ALABAMA DEPARTMENT OF MENTAL HEALTH
SUBSTANCE ABUSE SERVICES
ADMINISTRATIVE CODE

CHAPTER 580-9-44
PROGRAM OPERATIONS

580-9-44-.28 Level 3.7-D: Medically Monitored Residential Detoxification Program And Level 3.7-D NTP: Medically Monitored Residential Detoxification Narcotic Treatment Program.

(1) Scope. This Chapter establishes rules for the operation of Medically Monitored Residential Detoxification Programs (Level 3.7-D) and Medically Monitored Residential Detoxification Programs designated as Narcotic Treatment Programs (Level 3.7-D NTP).

(2) Definitions. The following definitions apply to this Chapter:

(a) Accreditation elements: The standards that are developed and adopted by an accreditation body and approved by the Substance Abuse and Mental Health Services Administration (SAMHSA).

(b) Detoxification: The dispensing of medication, approved for such purposes, in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of alcohol and/or other relevant addictive drugs. Detoxification functions, also, as a method of bringing the individual to a drug-free state within such period.

(c) Federal opioid treatment standards: 42 CFR 8.12.

(d) Level 3.7-D Medically Monitored Residential Detoxification Program: An organized regimen of services provided by nursing and medical professionals, which provides for 24-hour medically supervised alcohol or other drug withdrawal management with medication approved for such use.

(e) Level 3.7-D NTP Medically Monitored Residential Detoxification Program: An organized regimen of services provided by nursing and medical professionals, which provides for 24-hour medically supervised opioid withdrawal management utilizing buprenorphine or a buprenorphine combination product approved for treatment of opioid use disorders by the Food and Drug Administration (FDA). A Level 3.7-D NTP may not dispense Methadone unless the entity is certified by the Alabama Department of Mental Health to operate an Opioid Treatment Program in compliance with Chapter 580-9-44-.29 of these rules and holds a valid Certificate of Need for the operation of a

Methadone Treatment Program issued by the Alabama State Health Planning and Development Agency.

(f) Long-term detoxification: Detoxification treatment services provided for a period more than 30 days, but not in excess of 180 days.

(g) Medical director: A physician, licensed to practice medicine in Alabama, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

(h) Program sponsor: The individual, named in the entity's application for certification by SAMHSA as according to 42 CFR 8.11, who is responsible for the operation of the Level 3.7-D NTP. The sponsor assumes responsibility for all of the entity's employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services.

(i) Short-term detoxification: Detoxification treatment for a period not in excess of 30 days.

(3) Rule Compliance.

(a) In addition to compliance with the rules as specified in this chapter, each Level 3.7-D and 3.7-D NTP shall comply with the rules as specified in the following chapters: 580-9-44-.02 Personnel, 580-9-44-.03 Client Rights, 580-9-44-.04 Abuse and Neglect, 580-9-44-.05 Grievances, Complaints and Appeals, 580-9-44-.06 Confidentiality and Privacy, 580-9-44-.07 Seclusion and Restraint, 580-9-44-.08 Child and Adolescent Seclusion and Restraint, 580-9-44-.09 Incident Reporting, 580-9-44-.10 Infection Control, 580-9-44-.11 Performance Improvement, 580-9-44-.12 Operational Policies and Procedures Manual, and 580-9-44-.13 Program Description.

(b) Each Level 3.7-D NTP shall comply with all regulations enforced by the DEA under 21 CFR Chapter II, and
Chapter 580-9-44 Mental Health
Revised 3/17/23 9-44-156
must be registered by the DEA before administering or dispensing opioid agonist treatment medications.

(c) Each Level 3.7-D NTP must operate in accordance with Federal opioid treatment standards and approved accreditation elements.

(4) Program Description. The entity shall develop, maintain and implement a written program description that defines its Level

3.7-D program or Level 3.7-D NTP, as according to Rule 580-9-44-.13 and the following specifications:

(a) Location. The entity shall specifically identify and describe the setting in which the Level 3.7-D Program or Level 3.7-D NTP is provided. Services may be provided in any facility that meets all applicable federal, state and local certification, licensure, building, life-safety, fire, health and zoning regulations including the DMH facility certification standards.

(b) Admission Criteria:

1. Level 3.7-D. The entity's admission criteria shall specify the target population for the Level 3.7-D Program, which shall include, at a minimum, individuals who are experiencing signs and symptoms of withdrawal, or for whom there is evidence that a withdrawal syndrome is imminent, and who have a history of insufficient skills and supports to complete detoxification at a less intense level of care.

(i) The entity shall provide written documentation in individual case records that each patient admitted to receive Level 3.7-D services meets the diagnostic criteria for a Substance Related Disorder as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association.

(ii) The entity shall provide written documentation in individual case records that each patient admitted to receive Level 3.7-D services meets the dimensional criteria for admission to this level of care as defined in the most recent edition of the ASAM Criteria.

