CABINET FOR HEALTH AND FAMILY SERVICES
Department for Behavioral Health, Developmental and Intellectual Disabilities
Division of Program Integrity
(Amended After Comments)

908 KAR 1:374. Licensure of nonhospital-based outpatient alcohol and other drug treatment entities.

RELATES TO: KRS 198B.260, 218A.180, 218A.202, 222.231, 222.462, 21 C.F.R. 1301.72, 1301.74, 1301.75, 1301.91, 1301.92, 42 C.F.R. Part 8, 15 U.S.C. 1471

STATUTORY AUTHORITY: KRS 222.231(2), (12), 222.462

NECESSITY, FUNCTION, AND CONFORMITY: KRS 222.231(2) requires the cabinet to promulgate administrative regulations to establish requirements and standards for treatment programs, including health and safety standards, patient care standards, and classification of alcohol and other drug use~~[abuse]~~ programs according to type, range of services, and level of care provided. KRS 222.231(12) requires the cabinet to promulgate administrative regulations to establish standards of operation for narcotic treatment programs. KRS 222.462 requires the cabinet to develop enhanced licensure and quality standards for substance use disorder treatment and recovery. This administrative regulation establishes standards for nonhospital-based alcohol and other drug treatment entities (AODE) that provide ambulatory withdrawal management, outpatient treatment services, intensive outpatient services, partial hospitalization, or office-based opiate treatment services. This administrative regulation further establishes standards for the operation of narcotic treatment programs in accordance with KRS 222.231(12) and 42 C.F.R. Part 8.

Section 1. Definitions.

(1) "Approved controlled substance" means the drugs methadone, buprenorphine, or other FDA-approved **medication for opioid use disorder (MOUD)**~~**[drug]**~~ used in the treatment of **opioid**~~**[narcotic]**~~ addiction in a Narcotic Treatment Program.

(2) "CHFS" or "cabinet" means the Cabinet for Health and Family Services.

(3) "Central Registry" means a cabinet-approved electronic system used to register patients at a licensed narcotic treatment program (NTP) for the purpose of preventing simultaneous enrollment in other NTPs, gathering program-compliance information, and monitoring performance data.

(4) "Correctional Facility" means a jail, prison, or other place of incarceration by a government official.

(5) ~~[(3)]~~ "CSAT" means the Center for Substance Abuse Treatment.

(6) ~~[(4)]~~ "DEA" means the Drug Enforcement Administration.

(7) ~~[(5)]~~ "Dose" means a one (1) day quantity of an approved controlled substance~~[,]~~ administered on site at a narcotic treatment program~~[, in not less than one (1) fluid ounce of an oral solution, formulated to minimize misuse by injection]~~.

(8) ~~[(6)]~~ "Drug screening" means the process by which a program determines the presence or the absence of drugs in the body fluids.

(9) ~~[(7)]~~ "Main program" means the location where all administrative and medical information related to a narcotic treatment program is retained for the purpose of on-site reviews by federal agencies or the state narcotic authority.

(10) ~~[(8)]~~ "Medication station" means any dosing location that ~~[obtains its drug supply from the main program site and retains all records (except dosing, drug screens) at the main location]~~is defined and authorized as a medication unit in 42 C.F.R. 8. Medication stations are not extension sites as established in 908 KAR 1:370 Section 2(1)(c).

(11) "Mobile unit" means means a narcotic treatment program (NTP) operating from a motor vehicle that:

(a) Serves as a mobile component for an existing licensed NTP;

(b) Operates under the registration of the NTP; and

(c) Engages in maintenance or detoxification treatment with narcotic drugs in schedules II-V at a location or locations remote from its registered and licensed location in Kentucky.

(12) "Program prescriber" means:

(a) A practitioner as defined in KRS 218A.010(40); and

(b) Is authorized to prescribe Schedule II **–V** controlled substances by state and federal requirements;

(13) ~~[(9)]~~ "SNA" means the state narcotic authority **and is synonymous with state opioid treatment authority (SOTA)**. The Department for Behavioral Health, Developmental and Intellectual Disabilities is the SNA, **or SOTA,** for Kentucky.

(14) ~~[(10)]~~ "Take-home dose" means a quantity of an approved controlled substance, which the patient~~[client]~~ is eligible to take off the premises of a narcotic treatment program.

(15) ~~[(11)]~~ "Treatment phase" means a stage in the patient's~~[client's]~~ progress through a narcotic treatment program's sequential treatment system.

(16) ~~[(12)]~~ "Voluntary withdrawal management" means a medically supervised withdrawal from the approved controlled substance requested by a patient~~[client]~~ of a narcotic treatment program.

Section 2. Ambulatory Withdrawal Management.

(1) In addition to the licensing requirements of 908 KAR 1:370, an outpatient AODE that provides ambulatory withdrawal management or maintenance services shall accept and provide services only to patients~~[clients]~~ meeting the:

(a) Diagnostic criteria for a substance-related disorder for alcohol, tobacco, and other drug use as established by the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM); and

(b) Dimensional criteria for outpatient services as established in the most recent version of The American Society of Addiction Medicine (ASAM) Criteria.

(2) Ambulatory withdrawal management services shall:

(a) Be provided in regularly scheduled sessions;

(b) Be delivered in accordance with:

1. Clinical protocols established for ambulatory withdrawal management in the most recent version of The ASAM Criteria; or

2. Nationally recognized, evidence-based clinical protocols approved by the cabinet; and

(c) Include the following features:

1. Specialized psychological and psychiatric consultation and supervision for biomedical, emotional, behavioral, and cognitive problems as indicated;

2. Completion of a comprehensive medical history and physical examination of the patient~~[client]~~ at admission;

3. Affiliation with other levels of care, including other levels of specialty addiction treatment for additional problems identified through the comprehensive biopsychosocial assessment required by 908 KAR 1:370, Section 18;

4. Appropriate laboratory and drug screening; and

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

(3) Staff shall include:

(a) Physicians and licensed health practitioners acting within their scope of practice who, if not present on-site at the time of admission, shall be readily available to

evaluate and confirm that ambulatory withdrawal management is safe for the patient~~[client]~~; and

(b) Clinical staff who shall be knowledgeable about the biopsychosocial dimensions of alcohol, tobacco, and other substance use disorders, including the signs and symptoms of alcohol and other drug intoxication and withdrawal.

(4) Therapies offered by ambulatory withdrawal management services shall include:

(a) Individual assessment;

(b) Medication or non-medication methods of withdrawal management;

(c) Monitoring, assessment, and management of signs and symptoms of intoxication and withdrawal by a physician or licensed health practitioner acting within their~~[his or her]~~ scope of practice;

(d) Patient education;

(e) Non-pharmacological clinical support;

(f) Involvement of family members or significant others in the withdrawal management process; and

(g) Discharge or transfer planning, including referral for counseling and involvement in community recovery support groups.

(5) A program shall establish an individualized treatment plan in accordance with 908 KAR 1:370, Section 19 that includes:

(a) Problem identification in dimensions two (2) through six (6) of the most recent version of The ASAM Criteria;

(b) Development of treatment goals and measurable treatment objectives;

(c) Activities designed to meet the treatment objectives and management of withdrawal syndrome;

(d) Daily assessment of:

1. Progress during withdrawal management; and
2. Any treatment changes;

(e) Transfer and discharge planning, beginning at the point of admission; and

(f) Referral and linkage arrangements for:

1. Counseling;
2. Medical care;
3. Psychiatric care; and
4. Continuing care.

(6) Progress notes shall:

(a) Be maintained in the patient~~[client]~~ record in accordance with 908 KAR 1:370, Section 17(4)(h);

(b) Reflect implementation of the treatment plan;

(c) Document the patient's~~[client's]~~ response to treatment; and

(d) Include each amendment of the treatment plan.

(7) Withdrawal rating scale tables and flow sheets that include tabulation of vital signs shall be used as needed.

(8) Treatment of a patient~~[client]~~ shall continue until:

(a) Withdrawal signs and symptoms are sufficiently resolved so that the patient~~[client]~~ can participate in:

1. Self-directed recovery; or
2. Ongoing treatment without the need for further medical or nursing withdrawal management monitoring;

(b) The patient's~~[client's]~~ signs and symptoms of withdrawal have:

1. Failed to respond to treatment; and
2. Intensified so that transfer to a more intensive level of withdrawal management is indicated; or

(c) Ambulatory. ~~[The client is unable to complete ambulatory]~~ withdrawal management is not adequate to meet the severity of the patient's substance use disorder~~[despite an adequate trial, meaning the client is experiencing intense craving and evidencing insufficient coping skills to prevent continued alcohol or other drug use concurrent with the withdrawal management medication, indicating a need for more intensive service]~~.

