BAART Community HealthCare

Facsimile Transmittal

To: Caitlin Hicks From: Wilda Smith

Company: DHSR/DHHS

Fax: Date: ~~919-855-3795~~ 03/12/2020

Phone: 919-855-3795 Pages: X (including cover page)

Subject: BAART POC

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FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MHL032-412	A. BUILDING: _____ B. WING _____	01/29/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
BAART COMMUNITY HEALTHCARE	800 NORTH MANGUM STREET, SUITE 300 & 400 DURHAM, NC 27701

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 000	INITIAL COMMENTS A complaint survey was completed on January 29, 2020. Two complaints were unsubstantiated (Intake #NC00158307 & #NC00160210). One complaint was substantiated (Intake #NC00158588). Deficiencies were cited. 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 The client census was 475 at the time of the survey.	V 000	DHSR - Mental Health MAR 12 2020 Lic. & Cert. Section	
V 105	27G .0201 (A) (1-7) Governing Body Policies 10A NCAC 27G .0201 GOVERNING BODY POLICIES (a) The governing body responsible for each facility or service shall develop and implement written policies for the following: (1) delegation of management authority for the operation of the facility and services; (2) criteria for admission; (3) criteria for discharge; (4) admission assessments, including: (A) who will perform the assessment; and (B) time frames for completing assessment. (5) client record management, including: (A) persons authorized to document; (B) transporting records; (C) safeguard of records against loss, tampering, defacement or use by unauthorized persons; (D) assurance of record accessibility to authorized users at all times; and	V 105		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Julie M. Smith, MS, LCAS — TITLE: Treatment Center Director — (X6) DATE: 03/12/2020

STATE FORM 6899 C02M11 If continuation sheet 1 of 13

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V 105	Continued From page 1 (E) assurance of confidentiality of records. (6) screenings, which shall include: (A) an assessment of the individual's presenting problem or need; (B) an assessment of whether or not the facility can provide services to address the individual's needs; and (C) the disposition, including referrals and recommendations; (7) quality assurance and quality improvement activities, including: (A) composition and activities of a quality assurance and quality improvement committee; (B) written quality assurance and quality improvement plan; (C) methods for monitoring and evaluating the quality and appropriateness of client care, including delineation of client outcomes and utilization of services; (D) professional or clinical supervision, including a requirement that staff who are not qualified professionals and provide direct client services shall be supervised by a qualified professional in that area of service; (E) strategies for improving client care; (F) review of staff qualifications and a determination made to grant treatment/habilitation privileges: (G) review of all fatalities of active clients who were being served in area-operated or contracted residential programs at the time of death; (H) adoption of standards that assure operational and programmatic performance meeting applicable standards of practice. For this purpose, "applicable standards of practice" means a level of competence established with reference to the prevailing and accepted methods, and the degree of knowledge, skill and care exercised by other practitioners in the field;	V 105		

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V 105	Continued From page 2 This Rule is not met as evidenced by: Based on records review and interviews, the facility failed to ensure policies and procedures to assure meeting of applicable standards of practice were implemented. The findings are: Review on 12/13/19 and 1/24/20 of deceased client #1's (DC #1's) record revealed the following information; -- 64 year old male. -- Admitted to the facility on 1/11/18. -- Date of death 11/19/19. -- Last contact with client at the clinic was on 11/9/19 when he attempted to dose with his daily Methadone. -- Last documented contact with Counselor 9/3/19. -- This was the client's first time in an Opioid Treatment Program -- Diagnoses of Opioid Use Disorder - Severe. -- 20 year history of use/abuse of opioids due to chronic pain. -- Switched to heroin when medications became too expensive and was actively using 1/2 to 1 gram daily. -- Had been a patient at 2 different pain management clinics (last one ending in January 2017), but was discharged due to continued illicit use of other medication. -- During his time in treatment, the client remained at Level 1, with no take-home doses of Methadone earned.	V 105		

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V 105	Continued From page 3 Review on 1/27/20 of DC #1's Intake Assessment dated 1/11/18 revealed the following information; -- "Client indicates that he does not have any mental health issues..." -- "Counselor provided client with...policies and procedures surrounding prescription medications, and Benzodiazepines, alcohol, and barbiturates." Review on 1/27/20 of the "Patient Handbook" given to patients upon admission to the program revealed the following information; -- "There are several medications that you should not take while on Methadone... Other dangerous medications to take while on Methadone are... Benzodiazepines... These medications all depress the heart rate and respiratory (breathing) systems... Methadone depresses these systems as well so there is an increased risk of overdose associated with combining these medications..." -- "Many prescription drugs have possibly fatal results if combined with Methadone... Benzodiazepines." -- "Alcohol also depresses your heart rate and respiratory systems. It also interferes with the breakdown of Methadone in your system and may cause overmedication or sedation... " -- "Breathalyzer - BAART has a zero tolerance policy for alcohol use. This is because alcohol mixed with Methadone can be fatal..." -- "Counseling Services: You will be assigned a Counselor and you will see this Counselor regularly. Regularly could be a couple of times per week or it could mean once per month; it depends on your individual needs, how long you have been in treatment and what medications you are taking." -- "Drug Testing: You will be required to provide urine samples to test for illicit drug use, no less than once per month... Urinalysis results are	V 105		

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V 105	Continued From page 4 useful in making decisions about your health, your medication and your overall success treatment. Review on 1/27/20 of a form called "Patient Acknowledgement of Benzodiazepine Policy" signed by DC #1 on 1/11/18 revealed the following information; -- "If you are being treated with Methadone and use benzodiazepines (such as: Valium, Xanax, Ativan, Klonopin)... you may increase your chances of accidents and injuries to yourself or others and also possible death by overdose..." -- "Any use of these medications without a documented prescription on file with the program is considered 'illicit use' and is considered non-compliance with program expectations..." -- "Use of these medications while also taking Methadone, even with a prescription, still carries risks. Clouded thinking and slowed reactions can be subtle and hard to recognize by the person involved. In addition, these medications all have the potential for abuse and dependence, particularly in individuals with histories of addiction..." Review on 1/24/20 of the clinic's "Medical - Benzodiazepine Policy" (Updated on 8/13/18) revealed the following information; -- "... For patient safety, the 'maximum dose' of Methadone for a patient taking prescription or illicit Benzodiazepines will be 110 mg..." Interview on 1/27/20 with the Medical Director and the Physician's Assistant confirmed that the maximum dose of Methadone that should be administered to a client who is taking Benzodiazepines is 110 mg. Review on 1/27/20 of DC #1's medication	V 105		

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V 105	Continued From page 5 administration records from March 2018 through April 2018 revealed the following information; 110 mg. for 4 days from 3/20/18 through 3/23/18 115 mg. for 4 days from 3/24/18 through 3/27/18 120 mg. for 6 days from 3/28/18 through 4/2/18 115 mg. for 7 days from 4/3/18 through 4/9/18 110 mg. for 13 days from 4/9/18 through 4/21/18 The above information reflects that DC #1 was at the maximum or higher dose of Methadone for a total of 34 days. Review on 1/24/20 of DC #1's record revealed the following information; -- The North Carolina Controlled Substance Reporting System) was checked on the following dates; 1/11/18 (on admission to the program), 6/29/18, 10/8/18, 1/16/19, 4/25/19, 7/26/19, 9/3/19 and one on 11/20/19 following the report of his death. -- The client filled prescriptions every month from 4/11/18 through 10/14/19 (1 and 1/2 years) for Klonopin 0.5 mg. to be taken twice a day. -- There were 4 different prescribing Physician's for the Klonopin. Review on 1/27/20 of DC #1's record revealed the following UDS results; 2/20/18 - Negative. 3/5/18 - Negative. 4/9/18 - Negative 5/23/18 - Positive for Alcohol. 6/22/18 - Positive for Alcohol. 7/10/18 - Positive for Alcohol. 8/27/18 - Positive for Alcohol. 9/24/18 - Negative. 10/24/18 - Positive for Alcohol. 11/9/18 - Positive for Alcohol. 12/14/18 - Negative. 1/18/19 - Positive for Alcohol.	V 105	The Medical Director made the decision to increase the dose in an efffort to try and stabilize the patient. This was done for a short time period and monitored. The Medical Director then started tapering the patient after the patient was stabilized.	

