

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 09/21/2022
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 and follow up survey was completed on September 21, 2022. 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>This facility has a current census of 407. The survey sample consisted of audits of 18 current clients and 2 deceased clients.</p>	V 000		
V 235	<p>27G .3603 (A-C) Outpt. Opiod Tx. - Staff</p> <p>10A NCAC 27G .3603 STAFF (a) A minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients and increment thereof shall be on the staff of the facility. If the facility falls below this prescribed ratio, and is unable to employ an individual who is certified because of the unavailability of certified persons in the facility's hiring area, then it may employ an uncertified person, provided that this employee meets the certification requirements within a maximum of 26 months from the date of employment. (b) Each facility shall have at least one staff member on duty trained in the following areas: (1) drug abuse withdrawal symptoms; and (2) symptoms of secondary complications to drug addiction. (c) Each direct care staff member shall receive continuing education to include understanding of the following: (1) nature of addiction;</p>	V 235		

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

TITLE

(X6) DATE

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V 235	<p>Continued From page 1</p> <p>(2) the withdrawal syndrome; (3) group and family therapy; and (4) infectious diseases including HIV, sexually transmitted diseases and TB.</p> <p>This Rule is not met as evidenced by: Based on record review and interviews, 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 9/20/22 of facility records revealed: -The facility had a census of 407 clients. -The facility had six full time substance abuse counselors. -Staff #1 had a caseload of 64 clients. -Staff #2 had a caseload of 70 clients. -Staff #3 had a caseload of 67 clients. -Staff #4 had a caseload of 64 clients. -Staff #5 had a caseload of 72 clients. -Staff #6 had a caseload of 64 clients.</p> <p>Interview on 9/20/22 with Staff #3 revealed: -Caseload consisted of 66 or 67 clients, but aware that the maximum is 50 required by the state of North Carolina. -Caseload was overwhelming because clients had a lot of needs. -It was difficult to provide all of the client 's needs in one session due to the lack of additional counselors. -Clients were seen once monthly.</p>	V 235		

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V 235	Continued From page 2 -Assumed an additional 10 to 12 clients due to a counselor ' s absence. -It would be feasible to effectively serve a caseload of 35 clients. -Services could not be adequately served with current caseload. Interview on 9/21/22 with Staff #4 revealed: -Employed since January 2022. -He confirmed his caseload. -Reported the difficulties meeting with clients on his caseload. -Sessions with clients were not long. -He was able to meet with some clients during dosing visit. Interview on 9/21/22 with the Treatment Center Director revealed: -She was aware the counselor's caseload was above 50. -She just hired a clinical supervisor. -The clinical supervisor would carry a caseload and supervise the counselors. -Cases would be moved from the counselor's caseload to the clinical supervisor. -There were plans to hire 2 more counselors. -She found it difficult to hire staff due to the pay rate. -She confirmed the facility failed to ensure there was a ratio of one counselor to every 50 or less clients.	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	V 237		

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V 237	Continued From page 3 the client. (b) Compliance with The Substance Abuse and Mental Health Services Administration (SAMHSA) or The Center for Substance Abuse Treatment (CSAT) Regulations. Each facility shall be certified by a private non-profit entity or a State agency, that has been approved by the SAMHSA of the United State Department of Health and Human Services and shall be in compliance with all SAMHSA Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction regulations in 42 CFR Part 8, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the CSAT, SAMHSA, Rockwall II, 5600 Fishers Lane, Rockville, Maryland 20857 at no cost. (c) Compliance With DEA Regulations. Each facility shall be currently registered with the Federal Drug Enforcement Administration and shall be in compliance with all Drug Enforcement Administration regulations pertaining to opioid treatment programs codified in 21 C.F.R., Food and Drugs, Part 1300 to end, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the United States Government Printing Office, Washington, D.C. 20402 at the published rate. (d) Compliance With State Authority Regulations. 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	V 237		

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V 237	<p>Continued From page 4</p> <p>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 record reviews and interviews, the facility management failed to assure compliance with regulations in 42 CFR Part 8 which require an annual physical during treatment for Opioid Addiction affecting three of eighteen audited current clients (#1, #3 and #4). The findings are:</p> <p>a. Review on 9/21/22 of client #1's record revealed: - Admission date of 11/9/20. - Diagnosis of Opioid Use Disorder. - Documentation of the client's last physical examination by a physician was completed on 11/9/20. - There was no documentation an annual physical was completed by a physician within the last year.</p> <p>b. Review on 9/21/22 of client #3's record revealed: - Admission date of 9/20/18. - Diagnosis of Opioid Use Disorder. - Documentation of the client's last physical examination by a physician was completed on 9/20/18. - There was no documentation an annual physical was completed by a physician within the last year.</p> <p>c. Review on 9/21/22 of client #4's record revealed:</p>	V 237		