Section 3. Outpatient Treatment Services.

(1) In addition to the licensing requirements of 908 KAR 1:370, an outpatient AODE that offers outpatient treatment services:

(a) Shall provide alcohol and other drug use~~[abuse]~~ counseling to each patient~~[client]~~, with counseling provided to no more than twelve (12) patients~~[clients]~~ per clinician if provided in a group;

(b) Shall provide each patient~~[client]~~ with education regarding:

1. The disease of addiction;
2. The patient's~~[client's]~~ diagnosis;
3. The effects of alcohol and other drug use~~[abuse]~~;
4. The risks of exposure to human immunodeficiency virus (HIV), hepatitis, and other health consequences of substance use disorder;
5. Family issues related to substance use disorder; and
6. Relapse prevention;

(c) Shall refer each patient~~[client]~~ to ~~[recovery support]~~services specific to addiction treatment and recovery, which may include:

1. Support groups;
2. Peer support;
3. Recovery housing;
4. Community supports;
5. Supported employment;
6. Co-occurring disorders; and
7. Medications for addiction treatment ~~[Medication assisted treatment]~~;

(d) Shall have a direct affiliation with, or close coordination through referral to more intensive levels of care and medication management;

(e) Shall have a procedure to inform patients~~[clients]~~ of the availability of emergency services available twenty-four (24) hours a day, seven (7) days a week; and

(f) May provide additional therapies including:

1. Motivational enhancement;
2. Occupational and recreational therapy;
3. Psychotherapy; or
4. Medications for addiction treatment ~~[Medication assisted therapy]~~.

(2) Staff who provide outpatient treatment services:

(a) Shall be able to obtain and interpret information regarding the patient's~~[client's]~~ biopsychosocial needs;

(b) Shall be knowledgeable about the biopsychosocial dimensions of alcohol, tobacco, and other substance use disorders, including assessment of the patient's~~[client's]~~ stage of readiness to change;

(c) Shall be capable of monitoring stabilized mental health problems and recognizing any instability in a patient~~[client]~~ with co-occurring disorders; and

(d) May include physicians and other licensed health care practitioners acting within their scope of practice on staff if medications for addiction treatment are~~[medication assisted therapy is]~~ provided.

(3) Progress notes shall:

(a) Be maintained in the patient~~[client]~~ record in accordance with 908 KAR 1:370, Section 17(4)(h);

(b) Reflect implementation of the treatment plan;

(c) Document the patient's~~[client's]~~ response to therapeutic interventions for all disorders treated; and

(d) Include each amendment of the treatment plan.

(4) The patient's~~[client's]~~ discharge summary shall be completed within thirty (30) calendar days of discharge.

Section 4. Intensive Outpatient Program.

(1) In addition to the licensing requirements of 908 KAR 1:370 and Section 3 of this administrative regulation, an outpatient AODE that offers intensive outpatient services shall ensure that the program provides a multi-modal, multi-disciplinary structured approach to services that:

(a) Are more intensive than outpatient treatment services; and

(b) Provide a minimum of services:

1. For adults:

a. Nine (9) hours per week; and

b. Given on no less than three (3) days per week; or

2. For adolescents:

a. Six (6) hours per week; and

b. Given on no less than two (2) days per week.

(2) Services shall include:

(a) Individual outpatient therapy;

(b) Group outpatient therapy;

(c) Family outpatient therapy, unless contraindicated;

(d) Crisis intervention; and

(e) Psycho-education during which the patient or patient's~~[client or client's]~~ family member shall be provided with information regarding:

1. The patient's~~[client's]~~ diagnosis;

2. Reasons why a particular treatment might be effective for reducing symptoms; and

3. How to cope with the patient's~~[client's]~~ diagnosis or condition in a successful manner.

(3) A program shall:

(a) Maintain a patient~~[client]~~-to-staff ratio of no more than ten (10) patients~~[clients]~~ to one (1) staff;

(b) Establish an individualized treatment plan for each patient~~[client]~~ in accordance with 908 KAR 1:370, Section 19 that focuses on stabilization and transition to a lower level of care;

(c) Provide access to a:

1. Board-certified or board-eligible psychiatrist for consultation, which may be delivered through the use of telehealth technology; and

2. Psychiatrist, other physician, or advanced practice registered nurse for medication prescribing and monitoring; and

(d) Provide each patient~~[client]~~ with a schedule of all planned therapeutic activities or otherwise ensure that the schedule is conspicuously posted in a public area of the facility.

(4)

(a) If the program prepares meals on-site for a patient~~[client]~~ who receives services for at least five (5) or more consecutive hours, the program shall be subject to inspection in accordance with 902 KAR 45:005.

(b) If patients~~[clients]~~ prepare their own meals on-site or are otherwise responsible for their meals, a food service permit shall not be required.

Section 5. Partial Hospitalization.

(1) In addition to the licensing requirements of 908 KAR 1:370, an outpatient AODE that offers partial hospitalization services shall be fully accredited by at least one (1) of the following:

(a) Joint Commission;

(b) Commission on Accreditation of Rehabilitation Facilities;

(c) Council on Accreditation; or

(d) Other nationally recognized accrediting organization with comparable standards.

(2) Partial hospitalization services shall:

(a) Be short-term, four (4) to six (6) weeks on average;

(b) Meet the same standards required for intensive outpatient services, except for Section 4(1)(b) of this administrative regulation;

(c) Be provided at least five (5) hours a day and at least four (4) days per week; and

(d) Provide access to educational services for adolescent patients~~[clients]~~.

(3) An AODE program that provides partial hospitalization shall comply with 902 KAR 45:005 if the program provides meals directly to its patients~~[clients]~~.

Section 6. Office-based Opioid~~[Opiate]~~ Treatment Services.

(1) Excluding methadone-based treatment, a facility shall be licensed as an outpatient AODE that provides office-based opioid~~[opiate]~~ treatment (OBOT) services if:

(a) Any individual with ownership interest in the facility is not a Kentucky-licensed physician; and

(b) The facility employs or has an affiliation with a physician, physician assistant, or advanced practice registered nurse who prescribes ~~[products containing buprenorphine or other]~~FDA-approved medications~~[drugs]~~ for the treatment of opioid use disorder to fifty (50) percent or more of the facility's patients.

(2) In addition to the licensing requirements of 908 KAR 1:370, an OBOT shall:

(a) Designate a medical director who shall:

1. Be responsible for the supervision of all medical staff and the administration of all medical services at the facility, including compliance with all federal, state, and local laws and administrative regulations regarding the medical treatment of opioid use disorder;

2. Be physically present at the facility at least twenty-five (25) percent of the time the facility is open to the public each week;

3. Conduct a monthly review of ten (10) percent of the medical charts for patients currently admitted at the facility and document each chart review; and

4. Not serve as medical director of more than three (3) OBOT facilities;

(b) Have sufficient medical staff on-site to provide the medical treatment and oversight necessary to serve patient needs, including a practitioner authorized to prescribe ~~[products containing buprenorphine or other]~~FDA-approved medications~~[drugs]~~[]for the treatment of opioid use disorder on-site during **fifty (50) percent of clinic weekly**~~**[all]**~~ hours of operation;

(c) Ensure that each practitioner authorized to prescribe~~[physician or advanced practice registered nurse]~~complies with the prescribing and dispensing standards in accordance with 201 KAR 9:270 or 201 KAR 20:065 respectively for FDA-approved medications~~[drugs]~~ used for the treatment of opioid addiction;

(d) Ensure that a practitioner authorized to prescribe~~[physician or advanced practice registered nurse]~~documents in the patient's record whether or not the patient is compliant with prescribed dosing as evidenced by the results of:

1. A KASPER report released in accordance with KRS 218A.202(7)(e); and

2. Drug screening;

(e) Offer individual and group outpatient therapy;

(f) Monitor compliance with recommended non-medication therapies;

(g) Provide case management or care coordination services; and

(h) Implement pre-employment and ongoing random drug screening of all facility employees.

(3) Admission and discharge.

(a) Each ~~[Prior to admission to the OBOT facility, each prospective]~~ patient shall be evaluated to determine and document whether or not the patient meets the diagnostic criteria for an opioid use disorder as defined in the most recent version of the DSM. ~~[A prospective patient shall not be admitted unless he or she meets those criteria.]~~

(b) The OBOT facility shall use evidence-based assessment and evaluation tools that have been peer reviewed and validated, including the most recent edition of:

1. ASAM placement criteria;
2. Addiction Severity Index;
3. Substance Abuse and Mental Health Services Administration (SAMHSA) Treatment Improvement Protocol; or
4. Any other equivalent assessment and evaluation tool.