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V 105	Continued From page 6 2/25/19 - Positive for Alcohol. 3/13/19 - Negative. 4/10/19 - Positive for Alcohol. May 2019 - No UDS obtained (this results in a positive result). 6/20/19 - Positive for Alcohol. 7/19/19 - Positive for Alcohol. 8/17/19 - Positive for Alcohol. 9/3/19 - Positive for Alcohol. 10/28/19 - Positive for Alcohol. Of the 20 UDSs collected in the 21 month period from 2/20/18 through 10/28/19, 15 were positive for Alcohol and 6 were negative. All of these UDSs were tested for Benzodiazepines and the results were negative. Review on 1/24/20 of DC #1's record revealed the following documentation by the Medical Director or his Physician's Assistant; 1/11/18 Intake Assessment, initial history and physical; -- "HX (history) of minimal benzo (Benzodiazepine) use - discussed half life of Methadone and heroin. Discussed importance of no Benzo (Benzodiazepine Policy) - pt (patient) commits to safety Does have hx of panic disorder. Pt commits to no benzo - and treatment of panic with his MD (physician) with gabapentin (Neurontin)..." -- "Current meds (medications) include Neurontin for migraine - hx of ? (questionable) BP (blood pressure) elevation, on no meds..." -- "No psychiatric history..." -- "EKG (electrocardiogram) Long QT interval: 418/470" --"BP (blood pressure) elevated see exam sheet... -- "CSRS (controlled substance reporting system)	V 105	Testing has been changed to cover klonopin by random tests for patients who have a verified perscription for Klonopin or any benzodiazepine. The staff can request this test at any time. The Controlled Substance Reporting System (CSRS) is ran quarterly and saved to the patient's medical record. This is reviewed by the clinical staff and medical staff. Any patient that has a benzodiazepine perscription will be subject to additonal random UDS screens to include testing for Klonopin and the results verified.	

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V 105	Continued From page 7 okay, Oxy (an opiate pain medication prescription) in August..." -- (Methadone is a synthetic opioid associated with prolonged QT intervals and TdP (Torsades de Pointes). As the QT interval increases, so does the risk for life threatening arrhythmias. An arrhythmia is a problem with the rate or rhythm of your heartbeat. It means that your heart beats too quickly, too slowly, or with an irregular pattern. Identify high risk patient populations - personal or family history of arrhythmias). (On 3/19/19 DC #1 reported to his Counselor that his Mother had two heart attacks while she was alive). 1/22/18; -- "Pt is on 50 mg (of Methadone) a day." -- "Has Neurontin 300 mg. BID (twice a day) and PRN (as needed) for migraine prevention..." -- "Recent panic attack. Aware of no benzo in this clinic. Managed with Neurontin and slow breathing..." -- "Hx of some panic and has used benzo in past - but aware of no benzo and commits to safety..." -- "Committed to no benzo use..." 1/29/18; -- "...Pt started on pain management - and abused the pain pills (past history) after a severe motorcycle accident.." -- "On Gabapentin (Neurontin) 300 mg. TID (three times a day) - no other drugs..." -- "Current dose (of Methadone) is 65 mg. going to 75 mg...." -- "Plan: will repeat EKG and evaluate for inc (increased) dose over next 3 weeks." 3/7/18; -- "Patient started to feel good on current Methadone - but lately - not sleeping - lot on mind - so worries a lot..."	V 105		

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V 105	Continued From page 8 -- "Plan: inc Methadone to 120 mg. at 5 mg, q (every) 4 days then trough (a blood test drawn at the time of lowest Methadone level, called a trough level, just before the next dose is due), than see again." 4/12/18; -- "Pt has been asking to dec (decrease Methadone dose) met with pt to understand issue..." -- "Plan: dec Methadone from 110 mg. to 90 mg. at 5 mg. a week starting 4/23..." 12/19/18; -- "Current dose is 60 mg. (of Methadone) and he has been trying to taper..." - "Needs to go to groups and get off alcohol and bring in Klonopin script (prescription) - takes 0.5 mg. every other day." -- "Patient is on Gabapentin (Neurontin) 300 mg. 2 (tablets) TID (three times a day) - for nerve pain - only takes 2 (tablets) BID (twice a day) and is on Nyquil and PRN Klonopin..." -- "Patient to see therapist. To get PE (physical exam) and labs and return one year." 12/19/18; -- "Patient presents for his APE (annual physical exam). His current dose is at 60 mg. which keeps him comfortable. Pt had recent bronchitis, UDS EtOH on. Consider treatment team..." *See Tag V-238, Outpatient - Operations for additional specific information regarding urine drug testing. Interview on 1/24/20 with Counselor #1 revealed that he had on one occasion requested that DC #1 bring in his prescription or the bottles with his Klonopin in them for review by the medical staff.	V 105	Ref. previous correction action on pg. 7	

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V 105	Continued From page 9 Interview on 1/24/20 with the Clinic Director revealed the following information; -- All clients on prescription controlled medications are required to bring in the prescription and/or the medications and give them to the nursing staff to document in the client records. -- She confirmed that this procedure did not occur during DC #1's treatment episode (1 year, 10 months). -- She was unable to state why this procedure did not occur. This deficiency is cross referenced into 10A NCAC 27G .3601 Outpatient Opioid Treatment Scope (V-233) for a Type A1 rule violation and must be corrected within 23 days.	V 105	A training was conducted for all clinical staff on 3/2/2020 to discuss the procedures when a patient fails to present current medications in a timely manner. The Medical staff reviews all positive urine drug screen(UDS) and any result that is positive for an illicit substance requires the medcial staff to notify the Clinical staff. The patients clinician will place a dosing hold on the patient, conduct a session with the patient to verify if it is a legitimate pescription and schedule a medical appointment with the Medical staff to address it. Without a valid pescription in the patients chart, the test will be considered illicit thus revoking any privileges such as take home doses. This will also be addressed in a treatment team meeting to provide the Medical Director with any additional information revelant to the patient.	
V 112	27G .0205 (C-D) Assessment/Treatment/Habilitation Plan 10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN (c) The plan shall be developed based on the assessment, and in partnership with the client or legally responsible person or both, within 30 days of admission for clients who are expected to receive services beyond 30 days. (d) The plan shall include: (1) client outcome(s) that are anticipated to be achieved by provision of the service and a projected date of achievement; (2) strategies; (3) staff responsible; (4) a schedule for review of the plan at least annually in consultation with the client or legally	V 112	The Treatment plan should be reviewed with the patient once a month if they have been with BAART for more than a year. Twice a month if less than a year.Coulselors are responsible for this and a training was conducted on 2/27/2020 with the clinical staff to reiterate the requirements to them. Patient's goals and timeframe for review will have as an objective to minimize behaviors that are disruptive to patient's daily life skills, including the use of illicit substances, not attending sessions with a primary care provider if physical health issues are evident, or obtaining a primary care provider even through charity care if patient is uninsured, etc.	