2. Level 3.7-D NTP. The entity's admission criteria shall specify the target population for the Level 3.7-D NTP Program, which shall include, at a minimum, individuals who are experiencing signs and symptoms of opioid withdrawal, or for whom there is evidence that a withdrawal syndrome is imminent; and who have a history of insufficient skills and supports to complete detoxification at a less intense level of care.

(i) The entity shall provide written documentation in individual case records that each patient admitted to receive Level 3.7-D NTP services meets the diagnostic criteria for an Opioid Related Disorder as defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association.

(ii) The entity shall provide written documentation in individual case records that each patient admitted to receive Level 3.7-D NTP services meets the dimensional criteria for admission to this level of care as defined in the most recent edition of the ASAM Criteria.

(iii) The entity shall not admit a patient for more than two detoxification treatment episodes in one year. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the program's Medical Director or other authorized medical professional for other forms of treatment.

(c) Core Services: At a minimum, each Level 3.7-D Program and 3.7D NTP shall document the capacity to provide the following core services:

1. Placement assessment.

2. Individual counseling.

3. Group counseling.

4. Psychoeducation.

5. Family counseling.

6. Peer support.

7. Medical and somatic services.

8. Medication administration.

9. Medication monitoring.

10. Alcohol and/or drug screening/testing.

11. Case management, including:

(i) Case planning.

(ii) Linkage.

(iii) Advocacy.

12. Patient Progress Monitoring.

(d) Therapeutic Component Implementation: The entity shall document implementation of medical and other clinical services organized to enhance the patient's understanding of addiction, support completion of the detoxification process and initiate

transfer to an appropriate level of care for continued treatment. At a minimum, this shall include the following therapeutic components:

1. For each Level 3.7-D program:

(i) Completion of a comprehensive medical history and physical examination of the patient at admission.

(ii) Protocols established by the entity's medical director, for management of detoxification from each major drug category of abused drugs that are consistent with guidelines published by nationally recognized organizations (e.g., SAMHSA, ASAM, American Academy of Addiction Psychology) and with product labeling of medications utilized.

(iii) Level 3.7-D Programs that utilize benzodiazepines in the detoxification protocol shall have:

(I) Written protocols and procedures to show that all doses or amounts of benzodiazepines are carefully monitored and are slowly reduced as appropriate.

(II) Written longer-term detoxification protocols and procedures that adhere to general principles of management, including clear indications of benzodiazepine dependence, clear intermediate treatment goals and strategies, regular review and methods to prevent diversion from the plan.

2. For each Level 3.7-D NTP:

(i) The Level 3.7-D NTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria.

(ii) Each patient must undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the Level 3.7-D NTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(iii) The program must maintain current policies and procedures that reflect the special needs of patients

who are pregnant. Prenatal care and other gender specific services for pregnant patients must be provided either by the Level 3.7-D NTP or by referral to appropriate healthcare providers.

(iv) The entity shall maintain current procedures adequate to ensure that each buprenorphine and/or buprenorphine combination product used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administering decisions shall be made by a program physician familiar with the most up-to-date product labeling.

(v) Medication orders and changes in dosage shall be written on an acceptable order sheet and signed by a program physician or through utilization of a comparable electronic signatory process.

(vi) Policies and procedures for medication administration, dispensing, and use shall ensure that buprenorphine and buprenorphine combination products are administered or dispensed only by a physician, pharmacist, registered nurse, or licensed practical nurse.

(vii) At least one (1) initial drug test should be conducted for patients in short-term detoxification treatment for analysis of illicit drug use or prescription drug misuse.

(viii) Buprenorphine and/or buprenorphine combination products shall only be dispensed or administered to patients who are admitted to the Level 3.7-D NTP. The entity shall not prescribe or dispense buprenorphine and/or buprenorphine combination products for unsupervised and/or take-home use or for use in another level of treatment.

3. Each Level 3.7-D Program and Level 3.7-D NTP shall provide:

(i) On duty awake staff shall provide supervision each patient’s health, welfare and safety twenty-four (24) hours a day, seven (7) days a week.

(ii) On-site physician care and phone availability twenty-four (24) hours a day, seven (7) days a week.

(iii) Nurse monitoring, assessment and management of signs and symptoms of intoxication and withdrawal twenty-four (24) hours a day, seven (7) days a week.

(iv) A pregnancy test for females of childbearing age prior to administration of medication.

(v) Medication administration and monitoring services, including specific procedures for pregnant women.

(vi) Continuous assessment.

(vii) Planned counseling and other therapeutic interventions.

(viii) Motivational enhancement therapy.

(ix) Peer support services.

(x) Relapse prevention counseling.

(xi) Overdose prevention education.

(xii) Direct affiliation with other levels of care.

