

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL059-024	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 03/27/2019
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NAME OF PROVIDER OR SUPPLIER MCLEOD ADDICTIVE DISEASE CENTER - MARION	STREET ADDRESS, CITY, STATE, ZIP CODE 117 WEST MEDICAL COURT MARION, NC 28752
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V 000	<p>INITIAL COMMENTS</p> <p>An annual, complaint and follow up survey was completed on 3/27/19. The complaints were unsubstantiated (intake # NC00145758 and #NC00148505). Deficiencies were cited.</p> <p>This facility is licensed for the following service categories: 10A NCAC 27G .3600 Outpatient Opioid Treatment.</p> <p>The census at the time of the survey was 298.</p>	V 000		
V 235	<p>27G .3603 (A-C) Outpt. Opiod Tx. - Staff</p> <p>10A NCAC 27G .3603 STAFF</p> <p>(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.</p> <p>(b) Each facility shall have at least one staff member on duty trained in the following areas:</p> <p>(1) drug abuse withdrawal symptoms; and</p> <p>(2) symptoms of secondary complications to drug addiction.</p> <p>(c) Each direct care staff member shall receive continuing education to include understanding of the following:</p> <p>(1) nature of addiction;</p> <p>(2) the withdrawal syndrome;</p> <p>(3) group and family therapy; and</p> <p>(4) infectious diseases including HIV, sexually transmitted diseases and TB.</p>	V 235		

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>This Rule is not met as evidenced by: Based on record review and interview, the facility failed to maintain the staffing ratio of one certified counselor to each 50 clients. The findings are:</p> <p>Review on 3/26/19 of the "Caseload By Attending Practitioner" dated 3/26/19 revealed: -The caseload of Counselor #2 was 60; -The caseload of Counselor #3 was 60; -The caseload of Counselor #4 was 60; -The caseload of Counselor #5 was 60; -The caseload of Counselor #6 was 58; -The caseload of "Inactive Counselor" was 3.</p> <p>Interview on 3/26/19 with the Program Manager revealed: -She had 5 current counselors and 3 vacant counselor positions that she was trying to fill; -No new clients were being admitted due to these vacancies; -She was aware of the required staffing ratio of 1 counselor to 50 clients and the counselors' caseloads exceeded the 1:50 staffing requirement.</p> <p>This deficiency constitutes a recited deficiency and must be corrected within 30 days.</p>	V 235		
V 238	<p>27G .3604 (E-K) Outpt. Opiod - Operations</p> <p>10A NCAC 27G .3604 OUTPATIENT OPIOD TREATMENT. OPERATIONS.</p> <p>(e) The State Authority shall base program approval on the following criteria: (1) compliance with all state and federal</p>	V 238		

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V 238	<p>Continued From page 2</p> <p>law and regulations;</p> <p>(2) compliance with all applicable standards of practice;</p> <p>(3) program structure for successful service delivery; and</p> <p>(4) impact on the delivery of opioid treatment services in the applicable population.</p> <p>(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.</p> <p>(1) Levels of Eligibility are subject to the following conditions:</p> <p>(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;</p> <p>(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;</p> <p>(C) Level 3. After 180 days of continuous treatment and a minimum of 90 days of continuous program compliance at level 2, a</p>	V 238		

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V 238	<p>Continued From page 3</p> <p>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;</p> <p>(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;</p> <p>(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;</p> <p>(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</p> <p>(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.</p> <p>(2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility:</p> <p>(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;</p> <p>(B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and</p> <p>(C) The reinstatement of take-home</p>	V 238		

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V 238	<p>Continued From page 4</p> <p>eligibility shall be determined by each Outpatient Opioid Treatment Program.</p> <p>(3) Exceptions to Take-Home Eligibility:</p> <p>(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.</p> <p>(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.</p> <p>(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:</p> <p>(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.</p> <p>(B) No more than a three-day supply of methadone or other medications approved for the treatment of opioid addiction may be dispensed</p>	V 238		

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V 238	<p>Continued From page 5</p> <p>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.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(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</p>	V 238		

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V 238	<p>Continued From page 6</p> <p>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.</p> <p>(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> <ol 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 review and interview the facility failed to ensure each client attended the required counseling sessions each month for 1 of 16 audited clients (#5). The findings are:</p>	V 238		

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V 238	<p>Continued From page 7</p> <p>Review on 3/26/19 of the record for Client #5 revealed:</p> <ul style="list-style-type: none"> -Admission date of 3/7/16 with diagnoses of Severe Opioid Use Disorder and Hepatitis C. -Medical staffing on 1/4/19 which included the physician with the recommendation to increase counseling to 2 times each week. -Counseling sessions were not increased until 1/28/19. <p>Interview on 3/27/19 with the Director revealed:</p> <ul style="list-style-type: none"> -The counselor who was working with Client #5 was no longer employed at the clinic. -The counseling sessions should have been increased based on the recommendation by the physician. -The increased sessions were missed until 1/28/19. -Client #5 was currently being seen 2 times each week 	V 238		