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V 112	Continued From page 10 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. This Rule is not met as evidenced by: Based on interview and record review, the facility management failed to develop and implement strategies and interventions to address the identified needs of 1 of 2 deceased clients reviewed (DC #1). The findings are: Review on 12/13/19 and 1/24/20 of DC #1's record revealed the following information; -- 64 year old male. -- Admitted to the facility on 1/11/18. -- Date of death 11/19/19. -- Last contact with client at the clinic was on 11/9/19 when he attempted to dose with his daily Methadone. -- Last documented contact with Counselor 9/3/19. -- This was the client's first time in an Opioid Treatment Program -- Diagnoses of Opioid Use Disorder - Severe. -- 20 year history of use/abuse of opioids due to chronic pain. -- Switched to heroine when medications became too expensive and was actively using 1/2 to 1 gram daily. -- Had been a patient at 2 different pain	V 112	Counselor will review progress of patient or lack of progress on a weekly basis if patient is using benzodiazepines or alcohol. Breathalyzer will continue to be utilized on a daily basis for patients who present at the clinic as being intoxicated from alcohol and patient will not be dosed if presented as being under the influence of unknown substances. Training was conducted to reiterate to the staff the requirements and expectations.	

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V 112	Continued From page 11 management clinics (last one ending in January 2017), but was discharged due to continued illicit use of other medication. -- During his time in treatment, the client remained at Level 1, with no take-home doses of Methadone earned. Review on 1/27/20 of DC #1's record revealed the following information; -- DC #1's initial treatment plan dated 1/11/18 identified a Panic Disorder diagnosis. This treatment plan was signed by the treatment team and the Medical Director on 1/11/18. Review on 1/27/20 of DC #1's record revealed the following information; -- DC #1's current treatment plan dated 1/16/19 signed by the treatment team including Counselor #1 and the same Medical Director on 1/16/19 document the following information; -- "No Mental Health Diagnoses." -- "Panic Attacks: Denies Symptoms." -- "Anxiety: Denies Symptoms." Review on 1/24/20 of DC #1's current treatment plan dated 1/16/19 revealed the following goals; -- #1 Abstinence from illicit drugs. -- #2 Medical/Primary care. -- #3 Mental Health. To obtain his goals the following interventions will be used; -- "[DC #1] will attend a program orientation group within the 1st 30 days of treatment. Frequency: 1 time in the first 30 days of treatment." -- "[DC #1] will participate with treatment by attending all scheduled individual counseling sessions. Frequency: 1 unit a month or as needed." -- "[DC #1] will participate in treatment by	V 112		

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V 112	Continued From page 12 attending group counseling sessions to provide treatment support and aid in recovery. Frequency: 1 unit a week or as needed." -- "[DC #1] will provide random drug screens (observed and unobserved) when requested. Frequency: 1 time a month and when requested by staff." Review on 1/24/20 of DC #1's current treatment plan dated 1/16/19 revealed updates to this treatment plan on 1/16/19, 4/25/19, 7/26/19 and 9/3/19 documenting the following information; -- All updates identify urine drug screens both negative and positive for alcohol. -- All updates identify the client picking up prescribed Klonopin every month. -- All updates indicate "[DC #1] continues to meet criteria for OST (Opioid substitution therapy) and is recommended to continue services, including dosing, counseling, group counseling, medication management and medical support." -- In reviews on 7/26/19 and 9/3/19 the client and Counselor #1 were discussing and working toward a transition/discharge plan. -- Review on 9/13/19 documents "All current medications: Klonopin 0.5 mg. daily." -- Review of Goal #2 on 1/16/19 revealed the following information; "A letter has been faxed to any current medical providers, providing important information necessary for proper coordination of care (intake date, current dose, contact information) and requesting information on any medications that he is currently prescribed..." -- No strategies and interventions to address continued alcohol consumption or use of a Benzodiazepine while on Methadone. Review on 1/24/20 of DC #1's record revealed the following Individual Counselor notes;	V 112		

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V 112	Continued From page 13 No documentation of any individual counseling in April or May 2018. 6/29/18 (DC #1's first meeting with Counselor #1); -- Current dose of Methadone 90 mg. a day. -- "Counselor introduced himself to patient as a new counselor and conducted a brief check-in..." -- "Counselor and patient reviewed patient's recent UDS (urine drug screen) results: 6/22/18 positive for EtOH (alcohol); 5/23/18 positive for EtOH; 4/9/18 negative..." -- "Counselor provided information regarding dangers of mixing drugs like alcohol and Methadone... Patient reported that he was unaware of the danger of drinking alcohol while taking opiates and that he appreciates the information given to him today about drug combinations and contraindications." -- "Patient reported that he and his wife 'drank some wine with friends at their house while having dinner,' reported that he foresees no issues with eliminating his drinking while he remains on Methadone..." No documentation of any individual counseling in July, August or September 2018. 10/8/18; -- Current dose of Methadone 70 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 9/24/18 negative; 8/27/18 positive for EtOH; 7/10/18 positive for EtOH... Counselor completed a check of patient's NC (North Carolina) CSRS (Controlled Substance Reporting System) - as expected, patient has Klonopin Rx (prescription) 0.5 mg., QTY: (quantity) 30 (tablets), Days: 15, last fill date 9/19/18)."	V 112	All the current counselors are aware of the requirments for sessions and monitored by the Clinical Supervisor, Treatment Center Director and Corporate Compliance. Ref. above correction action	

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V 112	Continued From page 14 --" Patient reported understanding and accepting potential dangers of BZP (benzodiazepine) Rx and that he has kept his primary care provider and OPT (Opioid treatment) provider informed about all RX. Patient reports that 'I do enjoy just having a beer while watching a football game;' but that he has stopped drinking while in MAT (Methadone assisted treatment) program..." 11/16/18; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 11/9/18 positive for EtOH; 10/24/18 positive for EtOH; 9/24/18 negative... Counselor provided information regarding dangers of mixing alcohol and opiates... --"Patient reported that he does drink 'very infrequently' and 'really only when I'm watching a football game or relaxing at home.' Counselor and patient discussed dangers of mixing alcohol and opiates... Patient reported committing to not drinking through the holidays and returning for another session to evaluate how he enjoyed holiday time while not drinking..." 12/5/18; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 11/9/18 positive for EtOH; 10/24/18 positive for EtOH; 9/24/18 negative..." -- "Patient reported success in decreasing his alcohol use and being confident that his next UDS will be negative for all substances except Methadone... 1/16/19; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 12/14/18 negative; 11/9/18 positive for EtOH; 10/24/18 positive for EtOH..."	V 112		

