

Division of Health Service Regulation

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL064-089 | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 06/05/2018 |
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| NAME OF PROVIDER OR SUPPLIER ROCKY MOUNT TREATMENT CENTER | STREET ADDRESS, CITY, STATE, ZIP CODE 104 ZEBULON COURT ROCKY MOUNT, NC 27804 |
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| V 000 | <p>INITIAL COMMENTS</p> <p>An annual survey was completed on 6/5/18. A deficiency was cited.</p> <p>This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Methadone</p> | V 000 | | |
| 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:</p> <p>(1) compliance with all state and federal 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</p> | V 238 | | |

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE _____ TITLE _____ (X6) DATE _____

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| V 238 | Continued From page 1 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 treatment and a minimum of three years of continuous program compliance, a client may be | V 238 | | |

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| V 238 | <p>Continued From page 2</p> <p>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 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> | V 238 | | |

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| V 238 | <p>Continued From page 3</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 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</p> | V 238 | | |

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| V 238 | <p>Continued From page 4</p> <p>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 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 | V 238 | | |

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| V 238 | <p>Continued From page 5</p> <p>addiction; (5) client attendance minimums; and (6) procedures to ensure that clients properly ingest medication.</p> <p>This Rule is not met as evidenced by: Based on observation, record review and interview the facility failed to establish a diversion control plan that included procedures that ensured clients properly ingested medications. The findings are:</p> <p>Review on 6/5/18 of the facility s diversion control plan policy failed to address procedures to ensure clients properly ingest Buprenorphine.</p> <p>Observation at 11:00am on 6/4/18 revealed:</p> <ul style="list-style-type: none"> - a registered nurse (RN) & a licensed practical nurse (LPN) in the dosing room - the LPN administered methadone and the RN administered Buprenorphine - there were 2 separate dosing windows (on separate sides of the dosing room) - in front of the Buprenorphine window there were four chairs approximately 5 feet from the dosing window - there was a camera beside the nurse that sat at the methadone window that monitored areas surrounding the building but not the dosing area. <p>Further observation on 6/4/18 between 11:10am and 11:40am revealed the following administration of Buprenorpine:</p> <ul style="list-style-type: none"> - the RN "crushed" the Buprenorpine prior to administering - she asked the client if they needed to drink a | V 238 | | |

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| V 238 | <p>Continued From page 6</p> <p>cup of water prior to administering the Buprenorphine</p> <ul style="list-style-type: none"> - at 11:10am patient #764 entered the dosing area...Buprenorphine was administered...sat in one of the four chairs for Buprenorphine to dissolve; 11:15am client #933 was administered Buprenorphine...sat in a chair...at 11:20am client #929 was called by the RN to be dosed...each client stood in front of the nurse to be dosed which blocked the line of vision for the nurse - client #684 was called while 3 Buprenorphine clients dissolved...the RN put the Buprenorphine in a cup...stood up to get something out of the file cabinet while also attempting to monitor the Buprenorphine clients... <p>During interview on 6/4/17 the RN reported:</p> <ul style="list-style-type: none"> - she has been at the facility approximately 6 months - it could take up to 1 minute to 12-15 minutes for the buprenorphine to dissolve... - it depended on the moisture of the clients mouth...that's why some clients will drink water first - the Buprenorphine was placed under the tongue so it would dissolve into the mucous membrane...swallowing was not as effective - before the client left they had to tilt their head back...speak to her to ensure the Buprenorphine had completely dissolved <p>During interview on 6/4/17 the LPN reported:</p> <ul style="list-style-type: none"> - nurses could administer Buprenorphine up to four clients at a time - there were no cameras to monitor the dosing area - a camera would assist with monitoring the dosing area for diversion - most of the time it was at least 2 nurses during the week | V 238 | | |

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| V 238 | <p>Continued From page 7</p> <ul style="list-style-type: none"> - there was only one nurse on the weekend that administered Methadone and Buprenorphine - when she worked the weekends she only called 2 Buprenorphine clients at a time - it could be difficult at times to administer methadone while observing Buprenorphine clients - ...however she was called the "diversion queen" because she was good at monitoring the clients - they recently added the 2nd window about 2 months ago - they have administered Buprenorphine for at least 5 1/2 years <p>During interview on 6/5/17 the Program Director reported:</p> <ul style="list-style-type: none"> - there were no concerns of diversion at this time - the nurses are able to call back the number of Buprenorphine clients that felt comfortable with - 2 - 3 Buprenorphine clients are usually dosed at a time - the nurses chairs sat up high for them to get a better observation of the clients dissolving - if the nurses had any concerns about the dosing area or number clients being dosed they would make her aware - she was in the process of contacting a company to come out and install a camera system for the dosing area - by crushing the Buprenorphine it made diversion difficult - the clients have to open their mouth for the nurses before leaving the dosing area - there was no policy on the number of Buprenorphine clients a nurse could dose at one time <p>During interview on 6/5/17 the Regional Director/RN reported:</p> | V 238 | | |

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| V 238 | <p>Continued From page 8</p> <ul style="list-style-type: none"> - there were 2 nurses during the week unless one was sick or on vacation - one nurse worked on the weekends - there was not as many clients during the weekends due to take homes... - she was not aware of any diversions that has happened at the facility - installing a camera would cause nurses to have to view the camera while also attempting to monitor clients for diversion - she was more concerned about the weekend nurse who administered the Methadone and Buprenorphine - she planned to get with all the nurses to further discuss ways to prevent diversion of Buprenorphine - she will also update the diversion control policy to include Buprenorphine | V 238 | | |