STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MHL044-062	A. BUILDING: _____ B. WING _____	R 01/23/2019

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V 000	INITIAL COMMENTS A limited follow up survey for the Type A1 and a complaint survey was completed on 1/23/19. This was a limited follow up survey only 10A NCAC 27G .3601 Scope (V233), 10A NCAC 27G .0205 Assessment and Treatment/Habilitation or Service Plan (V112), 10A NCAC 27G .0208 Medication Requirements (V118) and 10A NCAC 27G .3604 (V238) were reviewed for compliance. The following were brought back into compliance: 10A NCAC 27G .3601 Scope (V233), 10A NCAC 27G .0205 Assessment and Treatment/Habilitation or Service Plan (V112) and 10A NCAC 27G .0208 Medication Requirements (V118) were brought back into compliance. The complaint was unsubstantiated (Intake #NC00147332). A deficiency was cited. The census was 157. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpaitient Opioid Treatment	V 000		
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	V 238		

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V 238	Continued From page 1 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 take-home doses and shall ingest all other doses under supervision at the clinic each week; (E) Level 5. After 364 days of continuous	V 238		

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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, 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

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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 approved for use in opioid treatment shall be discussed with each client at the initiation of treatment and annually thereafter.

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V 238	Continued From page 4 (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 State Authority for Opioid Treatment. (k) Diversion Control Plan. Outpatient Addiction Opioid Treatment Programs in North Carolina are	V 238		

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V 238	Continued From page 5 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; (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 upon record reviews and interviews the facility failed to ensure that during the first year of continuous treatment each client attended a minimum of two counseling sessions per month for 2 of 8 sampled clients (Clients #2, and #5) and failed to ensure after the first year and in all subsequent years of continuous treatment attended a minimum of one counseling session per month for 1 of 8 sampled clients (Client #1). The findings are: Review on 1/22/19 of Client #1's record revealed: -admitted on 2/22/17 with a diagnosis of Opioid Dependence. -no documentation of the required one counseling	V 238		

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V 238	Continued From page 6 session for December 2018. Review on 1/22/19 of Client #1's Urine Drug Screens (UDSs) from December 8, 2018 to January 22, 2019 revealed: -5 of 5 random UDSs were positive for illicit substances (12/14/18, 12/20/18, 12/27/18, 12/31/18 and 1/7/19). Interview on 1/22/19 with Client #1 revealed: -he was between counselors right now as his assigned counselor left "a couple of months ago." -he had not been assigned a new counselor, but had talked to both counselors currently working at the facility. -he felt like they would be available at any time he needed to speak with them. Review on 1/22/19 of Client #2's record revealed: -admitted on 10/9/18 with a diagnosis of Opioid Dependence. -no documentation of the required two counseling sessions for December 2018. Review on 1/22/19 of Client #2's UDSs from December 8, 2018 to January 22, 2019 revealed: -5 of 5 random UDSs were positive for illicit substances (12/13/18, 12/18/18, 12/28/18, 1/3/19 and 1/7/19). -in addition, 2 of the 5 were negative for methadone metabolite (quantification of methadone in the urine). On 1/23/19 Client #2 refused to be interviewed. Review on 1/23/19 of Client #5's record revealed: -admitted on 8/14/18 with a diagnosis of Opioid Dependence. -no documentation of the required two counseling sessions for December 2018.	V 238		

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V 238	Continued From page 7 On 1/23/19 Client #5 refused to be interviewed. Interview on 1/23/19 with Client #1, #2 and #5's counselor revealed: -she was the Clinical Manager for the facility. -she was not surprised the above client's did not have December counseling sessions. -she was managing a caseload of over 100 clients and doing the best she could. -the other counselor was new and did not have a full caseload yet. -she was also on-boarding and training another new counselor. Interview on 1/23/19 with the facility Director revealed: -he had one counselor that started yesterday. -another counselor was scheduled to start the beginning of February; this would make a total of four counselors. -he arranged for the sister facility in Asheville to do group sessions for them in December due to the shortage of counselors. -because there was difficulty in getting this documented successfully in their electronic records the sister facility did not continue to assist them.	V 238		