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V 000	INITIAL COMMENTS An annual and complaint survey was completed on 7/18/18. The complaint was unsubstantiated (Intake # NC140672). Deficiencies were cited. Current census in 3600 program was 233. This facility is licensed for the following service categories: 10A NCAC 27G .1100 Partial Hospitalization for Individuals who are Acutely Mentally Ill. 10A NCAC 27G .3700 Day Treatment for Individuals with Substance Abuse Disorders. 10A NCAC 27G .4400 Substance Abuse Intensive Outpatient Program. 10A NCAC 27G .5400 Day Activity for Individuals of All Disability Groups. 10A NCAC 27G .3600 Outpatient Opioid Treatment.	V 000	RECEIVED By DHSR - Mental Health Lic. & Cert. Section at 9:24 am, Aug 13, 2018	
V 233	27G .3601 Outpt. Opiod Tx. - Scope 10A NCAC 27G .3601 SCOPE (a) An outpatient opioid treatment facility provides periodic services designed to offer the individual an opportunity to effect constructive changes in his lifestyle by using methadone or other medications approved for use in opioid treatment in conjunction with the provision of rehabilitation and medical services. (b) Methadone and other medications approved for use in opioid treatment are also tools in the detoxification and rehabilitation process of an opioid dependent individual. (c) For the purpose of detoxification, methadone and other medications approved for use in opioid treatment shall be administered in decreasing doses for a period not to exceed 180 days. (d) For individuals with a history of being physiologically addicted to an opioid drug for at	V 233		

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V 233	Continued From page 1 least one year before admission to the service, methadone and other medications approved for use in opioid treatment may also be used in maintenance treatment. In these cases, methadone and other medications approved for use in opioid treatment may be administered or dispensed in excess of 180 days and shall be administered in stable and clinically established dosage levels. This Rule is not met as evidenced by: Based on record reviews and interviews, the facility failed to provide coordination of care with medical services for 2 of 14 sampled clients (Client #5 and Client #6). The findings are: Record review on 7/16/18 for Client #5 revealed: -Admission date of 11/22/17. -Diagnoses included: Opioid Use Disorder, Sedative Use Disorder, Depression, Anxiety Disorder, Post-Traumatic Stress Disorder, Borderline Personality Disorder and Agoraphobia. -Intake physical assessment by Medical Director dated 11/22/17 noted client "was followed by Psychiatrist-no meds." Had been on Remeron and Gabapentin in past. -Controlled Substance Report dated 11/27/17 revealed no controlled prescriptions. -Monthly Urine Drug Screens (UDS) were positive for amphetamines and/or Benzodiazepines each month since admit date. -Treatment Plan dated 4/6/18 revealed a goals of: ---"Integrate treatment of current medical issues with opioid treatment. Obtain referral to Primary Care Physician (PCP) or other medical providers to assess kidney, intestinal issues as well as migraines.	V 233		

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V 233	Continued From page 2 ---Address co-occurring mental health issues of anxiety and ADHD." -While counseling notes revealed discussion of positive UDS there was no indication of referral to a PCP or mental health professionals. -No other documentation of referral to PCP or mental health professionals. Record review on 7/16/18 for Client #6 revealed: -Admission date of 6/28/18. -Diagnoses included: Opioid Use Disorder, Hypertension, Insulin Dependent (Type II) Diabetes, Hyperlipidemia and Gastro Esophageal Reflux. -Physician ordered medication included: Levemir, Atorvastatin, Lisinopril, Metformin, Gabapentin and Amitriptyline. -Treatment Plan dated 6/28/18 revealed a goal to "integrate treatment of current medical issues with opioid treatment." -Previous treatment documents from local methadone clinic included note by their medical director regarding EKG tests showing continued high QT prolongation scores due to complex medical issues/medications. -No documentation of coordination of care with the PCP. Interview on 7/17/18 with Client #5 revealed: -She had previous prescriptions for Klonopin 4mg daily and Adderall. -She was trying to get a new doctor as well as insurance. -No one from the clinic had made a specific referral for a physician. Interview on 7/17/18 with Client #6 revealed: -"He transferred from a local clinic about 1 month ago because they reduced his dose." -"Had a benzo prescription but not since 2012	V 233		

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V 233	Continued From page 3 and while his anxiety had increased he did not take anything for it." -"His sugar had been out of whack but was stable now." Interview on 7/17/18 with the Medical Director revealed: -There was no EKG machine here. -"QTC was just one way to measure but not the end all to maintain a patient." -"We should coordinate care with the primary care" for Client #6. -"We look at COWs scores and relapse potential." Interview on 7/18/18 with the Program Director revealed: -"I looked into Client #5's record and did not find an actual referral." -"We need to do a better job of coordinating care for our folks."	V 233	V 233 Coordination of Care will be obtained and maintained with medical professionals who provide care to our patients. Additionally, referrals will be made and documented in the event that a patient needs to establish a relationship with a Primary Care Physician. Responsible Person: Nursing Supervisor	9/1/2018
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	V 238		

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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 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

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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 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

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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 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.

