

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL013-101	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 06/24/2021
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NAME OF PROVIDER OR SUPPLIER MCLEOD ADDICTIVE DISEASE CENTER-CONC	STREET ADDRESS, CITY, STATE, ZIP CODE 300 COPPERFIELD BLVD. SUITES 105&106 CONCORD, NC 28025
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V 000	<p>INITIAL COMMENTS</p> <p>An annual and follow up survey was completed on June 24, 2021. Deficiencies were cited.</p> <p>This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment.</p> <p>The client census was 533 at the time of the survey.</p>	V 000		
V 112	<p>27G .0205 (C-D) Assessment/Treatment/Habilitation Plan</p> <p>10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN</p> <p>(c) The plan shall be developed based on the assessment, and in partnership with the client or legally responsible person or both, within 30 days of admission for clients who are expected to receive services beyond 30 days.</p> <p>(d) The plan shall include:</p> <p>(1) client outcome(s) that are anticipated to be achieved by provision of the service and a projected date of achievement;</p> <p>(2) strategies;</p> <p>(3) staff responsible;</p> <p>(4) a schedule for review of the plan at least annually in consultation with the client or legally responsible person or both;</p> <p>(5) basis for evaluation or assessment of outcome achievement; and</p> <p>(6) written consent or agreement by the client or responsible party, or a written statement by the provider stating why such consent could not be obtained.</p>	V 112		

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

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V 112	<p>Continued From page 1</p> <p>This Rule is not met as evidenced by: Based on record reviews and interview, the facility failed to have written consent or agreement by the client or responsible party affecting 3 of 21 current clients (#3, #5 and #6). The findings are:</p> <p>a. Review on 6/23/21 of client #3's record revealed: -Admission date of 6/29/12. -Diagnosis of Opioid Dependence. -The Person Centered Plan (PCP) was dated 9/23/20. -Client #3's treatment plan had no written consent or agreement by the client or responsible party.</p> <p>b. Review on 6/23/21 of client #5's record revealed: -Admission date of 9/13/17. -Diagnosis of Opioid Use Disorder. -The PCP was dated 7/15/20. -Client #5's treatment plan had no written consent or agreement by the client or responsible party.</p> <p>c. Review on 6/23/21 of client #6's record revealed: -Admission date of 4/17/12. -Diagnosis of Opioid Use Disorder, Severe. -The date of the PCP was unknown. -Client #6's treatment plan had no written consent or agreement by the client or responsible party.</p> <p>Interview on 6/23/21 with the Director of Medication Assisted Treatment revealed:</p>	V 112		

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V 112	Continued From page 2 -When COVID first happened in 2020, we could only work with the clients via telephone. -We contacted the Management Care Organizations and was told to obtain verbal confirmation from clients. -We completed the signature pages when clients returned to the facility, we used the dates from our verbal confirmations. -She confirmed the facility failed to have written consent or agreement by the client or responsible party.	V 112		
V 235	27G .3603 (A-C) Outpt. Opiod Tx. - Staff 10A NCAC 27G .3603 STAFF (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. (b) Each facility shall have at least one staff member on duty trained in the following areas: (1) drug abuse withdrawal symptoms; and (2) symptoms of secondary complications to drug addiction. (c) Each direct care staff member shall receive continuing education to include understanding of the following: (1) nature of addiction; (2) the withdrawal syndrome; (3) group and family therapy; and (4) infectious diseases including HIV, sexually transmitted diseases and TB.	V 235		

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V 235	<p>Continued From page 3</p> <p>This Rule is not met as evidenced by: Based on record review and interview, the facility failed to ensure 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. The findings are:</p> <p>Review on 6/22/21 of the facility's record revealed:</p> <ul style="list-style-type: none"> -The facility had a census of 533 clients. -The facility currently had 10 counselors with a caseload. -Six of the counselors had over 50 clients on their caseload. -Counselor #1 had a caseload of 54 clients. -Counselor #3 had a caseload of 55 clients. -Counselor #4 had a caseload of 52 clients. -Counselor #5 had a caseload of 51 clients. -Counselor #6 had a caseload of 53 clients. -Counselor #7 had a caseload of 76 clients. <p>Interview on 6/22/21 with the Director of Medication Assisted Treatment revealed:</p> <ul style="list-style-type: none"> -She was aware some of the counselors had a caseload of over 50 clients. -The agency had some staff shortages and planned to hire more staff. -The newly hired counselors had 30 clients on their caseload. -Once the newer counselors are fully trained they would acquire the over flow of clients from the other counselors. -She confirmed the facility failed to ensure there was a ratio of one counselor to every 50 or less 	V 235		

