiazepines. Additionally, counselors will review drug screen results for all patients at least weekly and communicate any positive UA (urinalysis) results for illicit Benzodiazepines to the management team. All staff will be retrained on the Benzodiazepine Policy by 06/18/2021.</p> <p>Counselor Supervisor and/or TCD (Treatment Center Director) will monitor clinical contact and urinalysis results through SAMMS' reports.</p> <p>Counselor Supervisor and/or TCD will facilitate a discussion during each weekly staff meeting regarding each counselor's progress concerning</p>	V 233		

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V 233	<p>Continued From page 16</p> <p>clinical contact with increased risk patients presenting unfavorable urinalysis results. The facility's Regional OTP (Opioid Treatment Program) Compliance Manager will continue to perform internal audits to assess for compliance. The facility's counselors will each audit at least 2 patient records weekly. The Counselor Supervisor will perform at least 10 peer reviews on patient records monthly.</p> <p>V238</p> <p>BayMark Health Services as implemented a "Patients at Increased Risk Policy" (attached). This policy was rolled out at all programs October of 2020. The policy identified patients at increased risk as identified as meeting one of the following criteria:</p> <ol style="list-style-type: none"> 1. Continued illicit substance use after 6 months of treatment; 2. Homelessness; 3. Living with someone that uses illicit substances; 4. Age 65 or older; 5. Disabled; 6. Exhibiting behavioral issues; 7. Experiencing suicidal ideation or history of attempts; 8. Have a co-occurring condition; or, 9. Have other health factors that may require increased care <p>Treatment of patients identified in this policy as being at an increased risk will received the follow treatment enhancements:</p> <ol style="list-style-type: none"> 1. Reduced take homes in order to ensure the patient is seen by dispensing staff at least once per week; 2. Increased counseling to at least twice per month; 3. Obtain a signed release of information to coordinate care with outside providers; and, 	V 233		

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V 233	<p>Continued From page 17</p> <p>4. Increased access to a provider as needed</p> <p>The Program clinical team will receive training on this policy no later than June 18th, 2021 The Counselor Supervisor and/or TCD will monitor clinical compliance with the "Patients at Increased Risk Policy" to ensure compliance."</p> <p>The BAART Clinic serves clients with substance use/abuse diagnoses; Opiates, Benzodiazepines. Also use of illegal substances; Heroin, Cocaine, Marijuana. These clients also frequently also have mental health diagnoses.</p> <p>Essential of this treatment include monitoring urine drug screens for the continued or new use of Opioids and/or illicit substances. The Certified Substance Abuse Counselors then addressing any use/misuse through focused counseling sessions aimed at decreasing or eliminating this use. For clients in compliance with continuous active treatment, increased independence is offered through the supply of take-home doses of Methadone thus decreasing reliance on attending the clinic daily.</p> <p>The facility lost its Clinical Director February 2021 and its Medical Director August 2020. Since this time the clinic has been understaffed. The clinic continued to assess and admit additional clients during this time despite being understaffed. The clinic continued to dose clients despite them having positive UDS's for illicit and illegal drug use.</p> <p>This clinic did not address DC #1's significant mental health issues including a prior suicide attempt, multiple (2-3) previous overdose events and Panic Attacks. There was no documentation that coordination of care was attempted with DC</p>	V 233		

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V 233	Continued From page 18 #1's Physician who was continuing to prescribe an ongoing psychotropic medication (medications that affect a person's mental state - Seroquel). Other medications that were reported to be prescribed include: Klonopin, Adderal, Lyrica/Neurontin, Zyprexa and Celexa (all of these medications carry a risk of respiratory depression). Methadone and the previously listed medications can cause drowsiness, slowed breathing and confusion increasing the risk of Hypoxia (a condition that results when too little Oxygen reaches the brain, and can cause coma or even death). DC #1 also had several medical conditions which further reduced her ability to experience normal effective breathing (Asthma, Chronic Bronchitis and Morbid Obesity). Being understaffed rendered the clinic unable to meet the complex needs of DC #1 and multiple other clients to assist in adequate effective treatment for their substance use/misuse. The accumulation of the identified deficient practices constitutes negligence of use of proven strategies and interventions to increase program compliance and reduce the effects of continued use of substances. This deficiency constitutes a Failure to Correct the Type A1 rule violation originally cited for serious neglect. An administrative penalty of \$500.00 per day is imposed for failure to correct within 23 days.	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	V 235		