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V 112	Continued From page 15 -- "Counselor completed a check of patient's NC CSRS - as expected, Klonopin Rx (last filled 1/13/19, 45, 0.5 mg. for 22 days)." -- "Counselor informed patient of requirement to bring in all medications for counting and approval by BAART medical staff.. 2/12/19; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 1/18/19 positive for EtOH; 12/14/18 negative; 11/9/18 positive for EtOH." 3/19/19; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 3/13/19 negative; 2/25/19 positive for EtOH; 1/18/19 positive for EtOH." -- "Patient reported having completed an MRI (magnetic resonance imaging test) at [name of local hospital] on 3/14/19 per follow-up from his primary care provider concerning patient's episodes of shortness of breath. Patient reported that his Mother had two heart attacks while she was alive..." -- "Patient experience of having used Nyquil and having been instructed by BAART lead Nurse to use a different medication due to patient testing positive for EtOH..." 4/25/19; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 4/10/19 positive for EtOH; 3/13/19 negative; 2/25/19 positive for EtOH." -- "Counselor completed a check of patient's NC CSRS - Patient continues to fill regular Klonopin Rx (QTY: 30, 0.5 mg, 15 days, last filled on 4/16/19). -- "Patient reported 'I was happy about the	V 112		

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V 112	Continued From page 16 progress I had made to taper my Methadone dose, but here in the last month, I have been waking up in the night with withdrawals, shaking terribly, stomach issues, issues going to the bathroom, sweating. I'd like to ask for a small increase to my Methadone dose today'..." 5/30/19; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 4/10/19 positive for EtOH; 3/13/19 negative; 2/25/19 positive for EtOH." -- "Patient reported feeling like he has struggled to make progress toward his treatment goals due to his continued experience of physical health problems. Patient reported being confident that his May UDS results would be negative for all illicit substances and EtOH..." -- "Counselor and patient processed patient's recent experience increasing his Methadone dose only to immediately decrease due to excessive drowsiness, processed patient's fears associated with overmedication..." -- "Patient reported having an MRI scheduled for tomorrow 8:45 am to assess stomach/liver pain he has had for about a week..." 6/14/19; -- Current dose of Methadone 60 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 4/10/19 positive for EtOH; 3/13/19 negative; 2/25/19 positive for EtOH." 7/26/19; -- Current dose of Methadone 52 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 7/19/19 positive for EtOH; 6/20/19 positive for EtOH; 4/10/19 positive for EtOH." -- "Counselor completed a check of patient's NC	V 112		

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V 112	Continued From page 17 CSRS - Patient continues to fill regular Klonopin Rx (last filled 7/13/19: QTY: 30, 0.5 mg, 15 days)." -- "Patient reported that he continues to taper at a rate of 2 mg. per week, reported having dosed today at 52 mg. Methadone..." 8/29/19; -- Current dose of Methadone 52 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results; 8/7/19 positive for EtOH; 7/19/19 positive for EtOH; 6/20/19 positive for EtOH." -- "Patient reported plans to have blood sugar tested by medical provider..." 9/3/19 (Counselors last documented contact with client); -- Current dose of Methadone 52 mg. a day. -- "Counselor and patient reviewed patient's recent UDS results: 8/7/19 positive for EtOH; 7/19/19 positive for EtOH; 6/20/19 positive for EtOH." -- "Counselor completed a check of patient's NC CSRS - continues to fill monthly Klonopin prescription (last filled 8/14/19: QTY: 60, 0.5 mg, 30 days)..." No documentation of any individual counseling in October or November 2019. Urine Drug Screens were obtained monthly (except for in May 2019), and of the 20 UDSs collected in the 21 month period from 2/20/18 through 10/28/19, 14 were positive for Alcohol and 6 were negative. Review on 1/27/20 of the above Individual Counseling notes revealed the following; -- No strategies or interventions to address DC	V 112	Ref. previous corrective action on pg. 14	

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V 112	Continued From page 18 #1's continued UDSs positive for alcohol. – No strategies or interventions to address DC #1's continued ingestion of the Benzodiazepine Klonopin. This deficiency is cross referenced into 10A NCAC 27G .3601 Outpatient Opioid Treatment Scope (V-233) for a Type A1 rule violation and must be corrected within 23 days.	V 112	A training was conducted on 2/27/2020to address the regulations regarding any sceen that results in an illicit substance to include alcohol and what happens as a result of the illicit screen.	
V 233	27G .3601 Outpt. Opiod Tx. - Scope 10A NCAC 27G .3601 SCOPE (a) An outpatient opioid treatment facility provides periodic services designed to offer the individual an opportunity to effect constructive changes in his lifestyle by using methadone or other medications approved for use in opioid treatment in conjunction with the provision of rehabilitation and medical services. (b) Methadone and other medications approved for use in opioid treatment are also tools in the detoxification and rehabilitation process of an opioid dependent individual. (c) For the purpose of detoxification, methadone and other medications approved for use in opioid treatment shall be administered in decreasing doses for a period not to exceed 180 days. (d) For individuals with a history of being physiologically addicted to an opioid drug for at least one year before admission to the service, methadone and other medications approved for use in opioid treatment may also be used in maintenance treatment. In these cases, methadone and other medications approved for use in opioid treatment may be administered or dispensed in excess of 180 days and shall be administered in stable and clinically established dosage levels.	V 233		

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V 233	Continued From page 19 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 1 of 2 deceased clients reviewed (DC #1). The findings are: Review on 12/13/19 and 1/24/20 of DC #1's record revealed the following information; -- 64 year old male. -- Admitted to the facility on 1/11/18. -- Date of death 11/19/19. -- Last contact with client at the clinic was on 11/9/19 when he attempted dose with his daily Methadone. -- Last documented contact with Counselor 9/3/19. -- This was the client's first time in an Opioid Treatment Program -- Diagnoses of Opioid Use Disorder - Severe. -- 20 year history of use/abuse of opioids due to chronic pain. -- Switched to heroine when medications became too expensive and was actively using 1/2 to 1 gram daily. -- Had been a patient at 2 different pain management clinics (last one ending in January 2017), but was discharged due to continued illicit use of other medication. -- During his time in treatment, the client remained at Level 1, with no take-home doses of Methadone earned.	V 233	During the course of treatment, the patient was not allowed to recieve any privileges such as take home doses. The patient was screened consistently and given breathalyzer tests on multiple occasions resulting in multiple refusals to dose. This is an example of the clinics repeated efforts to encourage the patient to discontinue the use of alcohol.	

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V 233	Continued From page 20 Cross Reference: Tag V-105, 10A NCAC 27G .0201, GOVERNING BODY POLICIES. Based on records review and interviews, the facility failed to ensure policies and procedures to assure meeting of applicable standards of practice were implemented. Cross Reference: Tag V-112, 10A NCAC 27G .0205, ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN. Based on interview and record review, the facility management failed to develop and implement strategies and interventions to address the identified needs of 1 of 2 deceased clients reviewed (DC #1). Cross Reference: Tag V-238, 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 Screens (UDSs) frequency, UDS testing requirements, take home doses of Methadone and orientation to the program affecting 1 of 2 deceased clients reviewed (DC #1). FINDING #1; Review on 12/13/19 of DC #1's record revealed the following interactions documented with the nursing staff: 3/4/19 - Nurses Note; -- "Patient presented to the dosing window 2, face flushed and smell of alcohol noted. Writer performed a breathalyzer. Reading .037. Writer informed patient that he would not be able to dose." – "Patient stated 'I have a cold. I have been	V 233	Testing was done to identify any illicit drug use. Sessions were done to encourage the patient to address his identified needs. It was noted that a stated goal for the patient was to primary care as noted on pg. 12 of this report. The Medical Director's decision to keep this patient in the clinic is one that we feel was the right decision and disagree with the finding that we failed to develop a strategy that was the best for the patient.	