(c) Prior to receiving treatment at the facility, the patient shall acknowledge in writing having received education on:

1. Treatment options, including withdrawal management, and the benefits and risks associated with each treatment option;
2. The risk of neonatal abstinence syndrome and use of voluntary long-acting reversible contraception for all female patients of child-bearing age and potential;
3. Prevention and treatment of chronic viral illnesses, such as HIV and hepatitis;
4. Expected therapeutic benefits and adverse effects of treatment medication;
5. Risks for overdose, including drug interactions with central nervous system depressants, and return to use~~[relapse]~~ after a period of abstinence from opioids; and
6. Overdose prevention and reversal agents.

(d) An OBOT facility shall not provide any type of reward to a third party for referral of potential patients to the clinic.

(4) Comprehensive assessment. The facility shall complete a comprehensive assessment in accordance with 908 KAR 1:370, Section 18 and in accordance with peer-reviewed opioid use disorder~~[medication-assisted]~~ treatment guidelines developed by nationally recognized organizations, such as SAMHSA and the American Society of Addiction Medicine.

(5) Treatment planning. An OBOT facility shall complete an individualized treatment plan for each patient in accordance with 908 KAR 1:370, Section 19, featuring a plan for aftercare that includes the development of a list of appropriate treatment resources available to the patient in their~~[his or her]~~ community.

(6) Discharge.

(a) A discharge plan shall be completed at the time of the patient's discharge by the staff person who has primary responsibility for coordinating or providing for the care of the patient, including a final assessment of the patient's status at the time of discharge.

(b) If applicable, a parent, guardian, family member, or responsible person may participate in aftercare and discharge planning.

(c) The reason for any patient not participating in aftercare and discharge planning shall be documented in the patient's record.

(d) The OBOT facility shall document if a patient discontinues services.

(e) Determination of the events that constitute a patient's discontinuation of services at an OBOT shall be at the discretion of the facility.

Section 7. Narcotic Treatment Programs.

(1) In addition to the licensing requirements of 908 KAR 1:370, an outpatient AODE that operates a narcotic treatment program (NTP) using an FDA-approved medication[~~methadone~~] to treat individuals with substance use disorder shall comply with:

(a) 42 C.F.R. Part 8;[~~ and~~]

(b) The requirements of this section; and

(c) Submit and maintain all required data **to:**

1. The [~~ in the ~~] Central Registry **; and**

2. KASPER as required by KRS 218A.202 and 902 KAR 55:110.

(2) An NTP requesting a change of location shall:

(a) Comply with 908 KAR 1:370, Section 4; and

(b) Provide information regarding any:

1. Dosing procedural changes; and

2. Drug distribution problems that could occur due to the relocation.

(3) Organization and operation.

(a) In addition to meeting the requirements of 908 KAR 1:370, Section 9, an NTP shall develop and comply with policies and procedures that include:

1. Waiting list criteria;

2. Data collection for participation in the program in accordance with 908 KAR 1:300;

3. A protocol that ensures the integrity of the chain of custody for all drug screens;

4. A protocol for voluntary and involuntary termination of a patient's[~~client's~~] participation in the program, including reasons for termination for cause;

5. Requirements for the preparation and labeling of patient[~~client~~] doses in accordance with the requirements of subsection (10) of this section;

6. Quality assurance and utilization review;

7. A patient[~~client~~] identification system;

8. A system to prevent multiple program registrations;

9. Inventory maintenance;

10. A protocol for daily dosing schedules; and

11. Drug screening procedures that utilize random selection or unannounced collection.

(b) An NTP shall order approved controlled substances from the manufacturer or approved wholesalers in accordance with 42 C.F.R. Part 8.

(c) Policies for voluntary withdrawal management and involuntary termination from NTP treatment shall be in accordance with 42 C.F.R. Part 8.12.

(d) An NTP shall have and follow policies that prohibit recruitment of new patients[~~clients~~] into the program by offering:

1. A bounty;

2. Monetary, equipment, or merchandise rewards; or

3. Free services for individuals.

(e) An NTP shall implement the system of treatment phases established in subsection (12) of this section.

(f) An NTP shall be open for dosing services **at least** six (6)[~~seven (7)~~] days a week with the optional exception of:

1. New Year's Day, January 1;

2. Presidents Day;

3. Martin Luther King Day;

4. Easter Sunday;

5. Memorial Day, last Monday in May;

6. Independence Day, July 4;

7. Labor Day, first Monday in September;
8. Thanksgiving Day, fourth Thursday in November; ~~[and]~~
9. Christmas Day, December 25; and
10. Any **observed** federal holiday.

(g) An NTP shall have dosing times sufficient to meet the needs of its patients~~[clients]~~.

(h) An NTP shall have a written emergency plan that complies with 908 KAR 1:370, Section 9, establishing the course of action in the event of a natural or manmade disaster or any sudden closing. The plan shall also include:

1. Alternate providers for each payment type that the NTP accepts; and
2. A communication plan to reach each patient~~[client]~~ and provide information and instructions.

(i) The initial drug screens and confirmatory tests for drugs tested on behalf of the NTP shall meet federal~~[the following]~~ standards for the following:

1. ~~[Marijuana metabolites:]~~
   ~~[a.] [Initial screen 50ng/ml; and]~~
   ~~[b.] [Confirmation test 15ng/ml;]~~
~~[2.]~~ Cocaine metabolites;~~[:]~~
   ~~[a.] [Initial screen 300ng/ml; and]~~
   ~~[b.] [Confirmation test 150ng/ml;]~~
2. ~~[3.]~~ Opioid ~~[Opiates]~~ metabolites;~~[:]~~
   ~~[a.] [Initial screen 300ng/ml; and]~~
   ~~[b.] [Confirmation test 300ng/ml;]~~
3. ~~[4.]~~ Amphetamines;~~[:]~~
   ~~[a.] [Initial screen 1000ng/ml; and]~~
   ~~[b.] [Confirmation test of amphetamine 500ng/ml and methamphetamine confirmation test 500ng/ml;]~~
4. ~~[5.]~~ Barbiturates;~~[:]~~
   ~~[a.] [Initial screen 300ng/ml; and]~~
   ~~[b.] [Confirmation test 300ng/ml; and]~~
5. ~~[6.]~~ Benzodiazepines;~~[:]~~
   ~~[a.] [Initial screen 300ng/ml; and]~~
   ~~[b.] [Confirmation test 300ng/ml.]~~

(j) An NTP that dispenses buprenorphine shall:

1. Have sufficient medical staff on-site to provide the medical treatment and oversight necessary to serve patient needs, including a practitioner authorized to prescribe FDA-approved medications for the treatment of opioid use disorder on-site during **fifty (50) percent of clinic weekly ~~[all]~~** hours of operation;
2. Ensure that each practitioner authorized to prescribe or dispense complies with the prescribing and dispensing standards in accordance with 201 KAR 9:270 or 201 KAR 20:065 respectively for FDA-approved medications used for the treatment of opioid use disorder;
3. Ensure that a practitioner authorized to prescribe or dispense documents in the patient's record whether or not the patient is compliant with prescribed dosing as evidenced by the results of:
   a. A KASPER report released in accordance with KRS 218A.202(7)(e); and
   b. Drug screening;
   c. Provide patient dosing of buprenorphine which is exempt from treatment protocol phasing as outlined in subsection (12) of this section.

(4) Medication stations.

(a) Medication stations shall not require a separate license.

(b) To establish a medication station, the NTP shall submit to the SNA, an Application for License to Operate a Nonhospital-based Alcohol and Other Drug Treatment Entity

(AODE) form incorporated by reference in 908 KAR 1:370.

(c) ~~[A medication station shall be located between forty-five (45) miles and ninety (90) miles from the main NTP.]~~

~~[(d)]~~ ~~[The medication station shall obtain its supply of approved controlled substances from the stocks of the main NTP.]~~

~~[(e)]~~ The medication station shall provide the following services:

1. Dosing; and
2. Drug screen collection.

(d) ~~[(f)]~~ The program director shall develop a system to prevent patients~~[clients]~~ from dosing at both the main NTP and the medication station.

~~[(g)]~~ ~~[Other services shall not be provided at the medication station without prior approval of the CSAT and SNA.]~~

(5) Personnel.

(a) An NTP shall have a program director who shall:

1. Have at least two (2) years of experience in the treatment of addiction; and
2.
   a. Be certified by the Board of Certification of Alcohol and Drug Counselors;
   b. Hold at least a master's degree in the field of addiction or a related field; or
   c. Be a physician, registered nurse, physician assistant, pharmacist, or nurse practitioner certified by the licensing subspecialty.