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V 235	<p>Continued From page 19</p> <p>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 on interview and record review, the facility failed to have a minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients. The findings are:</p> <p>Review on 6/10/21 of Counselor #1's personnel record and a facility spread sheet revealed: -Hired date of 3/29/21. -Current caseload 91 clients.</p> <p>Review on 6/10/21 of Counselor #2's personnel record and a facility spread sheet revealed:</p>	V 235		

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V 235	<p>Continued From page 20</p> <p>-Hired date of 10/15/19. -Current caseload 108 clients.</p> <p>Review on 6/10/21 of Counselor #3's personnel record and a facility spread sheet revealed: -Hired date of 3/22/21. -Current caseload 86 clients.</p> <p>Review on 6/10/21 of Counselor Supervisor personnel record and a facility spread sheet revealed: -Hired date of 4/26/21. -Current caseload 107 clients.</p> <p>Interview on 6/10/21 with the Counselor Supervisor revealed: -Confirmed the clinic was currently serving 476 clients. -The clinic currently had five full-time counselors with him included. -Confirmed counselors had a caseload of more than 50 clients. -Reason for the increased caseload was due to staff shortage. -He was in the process of reviewing resumes and hiring staff.</p> <p>During an interview on 6/10/21 Counselor #1 stated: - She currently has a caseload of 91 - "The caseloads changes weekly due to the high turnover rate of counselors." - "The highest my caseload has been is over 100." - " I have to place clients on a hold status to at least see them once per week. The goal is to see the clients bi-weekly, however; that is not occurring."</p> <p>During an interview on 6/10/21 Counselor #3</p>	V 235		

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V 235	Continued From page 21 stated: - She currently has a caseload of 86 - "I'm trying to see my clients daily, however; that's not occurring. We started putting a hold status on the clients so they would visit their counselors. We count that time as a counseling session." - "The high turnover rate of counselors within the agency has caused our caseload to increase." - "Work hours are Monday through Friday from 5:30am until 2:30pm." To meet the staff requirements for the current census (476 clients) the program should have 10 counselors on staff. **NOTE: Counselor #4 has a current caseload of 40 clients. This leaves 45 clients not assigned to any counselor.** This deficiency is cross referenced into 10A NCAC 27G .3601 SCOPE (Tag V- 233) for a failure to correct a Type A1 rule violation.	V 235		
V 237	27G .3604 (A-D) Outpt. Opiod - Operations 10A NCAC 27G .3604 OPERATIONS (a) Hours. Each facility shall operate at least six days per week, 12 months per year. Daily, weekend and holiday medication dispensing hours shall be scheduled to meet the needs of the client. (b) Compliance with The Substance Abuse and Mental Health Services Administration (SAMHSA) or The Center for Substance Abuse Treatment (CSAT) Regulations. Each facility shall be certified by a private non-profit entity or a State agency, that has been approved by the SAMHSA of the United State Department of Health and	V 237		

