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V 000	INITIAL COMMENTS An annual survey was completed on 4/3/18. Deficiencies were cited. This facility is licensed for the following service category: 10A NCAC 27G .3600 Outpatient Opioid Treatment.	V 000		
V 105	27G .0201 (A) (1-7) Governing Body Policies 10A NCAC 27G .0201 GOVERNING BODY POLICIES (a) The governing body responsible for each facility or service shall develop and implement written policies for the following: (1) delegation of management authority for the operation of the facility and services; (2) criteria for admission; (3) criteria for discharge; (4) admission assessments, including: (A) who will perform the assessment; and (B) time frames for completing assessment. (5) client record management, including: (A) persons authorized to document; (B) transporting records; (C) safeguard of records against loss, tampering, defacement or use by unauthorized persons; (D) assurance of record accessibility to authorized users at all times; and (E) assurance of confidentiality of records. (6) screenings, which shall include: (A) an assessment of the individual's presenting problem or need; (B) an assessment of whether or not the facility can provide services to address the individual's needs; and (C) the disposition, including referrals and recommendations; (7) quality assurance and quality improvement activities, including:	V 105		

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V 105	Continued From page 1 (A) composition and activities of a quality assurance and quality improvement committee; (B) written quality assurance and quality improvement plan; (C) methods for monitoring and evaluating the quality and appropriateness of client care, including delineation of client outcomes and utilization of services; (D) professional or clinical supervision, including a requirement that staff who are not qualified professionals and provide direct client services shall be supervised by a qualified professional in that area of service; (E) strategies for improving client care; (F) review of staff qualifications and a determination made to grant treatment/habilitation privileges: (G) review of all fatalities of active clients who were being served in area-operated or contracted residential programs at the time of death; (H) adoption of standards that assure operational and programmatic performance meeting applicable standards of practice. For this purpose, "applicable standards of practice" means a level of competence established with reference to the prevailing and accepted methods, and the degree of knowledge, skill and care exercised by other practitioners in the field; This Rule is not met as evidenced by: Based on records review and interviews, the facility failed to ensure adoption of standards that assure operational and programmatic performance meeting applicable standards of practice. The findings are:	V 105		

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V 105	Continued From page 2 Finding #1: Review on 4/3/18 of client #2's record revealed: -admission date of 12/7/17 with diagnosis of Opioid Dependence; -physician's order dated 12/7/17 for a peak and trough on 12/1017; -no documentation of a completed peak and trough present in the record; -no documentation of an explanation why peak and trough was not completed on the record. Interview on 4/2/18 with client #2 revealed: -was supposed to get a peak and trough; -saw the request in her counselor's box; -took it to the doctor herself; -could not stay to get done, had to go home; -still have not completed a peak and trough. Interview on 4/3/18 with the Registered Nurse revealed: -client #2 decided she would use her peak and trough from another out of state facility; -decided against getting a new one, "that was on her;" -it was just a trough so the doctor at this facility did not accept it; -"we were going to look into getting her one but she had a miscarriage." Finding #2: Review on 4/2/18 of client #4's record revealed: -admission date of 1/27/17 with diagnosis of Opioid Dependence-Severe; -a positive drug screen for alcohol dated 2/20/18; -physician's order dated 2/21/18 for breathalyzers four times a week for 30 days for a total of 16 breathalyzers; -documentation of breathalyzers completed on the following dates: 2/26/18, 2/27/18, 3/1/18,	V 105		