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V 235	Continued From page 4 clients. This deficiency constitutes a re-cited deficiency and must be corrected within 30 days.	V 235		
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 month. (1) Levels of Eligibility are subject to the following conditions: (A) Level 1. During the first 90 days of	V 238		

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V 238	<p>Continued From page 5</p> <p>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 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</p>	V 238		
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V 238	<p>Continued From page 6</p> <p>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> <p>(4) Take-Home Dosages For Holidays: Take-home dosages of methadone or other</p>	V 238		

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V 238	<p>Continued From page 7</p> <p>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 be discharged from the facility while physically dependent upon methadone or other medications</p>	V 238		

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V 238	<p>Continued From page 8</p> <p>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 addiction; (5) client attendance minimums; and 	V 238		

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V 238	<p>Continued From page 9</p> <p>(6) procedures to ensure that clients properly ingest medication.</p> <p>This Rule is not met as evidenced by: Based on record reviews and interview, the facility failed to ensure compliance with federal regulations and applicable standards of practice for clients receiving substance abuse treatment with Methadone to require an annual physical affecting 4 of 21 current clients (clients #1, #2, #3, and #4). The findings are:</p> <p>Review on 6/24/21 of client #1's record revealed: -Admission date of 9/13/21. -Diagnosis of Opioid Use Disorder, Severe. -Most recent physical exam was 6/25/19.</p> <p>Review on 6/24/21 of client #2's record revealed: -Admission date of 7/8/08 . -Diagnosis of Opioid Use Disorder, Severe. -Most recent physical exam was 3/3/20.</p> <p>Review on 6/24/21 of client #3's record revealed: -Admission date of 6/29/12. -Diagnosis of Opioid Use Disorder. -Most recent physical exam was 2/28/20.</p> <p>Review on 6/24/21 of client #4's record revealed: -Admission date of 8/16/11. -Diagnosis of Opioid Use Disorder, Severe. -Most recent physical exam was 1/31/20.</p> <p>Interview on 6/24/21 with the Director of Medication Assisted Treatment revealed: -She was aware that some client's physical</p>	V 238		

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V 238	Continued From page 10 examinations were overdue. -She reported that situation with COVID-19 delayed some of the physicals that needed to be conducted. -She acknowledged that clients #1, #2, #3, and #4 did not have their annual physical examinations completed. This deficiency constitutes a re-cited deficiency and must be corrected within 30 days.	V 238		
V 536	27E .0107 Client Rights - Training on Alt to Rest. Int. 10A NCAC 27E .0107 TRAINING ON ALTERNATIVES TO RESTRICTIVE INTERVENTIONS (a) Facilities shall implement policies and practices that emphasize the use of alternatives to restrictive interventions. (b) Prior to providing services to people with disabilities, staff including service providers, employees, students or volunteers, shall demonstrate competence by successfully completing training in communication skills and other strategies for creating an environment in which the likelihood of imminent danger of abuse or injury to a person with disabilities or others or property damage is prevented. (c) Provider agencies shall establish training based on state competencies, monitor for internal compliance and demonstrate they acted on data gathered. (d) The training shall be competency-based, include measurable learning objectives, measurable testing (written and by observation of behavior) on those objectives and measurable methods to determine passing or failing the course.	V 536		

