

10A NCAC 27G .3604 OPERATIONS

(a) Hours. Each facility shall operate at least six days per week, 12 months per year. Daily, weekend and holiday medication dispensing hours shall be scheduled to meet the needs of the client.

(b) Compliance with The Substance Abuse and Mental Health Services Administration (SAMHSA) or The Center for Substance Abuse Treatment (CSAT) Regulations. Each facility shall be certified by a private non-profit entity or a State agency, that has been approved by the SAMHSA of the United State Department of Health and Human Services and shall be in compliance with all SAMHSA Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction regulations in 42 CFR Part 8, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the CSAT, SAMHSA, Rockwall II, 5600 Fishers Lane, Rockville, Maryland 20857 at no cost.

(c) Compliance With DEA Regulations. Each facility shall be currently registered with the Federal Drug Enforcement Administration and shall be in compliance with all Drug Enforcement Administration regulations pertaining to opioid treatment programs codified in 21 C.F.R., Food and Drugs, Part 1300 to end, which are incorporated by reference to include subsequent amendments and editions. These regulations are available from the United States Government Printing Office, Washington, D.C. 20402 at the published rate.

(d) Compliance With State Authority Regulations. Each facility shall be approved by the North Carolina State Authority for Opioid Treatment, DMH/DD/SAS, which is the person designated by the Secretary of Health and Human Services to exercise the responsibility and authority within the state for governing the treatment of addiction with an opioid drug, including program approval, for monitoring compliance with the regulations related to scope, staff, and operations, and for monitoring compliance with Section 1923 of P.L. 102-321. The referenced material may be obtained from the Substance Abuse Services Section of DMH/DD/SAS.

(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 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
- (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 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 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;
- (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.

History Note: Authority G.S. 122C-26; 143B-147; 21 C.F.R. Part 1300; 42 C.F.R. Part 8;
Eff. May 1, 1996;
Temporary Amendment Eff. February 7, 2000;
Amended Eff. April 1, 2001;
Temporary Amendment Eff. December 3, 2001;
Amended Eff. April 1, 2003;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. July 20, 2019.