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V 237	Continued From page 5 - Admission date of 8/13/07. - Diagnosis of Opioid Use Disorder. - Documentation of the client's last physical examination by a physician was completed on 8/21/19. - There was no documentation an annual physical was completed by a physician within the last year. Interview on 9/21/22 with the Lead Nurse revealed: -She thought client #1 was scheduled to have his annual physical completed October 2022. -She thought clients #3 and #4 were also scheduled to have their annual physical completed as well. -She confirmed the annual physical examination was not completed by the physician for clients #1, #3 and #4. Interview on 9/21/22 with the Treatment Center Director confirmed: -The annual physical examination was not completed by the physician for clients #1, #3 and #4.	V 237		
V 238	27G .3604 (E-K) Outpt. Opiod - Operations 10A NCAC 27G .3604 OUTPATIENT OPIOD TREATMENT. OPERATIONS. (e) The State Authority shall base program approval on the following criteria: (1) compliance with all state and federal law and regulations; (2) compliance with all applicable standards of practice; (3) program structure for successful service delivery; and (4) impact on the delivery of opioid treatment services in the applicable population.	V 238		

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V 238	Continued From page 6 (f) Take-Home Eligibility. Any client in comprehensive maintenance treatment who requests unsupervised or take-home use of methadone or other medications approved for treatment of opioid addiction must meet the specified requirements for time in continuous treatment. The client must also meet all the requirements for continuous program compliance and must demonstrate such compliance during the specified time periods immediately preceding any level increase. In addition, during the first year of continuous treatment a patient must attend a minimum of two counseling sessions per month. After the first year and in all subsequent years of continuous treatment a patient must attend a minimum of one counseling session per month. (1) Levels of Eligibility are subject to the following conditions: (A) Level 1. During the first 90 days of continuous treatment, the take-home supply is limited to a single dose each week and the client shall ingest all other doses under supervision at 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	V 238		

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V 238	Continued From page 7 take-home doses and shall ingest all other doses under supervision at the clinic each week; (E) Level 5. After 364 days of continuous treatment and a minimum of 180 days of continuous program compliance, a client may be granted for a maximum of six take-home doses and shall ingest at least one dose under supervision at the clinic each week; (F) Level 6. After two years of continuous treatment and a minimum of one year of continuous program compliance at level 5, a client may be granted for a maximum of 13 take-home doses and shall ingest at least one dose under supervision at the clinic every 14 days; and (G) Level 7. After four years of continuous treatment and a minimum of three years of continuous program compliance, a client may be granted for a maximum of 30 take-home doses and shall ingest at least one dose under supervision at the clinic every month. (2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility: (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,	V 238		

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V 238	Continued From page 8 personal or family crisis, travel or other hardship may be permitted a temporarily reduced schedule by the State authority, provided she or he is also found to be responsible in handling opioid drugs. Except in instances involving a client with a verifiable physical disability, there is a maximum of 13 take-home doses allowable in any two-week period during the first two years of continuous treatment. (B) A client who is unable to conform to the applicable mandatory schedule because of a verifiable physical disability may be permitted additional take-home eligibility by the State authority. Clients who are granted additional take-home eligibility due to a verifiable physical disability may be granted up to a maximum 30-day supply of take-home medication and shall make monthly clinic visits. (4) Take-Home Dosages For Holidays: Take-home dosages of methadone or other medications approved for the treatment of opioid addiction shall be authorized by the facility physician on an individual client basis according 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	V 238		

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V 238	Continued From page 9 approved for use in opioid treatment shall be discussed with each client at the initiation of treatment and annually thereafter. (h) Random Testing. Random testing for alcohol and other drugs shall be conducted on each active opioid treatment client with a minimum of one random drug test each month of continuous treatment. Additionally, in two out of each three-month period of a client's continuous treatment episode, at least one random drug test will be observed by program staff. Drug testing is to include at least the following: opioids, methadone, cocaine, barbiturates, amphetamines, THC, benzodiazepines and alcohol. Alcohol testing results can be gathered by either urinalysis, breathalyzer or other alternate scientifically valid method. (i) Client Discharge Restrictions. No client shall be discharged from the facility while physically dependent upon methadone or other medications approved for use in opioid treatment unless the client is provided the opportunity to detoxify from the drug. (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	V 238		