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V 233	Continued From page 21 taking Nyquil' writer informed patient that he should take cough syrup that doesn't contain alcohol." 9/6/19 - Nurse's Note; -- Client was given a breathalyzer test at 10:12 am prior to dosing. -- Results - .000, Client dosed at 52 mg. of Methadone. -- No documentation regarding reason for breathalyzer test. 10/9/19 - Nurse's Note; -- "Patient came in to dose today early am - Nurse at first dosing window advised patient to come to the second window to have BZ (breathalyzer alcohol test). Patient elected to leave clinic without BZ and dosing." -- "Patient came back in afternoon close to closing asking if he could dose, Nurse informed him a BZ would have to be done prior to dosing. Patient stated that's why he won't do the BZ, he doesn't feel well stating he is sick." -- "Patient did not perform BZ and therefore was not dosed today. UDS's 9/6, 7/19, 6/20/19 positive for EtOH (alcohol). Patient flagged for BZ tomorrow." -- "Counselor notified by BAART email." 10/10/19 - Nurse's Note; -- Client was given a breathalyzer test at 7:23 am prior to dosing. -- Results - .000, Client dosed at 52 mg. of Methadone. 11/6/19 - Nurse's Note; -- "Patient came in to clinic today and was to be breathylized - patient voiced he had EtOH last evening asking if he could come back later to be breathylized and dose before we close."	V 233	A training was conducted with the nursing staff On 2/27/2020 to ensure that they complete the notes for any testing done. They are aware that they should not dose a patient if they percieve that the patient is not in an adequate physical condition to recieve the medication. Ref. above corrective action	

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V 233	Continued From page 22 --"Nurse agreed - patient did not return to dose." -- "Counselor notified per BAART email." 11/7/19 - Nurse's Note; -- "Patient missed 2nd day of dosing. Patient's voice mail at [phone number] does not identify patient, so unable to leave a message." 11/8/19 - Nurses's Note; -- Client was given a breathalyzer test at 7:43 am prior to dosing. -- Results - .058, Client not dosed. -- "No dose due to positive breathalyzers previous 3 (three) days." -- "Counselor has been informed, and a Level 1 incident report has been submitted to CD (Clinic Director)." 11/9/19 - Nurses's Note (last clinic contact with client prior to his death on 11/19/19); -- "Patient present to dosing window; skin flushed, hands shaky, stating 'I should be fine today as I have not drank in two days and missed three days of dosing.' Breathalyser reading today (at 9:06 am) .076 no dose given per protocol. Patient has missed four (4) days of dosing." -- "Advised to go to ER (emergency room) for evaluation for EtOH seizures." Review on 1/24/20 of DC #1's record revealed no documentation of any attempted outreach to the client after being absent from the clinic until his death was reported (11 days later). This was despite having multiple recent positive alcohol breathalyzer tests, and being unable to receive his Methadone dose due to this. Interview on 1/24/20 with the Medical Director and his Physician's Assistant revealed that neither of them were informed of the positive	V 233	A Training was conducted on 2/27/2020 and 3/2/2020 that covered the following reiterating the procedures. The clinical staff are required to call every patient that misses two consecutive doses and any patient that misses 3 consecutive days requires an incident report be completed which is reviewed by the Medical Director and Treatment Center Director. If a patient returns after 3 consecuitive missed days, they must be reinstated by the Medical Director. The patients are discharged after 14 days with no contact. If the patients contact information is valid, additional attempts will be made periodically to reach out any those previous patients.	

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V 233	Continued From page 23 breathalyzer tests. FINDING #2; Review on 1/27/20 of DC #1's record revealed the following information; -- A Release Of Information (ROI) dated 1/11/18, signed by the client permitting exchange of information with his Primary Care Physician. -- A fax cover sheet indicating that the ROI was sent to the client's Physician. -- The North Carolina Controlled Substance Reporting System (NC CSRS) was checked on the following dates; 1/11/18 (on admission to the program), 6/29/18, 10/8/18, 1/16/19, 4/25/19, 7/26/19, 9/3/19 and one on 11/20/19 following the report of his death. -- Results of the above NC CSRS reports revealed the client filled prescriptions every month from 4/11/18 through 10/14/19 for Klonopin 0.5 mg. to be taken twice a day, and there were 4 different prescribing Physician's for this Klonopin. 1/29/18 - Medical Director note; -- "On Gabapentin (Neurontin) 300 mg. TID (three times a day) - no other drugs..." 12/19/18 - Medical Director note; -- "Current dose is 60 mg. (of Methadone) and he has been trying to taper..." - "Needs to go to groups and get off alcohol and bring in Klonopin script (prescription) - takes 0.5 mg. every other day." -- "Patient is on Gabapentin (Neurontin) 300 mg. 2 (tablets) TID (three times a day) - for nerve pain - only takes 2 (tablets) BID (twice a day) and is on Nyquil and PRN Klonopin..." 3/19/19 - Counselor Note; -- "Patient reported having completed an MRI	V 233	All positive tests are to be given to the Medical Staff. Training was conducted on this on Ref. previous corrective action on pg.7	

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V 233	Continued From page 24 (magnetic resonance imaging test) at [name of local hospital] on 3/14/19 per follow-up from his Primary Care Provider concerning patient's episodes of shortness of breath. Patient reported that his Mother had two heart attacks while she was alive..." 4/25/19 - Counselor note; -- "...[DC #1] reports that his primary care provider started him on a new blood pressure medication last month due to an irregularity found during one of [DC #1's] MRI..." -- No documentation that any information was received by the client's Physician. -- No documentation that any additional attempts were made to establish contact with this Physician, or obtain any medical information on DC #1. Review on 1/24/20 of the Plan Of Protection dated 1/24/20 written by the Clinic Director revealed the following information; "What immediate action will the facility take to ensure the safety of consumers in your care? The Clinic Director will meet with counseling staff on Monday, January 27, 2020 to discuss the Plan of Protection due to possible neglect of patient [DC #1's patient number] that could have contributed to his death. - Counselors from this point forward will review monthly drug screen results for all patients assigned to their caseload and communicate any positive UA (urinalysis) results for Benzodiazepines to the Clinical Director. - The Clinical Director will call a meeting with the Management Team that includes the Medical Director to discuss next steps for the patient, including coordination of care with the patient's Primary Care Physician.	V 233	Training was conducted on that discussed Coordination of Care (CoC) and how this can be improved upon. The clinic is also recuriting for a clinician that will also serve a role as the Coordination of Care liaison for the clinic. This person will have a background in CoC and work to establish contacts in the area that meet the needs of our referred patients.	