(b) The program director may be the program sponsor as required by 42 C.F.R., Part 8.

(c) The program director shall:

1. Be responsible for ensuring compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the facility;
2. Provide onsite supervision of employees;
3. Ensure the laboratory performing the testing required under this administrative regulation is approved by the SNA and is certified by the Centers for Medicare and Medicaid Services as a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory; and
4. Ensure that initial drug screens and confirmatory tests for drugs tested on behalf of the program meet the standards in subsection (3)(i) of this section.

(d) An NTP shall have a medical director who shall be:

1. Licensed by the Commonwealth of Kentucky to practice medicine within the Commonwealth; and
2.
   a. A board eligible psychiatrist with at least three (3) years of experience in the provision of services to persons who have a substance use disorder; or
   b. Board-certified as an addiction medicine specialist.

(e) The medical director shall function autonomously within an NTP free from any protocol imposed by an NTP, director, or any other entity except under the guidelines established in 42 C.F.R. Part 8 and this administrative regulation.

(f) The medical director shall be responsible for the NTP's adherence to federal, state, and local laws and administrative regulations pertaining to the operation of the facility.

(g) An NTP may have a program **physician**~~**[prescriber]**~~[~~physician~~]. If an NTP has a program **physician**~~**[prescriber]**~~[~~physician~~], the **physician**~~**[prescriber]**~~[~~physician~~] shall be:

1. Licensed by the Commonwealth of Kentucky to prescribe controlled substances~~[practice medicine within the Commonwealth]~~; and
2.
   a. Board-certified as an addiction medicine specialist; or
   b. A person who has at least one (1) year of experience in providing service to individuals with a substance use disorder.

(h) A program **physician~~[preseriber]~~**[~~physician~~] shall be under the supervision of the medical director and shall function autonomously within the NTP free from any protocol imposed by any NTP, director, or any other entity except under the guidelines imposed by 42 C.F.R. Part 8 and this administrative regulation.

(i) **An NTP may have a program prescriber. If an NTP has a program prescriber, the program prescriber shall be:**

1. Licensed by the Commonwealth of Kentucky to prescribe controlled substances;

2. A person who has at least one (1) year of experience in providing services to individuals with a substance use disorder; and

3. Under the supervision of the medical director or program physician ~~[A program] [preseriber] [physician] [shall be responsible for the NTP's compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the facility]~~.

(j) The medical director may be the program **physician~~[preseriber]~~**[~~physician~~].

(k)

1. There shall be a minimum of one (1) medical director**, program physician,** or program prescriber[~~physician~~] on staff for every 300 patients[~~clients~~], or fraction thereof, enrolled in an NTP; and

2. The medical director **, program physician,** or program prescriber shall not be responsible for more than 300 total patients, which includes all patients of the NTP ~~[nationally]~~.

(l) The medical director,~~[or]~~program **physician or** prescriber[~~physician~~] shall:

1. Ensure ~~[there is evidence of physiologic dependence on narcotics for]~~all patients[~~clients~~] admitted to the NTP meet the most recent version of DSM criteria for opioid use disorder;

2. Ensure ~~[there is a history of addiction, or]~~ that any exceptions to admissions criteria are approved by the SNA and documented in the patient's[~~client's~~] record before the first dose is administered;

3. Ensure that appropriate medical histories and physical examinations have been performed before the first dose shall be administered;

4. Ensure that appropriate laboratory studies have been performed;

5. Review all laboratory testing results and documents;

6. Document, sign, or cosign all medical orders, within forty-eight (48) hours, including the first dose of an approved controlled substance;

7. Document, sign, or cosign all subsequent medication orders within forty-eight (48) hours, including dose increases and decreases, changes in frequency of take-home doses, emergency situations, or special circumstances;

8. Ensure that a review and cosignature of all telephone or other verbal orders are documented within forty-eight (48) hours of the order;

9. Supervise staff responsible for preparation and administration of the approved controlled substances;

10. Ensure compliance with program procedures and administrative regulations; and

11. Order through the licensed NTP all:

a. Initial doses; and

b. Increases or decreases.

(m) An NTP shall hire dosing personnel who shall:

1. Hold a license as a registered nurse, licensed practical nurse, or pharmacist; and

2. Not be dually assigned as clinicians.

(n) An NTP shall provide dosing personnel in sufficient numbers to meet the needs of the patients[~~clients~~] during dosing hours.

(o) Dosing prescribers[physicians] and pharmacists shall comply with KRS 218A.180 related to labeling if preparing doses to be taken outside the program site.

(p) An NTP shall hire clinicians who meet the requirements of 908 KAR 1:370, Section 11.

(q) There shall be at least one (1) clinician for every **fifty-five (55)[fifty (50)]** patients[forty (40)][clients] in the program.

(6) Security and control.

(a) The program director and dosing nurse supervisor or pharmacist shall conduct quarterly reviews to ensure compliance with this subsection and 42 C.F.R. Part 8.12.

(b) Security of the **controlled substance[narcotic]** safe and the building perimeter shall be checked at least quarterly with the contracted security company.

(c) The safe shall be locked at all times while staff are not obtaining, restocking, or inventorying controlled substances.

(d)

1. Inventory reconciliation shall be conducted at least quarterly;
2. All reconciliation documents shall be retained by the program for at least five (5) years; and
3. All DEA and federal regulations concerning [Five (5) percent or more of any] inventory discrepancies shall be followed, and any inventory discrepancy required to be reported to the [SNA and the]DEA offices shall also be reported to the SNA within forty-eight (48) hours of reconciliation.

(e) Dosing personnel shall count all new bottles of **controlled substance[narcotic]** tablets before removing any for patient[client] doses.

(f) Any discrepancies in **controlled substance[narcotic]** tablet count shall be reported to the SNA, DEA, CSAT, and the cabinet within forty-eight (48) hours of the event.

(g) A system shall be in place to assure the NTP completes the DEA biennial inventory of **controlled substance[narcotic drugs]** on hand.

(h) Order forms for controlled substances, the dosing records, and inventory reconciliation records shall conform with 42 C.F.R. Part 8.12 and shall be maintained in a locked, secured area separate from the storage site of the controlled substances.

(i) Quarterly, the program director or designee shall review a ten (10) percent random sample of patient[client] records for:

1. A consent to treatment form signed by the patient[client]; and
2. A release of information form signed by the patient[client] that includes:
   a. A description of the specific type of confidential information to be obtained or released; and
   b. The specific dates that the release is to cover.

(j) If the program director serves as a clinician, the medical director shall review a ten (10) percent random sample of the program director's patient[client] records for inclusion of the documents listed in paragraph (i) of this subsection.

(k) An NTP shall retain on file documentation that quarterly reviews were conducted, which shall be available for review by regulatory agencies for at least five (5) years.

(7) Admission policies.

(a) The admitting physician or licensed health practitioners acting within their scope of practice for the NTP shall comply with the admission requirements of 42 C.F.R. Part 8.12.

(b) When a patient[client] applies for admission to an NTP, the patient[client] shall be required to sign a release of information that authorizes a program to release or solicit information regarding the patient's[client's] status in any other substance use disorder treatment[abuse] program.

(c) In addition to complying with the requirements of 908 KAR 1:370, Section 16, an NTP shall:

1. Provide each patient~~[client]~~ written information describing all facets of the program in a manner that the patient~~[client]~~ understands; and

2. Explain the contents of all required federal forms to the patient~~[client]~~ before he or she is asked to sign.

(d) At admission, readmission, and at six (6) month intervals for the first two (2) years of treatment, and as indicated clinically after two (2) years, an NTP shall give the patient~~[client]~~ information on communicable diseases including:

1. Tuberculosis;
2. Hepatitis;
3. Sexually transmitted diseases; and
4. HIV/AIDS.

(e) A patient~~[client]~~ shall have access to voluntary HIV testing at admission and if clinically indicated thereafter and shall receive HIV/AIDS pre-test and post-test counseling if the patient~~[client]~~ elects to be tested.

(f) In order for an NTP to admit or continue to treat a patient~~[client]~~ who is pregnant, the medical director**, program physician,** or program prescriber~~[physician]~~ shall determine and document in the patient's~~[client's]~~ record that the patient~~[client]~~ is medically able to participate in the program.

(g) Pregnant individuals with an opioid~~[opiate]~~ use disorder shall be given priority for admission and services if the NTP has a waiting list.

(8) Patient ~~[client]~~ transfers and guest dosing.