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V 237	<p>Continued From page 22</p> <p>Human Services and shall be in compliance with all SAMHSA Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction regulations in 42 CFR Part 8, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the CSAT, SAMHSA, Rockwall II, 5600 Fishers Lane, Rockville, Maryland 20857 at no cost.</p> <p>(c) Compliance With DEA Regulations. Each facility shall be currently registered with the Federal Drug Enforcement Administration and shall be in compliance with all Drug Enforcement Administration regulations pertaining to opioid treatment programs codified in 21 C.F.R., Food and Drugs, Part 1300 to end, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the United States Government Printing Office, Washington, D.C. 20402 at the published rate.</p> <p>(d) Compliance With State Authority Regulations. Each facility shall be approved by the North Carolina State Authority for Opioid Treatment, DMH/DD/SAS, which is the person designated by the Secretary of Health and Human Services to exercise the responsibility and authority within the state for governing the treatment of addiction with an opioid drug, including program approval, for monitoring compliance with the regulations related to scope, staff, and operations, and for monitoring compliance with Section 1923 of P.L. 102-321. The referenced material may be obtained from the Substance Abuse Services Section of DMH/DD/SAS.</p> <p>This Rule is not met as evidenced by: Based on interview and record review, the facility</p>	V 237		

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V 237	<p>Continued From page 23</p> <p>management failed to ensure program compliance in the areas of Individual Counseling, Urine Drug Screen (UDS) frequency and dual enrollment requirements affecting 10 of 22 current audited clients (#2 #3 #4 #5 #6 #7 #9 #13 #18 #22) and 1 of 1 deceased client (DC #1). The findings are:</p> <p>**NOTE: Only clinical treatment information from after the date of correction (2/21/20) from the last survey (1/29/20) is included in this report.**</p> <p>Review on 6/14/21 of the North Carolina State Opioid Treatment Authorities (SOTA) program requirements revealed the following information;</p> <p>-- Individual Counseling requirements: "During the first year of continuous treatment each client attended a minimum of two counseling sessions per month, and after the first year of treatment attended at least one counseling session per month."</p> <p>-- Urine Drug Screening requirements: "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."</p> <p>-- 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..."</p> <p>1. Review on 6/10/21 of DC #1's record revealed the following information;</p> <p>-- A 33-year-old female.</p> <p>-- Admitted to the program on 4/3/19.</p>	V 237		

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V 237	<p>Continued From page 24</p> <p>-- Date of death 7/8/20.</p> <p>-- Last documented face to face contact at the clinic: 7/7/20, dosed with 90 mg. of Methadone.</p> <p>-- Married with three children (3, 5, & 7 years old).</p> <p>-- Had been in Methadone Maintenance Treatment (MMT) 4 times previously.</p> <p>-- Diagnoses include Opioid Use Disorder-Severe, on Maintenance Therapy, Opioid Dependence, Low Income, Obesity (weight 374 pounds on 5/26/20), Hepatitis C, Hypertension, Asthma, Insomnia, Depression, Panic Attacks, Anxiety Disorder, ADHD (Attention Deficit Hyperactivity Disorder), PTSD (Post Traumatic Stress Disorder), History of a D & C (Dilation and Curettage procedure) for a perforated uterus and History of having Bell's Palsy and a stroke about 3 years ago (approximately 2016).</p> <p>-- Hospitalized for overdose 2 to 3 times from Percocets and Heroin. Last hospitalization 3 to 4 years ago.</p> <p>-- Began using Opioids (Oxycontin) at age 16, given to her by her mother.</p> <p>-- Had used IV (Intravenous) Heroin since she was 20 years old. "Reports she has utilized other Opioids on a daily basis via inhalation or IV as well."</p> <p>-- Reports use of Heroin for the last 15 to 16 years. Currently IV use in right upper breast.</p> <p>-- Using 2 grams of Heroin every day.</p> <p>-- Past use of Cocaine.</p> <p>-- Reports history of "being molested" from age 7 to 11.</p> <p>Interview on 6/8/21 with the Counselor Supervisor revealed that DC #1's Counselor is no longer employed by BAART.</p> <p>a. UDS results: 3/12/20 - Clean UDS.</p>	V 237		