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V 233	Continued From page 25 - The Medical Director will meet with each patient who presents with a positive Benzodiazepine result at least once a week to monitor Benzodiazepine use and continued coordination of care. - Counselors will continue to meet with patients with Benzodiazepine positives at least twice a month to monitor patient progress. - Counselors will develop a spreadsheet of the affected patients and will submit it to the Clinic Director at the end of each counseling session with progress made towards patient follow up with Medical Director." DC #1 had a 20 year history of Opiate use and misuse with Heroin use as well. This client used alcohol and Benzodiazepines on a regular basis in addition to his Methadone for months without attention to this issue, and during that extended period, he was administered Methadone at or above what the facility's policy states is safe thereby creating an additional risk of over sedation and heart irregularities. The facility failed to coordinate care with the prescriber of the client's medications. Of the 20 UDSs collected in the 21-month period from 2/20/18 through 10/28/19, 15 were positive for Alcohol and 6 were negative. He began continuously testing positive for alcohol in April 2019 and had 7 consecutive urine drug screens positive for alcohol prior to his death on 11/19/19. There were no goals or strategies developed or implemented to address his alcohol use. Weekly urine drug screens were never implemented, and counseling sessions did not indicate attention to his alcohol or Benzodiazepine use. DC #1 was in treatment at the facility for almost 2 years (1 year and 10 months). The failures to adhere to multiple clinic policies and	V 233	The patient was given multiple breathalyzer tests and was not allowed to dose on multiple occasions due to his alcohol use. The patient was denied privileges as a result of alcohol use.	

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V 233	Continued From page 26 state/government rules and regulations placed this client at a significant increased risk of suppression to the central nervous system or fatal overdose. This constitutes a Type A1 rule violation for serious neglect and must be corrected within 23 days. An administrative penalty of $15,000.00 is imposed. If the violation is not corrected within 23 days an additional administrative penalty of $500.00 per day will be imposed for each day the facility is out of compliance beyond the 23rd day.	V 233		
V 238	27G .3604 (E-K) Outpt. Opiod - Operations 10A NCAC 27G .3604 OUTPATIENT OPIOD TREATMENT. OPERATIONS. (e) The State Authority shall base program approval on the following criteria: (1) compliance with all state and federal law and regulations; (2) compliance with all applicable standards of practice; (3) program structure for successful service delivery; and (4) impact on the delivery of opioid treatment services in the applicable population. (f) Take-Home Eligibility. Any client in comprehensive maintenance treatment who requests unsupervised or take-home use of methadone or other medications approved for treatment of opioid addiction must meet the specified requirements for time in continuous treatment. The client must also meet all the requirements for continuous program compliance and must demonstrate such compliance during the specified time periods immediately preceding any level increase. In addition, during the first year of continuous treatment a patient must	V 238		

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V 238	Continued From page 27 attend a minimum of two counseling sessions per month. After the first year and in all subsequent years of continuous treatment a patient must attend a minimum of one counseling session per month. (1) Levels of Eligibility are subject to the following conditions: (A) Level 1. During the first 90 days of continuous treatment, the take-home supply is limited to a single dose each week and the client shall ingest all other doses under supervision at the clinic; (B) Level 2. After a minimum of 90 days of continuous program compliance, a client may be granted for a maximum of three take-home doses and shall ingest all other doses under supervision at the clinic each week; (C) Level 3. After 180 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 2, a client may be granted for a maximum of four take-home doses and shall ingest all other doses under supervision at the clinic each week; (D) Level 4. After 270 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 3, a client may be granted for a maximum of five take-home doses and shall ingest all other doses under supervision at the clinic each week; (E) Level 5. After 364 days of continuous treatment and a minimum of 180 days of continuous program compliance, a client may be granted for a maximum of six take-home doses and shall ingest at least one dose under supervision at the clinic each week; (F) Level 6. After two years of continuous treatment and a minimum of one year of continuous program compliance at level 5, a client may be granted for a maximum of 13	V 238		

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V 238	Continued From page 28 take-home doses and shall ingest at least one dose under supervision at the clinic every 14 days; and (G) Level 7. After four years of continuous treatment and a minimum of three years of continuous program compliance, a client may be granted for a maximum of 30 take-home doses and shall ingest at least one dose under supervision at the clinic every month. (2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility: (A) A client's take-home eligibility is reduced or suspended for evidence of recent drug abuse. A client who tests positive on two drug screens within a 90-day period shall have an immediate reduction of eligibility by one level of eligibility; (B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and (C) The reinstatement of take-home eligibility shall be determined by each Outpatient Opioid Treatment Program. (3) Exceptions to Take-Home Eligibility: (A) A client in the first two years of continuous treatment who is unable to conform to the applicable mandatory schedule because of exceptional circumstances such as illness, personal or family crisis, travel or other hardship may be permitted a temporarily reduced schedule by the State authority, provided she or he is also found to be responsible in handling opioid drugs. Except in instances involving a client with a verifiable physical disability, there is a maximum of 13 take-home doses allowable in any two-week period during the first two years of continuous treatment. (B) A client who is unable to conform to the applicable mandatory schedule because of a verifiable physical disability may be permitted	V 238		

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V 238	Continued From page 29 additional take-home eligibility by the State authority. Clients who are granted additional take-home eligibility due to a verifiable physical disability may be granted up to a maximum 30-day supply of take-home medication and shall make monthly clinic visits. (4) Take-Home Dosages For Holidays: Take-home dosages of methadone or other medications approved for the treatment of opioid addiction shall be authorized by the facility physician on an individual client basis according to the following: (A) An additional one-day supply of methadone or other medications approved for the treatment of opioid addiction may be dispensed to each eligible client (regardless of time in treatment) for each state holiday. (B) No more than a three-day supply of methadone or other medications approved for the treatment of opioid addiction may be dispensed to any eligible client because of holidays. This restriction shall not apply to clients who are receiving take-home medications at Level 4 or above. (g) Withdrawal From Medications For Use In Opioid Treatment. The risks and benefits of withdrawal from methadone or other medications approved for use in opioid treatment shall be discussed with each client at the initiation of treatment and annually thereafter. (h) Random Testing. Random testing for alcohol and other drugs shall be conducted on each active opioid treatment client with a minimum of one random drug test each month of continuous treatment. Additionally, in two out of each three-month period of a client's continuous treatment episode, at least one random drug test will be observed by program staff. Drug testing is to include at least the following: opioids,	V 238		

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V 238	Continued From page 30 methadone, cocaine, barbiturates, amphetamines, THC, benzodiazepines and alcohol. Alcohol testing results can be gathered by either urinalysis, breathalyzer or other alternate scientifically valid method. (i) Client Discharge Restrictions. No client shall be discharged from the facility while physically dependent upon methadone or other medications approved for use in opioid treatment unless the client is provided the opportunity to detoxify from the drug. (j) Dual Enrollment Prevention. All licensed outpatient opioid addiction treatment facilities which dispense Methadone, Levo-Alpha-Acetyl-Methadol (LAAM) or any other pharmacological agent approved by the Food and Drug Administration for the treatment of opioid addiction subsequent to November 1, 1998, are required to participate in a computerized Central Registry or ensure that clients are not dually enrolled by means of direct contact or a list exchange with all opioid treatment programs within at least a 75-mile radius of the admitting program. Programs are also required to participate in a computerized Capacity Management and Waiting List Management System as established by the North Carolina State Authority for Opioid Treatment. (k) Diversion Control Plan. Outpatient Addiction Opioid Treatment Programs in North Carolina are required to establish and maintain a diversion control plan as part of program operations and shall document the plan in their policies and procedures. A diversion control plan shall include the following elements: (1) dual enrollment prevention measures that consist of client consents, and either program contacts, participation in the central registry or list exchanges;	V 238		