(a) An NTP may accept patients~~[clients]~~ transferring from another NTP if the patient~~[client]~~ meets the criteria for admission in subsection (7) of this section and in accordance with this subsection.

(b) The program prescriber**, program physician,**~~[physician]~~or medical director at the receiving NTP shall review the patient's~~[client's]~~ records on an individual basis to determine the patient's~~[client's]~~ placement on the receiving program's patient~~[client]~~ listing. Reviews for proposed transfers shall determine the patient's~~[client's]~~:

1. Need;
2. Program placement availability; and
3. Circumstances for the transfer request.

(c) If a patient transfers~~[client]~~ from an existing narcotic~~[out-of-state, medication-assisted]~~ treatment program~~[transfers to an NTP located in Kentucky]~~, the NTP shall ensure, if clinically indicated, the patient remains in their confirmed current phase from the sending NTP~~[designate the client as a new admission or "entry phase" as established in subsection (12) of this section unless other phase levels are approved by the SNA]~~.

(d) The sending NTP shall:

1. Forward all relevant patient~~[client]~~ records to the receiving NTP within seventy-two (72) hours of receipt of a request to transfer, excluding any day the NTP is closed; and
2. Continue dosing until the patient~~[client]~~ is enrolled at the receiving NTP.

(e) The receiving NTP shall:

1. Contact the sending NTP to confirm the patient's~~[client's]~~ enrollment prior to administering the patient's~~[client's]~~ initial dose at the receiving NTP; and
2. Include documentation in the patient's~~[client's]~~ medical record of the:
   a. Date of receipt of the patient's~~[client's]~~ records from the sending NTP, including reason for transfer; and
   b. Verification that the patient~~[client]~~ meets the admission criteria in subsection (7) of this section.

(f) An NTP may provide guest dosing to patients who are not eligible for take home doses.

(g) The NTP may develop policies based upon ~~[national]~~ federal guidelines and best practices.

(h) The NTP shall check the individual's enrollment in the central registry.

(i) The NTP shall confirm and provide the correct guest dosing arrangement with the home NTP.

(9) Drug screens.

(a) Drug screen sample collection policies intended to prevent falsification shall be developed and followed.

(b) Drug screens shall be analyzed for the following drugs:

1. Approved controlled substance;
2. Cocaine;
3. Opioids ~~[Opiates]~~;
4. Amphetamines;
5. Barbiturates;
6. ~~[Tetrahydrocannabinol;]~~

~~[7.]~~ Benzodiazepines;

7. ~~[8.]~~ Any other drug or drugs that has been determined by the NTP or the SNA to be misused~~[abused]~~ in that program's locality; and
8. ~~[9.]~~ Any other drugs that could have been misused~~[abused]~~ by the patient~~[client]~~.

(c) Drug screens shall be reviewed by the treatment team monthly to determine the patient's~~[client's]~~ reduction in the use of unauthorized medications.

(d) Controlled substance medications shall be considered unapproved usage if they are being used by the patient~~[client]~~ without a valid prescription.

(e) A drug screen that is negative for the approved controlled substances allowed to be used in the NTP shall be considered positive for unauthorized drug use.

(f) An NTP shall not use drug screens as the sole criteria for involuntarily terminating a patient's~~[client's]~~ participation in the program.

(g) When drug screening results are used, presumptive laboratory results shall be distinguished in the patient~~[client]~~ record from results that are definitive.

(h) Samples used for drug screening purposes shall be handled in a manner that ensures patient~~[client]~~ confidentiality.

(10) Dosing requirements.

(a) The dose prepared for a patient~~[client]~~ shall be the quantity of approved controlled substances that is indicated on the patient's~~[client's]~~ narcotic sheet within the medical record.

(b) The dose shall be labeled with the exact quantity of narcotic drug ordered.

(c) Take-home doses shall be formulated in a manner that reduces the likelihood of injecting the dose.

(d) Take-home doses of the approved controlled substances shall be packaged in containers in accordance with 15 U.S.C. 1471.

(e) The label of take-home doses shall include the:

1. Name of the program;
2. Address and telephone number of the program;
3. Name of the controlled substance;
4. Name of the patient~~[client]~~;
5. Name of the prescriber~~[physician]~~ ordering the substance;
6. Quantity of the controlled substance, unless the patient~~[client]~~ has requested in writing that the quantity of the substance not be revealed to him or her;
7. Date of filling order; and
8. Instructions for medicating, including dosage amount and dates medication is to be taken.

(f) Dosing personnel shall not alter patient~~[client]~~ doses without the medical director**, program physician,** or program prescriber's~~[physician's]~~ order.

(g) Verbal dosing orders shall be reduced to writing and signed by the medical director**, program physician,** or program prescriber~~[physician]~~ within forty-eight (48) hours of the order's receipt.

(h) The medical record shall indicate any reason for dose changes and shall be signed by the medical director**, program physician,** or program prescriber~~[physician]~~ within forty-eight (48) hours of the order's receipt.

(11) **Patients ~~[Patient]~~** ~~[Clients]~~ who are pregnant.

(a) If the medical director**, program physician,** or program prescriber~~[physician]~~ does not accept the responsibility for providing prenatal care for the term of the patient's~~[client's]~~ pregnancy, then the medical director**, program physician,** or program prescriber~~[physician]~~ shall refer the patient~~[client]~~ to:

1. A primary care physician who practices obstetrics; or
2. An obstetrician.

(b) The medical director**, program physician,** or program prescriber~~[physician]~~ shall inform the prescriber~~[physician]~~ accepting the referral of the patient's~~[client's]~~ participation in the NTP.

(c) The medical director**, program physician,** or program prescriber~~[physician]~~ shall ensure that appropriate arrangements have been made for the medical care of both the patient~~[client]~~ and the child following the birth of the child.

(d) The medical director**, program physician,** or program prescriber~~[physician]~~ shall notify the pregnant patient's~~[client's]~~ primary care physician **or obstetrician** of any changes in the patient's~~[client's]~~ treatment.

(e) The program shall ensure that the following services are available for pregnant individuals and are a part of the treatment plan:

1. Nutritional counseling; and
2. Parenting training that includes information about:
   a. Newborn care;
   b. Handling a newborn;
   c. Newborn health; and
   d. Newborn safety.

(12) Treatment protocol phases.

(a) In accordance with 42 C.F.R. Part 8.12, NTPs shall comply with the treatment phase system as outlined in paragraphs (e) through (j) of this subsection for the dosing of methadone for treatment of opioid use disorder~~[to achieve][the goals of:]~~

~~[1.] [Reduced health problems;]~~
~~[2.] [Reduced criminal activity;]~~
~~[3.] [Increased productivity;]~~
~~[4.] [Stabilization of family life; and]~~
~~[5.] [Eventual drug-free living]~~.

(b) Program infractions shall include:

1. ~~[Failed drug screens;]~~
~~[2.]~~ Disruptive behavior at the clinic site; or
2. ~~[3.]~~ Threats to staff or other patients~~[clients; or]~~
~~[4.] [Failure to attend scheduled dosing or counseling appointments]~~.

(c) Program non-compliance shall include:

1. Non-compliant drug screens; or
2. Failure to attend scheduled dosing or counseling appointments.

(d) Patient ~~[Client]~~ treatment plans shall be**:**

1. Established ~~[established]~~, reviewed, and updated in accordance with 908 KAR 1:370, Section 19**; and**

2. Reflect a patient's current needs for:

a. Medical, social, and psychological services; and

b. Education, vocational rehabilitation, and employment services.

(e) ~~[(d)]~~ The medical director**, program physician,** or program prescriber~~[physician]~~ shall sign the treatment plan within thirty (30) days.

(f) ~~[(e)]~~ A patient shall successfully complete current treatment protocol phase before entering the subsequent treatment protocol phase with no non-compliance issues, unless excused pursuant to paragraph (n) of this subsection, for at least ninety (90) consecutive days.

(g) Phase one (1). Days one (1) to ninety (90) in treatment ~~[Entry Phase. During the first 90 days of treatment]~~, all patients~~[clients]~~ shall:

1. Attend clinic six (6)~~[seven (7)]~~ times each week for observed ingestion of an approved controlled substance at the clinic site;

2. Be eligible to receive a one (1) day take-home dose of an approved controlled **substance ~~[sub-stance]~~** ;

3. Be provided ~~[weekly]~~counseling sessions to support the implementation of their treatment plan as clinically indicated;

4. ~~[3.]~~ Be informed about appropriate support groups; and

5. ~~[4.]~~ Provide a~~[an observed]~~ drug screen sample one (1) time per **month~~[week]~~** on a random basis.