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V 536	<p>Continued From page 11</p> <p>(e) Formal refresher training must be completed by each service provider periodically (minimum annually).</p> <p>(f) Content of the training that the service provider wishes to employ must be approved by the Division of MH/DD/SAS pursuant to Paragraph (g) of this Rule.</p> <p>(g) Staff shall demonstrate competence in the following core areas:</p> <ol style="list-style-type: none"> (1) knowledge and understanding of the people being served; (2) recognizing and interpreting human behavior; (3) recognizing the effect of internal and external stressors that may affect people with disabilities; (4) strategies for building positive relationships with persons with disabilities; (5) recognizing cultural, environmental and organizational factors that may affect people with disabilities; (6) recognizing the importance of and assisting in the person's involvement in making decisions about their life; (7) skills in assessing individual risk for escalating behavior; (8) communication strategies for defusing and de-escalating potentially dangerous behavior; and (9) positive behavioral supports (providing means for people with disabilities to choose activities which directly oppose or replace behaviors which are unsafe). <p>(h) Service providers shall maintain documentation of initial and refresher training for at least three years.</p> <ol style="list-style-type: none"> (1) Documentation shall include: <ol style="list-style-type: none"> (A) who participated in the training and the outcomes (pass/fail); 	V 536		

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V 536	<p>Continued From page 12</p> <p>(B) when and where they attended; and (C) instructor's name; (2) The Division of MH/DD/SAS may review/request this documentation at any time. (i) Instructor Qualifications and Training Requirements: (1) Trainers shall demonstrate competence by scoring 100% on testing in a training program aimed at preventing, reducing and eliminating the need for restrictive interventions. (2) Trainers shall demonstrate competence by scoring a passing grade on testing in an instructor training program. (3) The training shall be competency-based, include measurable learning objectives, measurable testing (written and by observation of behavior) on those objectives and measurable methods to determine passing or failing the course. (4) The content of the instructor training the service provider plans to employ shall be approved by the Division of MH/DD/SAS pursuant to Subparagraph (i)(5) of this Rule. (5) Acceptable instructor training programs shall include but are not limited to presentation of: (A) understanding the adult learner; (B) methods for teaching content of the course; (C) methods for evaluating trainee performance; and (D) documentation procedures. (6) Trainers shall have coached experience teaching a training program aimed at preventing, reducing and eliminating the need for restrictive interventions at least one time, with positive review by the coach. (7) Trainers shall teach a training program aimed at preventing, reducing and eliminating the need for restrictive interventions at least once</p>	V 536		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL013-101	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 06/24/2021
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NAME OF PROVIDER OR SUPPLIER MCLEOD ADDICTIVE DISEASE CENTER-CONC	STREET ADDRESS, CITY, STATE, ZIP CODE 300 COPPERFIELD BLVD. SUITES 105&106 CONCORD, NC 28025
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V 536	<p>Continued From page 13</p> <p>annually.</p> <p>(8) Trainers shall complete a refresher instructor training at least every two years.</p> <p>(j) Service providers shall maintain documentation of initial and refresher instructor training for at least three years.</p> <p>(1) Documentation shall include:</p> <p>(A) who participated in the training and the outcomes (pass/fail);</p> <p>(B) when and where attended; and</p> <p>(C) instructor's name.</p> <p>(2) The Division of MH/DD/SAS may request and review this documentation any time.</p> <p>(k) Qualifications of Coaches:</p> <p>(1) Coaches shall meet all preparation requirements as a trainer.</p> <p>(2) Coaches shall teach at least three times the course which is being coached.</p> <p>(3) Coaches shall demonstrate competence by completion of coaching or train-the-trainer instruction.</p> <p>(l) Documentation shall be the same preparation as for trainers.</p> <p> </p> <p>This Rule is not met as evidenced by: Based on record reviews and interview, the facility failed to ensure one of six staff (Nurse #2) had training on the use of alternatives to restrictive interventions prior to working with clients and the facility failed to ensure four of six staff (Nurse #1, Counselor #1, Counselor #2 and The Program Manager) had current training on the use of alternatives to restrictive interventions.</p>	V 536		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL013-101	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 06/24/2021
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V 536	<p>Continued From page 14</p> <p>The findings are:</p> <p>The following is evidence the facility failed the ensure staff had training on the use of alternatives to restrictive interventions prior to working with clients.</p> <p>Review on 6/24/21 of Nurse #2's personnel record revealed: -Hire date of 2/21/21. -There was no documentation of training on the use of alternatives to restrictive interventions for Nurse #2.</p> <p>The following is evidence the facility failed to ensure staff had current training on the use of alternatives to restrictive interventions.</p> <p>a. Review on 6/24/21 of Nurse #1's personnel record revealed: -Hire date of 8/13/18. -The Nonviolent Crisis Intervention training certificate expired on 12/4/20. -There was no documentation of a current training on the use of alternatives to restrictive interventions for Nurse #1.</p> <p>b. Review on 6/24/21 of Counselor #1's personnel record revealed: -Hire date of 11/26/18. -The Nonviolent Crisis Intervention training certificate expired on 2/5/21. -There was no documentation of a current training on the use of alternatives to restrictive interventions for Counselor #1.</p> <p>c. Review on 6/24/21 of Counselor #2's personnel record revealed: -Hire date of 2/3/20. -The Nonviolent Crisis Intervention training</p>	V 536		

