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V 000	INITIAL COMMENTS An annual, complaint and follow up survey was completed September 14, 2022. The complaint was substantiated (intake # NC00192343). Deficiencies were cited. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment. This facility has a current census of 145. The survey sample consisted of audits of 13 current clients.	V 000		
V 118	27G .0209 (C) Medication Requirements 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; (C) instructions for administering the drug; (D) date and time the drug is administered; and	V 118		

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V 118	Continued From page 1 (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. This Rule is not met as evidenced by: Based on record review and interview the facility failed administer medication on a written physician order for 1 of 13 audited clients (#459062). The findings are: Review on 09/14/22 of client #459062's record revealed: - 43 year old male. - Admission date of 08/17/22. - Diagnoses of Opioid Dependence, Traumatic Brain Injury and Attention Deficit Hyperactivity Disorder. - No signed physician order to increase Methadone to 35 milligrams (mg) daily on 09/01/22. Review on 09/14/22 of client #459062's signed physician's order revealed: 08/17/22 - Induction dose of 30 mg of Methadone daily. Review on 09/14/22 of client #459062's August 2022 and September 2022 MAR revealed: August 2022 - 08/17/22 thru 08/31/22 - Methadone 30mg administered daily.	V 118		

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V 118	Continued From page 2 September 2022 - 09/01/22 thru 09/12/22 - Methadone 35mg administered daily. Interview on 09/14/22 the Licensed Practical Nurse (LPN) stated: - The physician had given a verbal order to increase client #459062's Methadone to 35mg on 09/01/22. - The facility began obtaining a physician signature on increases of Methadone on 09/07/22 at the weekly staff meeting. Interview on 09/14/22 the Program Director stated: - The program used for documentation of Methadone administration did not currently have an area for a physician signature. - The facility began having the physician sign a document for all Methadone changes on 09/07/22. - The facility had begun to address the lack of physician signatures on medication changes.	V 118		
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.	V 235		

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V 235	Continued From page 3 (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. 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 increments thereof. The findings are: Review on 09/13/22 of facility records revealed: - The facility was serving a total of 145 clients. - 2 Licensed Clinical Addictions Specialists (LCAS) on staff as therapists/counselors. - Therapist #1 had a case load of 75 clients. - Therapist #2 had a case load of 68 clients. During interview on 09/13/22 Therapist #1 stated: - She was a LCAS. - She had a current caseload of 75 clients. - She met with clients at least one time a month and clients also attended groups.	V 235		

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V 235	Continued From page 4 - Her current case load was difficult to manage. During interview on 09/13/22 Therapist #2 stated: - She was a LCAS. - She had a current caseload of approximately 60 clients. - She met with clients one time a month and the clients also attend group therapy. - She conducted groups at the facility. During interview on 09/13/22 the Program Director stated she was aware the therapists case load were over the limit. She had been trying to hire new staff and they were currently under staffed. 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	V 238		

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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 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

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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 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

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V 238	Continued From page 7 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 30-day supply of take-home medication and shall make monthly clinic visits. (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: (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. (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. (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. (h) Random Testing. Random testing for alcohol and other drugs shall be conducted on each active opioid treatment client with a minimum of	V 238		

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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.
(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

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V 238	Continued From page 9 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 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. This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to ensure compliance with regulations and applicable standards of practice for exceptions to take home eligibility for 1 of 13 audited clients (#464273) and failed to conduct a minimum of one urine drug screen (UDS) each month for 1 of 13 audited client (#407706). The findings are: Finding #1 Reviews on 9/13/22 and 9/14/22 of client #464273's record revealed: - 52 year old female admitted 1/18/18. - Diagnoses included Opioid Dependence,	V 238		

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uncomplicated; Major Depressive Disorder, recurrent, moderate; Panic Disorder (episodic paroxysmal anxiety).
- Assessment dated 2/25/22 included ". . . recently had her gall bladder removed and 3 adhesions to her organs separated. She experienced complications from the surgery and was hospitalized for several days. . . "
- Take Home Exception request dated 11/23/21 for 4 take homes approved due to client #464273's illness and physical inability to conform to mandatory clinic attendance schedule.
- Dosing record for November 2021 included documentation of 11/24/21 administration of 5 take home doses of Methadone 100 mg for 11/25/21 - 11/29/21.
- Dosing records for January 2022 included documentation of 1/07/22 administration of 5 take home doses of Methadone 100 mg for 1/08/22 - 1/12/22; and 1/20/22 administration of 2 take home doses of Methadone 100 mg for 1/21/22 - 1/22/22.
- No approved take home exception requests for 1/08/22 - 1/12/22 or 1/21/22 - 1/22/22.

During interview on 9/14/22 client #464273 stated:
- She had 6 take homes in 2021, but lost them when she took a gabapentin for pain relief in November 2021.
- She did a urinary drug screen at the clinic and tested positive for gabapentin and subsequently lost her take homes.
- She experienced life threatening complications following a surgical procedure in November 2021.
- She had six follow up surgeries in rapid succession after her initial operation.
- She didn't know what was going to happen to her.
- She was not allowed to walk after her final

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V 238	Continued From page 11 surgery; she requested and was granted a take home exception because she was physically unable to attend the clinic to receive her dose. - The clinic was a "life saver." During interview on 9/13/22 the Medical Director stated: - She started working at the facility in March 2022. - One of her job responsibilities was to "sign off on take homes" after discussion with the treatment team. - She was also responsible for sending take home exception requests to SOTA. - When a take home exception was approved she notified the team including the dosing nurse. - Vacations and out of town work were the main reasons for take home exception requests. During interviews on 9/13/22 and 9/14/22 the Program Director stated: - Client #464273 had surgery in November 2021 and experienced complications requiring additional surgery. - There were four or five periods of time in late 2021 when client #464273 needed take home exceptions because she was bedridden. - The November 2021 take home exceptions for client #464273 were not requested via the State Opioid Treatment Authority (SOTA) website as required. - The current Medical Director took over responsibility for take home exception requests in March 2022. - She and the Medical Director have reviewed regulatory standards from SOTA, the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA) and reviewed the standards with facility staff during weekly staff meetings.	V 238		

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V 238	Continued From page 12 Finding #2 Review on 09/14/22 of client #407706's record revealed: -41 year old male. -Admission date of 09/21/07. -UDS completed on: 05/13/22, 06/02/22, 07/14/22. -No UDS completed for the month of August 2022. During interview on 09/14/22 the Program Director revealed: -Client #407706 had three dates in August for UDS and the laboratory worker was late to the clinic on all three dates he was scheduled. -She was aware the clients had to be drug screened every month.	V 238		