(h) ~~[(f)]~~ Phase two (2). Days ninety-one (91) to 180. ~~[Phase one (1).]~~

1. ~~[In order for a client to enter phase one (1), the client shall:]~~

~~[a.] [Have participated in the "entry phase" for at least ninety (90) consecutive days; and]~~

~~[b.] [Not have committed any program infractions for at least ninety (90) consecutive days.]~~

~~[2.]~~ Once the patient~~[client]~~ enters phase two (2)~~[one (1)]~~ the patient~~[client]~~ shall:

a. Attend clinic five (5)~~[six (6)]~~ times each week for observed ingestion of an approved controlled substance;

b. Be eligible to receive a two (2)~~[one (1)]~~ day take-home dose of an approved controlled substance;

c. Be provided ~~[weekly]~~ counseling sessions to support the implementation of their treatment plan as clinically indicated;

d. Provide a~~[an observed]~~ drug screen sample on a random basis at least monthly or more frequently if their treatment plan requires~~[every other week]~~; and

e. Be encouraged to attend ~~[an]~~ appropriate support groups~~[group]~~.

(i) ~~[(g)]~~ Phase three (3). Days 181 to 270. ~~[Phase two (2).]~~

1. In order for a patient~~[client]~~ to enter phase three (3)[t~~[wo (2)]~~, the patient~~[client]~~ shall**have successfully completed phase two (2).~~[be][:]**

~~[a.] [Have participated in phase one (1) for at least ninety (90) consecutive days;]~~

~~[b.] [Not have committed any program infractions for at least ninety (90) consecutive days;]~~

~~[c.] [Be] [:]~~

~~[a.] [(i)] [Pursuing or engaged in gainful employment;]~~

~~[b.] [(ii)] [] [Pursuing vocational training;]~~

~~[c.] [(iii)] [] [Attending school;]~~

~~[d.] [(iv)] [] [Engaged in volunteer work;]~~

~~[e.] [(v)] [] [Attending parenting classes if they are a parent at home with children; or]~~

~~[f.] [(vi)] [] [A] [patient]~~ ~~[client]~~ **~~[with disabilities or other circumstances that might make compliance with this clause unattainable, if the] [patient]~~**

[client] **[submitted a written waiver request to the SNA justifying specific reasons for the request that was not denied; and]**

[2.] [d.] [Have a treatment plan to meet any special needs, including disabilities.]]

2. [3] [.] [2.] Patients [Clients] in phase three (3)[two (2)] shall:

a. Attend clinic four (4)[five (5)] times each week for observed ingestion of an approved controlled substance;

b. Be eligible to receive up to three (3)[two (2)] days of take-home doses of an approved controlled substance;

c. Provide a[an observed] drug screen sample randomly on a monthly basis, or more frequently if their treatment plan requires;

d. Be provided [monthly]counseling sessions, [or more frequently if their treatment plan requires,]as clinically indicated; and

e. Be encouraged to attend appropriate support groups outside the clinic.

(j) [(h)] Phase 4. Days 271 to 365. [Phase three (3).]

1. In order for the patient[client] to enter phase four (4)[three (3)], the patient[client] shall:

a. Have completed phase 3; and[participated in phase two (2) for at least ninety (90) consecutive days:]

b. [Not have committed any program infractions for at least ninety (90) consecutive days; and]

[c.] Have met the same entry criteria requirements as established in phase three (3)[two (2)].

2. Patients [Clients] in phase four (4)[three (3)] shall:

a. Attend clinic one (1) time[three (3) times] each week for observed ingestion of an approved controlled substance;

b. Be eligible to receive up to six (6)[two (2)] days of take-home doses of an approved controlled substance;

c. Provide eight (8) random drug screen samples within a twelve (12) month period[an observed drug screen sample randomly on a monthly basis], or more frequently if their treatment plan requires;

d. Be provided [monthly] counseling sessions, [or more frequently if their treatment plan requires,]as clinically indicated; and

e. Be encouraged to attend appropriate support groups outside the clinic.

(k) [(i)] Phase 5. Days 365 to 730. [Phase three (4).]

1. In order for the patient[client] to enter phase five (5)[four (4)], the patient[client] shall have:

a. Successfully completed phase four (4)[three (3)]; and

b. Adhered to the requirements of the maintenance treatment program for at least 365 days[twelve (12) consecutive months].

2. Patient [Clients] in phase five (5)[four (4)] shall:

a. Be dosed at the clinic site **at least** once every fifteen (15) days[two (2) days per week] for observed ingestion of an approved controlled substance;

b. Be eligible for up to fourteen (14)[three (3)] days of take-home doses of an approved controlled substance;

c. Be provided an appropriate number of counseling sessions, which shall be based[:]

[(i)] [Based] on the clinical judgement of the program physician and program staff; and

[(ii)] [No less than one (1) per month; and]

d. Provide eight (8) random drug screen samples within a twelve month period[an observed drug screen sample randomly on a monthly basis], or more frequently if

their treatment plan requires.

~~[3.] [Prior to successful completion of phase four (4), a plan shall be developed that shall assist the client toward a drug free treatment regimen for continued support.]~~

(l) ~~[(j)]~~ Phase 6. Days 731 and up. ~~[Phase three (5).]~~

1. In order for the patient~~[client]~~ to enter phase six (6)~~[five (5)]~~, the patient~~[client]~~ shall have:

a. Successfully completed phase five (5)~~[four (4)]~~; and

b. Adhered to the requirements of the maintenance treatment program for at least 731 days~~[two (2) consecutive years]~~.

2. Patients[C~~lients]~~ in phase six (6)~~[five (5)]~~ shall:

a. Be dosed at the clinic site **at least** one (1) day per month~~[per week]~~ for observed ingestion of an approved controlled substance;

b. Be eligible for up to thirty one~~[six (6)]~~ days of take-home doses of an approved controlled substance;

c. Be provided an appropriate number of counseling sessions, which shall be based~~[.]~~

~~[(i)]~~ ~~[Based]~~ on the clinical judgement of the program prescriber~~[physician]~~ and program staff; and

~~[(ii)]~~ ~~[No less than one (1) per month; and]~~

d. Provide eight (8) random drug screen samples within a twelve month period~~[an observed drug screen sample randomly on a monthly basis]~~, or more frequently if their treatment plan requires.

(m) The medical director may excuse a non-compliance issue on a case-by-case basis focusing on the following:

1. The interactions between a positive drug screen and the medication used for treatment;

2. Past history of non-compliance issues;

3. Employment issues; and

4. Length of time in program.

(n) If the medical director excuses a non-compliance issue, as specified in paragraph (m) of this subsection, the non-compliance issue excused shall not be used to:

1. Move a patient out of a phase; or

2. Keep a patient from advancing phases.

(o) The medical director shall document the non-compliance excuse in the patient's medical record.

(13) Take home dose restrictions and terminations.

(a) In determining the patient's~~[client's]~~ take-home medications, the medical director**, program physician,** or program prescriber~~[physician]~~ shall act in accordance with 42 C.F.R. Part 8.12 and subsections (7) through (12) of this section.

(b) ~~[An NTP shall restrict a client's take-home dosage privileges by moving the client back at least one (1) phase level on the schedule for take-home dosages if the client's drug screening results disclose the unauthorized presence any substance established in subsection (9)(b) of this section.]~~

~~[(c)]~~ An NTP shall restrict a patient's~~[client's]~~ take-home dosage by moving the patient~~[client]~~ back on the take-home dosage schedule if the medical director**, program physician,** or program prescriber~~[physician]~~ concludes that the patient~~[cliens]~~ is no longer a suitable candidate for take-home privileges as presently scheduled.

(c) ~~[(d)]~~ An NTP shall revoke a patient's~~[client's]~~ take-home privileges for not less than thirty (30) days and shall require the patient~~[client]~~ to ingest each dosage at the facility for any of the following reasons:

1. The patient's~~[client's]~~ drug screening discloses an absence of the controlled substance prescribed by the program;

2. The patient~~[client]~~ is discovered to be misusing medication, as established in subparagraph 5. of this paragraph;

3. The patient~~[client]~~ attempts to enroll in another NTP;

4. The patient~~[client]~~ alters or attempts to alter a drug screen; or

5. The patient~~[client]~~ is not satisfactorily adhering to the requirements of the NTP by the following:

a. The patient~~[client]~~ has not complied with the rules of the NTP;

b. ~~[There is indication that the client has repeatedly used drugs improperly;]~~

~~[c.]~~ The patient~~[client]~~ is sharing, giving away, selling, or trading their~~[his or her]~~ approved controlled substance dosage; or

c. ~~[d.]~~ The patient~~[client]~~ is not ingesting their~~[his or her]~~ approved controlled substance dose in accordance with treatment program rules~~[;]~~

~~[e.] [There is indication that the client is selling, distributing, or otherwise involved with illicit drugs and their use; or]~~

~~[f.] [The client is not participating in an educational, vocational, or home-making activty]~~.

