

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MHL011-298</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>03/25/2022</b>
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NAME OF PROVIDER OR SUPPLIER  <b>CROSSROADS TREATMENT CENTER OF ASHEVILLE</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>6 ROBERTS ROAD, SUITE 103 ASHEVILLE, NC 28803</b>
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V 000	<p><b>INITIAL COMMENTS</b></p> <p>An annual, complaint and follow up survey was completed on March 25, 2022. The complaints were unsubstantiated (Intake #'s NC00164532, NC00168055, NC00168812, and NC00172970). Deficiencies were cited. The census at the time of the survey was 368.</p> <p>This facility is licensed for the following service category: 10A NCAC 27G.3600 Outpatient Opioid Treatment.</p> <p>The survey sample consisted of audits of 16 current clients, 1 former client, and 2 deceased clients.</p>	V 000		
V 105	<p><b>27G .0201 (A) (1-7) Governing Body Policies</b></p> <p>10A NCAC 27G .0201 GOVERNING BODY POLICIES</p> <p>(a) The governing body responsible for each facility or service shall develop and implement written policies for the following:</p> <p>(1) delegation of management authority for the operation of the facility and services;</p> <p>(2) criteria for admission;</p> <p>(3) criteria for discharge;</p> <p>(4) admission assessments, including:</p> <p>(A) who will perform the assessment; and</p> <p>(B) time frames for completing assessment.</p> <p>(5) client record management, including:</p> <p>(A) persons authorized to document;</p> <p>(B) transporting records;</p> <p>(C) safeguard of records against loss, tampering, defacement or use by unauthorized persons;</p> <p>(D) assurance of record accessibility to authorized users at all times; and</p> <p>(E) assurance of confidentiality of records.</p> <p>(6) screenings, which shall include:</p> <p>(A) an assessment of the individual's presenting</p>	V 105		

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

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V 105	Continued From page 1  problem or need; (B) an assessment of whether or not the facility can provide services to address the individual's needs; and (C) the disposition, including referrals and recommendations; (7) quality assurance and quality improvement activities, including: (A) composition and activities of a quality assurance and quality improvement committee; (B) written quality assurance and quality improvement plan; (C) methods for monitoring and evaluating the quality and appropriateness of client care, including delineation of client outcomes and utilization of services; (D) professional or clinical supervision, including a requirement that staff who are not qualified professionals and provide direct client services shall be supervised by a qualified professional in that area of service; (E) strategies for improving client care; (F) review of staff qualifications and a determination made to grant treatment/habilitation privileges: (G) review of all fatalities of active clients who were being served in area-operated or contracted residential programs at the time of death; (H) adoption of standards that assure operational and programmatic performance meeting applicable standards of practice. For this purpose, "applicable standards of practice" means a level of competence established with reference to the prevailing and accepted methods, and the degree of knowledge, skill and care exercised by other practitioners in the field;	V 105		

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V 105	<p>Continued From page 2</p> <p>This Rule is not met as evidenced by: Based on record review and interview, the facility failed to develop an adoption of standards that assured operational and programmatic performance meeting applicable standards of practice. The findings are:</p> <p>A confidential interview revealed: -Staff were required to discuss with their supervisor before a report could be made against a client for suspected child abuse/neglect. -The supervisor was to decide whether a report could be made to the Department of Social Services (DSS). -There was concern when a staff member was told no, they could not report suspected child abuse/neglect. -This was also according to facility policy.</p> <p>Review on 3/25/22 of a facility policy last revised 2/3/22 entitled "MANDATORY INCIDENT REPORTING POLICY (OTHER THAN DEATH)" revealed: -"...Crossroads identifies the following situations as critical incidents:...10. Mandated Reporting: Suspicion of Abuse or Neglect. (Prior to submitting any federal or state mandated report, the treatment team member will consult with the center's Medical Director and the Crossroads Chief Medical Officer...to ensure any submissions are appropriate and in compliance with patient privacy laws.)..." -"The OBOT/OTP [Office Based Opioid treatment/Opioid Treatment Program] shall not</p>	V 105		

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V 105	<p>Continued From page 3</p> <p>submit anything to any federal, state, local entity, or CARF [Commission on Accreditation of Rehabilitation Facilities] without first receiving instruction from the Compliance Department related to the incident..."</p> <p>Review on 3/25/22 of General Statue (GS) 7B-301 revealed:                      -(a) Any person or institution who has cause to suspect that any juvenile is abused, neglected...shall report the case of that juvenile to the director of the department of social services...."                      -(b) Any person or institution who knowingly or wantonly fails to report the case of a juvenile as required...or who knowingly or wantonly prevents another person from making a report...is guilty of a Class 1 misdemeanor."</p> <p>Interview on 3/24/22 with the Lead Counselor revealed:                      -"We are mandated reporters."                      -"They (counselors) need to call DSS and put that in the hands of that professional, to make that decision."</p> <p>Interview on 3/25/22 with the Program Director revealed:                      -"When I was a clinician, it was very much if you have questions or make a report, you have to do an incident report..."                      -"We used to have to call [Compliance Officer] in corporate for that."                      -Since she had been a clinician that was not a rule. "Each individual holds their own license, if they suspect abuse or neglect that is on them and their license."                      -She would not tell anyone not to report suspected child abuse/neglect.</p>	V 105		