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V 238	Continued From page 7 (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 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	V 238		

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V 238	Continued From page 8 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 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 thirteen of thirteen audited clients (Clients #1, #2, #3, #4, #5, #6, #7, #8, #9, #10, #11, #13 and #14) were not dually enrolled within a 75 miles radius .The findings are: Review on 7/17/18 of client #1's record revealed: -Admission date: 2/28/17 -Diagnoses of Opioid Use Disorder, Hepatitis C and High Blood Pressure. Review on 7/17/18 of client #2's record revealed: -Admission date: 10/10/17 -Diagnosis of Opioid Use Disorder.	V 238		

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V 238	Continued From page 9 Review on 7/17/18 of client #3's record revealed: -Admission date: 3/20/18 -Diagnosis of Opioid Use Disorder. Review on 7/17/18 of client #4's record revealed: -Admission date: 6/12/18 -Diagnosis of Opioid Use Disorder. Review on 7/17/18 of client #5's record revealed: -Admission date: 11/22/17 -Diagnoses of Opioid Use Disorder, Sedative Use Disorder, Depression, Anxiety Disorder, Post-Traumatic Stress Disorder, Borderline Personality Disorder and Agoraphobia. Review on 7/17/18 of client #6's record revealed: -Admission date: 6/28/18 -Diagnoses of Opioid Use Disorder, Hypertension, Insulin Dependent Diabetes, Hyperlipidemia and Gastro Esophageal Reflux. Review on 7/17/18 of client #7's record revealed: -Admission date: 4/10/18 -Diagnoses of Opioid Use Disorder, Asthma and Depression. Review on 7/17/18 of client #8's record revealed: -Admission date: 12/3/17 -Diagnosis of Opioid Use Disorder. Review on 7/17/18 of client #9's record revealed: -Admission date: 3/7/18 -Diagnosis of Opioid Use Disorder. Review on 7/17/18 of Client #10's record revealed: - Admission date of 1/2/18. -Diagnosis of Opioid Use Disorder. Review on 7/17/18 of Client #11's record	V 238		

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V 238	Continued From page 10 revealed: - Admission date of 1/30/18. -Diagnoses of Opioid Use Disorder and Hypertension. Review on 7/17/18 of Client #13's record revealed: - Admission date of 2/27/18. -Diagnosis of Opioid Use Disorder. Review on 7/17/18 of Client #14's record revealed: - Admission date of 2/16/18. -Diagnosis of Opioid Use Disorder and Attention Deficit Hyperactivity Disorder. Interview on 7/18/18 with the Program Director revealed: -It was the responsibility of the front desk/administrative staff to fax new client enrollment information to 21 clinics. Unfortunately, staff kept the original sheet faxed, not the sheet with the fax confirmation printed across it. -He had already corrected the problem.	V 238	V 238 The process of sending Dual Enrollment Notifications to the 21 Opioid Treatment Centers within 75 miles of Katharos Sanctuary will include filing the FAX coversheet verifying that the communication was received by each program. This will serve as evidence that all new patients are enrolled solely at Katharos Sanctuary. Moving forward, Katharos will be using the Central Registry system for the purpose of communicating with other North Carolina programs and, as it becomes available, neighboring states. Until neighboring state's information is available FAX confirmations will be kept for South Carolina and Tennessee programs. The Program Director will review FAX verifications weekly to ensure this protocol is followed. Responsible Persons: Administrative Assistant and Program Director	8/18/2018 FAX 9/1/2018 Central Registry
V 752	27G .0304(b)(4) Hot Water Temperatures 10A NCAC 27G .0304 FACILITY DESIGN AND EQUIPMENT (b) Safety: Each facility shall be designed, constructed and equipped in a manner that ensures the physical safety of clients, staff and visitors. (4) In areas of the facility where clients are exposed to hot water, the temperature of the water shall be maintained between 100-116 degrees Fahrenheit.	V 752		

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V 752	Continued From page 11 This Rule is not met as evidenced by: Based on observations and interviews, the facility failed to maintain the hot water temperatures between 100 - 116 degrees Fahrenheit (F) in areas where clients are exposed to water. The findings are: Observation on 7/16/18 at 11:20 AM of the hot water temperature in the client bathroom revealed the hot water measured 84 Degrees F. The temperature was tested again on 7/18/18 at 10:15AM in the client restroom and measured 65 Degrees F. Interview on 7/18/18 with the Program Director revealed: -He had already spoken to the landlord regarding the "on-demand" unit beneath the sink in the restroom. The landlord reported he would have to replace the unit.	V 752	V 752 The hot water box located under the sink has been replaced to ensure water temperature of 100-116 degrees is maintained for the purpose of sanitation when washing hands. Responsible Person: Program Director	8/10/2018