(d) ~~[(c)]~~ A patient~~[client]~~ whose daily dosage is twenty-five (25) milligrams or less shall be exempt from paragraph (c)~~[(d)1]~~. of this subsection.

(e) ~~[(f)]~~ A patient~~[client]~~ whose take-home privileges were revoked or restricted may regain take-home privileges according to the following schedule:

1. Phase one (1) – satisfactory adherence for at least thirty (30) days;

2. Phase two (2) – satisfactory adherence for at least thirty (30) days after regaining phase one (1) privileges;

3. Phase three (3) – satisfactory adherence for at least thirty (30) days after regaining phase two (2) privileges;

4. Phase four (4) – satisfactory adherence for at least thirty (30) days after regaining phase three (3) privileges;~~[and]~~

5. Phase five (5) – satisfactory adherence for at least thirty (30) days after regaining phase four (4) privileges; and

6. Phase six (6) - satisfactory adherence for at least thirty (30) days after regaining phase five (5) privileges.

(f) ~~[(g)]~~ This subsection shall not be used to circumvent the requirements of this administrative regulation. A patient~~[client]~~ shall not be advanced to a phase level pursuant to this subsection unless the patient~~[client]~~ has previously been at that phase level after having satisfied the requirements of each phase.

(g) ~~[(h)]~~ Treatment shall be continued as long as it is medically necessary based upon the clinical judgment of the medical director**, program physician,** or program prescriber~~[physician]~~ and staff.

(h) ~~[(i)]~~ Scheduled withdrawal shall be under the immediate direction of the medical director**, program physician,** or program prescriber~~[physician]~~ and shall be individualized.

(i) ~~[(j)]~~ A patient~~[client]~~ may voluntarily terminate participation in an NTP even if termination is against the advice of the NTP.

(j) ~~[(k)]~~ Except as established in subsection (15)(e) of this section, either voluntary or involuntary termination shall take place over a period of time not less than fifteen (15) days, unless:

1. The medical director**, program physician,** or program prescriber~~[physician]~~ deems it clinically necessary to terminate participation sooner and documents the reason in the patient's~~[client's]~~ record; or

2. The patient~~[client]~~ requests in writing a shorter termination period.

(k) Patients who are voluntarily and involuntarily terminated shall be offered the following prior to discharge:

1. Overdose education;

2.

a. A Federal Drug Administration approved opioid overdose reversal agent; or

b. A Federal Drug Administration approved opioid overdose reversal agent prescription; and

3. Referral with appointment to the level-of-care appropriate and accessible to the patient.

(14) Exceptions.

(a) The medical director**, program physician,** or program prescriber~~[physician]~~ may grant an exception to the criteria for take-home dosages for any of the following reasons:

1. The patient~~[client]~~ has a serious physical disability that would prevent frequent visits to the program facility; or

2.

a. The patient~~[cliens]~~ is subject to an exceptional circumstance such as acute illness, family **~~[add]~~**crisis, or necessary travel; and

b. Hardship would result from requiring exact compliance with the phase level schedule established in subsection (12) of this section.

(b) Exception to the criteria for take-home dosages shall:

1. Be subject to the limitations in this administrative regulation; and

2. Have written approval from the SNA that shall be filed in the patient~~[client]~~ record.

(c) If a patient~~[client]~~ is required to travel out of the program area, the medical director**, program physician,** or program prescriber~~[physician]~~ shall attempt to arrange for the patient's~~[client's]~~ daily dosage to be received at another program in lieu of increasing take-home dosages.

(d) The medical director**, program physician,** or program prescriber~~[physician]~~ shall document in the patient's~~[client's]~~ record the granting of any exception and the facts justifying the exception.

(e) Each program shall maintain a separate record for all exceptions granted.

(f) The SNA shall not grant additional exceptions, except in cases of medical emergency or natural disaster, such as fire, flood, or earthquake.

(g) Patient take home exceptions shall be entered into the Substance Abuse and Mental Health Services Administration's system in accordance with the system's requirements.

(h) Emergency Dosing.

1. Under emergency conditions a program may issue take-home doses in accordance with this subsection.

2. Within forty-eight (48) hours after administration of the first emergency dose, an NTP shall:

a. Notify the SNA in writing;

b. Submit justification of the emergency dose or doses; and

c. Request permission for any subsequent dose after the first two (2) doses.

3. Subsequent emergency doses shall not be given unless permission is received by the SNA.

4. This request shall include the:

a. Number of take-home doses requested;

b. Reason for the request;

c. Patient's ~~[Client's]~~ standing in program phases;

d. Patient's ~~[Client's]~~ adherence to program policies; and

e. Total length of time the patient~~[client]~~ has been enrolled at the NTP.

(15) Patient[C~~lient~~] program compliance and infractions.

(a) If a patient has a non-compliance issue as described in section 7(12)(c) of this administrative regulation~~[client commits a program infraction]~~, the counseling staff shall review and modify the treatment plan to assist the patient~~[client]~~ in complying with program policies.

(b) If a patient~~[client]~~ continues to have non-compliance issues~~[commit infractions]~~ and the medical director**, program physician,** or program prescriber~~[physician]~~ determines additional intervention is warranted, the director**, program physician,** or prescriber~~[physician]~~ may:

1. Move the patient~~[client]~~ back to an earlier treatment phase; ~~[or]~~
2. Limit or revoke the patient's~~[client's]~~ take-home privileges;
3. Increase the frequency of counseling sessions;
4. Increase the frequency of drug screen samples; or
5. Increase the medication dose to reduce cravings.

(c) If a patient commits a program infraction as described in section 7(12)(b) of this administrative regulation~~[the client continues to commit program infractions]~~, the patient~~[client]~~ may be involuntarily terminated from the program based on the recommendation of the medical director**, program physician,** or program prescriber~~[physician]~~.

(d) A patient's~~[client's]~~ participation in an NTP may be involuntarily terminated for cause. Cause shall include:

1. Polydrug use if risk of co-use outweighs risk of overdose death following termination of methadone treatment~~[abuse]~~;
2. Diversion of an approved controlled substance;
3. Violence or threat of violence to program staff or other patients~~[clients]~~ in the program; or
4. Dual enrollment in another NTP.

(e) If the medical director**, program physician,** or program prescriber~~[physician]~~ determines that the patient's~~[client's]~~ continued participation in the program creates a physically threatening situation for the staff or other patients~~[clients]~~, the patient's~~[client's]~~ participation may be terminated immediately.

(f) A patient~~[client]~~ shall be given written notice of a decision to terminate their~~[his or her]~~ participation in the program, which shall include the reasons for the termination.

(16) Program monitoring. If an NTP fails to comply with the requirements in this administrative regulation, the SNA may take action in accordance with 908 KAR 1:370, Sections 5 and 20. In addition to the authority to deny, suspend, or revoke a license in accordance with 908 KAR 1:370, the SNA may:

(a) Order the NTP to discontinue all or part of the take-home doses of any approved controlled substance used in the NTP;

(b) Restrict the NTP's take-home procedures to the provision of emergency take-home doses in accordance with subsection (14) of this section; or

(c) Order the NTP to discontinue the utilization of any drug approved for use in narcotic treatment programs.

(17) Waivers **~~[and Exemptions]~~** . (1) The cabinet may grant a waiver to any part of this administrative regulation if:

(a) The governor declares a state of emergency; or

(b) [**(2)**] An NTP may request **a waiver~~[an exemption]~~** in accordance to 42C.F.R 8.11(h)~~[a waiver]~~ from the SNA from any requirement of this administrative regulation.

(2)

(a) This application for **a waiver~~[an exemption]~~**~~[a waiver]~~ shall:

1. Be in the form of a letter to the SNA;

2. Identify the specific sections of this administrative regulation for which **a waiver[~~an exemption~~]**[~~a waiver~~] is being sought; and

3. Give the rationale for the request.

(b) If **a waiver[~~an exemption~~]**[~~a waiver~~] pertains to a client, a copy of **a waiver[~~an exemption~~]**[~~the waiver~~] request and response shall become part of the client's permanent record.

(c) An application for **a waiver[~~an exemption~~]**[~~a waiver~~] request shall be mailed to: Kentucky State Narcotic Authority Department for Behavioral Health, Developmental and Intellectual Disabilities, 275 East Main Street, Frankfort, Kentucky 40621.