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V 238	<p>Continued From page 10</p> <p>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:</p> <ul style="list-style-type: none"> (1) dual enrollment prevention measures that consist of client consents, and either program contacts, participation in the central registry or list exchanges; (2) call-in's for bottle checks, bottle returns or solid dosage form call-in's; (3) call-in's for drug testing; (4) drug testing results that include a review of the levels of methadone or other medications approved for the treatment of opioid addiction; (5) client attendance minimums; and (6) procedures to ensure that clients properly ingest medication. <p>This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to ensure after the first year and in all subsequent years of continuous treatment a client attended at least one counseling session per month affecting two of eighteen current audited clients (#4 and #6) and failed to ensure counseling sessions were completed after a positive urine drug screen affecting of four of</p>	V 238		

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V 238	<p>Continued From page 11</p> <p>eighteen current audited clients (#2, #3, #5 and #6) The findings are:</p> <p>The following is evidence the facility staff failed to ensure clients attended at least one counseling session per month.</p> <p>a. Review on 9/21/22 of client #4's record revealed: -Admission date of 8/13/07. -Diagnosis of Opioid Use Disorder. -Staff #1 was her current Counselor. -The last documented counseling session was on 5/27/22.</p> <p>b. Reviews on 9/21/22 of client #6's record revealed: -Admission date of 5/28/13. -Diagnosis of Opioid Use Disorder. -Staff #6 was his current Counselor. -The last documented counseling session was on 5/17/22.</p> <p>Interview on 9/21/22 with staff #1 revealed: -She was employed with the facility since July 2022. -She was the Counselor for client #4. -Client #4 was added to her caseload last month. -She had not met with client #4 for any counseling sessions. -She confirmed facility staff failed to ensure clients attended at least one counseling session per month.</p> <p>Staff #6 was not available for interview.</p> <p>Interview on 9/21/22 with the Treatment Center Director confirmed: -Facility staff failed to ensure clients attended at least one counseling session per month.</p>	V 238		

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V 238	<p>Continued From page 12</p> <p>The following is evidence the facility staff failed to ensure counseling sessions were completed after a positive urine drug screen.</p> <p>a. Review on 9/21/22 of client #2's record revealed: -Admission date of 2/14/17. -Diagnoses of Opioid Use Disorder, Major Depressive Disorder and Hepatitis C. -Staff #5 was her current Counselor. -Urinary Drug Screens (UDS) were completed on 8/15/22, 7/7/22 and 6/28/22. Client #2 tested positive for Cannabis. -There was no documentation of counseling sessions completed by client #2's Counselor to address the positive UDS results.</p> <p>b. Review on 9/21/22 of client #3's record revealed: -Admission date of 9/20/18. -Diagnosis of Opioid Use Disorder. -Staff #1 was his current Counselor. -UDS were completed on 8/19/22, 7/15/22 and 6/22/22. Client #3 tested positive for Cannabis. -There was no documentation of counseling sessions completed by client #3's Counselor to address the positive UDS results.</p> <p>c. Review on 9/21/22 of client #5's record revealed: -Admission date of 1/1/22. -Diagnosis of Opioid Use Disorder. -Staff #5 was his current Counselor. -UDS was completed on 9/2/22. Client #5 tested positive for Cocaine and Fentanyl. -There was no documentation of counseling sessions completed by client #5's Counselor to address the positive UDS results.</p>	V 238		

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V 238	<p>Continued From page 13</p> <p>d. Review on 9/21/22 of client #6's record revealed: -UDS were completed on 8/22/22, 7/12/22 and 6/1/22 . Client #6 tested positive for Cocaine and Fentanyl. -There was no documentation of counseling sessions completed by client #6's Counselor to address the positive UDS results.</p> <p>Interview on 9/21/22 with staff #1 revealed: -She was the Counselor for client #3. -She had her first counseling session with client #3 in August 2022. -She just had a counseling with client #3 on today (September 21, 2022). -She knew client #3 used Cannabis. She didn't discuss client #3's use of the Cannabis during their counseling sessions. -She confirmed facility staff failed to ensure counseling sessions were completed after a positive urine drug screen.</p> <p>Interview on 9/21/22 with staff #5 revealed: -She was the Counselor for client #2. -She knew client #2 tested positive for Cannabis several times. -Client #2 refused to stop using Cannabis because she said it helped with her anxiety. -She talked with client #2 several times about not using Cannabis during their counseling sessions. -She didn't document she talked with client #2 about her use of Cannabis during their counseling sessions. -Client #5 was also on her caseload. -She knew client #5 tested positive for illicit substances at the beginning of September 2022. -She wasn't sure why she had not met with client #5 after that positive UDS. -She confirmed facility staff failed to ensure counseling sessions were completed after a</p>	V 238		

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 09/21/2022
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 238	Continued From page 14 positive urine drug screen Staff #6 was not available for interview. Interview on 9/21/22 with the Treatment Center Director confirmed: -Facility staff failed to ensure counseling sessions were completed after a positive urine drug screen.	V 238			