Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MHL064-089	A. BUILDING: _____ B. WING _____	R 07/17/2019

DHSR - Mental Health
AUG 0 6 2019
Lic. & Cert. Section

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ROCKY MOUNT TREATMENT CENTER	104 ZEBULON COURT ROCKY MOUNT, NC 27804

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
V 000	INITIAL COMMENTS An Annual and Follow Up Survey was completed on 07/17/19. A deficiency was re-cited. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Methadone The census for the facility was 216.	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	We do not understand why DHSR has cited the Rocky Mount Treatment Center for Diversion Control for a second time in two years, without incident or reporting of diversion issues at the clinic. We think this is based on the DHSR staff "feeling" that we need additional staff nurses, PRN nurses, available for when our full-time nurses are out. On that day an RN was performing medication administration from two windows, 1 window was for methadone and 1 window was for buprenorphine. These windows are located in the same pharmacy. The buprenorphine window has an observation area directly in front of the window. Normally, there are two nurses, 1 for each window. Unfortunately, on that day a nurse was out sick. She called out early that morning prior to opening at 6am. As normal all patients receiving buprenorphine are required to wait, as the rough chopped buprenorphine dissolves in their mouth. They sit in the observation area directly outside of the window, in front of the nurse. Once the medication has dissolved, they present to the nurse to verify that the medication has dissolved by showing the nurse the inside of their mouth. They then leave the observation area. Staffing requirements for nursing does not exist in the regulations. Yet we continue to be pressured with the threat of citing our facility under the disguise of Diversion Control based on what DHSR staff would like to see when they come back or "it could be serious for us". The DHSR staff asked the Program Director to guess what the citation was prior to beginning the closing of the audit. We all realize that these same patients that are being held to such punitive and strict measures by DHSR are of the same acuity of patients being seen and medicated at OBOT offices throughout the state. Patients receiving services from OBOT facilities are given prescriptions to fill and self-medicate, without the requirement of being monitored by a nurse while the medication dissolves. The nurses at the facility have had no complaints of staffing, nor have the patients of the facility. Please note no complaints during staff interviews or patient interviews. There have been no reported incidents of diversion or concerns of diversion by the staff and/or patients on clinic property. Please note no report or concerns were expressed during staff interviews or patient interviews. Based on the DHSR statement quoted directly from the DHSR audit report and patient interviews recorded by DHSR staff the nurse followed the diversion control policy,	

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE TITLE (X6) DATE

Jam. McCall, PD 8/2/19

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V 238	Continued From page 1 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	V 238	" Medication administration... The nurse will ensure that the patient had ingested medication. There is a camera on the patient receiving methadone and a large mirror behind the patient to prevent the patient from concealing and diverting Methadone. Methadone medication ingestion will be ensured by the patient being asked to speak to the medication nurse before leaving the medication window. Buprenorphine medication will be roughly chopped. Buprenorphine medication ingestation will be ensured by the patient sitting in the view of the medication nurse for observation, to allow time for the sublingual tablet to dissolve... The patient will be asked to show the medication nurse that the sublingual tablet has dissolved before leaving the medication area". DHSR stated that our census has grown since last year. As this is true, DHSR staff does not understand that all of these patients are not seen daily at the clinic. The DHSR audit also reflects that the DHSR staff noted that "the RN looked over towards the Buprenorphine window to check on the clients" and " that no more than three clients at the same time seated near the Buprenorphine window awaiting the medication to dissolve". Let it also be noted that if this issue of "observation by the nurse for dissolving buprenorphine " was so critical that the DHSR staff made the decision to pull patients from this area for their patient interviews. This was done while these patients had dissolving medication in their mouths. DHSR has cited us for failure to follow our diversion control policy when actually the DHSR staff violated our clinics diversion control policy by doing this. This occurred when they decided not to wait for the patient and the nurse to complete the medication administration process stated in our Diversion Control Policy, therefore, removing the patient from the view of the nurse and the observation area with the medication still in their mouth. We do not understand the DHSR audit resulting in a conclusion of a re-cite under the regulation of diversion control. This could be interpreted as discrimination of the opioid treatment program (OTP) model and the patient population. We feel this type of treatment only exacerbates the ongoing stigma that we and many others in the state of North Carolina work very hard to eliminate. I	

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V 238	Continued From page 2 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	V 238	In conclusion, we have filled an additional weekend nurse position. The Program Director, Vanessa Walmsley, will be monitoring the on-going needs of the clinic. We have forwarded your concerns to the State Opioid Treatment Authority office and our response. We look forward to continuing to improve our services and meet best practice guidelines.	