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V 237	<p>Continued From page 25</p> <p>4/1/20 - Clean UDS. May 2020 - No results or documentation that a UDS was collected. 6/3/2020 - Positive for Opiates.</p> <p>b. Individual Counseling Sessions: 3/17/20: Positive UDS was addressed (discussed) (unclear which UDS this note refers to). 6/30/20: (Identified as a "Case Management" note) Positive UDS (6/3/20) was addressed.</p> <p>2. Review on 6/9/21 of Client #2's chart revealed the following information; -- A 29 year old male. -- Admitted to the BAART program on 2/22/21. -- Diagnoses include Opioid Dependence-Uncomplicated, Opiate Use DO-Severe, on maintenance therapy and Cocaine Use DO-Moderate. -- History of Fentanyl use. -- Current dose of Methadone is 65 mg. daily. -- Currently on Counselor #2's caseload.</p> <p>a. UDS results: 2/22/21 - (Admission screen) Positive for Cocaine. 3/19/21 - "FTS" (failure to submit - did not produce urine for a drug screen). 3/24/21 - Positive for Cocaine. 4/6/21 - FTS. 4/22/21 - Positive for Cocaine. 5/3/21 - FTS. 5/10/21 - Positive for Cocaine. 6/7/21 - FTS.</p> <p>b. Had only seen his Counselor once on 5/19/21 when she introduced herself to the client as his new Counselor.</p>	V 237		

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V 237	<p>Continued From page 26</p> <p>3. Review on 6/10/21 of Client #3's chart revealed the following information; -- A 30 year old female. -- Admitted to the BAART program on 10/27/20. -- Diagnoses include Opiate Use DO-Severe, Cannabis Use DO-Moderate and Cocaine Use DO-Mild. -- Current dose of Methadone is 75 mg. daily. -- Currently on Counselor #2's caseload.</p> <p>a. UDS results: 10/27/20 - (Admission screen) Positive for Cocaine and Cannabis. 11/9/20 - Positive for Cocaine and Cannabis. 12/8/20 - Positive for Cocaine and Cannabis. 1/5/21 - Positive for Cocaine and Cannabis. 1/14/21 - Positive for Cocaine and Cannabis. 2/22/21 - FTS. 2/24/21 - Positive for Cocaine. 3/24/21 - FTS. 3/29/21 - Positive for Cocaine and Cannabis. 4/8/21 - FTS. 5/5/21 - FTS. 5/27/21 - Positive for Cocaine and Cannabis.</p> <p>b. This client had only 2 sessions with his Counselor on 2/25/21 and 1/27/21. They both addressed continued use of illegal drugs.</p> <p>4. Review on 6/10/21 of Client #4's chart revealed the following information; -- A 55 year old male. -- Admitted to the BAART program on 2/19/20. -- Diagnoses include Opioid Dependence-Uncomplicated-Severe, PTSD and Depression. -- A history of suicidal ideation and attempts. -- Client reports 18 psychiatric hospitalizations. -- Other medications prescribed: Celexa and Trazadone (both antidepressants).</p>	V 237		

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V 237	<p>Continued From page 27</p> <p>-- Current dose of Methadone is 70 mg. daily. -- Currently on Counselor Supervisor's caseload.</p> <p>a. UDS results: 4/16/20 - Clean UDS. 5/12/20 - Positive for Cocaine. 6/10/20 - Positive for Cocaine. 7/24/20 - Clean UDS. 8/17/20 - Positive for Cocaine. 9/1/20 - Positive for Cocaine and Opiates. 10/13/20 - Positive for Opiates. 11/10/20 - Positive for Cocaine and Opiates. 12/18/20 - Positive for Cocaine and Opiates. 1/26/21 - Positive for Opiates. February 2021 - No results or documentation that a UDS was collected. 3/22/21 - Positive for Cocaine and Opiates. 4/29/21 - Positive for Cocaine and Opiates. 5/5/21 - Positive for Cocaine and Opiates.</p> <p>b. Individual Counseling Sessions: 2020- 4/22/20: UDS was NOT addressed. 5/27/20: UDS was NOT addressed. 6/24/20: UDS was NOT addressed. 9/14/20: UDS was NOT addressed. 11/10/20, 10/19/20 and 3/25/20: Positive UDSs were addressed. No documentation of any counseling in July 2020, August 2020 or December 2020.</p> <p>2021- 1/20/21: UDS was NOT addressed. 6/3/21: UDS was NOT addressed. 2/12/21, 2/26/21 and 4/12/21: Positive UDSs were addressed. No documentation of any counseling in March 2021 or May 2021.</p> <p>c. A Release of Information form signed by the</p>	V 237			

