

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MHL074-146</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/28/2018</b>
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NAME OF PROVIDER OR SUPPLIER  <b>PORT HEALTH SERVICES - PALADIN</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>501 PALADIN DRIVE GREENVILLE, NC 27834</b>
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V 000	<p><b>INITIAL COMMENTS</b></p> <p>An annual survey was completed on 11/28/18. A deficiency was cited.</p> <p>This facility is licensed for the following service categories: 10A NCAC 27G .4500 Substance Abuse Comprehensive Outpatient Treatment, 27G .4400 Substance Abuse Intensive Outpatient Program, 27G .3600 Outpatient Methadone.</p> <p>The census for this facility was 173.</p>	V 000		
V 238	<p><b>27G .3604 (E-K) Outpt. Opiod - Operations</b></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</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	<p>Continued From page 1</p> <p>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 dose under supervision at the clinic every 14</p>	V 238		

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V 238	<p>Continued From page 2</p> <p>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 authority. Clients who are granted additional</p>	V 238		

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V 238	<p>Continued From page 3</p> <p>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, amphetamines, THC, benzodiazepines and</p>	V 238		

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V 238	<p>Continued From page 4</p> <p>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 or solid dosage form call-in's;</p>	V 238		

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V 238	<p>Continued From page 5</p> <p>(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 record review and interview the facility failed to ensure a minimum of one random drug test was completed each month for one of ten (#1) clients. The findings are:</p> <p>Review on 11/28/18 of client #1's record revealed: - admitted 12/8/11 - diagnosis of Opioid Use Disorder</p> <p>Review on 11/28/18 of client #1's urine drug screens revealed: - a urine drug screen completed on 8/13/18 &amp; 10/19/18</p> <p>During interview on 11/28/18 a representative from the contract company reported: - she completed urine drug screens on a monthly basis and sent it to the laboratory (lab) - client #1's urine was collected on 9/10/18; 9/26/18 &amp; 11/26/18 - she was notified by the lab that client#1's September 2018 results were pending - she emailed her supervisor at the contracting office of the pending results - once she notified her supervisor, she was not sure what happened with the pending results</p>	V 238		

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V 238	<p>Continued From page 6</p> <ul style="list-style-type: none"> <li>- she had no documentation of the urine drug screens she collected on the above dates</li> </ul> <p>During interview on 11/28/18 the Director of the facility reported:</p> <ul style="list-style-type: none"> <li>- the facility contracted with an agency that completed the urine drug screens</li> <li>- he was not made aware when a urine drug screen was pending</li> <li>- drug screens are discussed in their staff meetings</li> <li>- he could not be for sure if client #1's drug screens had been discussed in staffing</li> <li>- the clinician would verbally asked the representative in staffing if a drug screen had returned...there were no written documentation of the representatives responses</li> <li>- he planned to meet with the supervisor from the contract company tomorrow</li> <li>- they will discuss how to ensure the facility received results of all completed urine drug screens</li> </ul>	V 238		