

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>MHL0411199</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>11/17/2021</b>
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NAME OF PROVIDER OR SUPPLIER  <b>ALEF HIGH POINT, LLC</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>919 PHILLIPS AVENUE, SUITE 107 HIGH POINT, NC 27262</b>
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V 000	<p><b>INITIAL COMMENTS</b></p> <p>An annual and complaint Survey was completed on November 17, 2021. The complaint was substantiated (Intake #NC00182687). Deficiencies were cited.</p> <p>This facility is licensed for the following service categories: 10A NCAC 27G .3600 Outpatient Opioid Treatment; 10A NCAC 27G .3700 Day Treatment Facility for Individuals with Substance Abuse Disorders and 10A NCAC 27G .4400 SAIOP: Substance Abuse Intensive Outpatient Program.</p> <p>Client Census was 16.</p>	V 000		
V 118	<p><b>27G .0209 (C) Medication Requirements</b></p> <p>10A NCAC 27G .0209 MEDICATION REQUIREMENTS (c) Medication administration: (1) Prescription or non-prescription drugs shall only be administered to a client on the written order of a person authorized by law to prescribe drugs. (2) Medications shall be self-administered by clients only when authorized in writing by the client's physician. (3) Medications, including injections, shall be administered only by licensed persons, or by unlicensed persons trained by a registered nurse, pharmacist or other legally qualified person and privileged to prepare and administer medications. (4) A Medication Administration Record (MAR) of all drugs administered to each client must be kept current. Medications administered shall be recorded immediately after administration. The MAR is to include the following: (A) client's name; (B) name, strength, and quantity of the drug;</p>	V 118		

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

Division of Health Service Regulation

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V 118	<p>Continued From page 1</p> <p>(C) instructions for administering the drug; (D) date and time the drug is administered; and (E) name or initials of person administering the drug. (5) Client requests for medication changes or checks shall be recorded and kept with the MAR file followed up by appointment or consultation with a physician.</p> <p>This Rule is not met as evidenced by: Based on interview and record review, the facility failed to ensure prescription drugs were only administered to clients on the written order of a person authorized by law to prescribe drugs, for 3 (client #1, client #4 and client #5) of 7 clients surveyed. The findings are:</p> <p>Review on 11-16-21 of client #1's facility record revealed: -An admission date of 10-5-21 -Was 63 years old -Diagnoses of Severe Opioid Use Disorder and Moderate Cocaine Use Disorder -A medical examination on 10-5-21 by the facility's Nurse Practitioner (NP) -90 milligrams (mg) of methadone, once daily was administered with an unsigned written order on 10-5-21 -93 mg of methadone, once daily was administered with an unsigned written order on 10-6-21, 10-5-21 order for 90 mg was signed on 10-21-21 and a 10-6-21 order for 93 mg was signed on 11-16-21</p>	V 118		

Division of Health Service Regulation

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V 118	<p>Continued From page 2</p> <p>Review on 11-16-21 of client #4's facility record revealed: -An admission date of 10-14-21 -34 years old -Diagnoses of Severe Opioid Use Disorder and Moderate Cannabis Use Disorder -A medical examination on 10-14-21 by the facility's Nurse Practitioner (NP) for 20 mg of methadone, once daily was administered with an unsigned written order on 10-14-21, 40 mg of methadone, once daily was administered with an unsigned written order on 10-15-21 and 10-14-21 and 10-15-21 orders were signed on 10-21-21</p> <p>Review on 11-16-21 of client #5's facility record revealed: -An admission date of 10-7-21 -Was 62 years old -Diagnoses of Opioid Use Disorder and Opioid Withdrawal -A medical examination on 10-7-21 by the facility's Nurse Practitioner (NP) for 25 mg of methadone, once daily was administered with an unsigned written order on 10-7-21, -30 mg of methadone, once daily was administered with an unsigned written order on 10-11-21 10-7-21 and 10-11-21 orders were signed on 10-21-21</p> <p>Interview on 11-17-21 with the Program Director (PD) revealed: -Was aware the Nurse Practitioner (NP) was late signing orders -"I had a discussion with her yesterday (11-16-21) about it." -The NP also worked at a hospital, and when they exit their digital records, all forms are</p>	V 118		

