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| V 000 | INITIAL COMMENTS<br><br>An Annual and Follow Up Survey was completed on 07/17/19. A deficiency was re-cited.<br><br>This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Methadone<br><br>The census for the facility was 216. | V 000 | | |
| V 238 | 27G .3604 (E-K) Outpt. Opiod - Operations<br><br>10A NCAC 27G .3604 OUTPATIENT OPIOD TREATMENT. OPERATIONS.<br>(e) The State Authority shall base program approval on the following criteria:<br>(1) compliance with all state and federal law and regulations;<br>(2) compliance with all applicable standards of practice;<br>(3) program structure for successful service delivery; and<br>(4) impact on the delivery of opioid treatment services in the applicable population.<br>(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 | V 238 | | |

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month.
(1) Levels of Eligibility are subject to the following conditions:
(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;
(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;
(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;
(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;
(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;
(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
(G) Level 7. After four years of continuous

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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.
(2) Criteria for Reducing, Losing and Reinstatement of Take-Home Eligibility:
(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;
(B) A client who tests positive on three drug screens within the same 90-day period shall have all take-home eligibility suspended; and
(C) The reinstatement of take-home eligibility shall be determined by each Outpatient Opioid Treatment Program.
(3) Exceptions to Take-Home Eligibility:
(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.
(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

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| V 238 | Continued From page 3<br>30-day supply of take-home medication and shall make monthly clinic visits.<br>(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:<br>(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.<br>(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.<br>(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.<br>(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 | V 238 | | |

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alternate scientifically valid method.
(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.
(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.
(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:
(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

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| V 238 | Continued From page 5<br>review of the levels of methadone or other medications approved for the treatment of opioid addiction;<br>(5) client attendance minimums; and<br>(6) procedures to ensure that clients properly ingest medication.<br><br>This Rule is not met as evidenced by:<br>Based on observation, record review and interview, the facility failed to adhere to its diversion control plan. The findings are:<br><br>Review on 07/17/19 of the facility's public file maintained by the Division of Health Service Regulation (DHSR) revealed:<br>- 06/05/18 statement of deficiencies report noted violation regarding diversion control plan regarding Buprenorphine and monitoring clients while medication dissolved<br><br>Review on 07/17/19 of the facility's diversion control plan policy updated 08/03/18 revealed "Medication administration...The nurse will ensure that the patient had ingested medication. There is a camera on the patient receiving methadone and a large mirror behind the patient to prevent the patient from concealing and diverting Methadone. Methadone medication ingestion will be ensured by the patient being asked to speak to the medication nurse before leaving the medication window. Buprenorphine medication will be roughly chopped. Buprenorphine medication ingestation will be ensured by the patient sitting in the view of the medication nurse for observation, to allow time for the sublingual tablet to dissolve...The patient will be asked to show the medication | V 238 | | |

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| V 238 | Continued From page 6<br>nurse that the sublingual tablet has dissolved before leaving the medication area. "<br><br>Observation at 6:40-6:50am on 07/17/19 revealed:<br>- a registered nurse (RN) on duty and administering medication in the dosing room<br>- there were 2 separate dosing windows (on separate sides of the dosing room)<br>- the RN fluctuated between administering Methadone from one window and Buprenorphine from the other window<br>- in front of the Buprenorphine window there were approximately 4-6 chairs approximately 5 feet from the dosing window<br>- there was a camera beside the nurse that sat at the Methadone window that monitored areas surrounding the building but not the dosing area.<br>- two clients (#911, #1070) seated in chairs on the Buprenorphine side<br>- from the Methadone dosing window, three clients were served<br>- the RN looked over towards the Buprenorphine window to check on clients..*note: it was difficult to fully see the Buprenorphine clients from the Methadone dosing window as well as monitor the Methadone clients<br><br>Further sporadic observations on 07/17/19 between 7:00-10:30am revealed:<br>- no more than three clients at the same time seated near the Buprenorphine window awaiting the medication to dissolve<br><br>During interview on 07/17/19, four of ten audited clients reported:<br>- Monday-Friday two nurses usually dispense medications from both windows<br>- one nurse dispensed medications Saturday and Sunday from 7:00-9:00am | V 238 | | |

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| V 238 | Continued From page 7<br>- whether weekends or weekdays, no more than 4 clients had been in the waiting area at the same time awaiting Buprenorphine to dissolve<br><br>During interview on 07/17/19, the RN reported:<br>- she had worked at the facility for two years<br>- it could take up to 12-15 minutes for Buprenorphine to dissolve<br>- the second nurse scheduled to work on this date, called in due to an emergency<br>- Methadone and Buprenorphine were dispensed from same window on the weekend...Methadone dispensing machine would be moved to the Buprenorphine window.<br><br>During interview on 07/17/19, the Program Director reported:<br>- she recalled during the June 2018 DHSR survey a citation was identified regarding monitoring clients, diversion plan and Buprenorphine/Methadone<br>- since 2018 changes had been made to their policy by adding wording and procedures for Buprenorphine clients and nursing staff should slow down the number of clients dosed to increase monitoring of Buprenorphine and Methadone clients<br>- conversations were held regarding increase of nursing on the weekend but that had not been secured. She anticipated a definitive resolution within the next 2-3 months regarding the addition of a second nurse on the weekend<br>- no back up or as needed nurses were available for assistance if someone called out. The agency had sister facilities but none were close in location to this clinic.<br>- an increase in client census numbers occurred between June 2018-July 2019 (reflecting more clients served since the June 2018 DHSR survey). | V 238 | | |

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| V 238 | Continued From page 8<br><br>This deficiency constitutes a re-cited deficiency and must be corrected within 30 days. | V 238 | | |