(e) Documentation:

1. Each Level 3.7-D Programs and Level 3.7-D NTP shall provide the following clinical record documentation:

(i) Documentation of each clinical/therapeutic intervention provided.

(ii) Daily assessment of progress, including response to medication, which also notes any treatment changes.

(iii) Monitoring of vital signs, at a minimum, every eight (8) hours until discharge.

(iv) The use of detoxification rating scale tables and flow sheets.

2. Each Level 3.7-D NTP.

(i) The entity shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care that complies with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(ii) The Level 3.7 NTP shall include, as an essential part of the recordkeeping system, documentation in

each patient's record that the entity made a good faith effort to review whether or not the patient is enrolled in an Opioid Treatment Program (OTP) or taking other opioids that would contraindicate buprenorphine treatment.

(f) Support Systems: Each Level 3.7-D Program and 3.7-D NTP shall develop, maintain, and document implementation of written policies and procedures utilized to provide patient access to support services on site, or through consultation or referral, which shall minimally include:

1. Specialized clinical consultation for biomedical, emotional, behavioral and cognitive problems.

2. Appropriate laboratory and toxicology testing.

3. Psychological and psychiatric services.

4. Transportation.

5. Twenty-four (24) hour access to emergency medical services.

(g) Staff Requirements.

1. Each Level 3.7-D and 3.7-D NTP shall, at a minimum, maintain the following positions as part of its staff:

(i) Medical Director. The medical director shall be a physician licensed to practice in the State of Alabama, who has a minimum of one (1) year experience treating substance related disorders. The medical director shall be responsible for admission, diagnosis, medication management, patient care, and for ensuring that the program is in compliance with all Federal, State, and local laws and regulations.

(ii) Each Program shall be coordinated by a full-time employee who is an Alabama licensed Registered Nurse, Nurse Practitioner, Physician, or Physician’s Assistant, with two (2) years direct care experience treating substance related disorders.

(iii) Nursing Services Director. Program shall have a nursing services director who shall be a Registered Nurse licensed according to Alabama law, with training and work experience in behavioral health.

(iv) There shall be a Registered Nurse (RN) or Licensed Practical Nurse (LPN) on site during all hours of the Program’s operation.

(v) Direct Care Personnel. All direct care personnel must have sufficient education, training, and experience, or a combination thereof, to enable that person to perform the assigned job responsibilities. All physicians, nurses, and other licensed professional care providers, including certified addiction counselors, must comply with the credentialing requirements of their respective professions.

(vi) The entity shall maintain an adequate number of personnel, including physicians, nurses, counselors and case managers to sustain the Program as delineated in its operational plan.

(vii) Administrative Support Personnel. The entity shall maintain an adequate number of support personnel to sustain the Program's administrative functions.

(h) Training: Each Level 3.7-D and 3.7-D NTP shall provide written documentation that:

1. All program personnel satisfy the requirements of the core training curriculum, as specified in Rule 580-9-44-.02(3).

2. All clinical and medical services staff receive training during the initial twelve (12) months employment and develop basic competencies in the following areas:

(i) Biopsychosocial dimensions of substance related disorders.

(ii) The signs and symptoms of alcohol and other drug intoxication and withdrawal.

(iii) Evidence-based treatment and monitoring strategies for alcohol and other drug intoxication and withdrawal.

(iv) Continuing care motivational and engagement strategies.

(v) Pharmacotherapy.

(vi) ASAM Criteria.

(vii) Assessment of and service planning to address biopsychosocial needs.

(i) Service Intensity: The entity shall document in the clinical record that the intensity of Level 3-D Services and

Level 3.7-D NTP is established on the basis of the unique needs of each served.

(j) Length of Service: The entity shall provide written documentation in the clinical record that the duration of treatment in each Level 3.-D Program and 3.7-D NTP varies as determined by the patient's assessed needs, and that the patient continues in treatment until:

1. Withdrawal signs and symptoms are sufficiently resolved; or

2. Withdrawal signs and symptoms have failed to respond to treatment and have intensified warranting a transfer to a more intense level of care; or

3. The patient is, otherwise, unable to complete detoxification at this level of care.

K. Diversion Control Plan. Each Level 3.7-D NTP shall maintain a current Diversion Control Plan (DCP) as part of its quality assurance program that, at a minimum:

1. Contains specific measures to reduce the possibility of diversion of controlled substances from legitimate use, and

2. Assigns specific responsibility to the medical and administrative staff of the Level 3.7-D NTP for carrying out the diversion control measures and functions described in the DCP.

(l) Emergency Administration of Medication. Each Level 3.7-D program and Level 3.7-D NTP shall maintain policies and procedures for administration of patient medication in the event of an emergency leading to the temporary closure of the program.

Author: Substance Abuse Services Division
Statutory Authority: Code of Ala. 1975, §22-50-11.
History: **New Rule:** Filed January 26, 2012; effective March 1, 2012.