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	MHL098-190	A. BUILDING: _____ B. WING _____	03/12/2019

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V 000	INITIAL COMMENTS An annual survey was completed on March 12, 2019. A deficiency was cited. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment. Census was 206 clients at the time of the survey.	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 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	V 238		

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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 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

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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 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

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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, methadone, cocaine, barbiturates, amphetamines, THC, benzodiazepines and alcohol. Alcohol testing results can be gathered by either urinalysis, breathalyzer or other

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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;
(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

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V 238	Continued From page 5 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 record review and interview, the facility failed to ensure 1 of eight audited clients (#2) met the minimum required counseling sessions per month (2) within their first year of treatment. The findings are: Review on 3/12/19 of client #2's record revealed: - admission date: 8/28/18 - diagnoses of Opioid Use Disorder - Severe, 9 months pregnant (baby being delivered on 3/14/19) - she submitted to supervised Urine Drug Screens (UDS) at least weekly and she had tested positive at least 18 times since 12/1/19 for fentanyl, morphine, cocaine, heroin and Oxycodone - some of the dates she tested positive UDS were: - 2/26/19, 2/21/19, 2/13/19, 2/4/19 - 1/31/19, 1/29/19, 1/11/19, 1/2/19 - 12/26/18, 12/19/18, 12/12/18, 12/5/18 - 11/29/18, 11/26/18, 11/16/18, 11/9/18 - 10/29/18 and 10/22/18 - a treatment plan dated 8/28/18 with documentation she was to meet with her counselor at least twice monthly - notes that she met with her counselor on: 9/21/18; 10/23/18; 11/14/18; 11/28/18 and	V 238		

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V 238	Continued From page 6 12/19/18 - notes that she canceled with her counselor on 10/22/18; 2/6/19 and 2/8/19 - no documentation she had attended any group session since her admission During interview on 3/12/19, client #2 reported: - she met with his counselor weekly but missed sometimes because of transportation issues - she attended group sessions monthly - she did not have any take homes - her UDS have been "clean" for a very long time During interview on 3/12/19, client #2's Counselor reported: - client #2 is 9 months pregnant and scheduled to deliver the baby this week - she has tried to meet with client #2 weekly but had not been successful - client #2 refused to attend group sessions - client #2 has had positive drug screens every week - the doctor tried increasing her methadone to stop her from drug seeking but that has not been successful. Her methadone cannot be decreased because of her pregnancy and the danger that would impose on the fetus. - client #2 needed a higher level of care than outpatient - she had referred her to a residential placement and she was accepted.. Client #2 then changed her mind and declined to go - client #2 will be re-assessed after the baby is delivered and she resumes services at the clinic During interview on 3/12/19, the Clinical Director reported:	V 238		

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V 238	Continued From page 7 - she had only started at the clinic 2 weeks prior - one of her job duties was to oversee day to day operations to ensure everything flowed -	V 238		