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V 237	<p>27G .3604 (A-D) Outpt. Opiod - Operations</p> <p>10A NCAC 27G .3604 OPERATIONS</p> <p>(a) Hours. Each facility shall operate at least six days per week, 12 months per year. Daily, weekend and holiday medication dispensing hours shall be scheduled to meet the needs of the client.</p> <p>(b) Compliance with The Substance Abuse and Mental Health Services Administration (SAMHSA) or The Center for Substance Abuse Treatment (CSAT) Regulations. Each facility shall be certified by a private non-profit entity or a State agency, that has been approved by the SAMHSA of the United State Department of Health and Human Services and shall be in compliance with all SAMHSA Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction regulations in 42 CFR Part 8, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the CSAT, SAMHSA, Rockwall II, 5600 Fishers Lane, Rockville, Maryland 20857 at no cost.</p> <p>(c) Compliance With DEA Regulations. Each facility shall be currently registered with the Federal Drug Enforcement Administration and shall be in compliance with all Drug Enforcement Administration regulations pertaining to opioid treatment programs codified in 21 C.F.R., Food and Drugs, Part 1300 to end, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the United States Government Printing Office, Washington, D.C. 20402 at the published rate.</p> <p>(d) Compliance With State Authority Regulations. Each facility shall be approved by the North Carolina State Authority for Opioid Treatment,</p>	V 237		

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V 237	<p>Continued From page 5</p> <p>DMH/DD/SAS, which is the person designated by the Secretary of Health and Human Services to exercise the responsibility and authority within the state for governing the treatment of addiction with an opioid drug, including program approval, for monitoring compliance with the regulations related to scope, staff, and operations, and for monitoring compliance with Section 1923 of P.L. 102-321. The referenced material may be obtained from the Substance Abuse Services Section of DMH/DD/SAS.</p> <p>This Rule is not met as evidenced by: Based on record reviews and interviews, the facility management failed to assure compliance with regulations in 42 CFR Part 8 which require an annual physical during treatment for Opioid Addiction affecting 3 of 16 audited clients (Clients #3, #13 and #16). The findings are:</p> <p>Review on 3/23/22 and 3/24/22 of Client #3's record revealed: -Date of Admission: 12/13/17. -Diagnosis: Opioid Use Dependency. -Last Annual Physical was dated 12/21/20.</p> <p>Review on 3/23/22 of Client #13's record revealed: -Date of Admission: 7/25/17. -Diagnosis: Opioid Use Dependency. -Last Annual Physical was dated 6/16/20. -A note for a physician follow-up dated 7/16/21 to see record. -No record was found for the physician's exam on 7/16/21.</p>	V 237		

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V 237	<p>Continued From page 6</p> <p>Review on 3/24/22 of Client #16's record revealed: -Date of Admission: 5/9/19. -Diagnosis: Opioid Use Dependency. -Last Annual Physical was dated 11/18/19.</p> <p>Interview on 3/22/22 with Lead Counselor revealed: -The physician came to the facility once a week.</p> <p>Interview on 3/25/22 with Program Director revealed: -She was unable to locate the above annual physical exams. -She was assigned to this facility in August 2021. -She assigned a staff member to help with monitoring and a spreadsheet was developed to keep track of due dates for annuals and doctors appointments. -This was part of her "wave of catching up."</p>	V 237		
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</p>	V 238		

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V 238	<p>Continued From page 7</p> <p>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 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</p>	V 238		



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V 238	<p>Continued From page 8</p> <p>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 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</p>	V 238		

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V 238	<p>Continued From page 9</p> <p>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 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>	V 238		

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V 238	<p>Continued From page 10</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 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</p>	V 238		

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V 238	<p>Continued From page 11</p> <p>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"> <li>(1) dual enrollment prevention measures that consist of client consents, and either program contacts, participation in the central registry or list exchanges;</li> <li>(2) call-in's for bottle checks, bottle returns or solid dosage form call-in's;</li> <li>(3) call-in's for drug testing;</li> <li>(4) drug testing results that include a review of the levels of methadone or other medications approved for the treatment of opioid addiction;</li> <li>(5) client attendance minimums; and</li> <li>(6) procedures to ensure that clients properly ingest medication.</li> </ol> <p>This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to ensure after the first year and in all subsequent years of continuous treatment a client attended at least one counseling session per month for 3 of 16 audited clients (Clients #3, #10 and #15). The findings are:</p> <p>Review on 3/23/22 and 3/24/22 of Client #3's record revealed: -Date of Admission: 12/13/17. -Diagnosis: Opioid Use Dependency</p>	V 238		

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MHL011-298</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>03/25/2022</b>
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NAME OF PROVIDER OR SUPPLIER  <b>CROSSROADS TREATMENT CENTER OF ASHEVILLE</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>6 ROBERTS ROAD, SUITE 103 ASHEVILLE, NC 28803</b>
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(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 238	<p>Continued From page 12</p> <p>-Documented monthly counseling sessions were not present for January or February 2022.</p> <p>Review on 3/23/22 and 3/24/22 of Client #10's record revealed: -Date of Admission: 7/9/18. -Diagnosis: Opioid Use Disorder. -No counseling session was documented for February 2022.</p> <p>Interview on 3/24/22 with Client #10 revealed: -She attended all her counseling sessions and hasn't missed any sessions. -She started seeing a new counselor (male) last week. -She did not want to see a male counselor. "I'm not a male counselor kind of person."</p> <p>Review on 3/24/22 of Client #15's record revealed: -Date of Admission: 8/20/20. -Diagnoses: Opioid Use Disorder and Marijuana Use Disorder. -No counseling session was documented for January 2022.</p> <p>Interview on 3/25/22 with Program Director revealed: -Client #3's counselor was out on maternity leave in January. Other clinicians should have picked up the sessions. -Client #10 had a counselor switch. "She specifically asked not to see [her assigned counselor]." -Client #15 should not have missed a counseling session in January. -All but three of the counselors were new. Currently, they were fully staffed.</p>	V 238		