

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: MHL036-100	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED R 12/12/2018
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NAME OF PROVIDER OR SUPPLIER MCLEOD ADDICTIVE DISEASE CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 549 COX ROAD GASTONIA, NC 28054
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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 000	<p>INITIAL COMMENTS</p> <p>An annual, complaint and follow up survey was completed on 12/12/18. The first complaint was substantiated (Intake #NC145336). The second complaint was unsubstantiated (Intake #NC144348). Deficiencies were cited.</p> <p>This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment.</p> <p>Current Census: 473</p>	V 000		
V 238	<p>27G .3604 (E-K) Outpt. Opiod - Operations</p> <p>10A NCAC 27G .3604 OUTPATIENT OPIOID 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</p>	V 238	<p style="text-align: center;">DHSR - Mental Health JAN 09 2013 Lic. & Cert. Section</p>	

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Monica Harris

TITLE

Director of Quality Assurance, 1.7.2019

(X6) DATE

Division of Health Service Regulation

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V 238	<p>Continued From page 1</p> <p>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 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</p>	V 238		

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

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

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V 238	<p>Continued From page 4</p> <p>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 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> <p>(1) dual enrollment prevention measures that consist of client consents, and either program contacts, participation in the central registry or list exchanges;</p> <p>(2) call-in's for bottle checks, bottle returns</p>	V 238		

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V 238	<p>Continued From page 5</p> <p>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> <p>This Rule is not met as evidenced by: Based on records review, observations and interviews, the facility failed to ensure staff implemented policies and procedures on take home dosages affecting 1 of 23 clients (#23). The findings are:</p> <p>Review on 12/7/18 of client #23's record revealed: -admission date of 8/18/09 with diagnoses of Opioid Use Disorder; -20 year history of opiate use, chronic back pain; -treatment plan dated 6/12/18 with goals to learn tools to manage cravings and live a lifestyle of recovery, be compliant with treatment; -current dose of 47mg and current Level 3 with 4 take homes; -clean urine drug screens for 9/18/18, 10/2/18, 10/26/18, 10/31/18, 11/5/18, 12/3/18; -bottle recall passed on 2/1/18; -achieved Level 6 with 13 take homes on 2/28/18; -Level 6 revoked to Level 1 on 10/22/18 per physician #1's order due to a failed bottle recall on 10/11/18; -physician #1 also documented on 10/22/18 client #23 had failed 2 bottle recalls in a row, will need</p>	V 238		2.10.19

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V 238	<p>Continued From page 6</p> <p>90 days for level reinstatements, also need to have serious reconsideration for eligibility for "Levels AT ALL;</p> <p>-physician #1 also ordered on 10/22/18 weekly urine drug screens and client #23 needs to meet with physician next available;</p> <p>-client #23 was left a message on 10/10/18 to come in for a bottle recall, failed to show up on 10/11/18;</p> <p>-physician #2 documented on 10/29/18 "incorrect," client #23 had only failed one bottle recall in 2 years, can be reinstated to Level 3 after a month then discontinue weekly urine drug screens.</p> <p>Review on 12/7/18 of a form titled "Responsibilities of Tae Home Level Clients: Contractual Agreement with McLeod Center" signed by client #23 on 5/22/18 revealed the following documented:</p> <p>"I will check phone and/or voicemail daily for correspondence from the McLeod Center in the case I am called for a bottle recall...;"</p> <p>"I will present for bottle recall within 24 hours of receiving a call...;"</p> <p>-I understand that I may fail a bottle recall due to:...not answering my phone or not responding to my voicemail when McLeod Center calls (and thereby failing to show up for my bottle recall;"</p> <p>"I understand that failed bottle recalls result in revocation to Level One status and may be subject to a decrease in dosage depending on the circumstances of the failed bottle recall-this will be determined upon staffing with the physician."</p> <p>Review on 12/12/18 of the facility criteria for emergency take homes dated 12/5/18 in response to the pending adverse weather (snow/ice) documented the following: "For</p>	V 238		

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V 238	<p>Continued From page 7</p> <p>emergency planning purposes, we plan to give state exception take homes to clients who meet certain criteria for Sunday December 9th and Monday December 10th. Clients not qualified include(unless specifically staffed with medical director): 1) Benzo/ETG/ETS/ETOH/Barbituarate/Fentanyl/No rfentanyl+on EIA or LCMSMS within the past 30 days 2) Induction<30days 3)Mandatory medically supervised withdrawal for medical or financial reasons 4)Impairment within the past 90 days 5) Diverting within the past 90 days 6) Missed dose in the past 5 days 7) Level one clients who have failed a bottle recall within the past 90 days."</p> <p>Further review on 12/12/18 of client #23's record revealed she did not receive a take home dose for Monday December 10, 2018 for the snow/ice storm.</p> <p>Interview on 12/11/18 with client #23 revealed: -upset about losing her Level 6 take home doses; -McLeod Center called her during the hurricane, the Governor had already declared a state of emergency; -did not check her phone for messages, was not expecting a bottle recall; -did not show up for the bottle recall because did not hear voicemail until too late, as soon as heard it, went to the clinic the next day; -was dropped to Level One with no take home doses; -obtained Level 3 with take home doses the day before Thanksgiving; -picked up take homes on Friday 12/7/18 for Saturday 12/8/18 and Sunday 12/9/18; -was not given a take home dose for Monday 12/10/18 for the snow/ice storm; -was told can not get take home dose for Monday 12/10/18 because she failed a bottle recall within</p>	V 238		