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V 237	<p>Continued From page 28</p> <p>client dated 1/13/21 allowing the clinic to share and receive clinical information from the VA (Veterans Administration) medical center. No documentation within this client's record that any information had been requested from or received from the VA (the VA was prescribing the psychiatric medications, Celexa and Trazadone).</p> <p>5. Review on 6/9/21 of Client #5's chart revealed the following information; -- A 57 year old male. -- Admitted to the BAART program on 1/28/20. -- Diagnoses include Opioid Use DO, Diabetes, Neuropathy (nerve pain) and Bipolar Disorder (per the client "20 + years ago. No longer has"). -- Current dose of Methadone is 55 mg. daily. -- Currently on Counselor #2's caseload.</p> <p>a. UDS results: Done monthly from March 2020 through March 2021, all negative for illicit substances. April 2021 and May 2021 - No results or documentation that a UDS was collected.</p> <p>b. Individual Counseling Sessions: Only 3 Individual Counseling Sessions (4/27/20, 7/27/20 and 10/5/20).</p> <p>c. Dual Enrollment: No documentation that this was completed.</p> <p>6. Review on 6/9/21 of Client #6's chart revealed the following information; -- A 40 year old female. -- Admitted to the BAART program on 4/5/18. -- Diagnosis of Opioid Dependence-Uncomplicated. -- Current dose of Methadone is 120 mg. daily. -- Currently on Counselor #2's caseload.</p>	V 237		

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V 237	<p>Continued From page 29</p> <p>a. USD results:</p> <p>2020-</p> <p>3/10/20 - Positive for Cocaine and Benzodiazepines.</p> <p>4/20/20 - Positive for Cocaine and Benzodiazepines.</p> <p>5/12/20 - Positive for Cocaine and Opiates.</p> <p>6/24/20 - Clean UDS.</p> <p>7/20/20 - Positive for Cocaine and Opiates.</p> <p>8/18/20 - Positive for Opiates.</p> <p>9/23/20 - Positive for Cocaine and Opiates.</p> <p>10/5/20 - Clean UDS.</p> <p>11/15/20 - Clean UDS.</p> <p>12/18/20 - FTS.</p> <p>12/23/20 - Positive for Opiates.</p> <p>2021-</p> <p>1/25/21 - FTS.</p> <p>1/26/21 - Positive for Opiates.</p> <p>2/23/21 - FTS.</p> <p>2/24/21 - Positive for Benzodiazepines.</p> <p>3/15/21 - FTS.</p> <p>3/18/21 - Positive for Cocaine and Opiates.</p> <p>4/12/21 - FTS.</p> <p>4/14/21 - Positive for Cocaine.</p> <p>5/28/21 - Positive for Opiates.</p> <p>b. Individual Counseling Sessions:</p> <p>2020-</p> <p>No documentation of any counseling in March 2020.</p> <p>4/14/20: Positive UDS was addressed.</p> <p>Encouraged to "talk to PCP (Primary Care Physician) to tell them she is on Methadone and also Benzos. Has an RX (prescription) for Klonopin (for anxiety, a benzodiazepine) and will bring it in."</p> <p>6/22/20, 7/22/20 and 10/15/20: Positive UDSs were addressed.</p> <p>5/19/20: UDS was NOT addressed.</p>	V 237			