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V 536	<p>Continued From page 15</p> <p>certificate expired on 2/5/21.</p> <p>-There was no documentation of a current training on the use of alternatives to restrictive interventions for Counselor #2.</p> <p>d. Review on 6/24/21 of the Program Manager's personnel record revealed:</p> <p>-Hire date of 7/8/19.</p> <p>-The Nonviolent Crisis Intervention training certificate expired on 7/31/20.</p> <p>-There was no documentation of a current training on the use of alternatives to restrictive interventions for the Program Manager.</p> <p>Interview on 6/24/21 with the Director of Medication Assisted Treatment revealed:</p> <p>-The agency used Nonviolent Crisis Intervention on the use of alternatives to restrictive intervention.</p> <p>-She thought the Nonviolent Crisis Intervention trainings were not completed for staff due to COVID.</p> <p>-The instructor was doing the trainings, however the trainings stopped at the start of the pandemic in March 2020.</p> <p>-There were scheduled trainings for staff last year, however the instructor cancelled the trainings.</p> <p>-The instructor had not done any Nonviolent Crisis Intervention trainings for staff in 2021.</p> <p>-She confirmed Nurse #2 had no training on the use of alternatives to restrictive intervention prior to working with clients.</p> <p>-She confirmed Nurse #1, Counselor #1, Counselor #2 and the Program Manager had no current training on the use of alternatives to restrictive intervention.</p>	V 536		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL013-101	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 06/24/2021
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V 736 V 736	<p>Continued From page 16</p> <p>27G .0303(c) Facility and Grounds Maintenance</p> <p>10A NCAC 27G .0303 LOCATION AND EXTERIOR REQUIREMENTS (c) Each facility and its grounds shall be maintained in a safe, clean, attractive and orderly manner and shall be kept free from offensive odor.</p> <p>This Rule is not met as evidenced by: Based on observation and interviews, the facility failed to ensure facility grounds were maintained in a safe, clean, attractive and orderly manner. The findings are:</p> <p>Observation on 6/23/21 at approximately 8:30 am at the group home revealed the following issues: -Patient waiting area-The carpet was stained. -Drug Screening area-The wall had reddish markings. -Dosing area -There was tape residue on the floor. The walls had black markings and peeling paint. -Front lobby-The walls had black markings and peeling paint. There was tape residue on the floor. The counter tops had peeling paint and dirt like stains. -Bathroom in dosing area-The walls had yellowish and grease stains. The soap dispenser and camera were dusty. -Hallway leading to dosing area-There was tape residue on the floor. -The walls needed to be painted and carpet cleaned throughout facility.</p> <p>Interview with the Director of Medication Assisted</p>	V 736 V 736		

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V 736	<p>Continued From page 17</p> <p>Treatment on 6/23/21 revealed: -They met at the beginning of 2020 about the maintenance issues cited by the previous surveyors. -They came up with a plan to address the maintenance issues and then COVID happened, "all their plans went out the window." -She confirmed facility staff failed to ensure facility grounds were maintained in a safe, clean, attractive and orderly manner.</p> <p>Interview with the Director of Operations on 6/23/21 confirmed: -Facility staff failed to ensure facility grounds were maintained in a safe, clean, attractive and orderly manner.</p> <p>This deficiency constitutes a re-cited deficiency and must be corrected within 30 days.</p>	V 736		