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V 105	Continued From page 3 3/2/18, 3/3/18, 3/4/18, 3/6/18, 3/7/18, 3/20/18 and 3/23/18 for a total of 10 breathalyzers. Interview on 4/2/18 with client #4 revealed: -had a positive drug screen for alcohol; -lost all his take home doses; -drug tested twice a month now. Interview on 4/3/18 with the Licensed Professional Nurse revealed: -was not able to do all the ordered breathalyzers; -facility physician ordered more than the usual breathalyzers for clients; -ran out of the mouth pieces required for the test; -Program Director even went to several pharmacies to try to purchase some to no avail; -ordered more but took over a week to be delivered.	V 105		
V 112	27G .0205 (C-D) Assessment/Treatment/Habilitation Plan 10A NCAC 27G .0205 ASSESSMENT AND TREATMENT/HABILITATION OR SERVICE PLAN (c) The plan shall be developed based on the assessment, and in partnership with the client or legally responsible person or both, within 30 days of admission for clients who are expected to receive services beyond 30 days. (d) The plan shall include: (1) client outcome(s) that are anticipated to be achieved by provision of the service and a projected date of achievement; (2) strategies; (3) staff responsible; (4) a schedule for review of the plan at least annually in consultation with the client or legally responsible person or both;	V 112		

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V 112	Continued From page 4 (5) basis for evaluation or assessment of outcome achievement; and (6) written consent or agreement by the client or responsible party, or a written statement by the provider stating why such consent could not be obtained. This Rule is not met as evidenced by: Based on records review and interviews, the facility failed to develop and implement strategies with the client affecting 4 of 14 clients (#1, #6, #8 and 10). The findings are: Review on 4/3/18 of client #1's record revealed: -admission date of 2/15/18 with diagnosis of Opiate Dependence with Polysubstance Abuse; -treatment plan dated 2/15/18 with goals listed; -no staff strategies listed. Review on 4/3/18 of client #6's record revealed; -admission date of 6/5/15 with diagnosis of Opioid Use Disorder; -expired treatment plan dated 2/6/17 with goals listed; -no staff strategies listed. Review on 4/3/18 of client #8's record revealed: -admission date of 4/15/13 with diagnosis of Opiate Dependence; -updated treatment plan dated 4/3/18 with listed goals and staff strategies; -treatment plan not signed by client #8. Review on 4/3/18 of client #10's record revealed:	V 112		

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V 112	Continued From page 5 -admission date of 11/5/10 with diagnosis of Opioid Use Disorder; -updated treatment plan dated 4/3/18 with listed goals and staff strategies; -treatment plan not signed by client #10. Interview on 4/3/18 with the Program Director revealed will address issues with treatment plans with staff.	V 112		
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 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	V 238		

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V 238	Continued From page 6 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 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	V 238		

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V 238	Continued From page 7 (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 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	V 238		

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V 238	Continued From page 8	V 238		

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 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

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V 238	Continued From page 9 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 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;	V 238		

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V 238	Continued From page 10 (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 records review and interviews, the facility failed to ensure during the first year of continuous treatment a patient attended a minimum of two counseling sessions per month and after the first year and in all subsequent years of continuous treatment a patient attended a minimum of one counseling session per month affecting 6 of 14 clients (#1, #2, #3, #5, #7, #9). The findings are: Review on 4/3/18 of client #1's record revealed: -admission date of 2/15/18 with diagnosis of Opiate Dependence with Polysubstance Abuse; -only one counseling session documented for 3/2018. Review on 4/3/18 of client #2's record revealed: -admission date of 12/7/17 with diagnosis of Opioid Use Severe; -only one counseling session documented for 1/2018, 2/2018 and 3/2018. Review on 4/2/18 of client #3's record revealed: -admission date of 6/23/16 with diagnosis of Opioid Dependence; -no counseling sessions documented for 2/2018 and 1/2018.	V 238		

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V 238	Continued From page 11 Review on 4/2/18 of client #5's record revealed: -admission date of 9/14/17 with diagnosis of Opioid Use Disorder-Severe; -only one counseling session documented for 1/2018 and 3/2018. Review on 4/3/18 of client #7's record revealed: -admission date of 10/31/14 with diagnosis of Opioid Dependence; -no counseling sessions documented for 1/2018, 2/2018 and 3/2018. Review on 4/2/18 of client #9's record revealed: -admission date of 9/5/14 with diagnosis of Opiate Dependence; -no counseling sessions documented for 3/2018. Interview on 4/3/18 with the Program Director revealed issue with counseling sessions will be addressed with staff.	V 238		