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V 238	<p>Continued From page 8</p> <p>last 90 days; -went without her methadone for Monday 12/10/18; -did not understand because back on Level 3; -has filed grievances with her concerns.</p> <p>Interview on 12/12/18 with client #23's counselor revealed: -just got client #23 on her caseload about one and a half months ago; -meet with her about two times; -was an "oversight unfortunately" client #23 did not get a take home dose for Monday 12/10/18 for the snow/ice storm; -understood clients who were on Level One and had failed a bottle recall within last 90 days did not get extra take homes for storm; -was a "miscommunication;" -was instructed to go over caseload and provide nursing staff with a list of clients who were eligible for extra take homes for storm on 12/5/18 and 12/6/18; -prepared list, gave to Program Manager and then was passed on to nursing staff; -"Thought I included her (client #23) on the list, I could be wrong."</p> <p>Interview on 12/12/18 with Administrative Staff revealed: -client #23 should have received a take home dose for Monday December 10, 2018 as she was eligible; -plan to address situation and ensure the facility follows take home criteria policies and procedures.</p>	V 238		
V 736	27G .0303(c) Facility and Grounds Maintenance 10A NCAC 27G .0303 LOCATION AND	V 736		

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V 736	<p>Continued From page 9</p> <p>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 observations and interviews, the facility and its grounds were not maintained in a safe, clean, attractive and orderly manner. The findings are:</p> <p>Observation on 12/6/18 at approximately 7:30am revealed: -a sidewalk leading to a front entrance with a small covered cement porch; -shrubbery on each side of porch with pine needles covering the ground; -sign posted instructing no smoking by front entrance; -a trashcan with an ashtray top with multiple cigarette butts in it; -numerous cigarette butts strewn across the ground on each side of porch in the pine needles; -one cigarette butt still smoking.</p> <p>Observation on 12/7/18 at approximately 7:30am revealed: -three clients smoking on the front covered porch; -cloud of smoke was around the front entrance; -clients had to walk through the cloud of smoke to get into the facility; -smell of smoke in the front foyer of the facility when come through front entrance door.</p> <p>Interview on 12/6/18 and 12/7/18 with several clients revealed: -not supposed to smoke on the front porch;</p>	V 736		1.11.2019

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V 736	<p>Continued From page 10</p> <ul style="list-style-type: none"> -another space designated to smoke at other end of building with ashtrays and covered area; -people still smoke on the front porch by the front entrance; -have to walk through the smoke, clings to clothes and hair; -people throw their cigarettes down on the ground by the front porch; -sometimes smoke so bad staff have to spray air freshener in foyer to get rid of smell coming into the facility. <p>Interview on 12/12/18 with Administrative staff revealed:</p> <ul style="list-style-type: none"> -observed the cigarette butts by the front entrance; -want the facility to look clean and well kept; -will address the issue and ensure the cigarette butts are cleaned up. <p>This deficiency constitutes a re-cited deficiency and must be corrected within 30 days.</p>	V 736		

Corrective Action Plan
McLeod Addictive Disease Center, Inc. - Gastonia MAT
DHSR Survey completed December 12, 2018

V238 27G.3604 (E-K) Outpt. Opioid - Operations
10A NCAC 27G .3604 OUTPATIENT OPIOID TREATMENT.
OPERATIONS.

McLeod Center's Medical Director will establish a standardized criteria for take home medication to be used in all emergency situations by 1.14.2019. Previously, a new criteria has been established per event. Having a standardized criteria will eliminate staff confusion and will ensure consistency across all McLeod Center programs as well as a clear understanding of the requirements from clinical and medical staff members. Once established, all staff will be trained on the criteria and the standards utilized for emergency take homes will be included in the program policy and procedures manual by 2.10.2019. The list of clients eligible for emergency take homes for all State Exceptions will be reviewed by a peer prior to a finalized review by the Gastonia MAT Program Manager to ensure accuracy.

V 736 27G .0303(c) Facility and Grounds Maintenance
10A NCAC 27G .0303 LOCATION AND EXTERIOR REQUIREMENTS

Effective immediately, Gastonia MAT staff members have been placed on a rotating schedule for monitoring the grounds on an hourly basis. Clients identified as smoking in a non-designated area, will be requested to move to the specified smoking area. The property owner plans to place/add new pine needles within the landscaping at the front entrance to enhance the appearance of the facility by 1.11.2019. In addition, the custodial company contracted by McLeod Center will begin cleaning the exterior of the building on a weekly basis to ensure that all unsightly waste is regularly removed. The Gastonia MAT Program Manager will monitor the grounds on a daily basis to ensure the facility maintains a clean appearance.

DHSR - Mental Health
JAN 09 2019
Lic. & Cert. Section