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V 238	Continued From page 31 (2) call-in's for bottle checks, bottle returns or solid dosage form call-in's; (3) call-in's for drug testing; (4) drug testing results that include a review of the levels of methadone or other medications approved for the treatment of opioid addiction; (5) client attendance minimums; and (6) procedures to ensure that clients properly ingest medication. This Rule is not met as evidenced by: Based on interview and record review, the facility management failed to ensure program compliance in the areas of Individual Counseling, Urine Drug Screens (UDSs) frequency, UDS testing requirements, take home doses of Methadone and orientation to the program affecting 1 of 2 deceased clients reviewed (DC #1). The findings are: Review on 12/13/19 and 1/24/20 of DC #1's record revealed the following information; -- 64 year old male. -- Admitted to the facility on 1/11/18. -- Date of death 11/19/19. -- Last contact with client at the clinic was on 11/9/19 when he attempted dose with his daily Methadone. -- Last documented contact with Counselor 9/3/19. -- This was the client's first time in an Opioid Treatment Program -- Diagnoses of Opioid Use Disorder - Severe. -- 20 year history of use/abuse of opioids due to chronic pain.	V 238		

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V 238	Continued From page 32 -- Switched to heroine when medications became too expensive and was actively using 1/2 to 1 gram daily. -- Had been a patient at 2 different pain management clinics (last one ending in January 2017), but was discharged due to continued illicit use of other medication. -- During his time in treatment, the client remained at Level 1, with no take-home doses of Methadone earned. FINDING #1 - (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"); Review on 1/24/20 of DC #1's record revealed the following information; -- From his admission to the program on 1/11/18 through when Counselor #1 was assigned to his case on 6/29/18, he did not have a consistent assigned Counselor. -- A Counselor met with the client in February, March and May 2018 (prior to Counselor #1 becoming responsible in June 2018). -- There was no documentation of any contact with a Counselor in April 2018. Additional review on 1/24/20 of DC #1's record revealed the following information; -- Counselor #1 met with him 1 time a month during his first year of treatment for individual counseling in the following months: June, October, November, December 2018 and in January 2019. -- There was no documentation of any individual counseling in July, August or September 2019 during his first year in treatment. -- During each of the above documented	V 238		

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V 238	Continued From page 33 individual counseling sessions, Counselor #1 and the client reviewed his UDS results. Review on 1/27/20 of DC #1's record revealed the following information; -- Counselor #1 met with him 1 time a month during his second year of treatment for individual counseling in the following months: February, March, April, May, June, July, August and September 2019. -- During each of the above documented individual counseling sessions, Counselor #1 and the client reviewed his UDS results. -- There was no documentation of any individual counseling in October or November 2019 during his second year in treatment despite his last 7 UDSs being positive for Alcohol. Interview on 1/24/20 with Counselor #1 revealed the following information; -- He was hired by the facility in June 2018. -- He had been DC #1's Counselor since 6/29/18. -- DC #1 had not been attending Individual Counseling the last few months of his treatment due to his wife having medical problems, and him having to attend to those. -- He did not provide any further information about DC #1 not attending the required amount of Individual Counseling prior to his last few months in treatment. FINDING #2 - (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"); Review on 1/27/20 of DC #1's record revealed the following UDS results; 2/20/18 - Negative.	V 238	Ref. previous corrected action on pg. 14 Ref. corrective action on pg. 14 Attempts were made to get the patient to attend the required sessions. The belief was withholding his dose would put the patient at greater risk.	

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V 238	Continued From page 34 3/5/18 - Negative. 4/9/18 - Negative 5/23/18 - Positive for Alcohol. 6/22/18 - Positive for Alcohol. 7/10/18 - Positive for Alcohol. 8/27/18 - Positive for Alcohol. 9/24/18 - Negative. 10/24/18 - Positive for Alcohol. 11/9/18 - Positive for Alcohol. 12/14/18 - Negative. 1/18/19 - Positive for Alcohol. 2/25/19 - Positive for Alcohol. 3/13/19 - Negative. 4/10/19 - Positive for Alcohol. May 2019 - No UDS obtained (this results in a positive result). 6/20/19 - Positive for Alcohol. 7/19/19 - Positive for Alcohol. 8/17/19 - Positive for Alcohol. 9/3/19 - Positive for Alcohol. 10/28/19 - Positive for Alcohol. Of the 20 UDSs collected in the 21 month period from 2/20/18 through 10/28/19, 15 were positive for Alcohol and 6 were negative. All of these UDSs were tested for Benzodiazepines and the results were negative. FINDING #3 - (UDS Requirements: "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."); Review on 1/27/20 of DC #1's record revealed the following information; -- All of the above UDSs were tested for Benzodiazepines and the results were all	V 238	Ref. previous corrective action on pg.7	

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V 238	Continued From page 35 negative. -- The North Carolina Controlled Substance Reporting System (NC CSRS) was checked on the following dates; 1/11/18 (on admission to the program), 6/29/18, 10/8/18, 1/16/19, 4/25/19, 7/26/19, 9/3/19 and one on 11/20/19 following the report of his death. -- Results of the above NC CSRS reports revealed the client filled prescriptions every month from 4/11/18 through 10/14/19 for Klonopin 0.5 mg. to be taken twice a day, and there were 4 different prescribing Physician's for this Klonopin. Review on 1/27/20 of the "Patient Handbook" given to patients upon admission to the program revealed the following information; -- "There are several medications that you should not take while on Methadone... Other dangerous medications to take while on Methadone are... Benzodiazepines... These medications all depress the heart rate and respiratory (breathing) systems... Methadone depresses these systems as well so there is an increased risk of overdose associated with combining these medications..." -- "Many prescription drugs have possibly fatal results if combined with Methadone including ...Benzodiazepines." -- "Alcohol also depresses your heart rate and respiratory systems. It also interferes with the breakdown of Methadone in your system and may cause overmedication or sedation... " -- "Breathalyzer - BAART has a zero tolerance policy for alcohol use. This is because alcohol mixed with Methadone can be fatal..." -- "Counseling Services: You will be assigned a Counselor and you will see this Counselor regularly. Regularly could be a couple of times per week or it could mean once per month; it depends on your individual needs, how long you have been in treatment and what medications you	V 238		

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V 238	Continued From page 36 are taking." -- "Drug Testing: You will be required to provide urine samples to test for illicit drug use, no less than once per month... Urinalysis results are useful in making decisions about your health, your medication and your overall success treatment." Review on 1/27/20 of a form called "Patient Acknowledgement of Benzodiazepine Policy" signed by DC #1 on 1/11/18 revealed the following information; -- "If you are being treated with Methadone and use Benzodiazepines (such as: Valium, Xanax, Ativan, Klonopin)... you may increase your chances of accidents and injuries to yourself or others and also possible death by overdose..." -- "Any use of these medications without a documented prescription on file with the program is considered 'illicit use' and is considered non-compliance with program expectations..." -- "Use of these medications while also taking Methadone, even with a prescription, still carries risks. Clouded thinking and slowed reactions can be subtle and hard to recognize by the person involved. In addition, these medications all have the potential for abuse and dependence, particularly in individuals with histories of addiction..." Review on 1/24/20 of The Substance Abuse and Mental Health Services Administration (SAMHSA) and The Center for Substance Abuse Treatment (CSAT) Regulations revealed the following information; -- There are 2 main types of UDSs, a screening and a confirmatory test. In general, immunoassay (IAs = screening) tests look for medication/drug metabolites (what a substance becomes when the body breaks it	V 238		