Division of Health Service Regulation

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V 118	Continued From page 3  automatically signed -Assured the orders would be signed in a timely manner going forward  Interview on 11/17/21 with the NP revealed: -Physician's orders: "signed late? Yes, [The PD] mentioned it to me yesterday (11/16/21) ..." -Also worked at a hospital. -"When I am at the hospital and completing documentation, once you put it in, then you noted is automatically signed ..." -Had anticipated the Methadone's system was the same as the hospital's system. -"I would go into the doctor's digital signature and I sign off on them (physician's orders), but I am not here every day ...I am not familiar with the system here (Methadone clinic) ... I was told yesterday (11/16/21) to sign (the orders) every day and I am fine with that	V 118		
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	V 238		

Division of Health Service Regulation

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V 238	<p>Continued From page 4</p> <p>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 treatment and a minimum of 180 days of continuous program compliance, a client may be</p>	V 238		

Division of Health Service Regulation

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V 238	<p>Continued From page 5</p> <p>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 found to be responsible in handling opioid drugs. Except in instances involving a client with a</p>	V 238		

Division of Health Service Regulation

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V 238	<p>Continued From page 6</p> <p>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> <p>(h) Random Testing. Random testing for alcohol and other drugs shall be conducted on each</p>	V 238		

Division of Health Service Regulation

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V 238	<p>Continued From page 7</p> <p>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 required to establish and maintain a diversion control plan as part of program operations and</p>	V 238		



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V 238	<p>Continued From page 8</p> <p>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 interview and record review, the facility staff failed to comply with all federal laws and regulations (42 CFR 8.12 Federal Opioid Treatment Standards), for 3 of 16 clients (#5, #6 and #7) of 16 clients. The findings are:</p> <p>Review on 11-15-21 of "42 CFR 8.12 Federal Opioid Treatment Standards (f) (2) Initial medical examination services" revealed: -"OTPs (Opioid Treatment Programs) shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP."</p>	V 238		

Division of Health Service Regulation

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V 238	<p>Continued From page 9</p> <p>Interview on 11-15-21 with the complainant revealed: -The facility was in violation of federal regulations involving initial physical examinations the exams had to be performed by a medical doctor, not a nurse practitioner -The facility needed to request and obtain a waiver of those rules before any additional intakes were performed by the nurse practitioner -3 additional intakes and examinations were completed after the facility was informed, they were in violation, prior to obtaining a waiver</p> <p>Review on 11-16-21 of client #4's facility record revealed: -An admission date of 10-14-21 -Was 34 years old -Diagnoses of Severe Opioid Use Disorder and Moderate Cannabis Use Disorder -An initial medical examination on 10-14-21 by the facility's Nurse Practitioner (NP)</p> <p>Further review on 11-17-21 failed to reveal any initial medical examination by, " ...a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP"</p> <p>Review on 11-16-21 of client #6's facility record revealed: -An admission date of 10-14-21 -Was 40 years old -A diagnosis of Opioid Use Disorder -An initial medical examination on 10-14-21 by the facility's NP</p> <p>Further review on 11-17-21 failed to reveal any initial medical examination by, " ...a program</p>	V 238		

Division of Health Service Regulation

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V 238	<p>Continued From page 10</p> <p>physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP"</p> <p>Review on 11-16-21 of client #7's facility record revealed: -An admission date of 10-15-21 -Was 43 years old -A diagnosis of Opioid Use Disorder -An initial medical examination on 10-15-21 by the facility's NP</p> <p>Further review on 11/17/21 failed to reveal any initial medical examination by, " ...a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP"</p> <p>Interview on 11-15-21 with the NP revealed: -She had worked in a sister facility where she had completed the intake exam -The sister facility had a waiver, allowing her to complete the initial exam without issue assumed this facility also had the waiver</p> <p>Interview on 11-15-21 with the Program Director revealed: -She thought the facility had the waiver -Applied for the waiver as soon as she was informed it was needed -The waiver was granted the same day</p>	V 238		