(d) Approval or denial of **a waiver[~~an exemption~~]**[~~a waiver~~] shall be based upon a review of the merits of the request, taking into consideration:

1. Public safety;

2. Practicality; and

3. The purpose of the requirement for which **a waiver[~~an exemption~~]**[~~waiver~~] is requested.

(e) **A waiver [~~an exemption~~]** [~~waiver~~] shall expire twelve (12) months from the date [~~t~~]he **waiver[~~an exemption~~]**[~~waiver~~] is granted unless the SNA gives an earlier expiration date.

[~~(f)~~] [~~A waiver given prior to January 1, 2020 shall expire on January 1, 2020.~~]

Section 8. **In-home services.**

(1) An outpatient AODE may provide the following services in person, in a patient's home:

(a) One (1) or more of the outpatient services established by Sections 2 through 5 of this administrative regulation; or

(b) . Medications for addiction treatment, excluding methadone-based treatment, under the direction of a Kentucky-licensed:

1. Physician who complies with the prescribing and dispensing standards of 201 KAR 9:270; or

2. Advanced practice registered nurse who complies with the prescribing and dispensing standards of 201 KAR 20:065.

(2) An outpatient AODE that provides in-person, in-home services exclusively shall be exempt from the physical environment requirements of Section 9 of this administrative regulation if the AODE has a business office located in Kentucky.

Section 9. Physical Environment.

(1) Accessibility. An outpatient AODE shall meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities in accordance with KRS 198B.260 and 815 KAR 7:120.

(2) Fire safety. An outpatient AODE shall be approved by the State Fire Marshal's office prior to initial licensure or if the AODE changes location.

(3) Physical location and overall environment.

(a) An outpatient AODE shall:

1. Comply with building codes, ordinances, and administrative regulations that are enforced by city, county, or state jurisdictions;

2. Display a sign that can be viewed by the public that contains the facility name, hours of operation, and a street address;

3. Have a publicly listed telephone number;

4. Have a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four (24) hours per day or use encrypted electronic messaging technology;

5. Have a reception and waiting area;

6. Provide a restroom for patient[~~client~~] use; and

7. Have an administrative area.

(b) The condition of the physical location and the overall environment shall be maintained in such a manner that the safety and well-being of patients~~[clients]~~, personnel, and visitors shall be assured.

(4) Additional requirements for NTPs.

(a) The building used for the NTP shall meet the requirements of 21 C.F.R. 1301.74(j).

(b) The waiting area shall be separated from the dosing area to permit each patient~~[client]~~ privacy and confidentiality at the time of dosing.

(c) The dosing area shall be clean and sanitary and shall contain:

1. A sink;
2. Hot and cold running water; and
3. Pill-counting trays if tablets are being used.

(d) The security and floor plan of the dosing area shall be in accordance with 21 C.F.R. 1301.72.

(e) The facility shall have two (2) restrooms, which shall be accessible to patients~~[clients]~~ with disabilities.

(f) Restrooms available to patients~~[clients]~~ to provide urine specimens shall be:

1. Secure;
2. Clean; and
3. Sanitary.

(g) The building shall be secured by a local security company approved by the DEA and the SNA.

(h) There shall be a minimum of two (2) panic buttons or similar devices for each NTP with:

1. One (1) in the reception area; and
2. One (1) in the dosing area.

(i) There shall be a telephone with an outside line accessible in the dosing area.

(j) Internal security shall meet the requirements of 21 C.F.R. 1301.74(b), (h), (i), (j), (k); 1301.91; 1301.92 and shall be installed only after consultation with the DEA and the SNA.

(k) Parking spaces at the clinic site shall be adequate to accommodate the maximum number of patients~~[clients]~~ expected to be at the clinic site at one (1) time.

Section 10. ~~**[Section 9.]**~~ Incarcerated Individuals.

(1) An NTP may provide FDA-approved medications for opioid use disorder for incarcerated individuals.

(2) The NTP shall:

(a) Submit a waiver application to the SNA identifying the services the NTP can and cannot provide directly to the incarcerated individual in accordance with Section (7); or

(b) Facilitate the transfer of the incarcerated individual to a corrections based NTP, if available.

(3) Document in the incarcerated individuals record:

(a) The program physician or program director's coordination efforts with the jail; and

(b) The date(s) of incarceration, reason(s), and circumstances involved.

WENDY T. MORRIS, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: December 13, 2022
FILED WITH LRC: December 13, 2022 at 2:13 p.m.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Rachael M. Ratliff and Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This amended administrative regulation establishes standards for nonhospital-based alcohol and other drug treatment entities (AODE) that provide ambulatory withdrawal management, outpatient treatment services, intensive outpatient services, partial hospitalization, or office-based opiate treatment services. This administrative regulation further establishes standards for the operation of narcotic treatment programs in accordance with KRS 222.231(12) and 42 C.F.R. Part 8.

(b) The necessity of this administrative regulation:
This amended administrative regulation is necessary to update federal standards and comply with Senate Bill 178 (2022 Regular Session).

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This amended administrative regulation conforms to the content of Senate Bill 178 (2022 Regular Session) by establishing guidelines for the use of buprenorphine at licensed narcotic treatment programs.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This amended administrative regulation assists in the effective administration of the statutes by establishing guidelines for licensure of non-hospital based alcohol and other drug treatment services.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
This amended administrative regulation will incorporate the provisions of SB 178 for the use of buprenorphine at narcotic treatment programs. Further amendments incorporate changes to federal guidelines to the certification and requirements of narcotic treatment programs.

(b) The necessity of the amendment to this administrative regulation:
The amendment to this administrative regulation is necessary to incorporate the provisions of SB 178 for the use of buprenorphine at narcotic treatment programs, as well as incorporating changes to federal guidelines to the certification and requirements of narcotic treatment programs.

(c) How the amendment conforms to the content of the authorizing statutes:
This amended administrative regulation incorporates the provisions of SB 178 for the use of buprenorphine at narcotic treatment programs.

(d) How the amendment will assist in the effective administration of the statutes:
This amended administrative regulation incorporates the provisions of SB 178 for the use of buprenorphine at narcotic treatment programs and will ensure compliance with updated federal guidelines and regulations.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This amended administrative regulation will impact up to 600 alcohol and other drug entities with thirty NTP programs statewide.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

This amended administrative regulation will provide updates to regulatory requirements and federal guidelines, as well as incorporating statutory changes as a result of SB 178. Narcotic treatment programs will need to ensure they have a prescribing and dosing provider who meets federal guidelines for the administration of buprenorphine.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

This amended administrative regulation will not result in a cost increase to the affected entitities.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

This amended administrative regulation should result in greater patient flexibility and access. Additionally, providing federal guidelines as requirements will allow greater flexibility when updated to reflect current opioid use disorder treatment guidance.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

This amended administrative regulation is implemented through the use of state general funds and federal grant funding currently.

(b) On a continuing basis:

This amended administrative regulation will continue to be implemented through existing department funding.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

This amended administrative regulation is implemented by state general funds and federal grant funding.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

This amended administrative regulation should not necessitate in an increase in funding or fees at this time.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not establish any fees.

(9) TIERING: Is tiering applied?

Tiering is not applied because this administrative regulation will be applied in a like manner statewide.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Department for Behavioral Health, Intellectual and Developmental Disabilities will be impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

This amended administrative regulation is authorized by 42 C.F.R. Part 8 and KRS 222.231.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

There will be no impact on the expenditure or revenues of state or local governmental agencies as a result of this amended administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This amended administrative regulation will not generate any revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This amended administrative regulation will not generate any revenue.

(c) How much will it cost to administer this program for the first year?

This is an existing administrative regulation and therefore will not require any new funding and will be administered within the current departmental budget.

(d) How much will it cost to administer this program for subsequent years?

This amended administrative regulation will continue to be administered within the departmental budget.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

This amended administrative regulation does not require new expenditures from the regulated entitities for the first full year. It is unknown if there will be cost savings to the regulated entities. Any costs savings would be determined by the regulated entitities choice in medications administered and provided to patients.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

It is unknown, if any, cost saving this amended administrative regulation would generate for the regulated entitities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

It is unknown, if any, cost saving this amended administrative regulation would generate for the regulated entitities.

(c) How much will it cost the regulated entities for the first year?

There will be no new or additional costs to the regulated entities for the first year.

(d) How much will it cost the regulated entities for subsequent years?

There will be no new costs for the regulated entitities in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This amended administrative regulation will not have a major economic impact.