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V 238	Continued From page 37 down). Confirmatory tests detect the presence or absence, and concentration, of a specific medication/drug. Clinicians need to understand that initial testing from IAs offers presumptive results that can be confusing with potential false-positive and false-negative results. -- All initial testing conducted with IAs need to be considered presumptive and can be confusing with potential false-positive and false-negative results. Clinicians need to use clinical judgment, patient history, and collaborative information to decide whether confirmatory testing is necessary for optimal patient care. Confirmatory testing should always be conducted when making legal, forensic, academic, employment or other decisions that have significant ramifications. -- Cutoff values for UDSs define the concentrations needed to produce positive results for IAs and confirmation testing. Results lower than the established cutoff values are reported as negative. Therefore, a negative result does not indicate that a substance is not present, but that the concentration was lower than the established cutoff concentration. -- Benzodiazepines are widely prescribed for use as sedatives, hypnotics, anxiolytics, anticonvulsants, and muscle relaxants. Because of their sedative properties, Benzodiazepines are frequently misused and abused, and chronic use can lead to physiological dependence and addiction. UDSs testing for Benzodiazepines is commonly used to check for medication adherence, evaluate abuse/misuse or to identify medications in overdose or emergency situations. -- Benzodiazepines are secondary to opiates in accidental or intentional overdose situations and are commonly prescribed with other sedating medications. Because of the widespread use of	V 238		

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V 238	Continued From page 38 Benzodiazepines, it is important that clinicians evaluate patient's medication regimen extensively when evaluating UDS results. Interpretation of urine Benzodiazepine IAs can be complex due to Benzodiazepine's metabolic pathway, half-life, potencies and the inability to differentiate between individual Benzodiazepines. -- There are 2 significant limitations of Benzodiazepine IAs that may lead to false-negative results: (1) the IA's inability to detect conjugated metabolites and (2) high cutoff values. The importance of confirmatory testing is emphasized to ensure an accurate and reliable UDS result. Interview on 1/24/20 with the SOTA (State Opioid Treatment Authority) Coordinator revealed the following information; -- She confirmed that it was a SAMHSA regulation that the UDSs obtained from clients have the capability of screening for all Benzodiazepines. -- Frequently Klonopin does not show up on a screening UDS (IAs). -- The clinic needs to do confirmatory testing on clients known to have prescriptions for Benzodiazepines and other medications that do not show up on their standard screening UDSs (some Benzodiazepines, Fentanyl, some sleeping pills, etc.). -- Without the confirmatory testing the clinic can't accurately address the use of these medications with clients. -- The risk of respiratory depression, and even death while taking Methadone is increased with combined use of these medications. Interview on 1/24/20 with the Medical Director revealed that he had instructed DC #1 to bring in	V 238	Ref. corrective action on pg. 7	

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V 238	Continued From page 39 his Klonopin to the clinic. (This is reflected one time when the Medical Director saw the client on 12/19/18 *See Tag V-105 Governing Body Policies for further specific information*). Interview on 1/24/20 with Counselor #1 revealed that he had on one occasion requested that DC #1 bring in his prescription or the bottles with his Klonopin in them for review by the medical staff. Interview on 1/24/20 with the Clinic Director revealed she was not aware that DC #1 had not brought his Klonopin prescription and/or his bottle of Klonopin in for the nursing staff to review. Interview on 1/24/20 with the Physician's Assistant revealed that ideally clients should bring their bottle of a prescribed controlled substances (medications) and show it to the nursing staff when they are about half way done with it, then the nursing staff can more accurately determine if client's are taking the medications as prescribed. None of the above staff interviewed were able to state why the controlled substance procedure was not followed for DC #1. Interview on 1/29/20 with Counselor #1 revealed no one on DC #1's treatment team had suggested the client may need a higher level of care. FINDING #4 - (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	V 238	Ref. corrective action on pg. 26	

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V 238	Continued From page 40 compliance..."); Review on 1/24/20 of the clinic's "Medical - Benzodiazepine Policy" (Updated on 8/13/18) revealed the following information; -- "Patients using Benzodiazepines by prescription will not receive any Take-Home dosages..." Review on 1/27/20 of DC #1's record revealed the following documentation; 9/12/18; -- "Miscellaneous - The patient read the Safety Plan to prevent a possible overdose and signed that it was understood how to remain safe. The patient signed the Safety Plan..." -- "The patient will pick up take homes for 9/14 - 9/16 (3 days) at the dosing window. The patient was offered additional NARCAN to have in case of emergency..." (NARCAN is the antidote to overdoses of Methadone and is used to revive clients who have died from an overdose) 12/7/18; -- "Miscellaneous - The patient read the Safety Plan to prevent a possible overdose and signed that it was understood how to remain safe. The patient signed the Safety Plan..." -- "The patient will pick up take homes for 12/9/18 - 12/10/18 (2 days) at the dosing window. The patient was offered additional NARCAN to have in case of emergency..." Based on review of the above individual counseling sessions, and the client's monthly UDS results, the client should not have been eligible for any take home doses of methadone during his stay in treatment. Interview on 1/24/20 with Counselor #1 revealed no further information regarding the above take	V 238		

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V 238	Continued From page 41 home doses. FINDING #5 - (Required Treatment Orientation Group); Review on 1/24/20 of DC #1's record revealed his initial treatment plan dated 1/11/18 and a subsequent one dated 1/16/19 with the following information; "To obtain his goals the following interventions will be used; [DC #1] will attend a program orientation group within the 1st 30 days of treatment. Frequency: 1 time in the first 30 days of treatment." Review on 1/27/20 of DC #1's Intake Assessment dated 1/11/18 revealed the following information; -- "Client was informed of the requirement of completing an orientation within the two weeks but no longer than 30 days." Review on 1/27/20 of DC #1's record revealed the following documentation; 8/24/18 Orientation Group; -- "Patient attended and participated in the Program Orientation addressing the nature of opiate addiction and the treatment using Medication Assisted Treatment (MAT) via Methadone, ...signs of overdose, interactions with other medications particularly benzodiazepines and alcohol..." --"The Counselor reviewed with the patients the BP (benzodiazepine) policy use of NARCAN and availability through the clinic..." The client was admitted to the clinic on 1/11/18 and was required to attend an Orientation Group within the first 30 days. He did attend the Orientation Group more than 7 months after he was admitted.	V 238		

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V 238	Continued From page 42 Interview on 1/24/20 with Counselor #1 revealed no further information regarding the above Orientation Group. This deficiency is cross referenced into 10A NCAC 27G .3601 Outpatient Opioid Treatment Scope (V-233) for a Type A1 rule violation and must be corrected within 23 days.	V 238	Group sessions are offered however some patients choose to only attend one on one sessions with their individual counselor. The patient in question did attend group but only after some time when they felt comfortable attending a group session. We encourage group session participation however only when we feel the patient's attendence will not impact his or her treatment.	