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V 237	<p>Continued From page 30</p> <p>11/13/20: "Discussed UDS, given praise for negative UAs (urinalysis - UDS)." No documentation of any counseling in August 2020 or September 2020.</p> <p>2021- 1/20/21 and 5/10/21: Positive UDSs were addressed. 3/29/21: UDS was not addressed. No documentation of any counseling in February 2021 or April 2021.</p> <p>c. No documentation that any contact was attempted or made with this client's PCP to coordinate care.</p> <p>d. No documentation that this client ever brought either her prescription or her bottle of Klonopin into the clinic to be verified and recorded.</p> <p>e. A Physician's order dated 4/6/21 to "Cascade up (increase her dose of Methadone) due to continued use (of illicit substances)."</p> <p>f. Dual Enrollment: No documentation that this was completed.</p> <p>7. Review on 6/14/21 of Client #7's record revealed the following information; -- A 59 year old male. -- Admitted to the BAART program on 1/15/20. -- Diagnosis of Opioid Dependence. -- Current dose of Methadone is 95 mg. daily. -- Currently on Counselor #4's caseload.</p> <p>a. UDS results: 3/9/21 - Positive for Opiates. 4/13/21 - Positive for Alcohol. 5/10/21 - Positive for Alcohol.</p>	V 237		

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V 237	<p>Continued From page 31</p> <p>b. Individual Counseling Sessions: The client's last counseling session was on 2/10/21.</p> <p>8. Review on 6/9/21 of Client #9's record revealed the following information; -- A 59 year old male. -- Admitted to the BAART program on 8/27/19. -- Diagnosis of Opioid Dependence. -- Current dose of Methadone is 240 mg. daily. -- Currently on Counselor #1's caseload.</p> <p>a. UDS results: 3/10/21 - Positive for Amphetamines. 4/9/21 - Positive for Amphetamines. 5/17/21 - Positive for Amphetamines.</p> <p>b. Individual Counseling Sessions: The client's last counseling session was on 2/17/21.</p> <p>9. Review on 6/9/21 of Client #13's record revealed the following information; -- A 39 year old female. -- Admitted to the BAART program on 6/7/19. -- Diagnosis of Opioid Dependence. -- "As of June 7, 2021 this client is 8 weeks pregnant." -- Due date of January 2022. -- Identified as a "High Risk" client due to pregnancy. -- Current dose of Methadone is 60 mg. daily. -- Currently on Counselor #1's caseload.</p> <p>a. UDS results: 6/3/21 - Positive for Cocaine. 5/26/21 - Positive for Cocaine 5/21/21 - Clean UDS.</p> <p>b. Individual Counseling Sessions:</p>	V 237		

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V 237	<p>Continued From page 32</p> <p>The client's last counseling session was on 2/23/21.</p> <p>10. Review on 6/10/21 of Client #22's record revealed the following information; -- A 41 year old male. -- Admitted to the BAART program on 12/29/20. -- Diagnosis of Opioid Dependence. -- Current dose of Methadone is 75 mg. daily. -- Currently on Counselor Supervisor's caseload.</p> <p>a. UDS results: 4/12/21 - Refused to test. 5/5/21 - Refused to test. 5/10/21 - Clean UDS.</p> <p>b. Individual Counseling Sessions: The client's last counseling session was on 3/25/21.</p> <p>11. Review on 6/9/21 of Client #18's record revealed the following information; -- A 41 year old male. -- Admitted to the BAART program on 2/2/17. -- Diagnosis of Opioid Dependence. -- Current dose of Methadone is 105 mg. daily. -- Currently on Counselor #1's caseload.</p> <p>a. UDS results: 3/29/21 - Failure to test. 4/6/ 21 - Positive for Opiates. 5/3/21 - Positive for Opiates.</p> <p>b. Individual Counseling Sessions: The client's last counseling session was on 4/6/21.</p> <p>This deficiency is crossed referenced into 10A NCAC 27G .3601 SCOPE (Tag V- 233) for a failure to correct a Type A1 rule violation.</p>	V 237		

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