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V 238	Continued From page 3 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	V 238		

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V 238	Continued From page 4 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	V 238		

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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 observation, record review and interview, the facility failed to adhere to its diversion control plan. The findings are: Review on 07/17/19 of the facility's public file maintained by the Division of Health Service Regulation (DHSR) revealed: - 06/05/18 statement of deficiencies report noted violation regarding diversion control plan regarding Buprenorphine and monitoring clients while medication dissolved Review on 07/17/19 of the facility's diversion control plan policy updated 08/03/18 revealed "Medication administration...The nurse will ensure that the patient had ingested medication. There is a camera on the patient receiving methadone and a large mirror behind the patient to prevent the patient from concealing and diverting Methadone. Methadone medication ingestion will be ensured by the patient being asked to speak to the medication nurse before leaving the medication window. Buprenorphine medication will be roughly chopped. Buprenorphine medication ingestation will be ensured by the patient sitting in the view of the medication nurse for observation, to allow time for the sublingual tablet to dissolve...The patient will be asked to show the medication	V 238		

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V 238	Continued From page 6 nurse that the sublingual tablet has dissolved before leaving the medication area. " Observation at 6:40-6:50am on 07/17/19 revealed: - a registered nurse (RN) on duty and administering medication in the dosing room - there were 2 separate dosing windows (on separate sides of the dosing room) - the RN fluctuated between administering Methadone from one window and Buprenorphine from the other window - in front of the Buprenorphine window there were approximately 4-6 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. - two clients (#911, #1070) seated in chairs on the Buprenorphine side - from the Methadone dosing window, three clients were served - the RN looked over towards the Buprenorphine window to check on clients..*note: it was difficult to fully see the Buprenorphine clients from the Methadone dosing window as well as monitor the Methadone clients Further sporadic observations on 07/17/19 between 7:00-10:30am revealed: - no more than three clients at the same time seated near the Buprenorphine window awaiting the medication to dissolve During interview on 07/17/19, four of ten audited clients reported: - Monday-Friday two nurses usually dispense medications from both windows - one nurse dispensed medications Saturday and Sunday from 7:00-9:00am	V 238		

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V 238	Continued From page 7 - whether weekends or weekdays, no more than 4 clients had been in the waiting area at the same time awaiting Buprenorphine to dissolve During interview on 07/17/19, the RN reported: - she had worked at the facility for two years - it could take up to 12-15 minutes for Buprenorphine to dissolve - the second nurse scheduled to work on this date, called in due to an emergency - Methadone and Buprenorphine were dispensed from same window on the weekend...Methadone dispensing machine would be moved to the Buprenorphine window. During interview on 07/17/19, the Program Director reported: - she recalled during the June 2018 DHSR survey a citation was identified regarding monitoring clients, diversion plan and Buprenorphine/Methadone - since 2018 changes had been made to their policy by adding wording and procedures for Buprenorphine clients and nursing staff should slow down the number of clients dosed to increase monitoring of Buprenorphine and Methadone clients - conversations were held regarding increase of nursing on the weekend but that had not been secured. She anticipated a definitive resolution within the next 2-3 months regarding the addition of a second nurse on the weekend - no back up or as needed nurses were available for assistance if someone called out. The agency had sister facilities but none were close in location to this clinic. - an increase in client census numbers occurred between June 2018-July 2019 (reflecting more clients served since the June 2018 DHSR survey).	V 238		

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V 238	Continued From page 8 This deficiency constitutes a re-cited deficiency and must be corrected within 30 days.	V 238		