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Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Tennessee Department of Mental Health
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Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	Gwen Hamer
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Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	Andrew Johnson Tower
Address 2:	710 James Robertson Pkwy.
City:	Nashville
Zip:	37243
Hearing Date :	01/05/2012
Hearing Time:	9:30 a.m. <input checked="" type="checkbox"/> CST/CDT <input type="checkbox"/> EST/EDT

Additional Hearing Information:

Andrew Johnson Tower, 1 st Floor Conference Room

Revision Type (check all that apply):

- ☐ Amendment
☒ New
☒ Repeal

Rule(s) (ALL chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	Chapter Title
0940-05-42	Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities

Rule Number	Rule Title
0940-05-42-.01	Definitions
0940-05-42-.02	Application of Rules
0940-05-42-.03	Licensing Procedures
0940-05-42-.04	Designation of State Opioid Treatment Authority (SOTA) and Powers and Duties of SOTA
0940-05-42-.05	Policies and Procedures
0940-05-42-.06	Intake, Admissions, and Discharges
0940-05-42-.07	Service Recipient Records
0940-05-42-.08	Multiple Enrollment
0940-05-42-.09	Orientation
0940-05-42-.10	Service Recipient Transfers
0940-05-42-.11	Individualized Program Plan
0940-05-42-.12	Special Populations
0940-05-42-.13	Professional Services
0940-05-42-.14	Counseling
0940-05-42-.15	Concurrent Alcohol and Polysubstance Abuse
0940-05-42-.16	Medication Management
0940-05-42-.17	Pharmacotherapy Guidelines
0940-05-42-.18	Drug Screens
0940-05-42-.19	Detoxification and Medically Supervised Withdrawal
0940-05-42-.20	Diversion Control Plan
0940-05-42-.21	Central Registry
0940-05-42-.22	Reporting Requirements
0940-05-42-.23	Quality of Care
0940-05-42-.24	Infectious Hazardous Waste
0940-05-42-.25	Infection Control
0940-05-42-.26	Managing Disruptive Behavior
0940-05-42-.27	Hours of Operation
0940-05-42-.28	Service Recipients' Rights
0940-05-42-.29	Community Relations
0940-05-42-.30	Personnel and Staffing Requirements
0940-05-42-.31	Posted Information

0940-05-42-.01 Definitions.

- (1) Definitions of general terms used in these rules can be found in Rules Chapter 0940-05-01.
- (2) Definitions specific to this chapter are as follows:
 - (a) "Opioid Treatment Program (OTP)" or "Non-Residential Substitution-based Treatment Center for Opiate Addiction" includes, but is not limited to, standalone clinics offering methadone, products containing buprenorphine such as Subutex and Suboxone, or products containing any other formulation designed to treat opiate addiction by preventing symptoms of withdrawal, with the goal of the service recipient becoming free from any drug which is not medically indicated. May also be referred to herein as "Facility" or "program".
 - (b) "Advanced Practice Nurse" means a person qualified by the Tennessee Board of Nursing under Rules Chapter 1000-04 as an advanced practice nurse with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs.
 - (c) "Buprenorphine" means a synthetic opioid agonist-antagonist; the hydrochloride salt is used as an analgesic and as a substitute in the management of opioid addiction. It has been approved by the FDA for detoxification in maintenance treatment of opioid addiction.
 - (d) "Central Registry" means an electronic system used to register service recipients currently receiving opioid replacement treatment at an OTP. The Tennessee Department of Mental Health (TDMH or Department) or State Opioid Treatment Authority (SOTA) may require OTPs to initiate a clearance inquiry and service recipient registration into an approved central registry for the purpose of gathering program information, performance data and to prevent simultaneous enrollment in other OTPs.
 - (e) "Counseling Session" means face-to-face, therapeutic discussion between service recipient(s) and a facility counselor in a private location for a period of no less than 30 minutes designated to address service recipient addiction issues or coping strategies and Individualized Program Plans.
 - (f) "DEA" means the United States Drug Enforcement Administration.
 - (g) "Detoxification" or "detoxification treatment" means the dispensing of an opioid agonist treatment medication in decreasing doses to the service recipient to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the service recipient to a drug-free state within that period.
 1. "Administrative detoxification" or "administrative withdrawal" means an involuntary withdrawal or discharge from opioid treatment usually relatively brief.
 2. "Long term detoxification" means a period of opioid replacement therapy services or programs not to exceed 180 days.
 3. "Medical Detoxification", "medical withdrawal" or "medically supervised withdrawal" means the voluntary and therapeutic withdrawal of the service recipient from opioid treatment.
 4. "30-Day Detoxification Treatment" or "short term detoxification" means a period of continuous detoxification treatment with narcotic replacement therapy not to exceed 30 days in length for the purpose of assisting the opioid dependent client in reaching a drug free state. An episode of 30-day detoxification is any length of time in which the client receives narcotic replacement therapy for three or more

days.

- (h) "Dispense" or "dispensing" means, for purposes of these rules, to prepare and give out more than one single dose of an opioid drug to a service recipient at a non-residential opioid treatment facility.
- (i) "Diversion Control Plan" means specific measures, including assigning responsibilities to medical and administrative staff, to reduce the possibility of diversion of controlled substances from legitimate treatment to illicit use.
- (j) "FDA" means the United States Food and Drug Administration.
- (k) "Guest Dose" means any dose provided on a temporary basis at a program other than the service recipient's home clinic.
- (l) "Home Clinic" means the program where an individual is admitted and primarily treatment as a program service recipient.
- (m) "Inspection" means any examination by the Department or its representatives of a provider including, but not limited to, the premises, staff, persons in care, and documents pertinent to initial and continued licensing, so that the Department may determine whether a provider is operating in compliance with licensing requirements or has violated any licensing requirements. The term inspection includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to licensing requirements.
- (n) "Opioid Maintenance Treatment" means the dispensing of an opioid drug, at relatively stable dosage levels, for a continuous, open-ended period deemed medically necessary by a program physician or medical director, in the treatment of an individual for dependence on heroin or other opioid drug(s). A "maintenance dose" or dose rendered as part of a service recipient's maintenance treatment is the level of opioid replacement therapy considered to consistently suppress signs or symptoms of withdrawal and drug cravings for individuals with opioid addiction; it usually represents the end of the induction period. It is individualized for each service recipient and may gradually change over time. Clients will be admitted or readmitted to this modality only after careful clinical evaluation by a multidisciplinary team.
- (o) "Medical Director" means a physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who has been designated by the governing body of the OTP to be responsible for the administration of all medical services performed by the OTP, including compliance with all federal, state and local law and rules regarding medical treatment of opioid addiction. The medical director shall have the experience and credentials specified in paragraph 0940-05-42-.30(4) of these rules.
- (p) "Medical Record" means medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to services rendered to service recipients.
- (q) "Methadone (trade name Dolophine)" means a synthetic opioid agonist with actions similar to those of morphine and heroin; the hydrochloride salt is used as an analgesic and as a replacement therapy for opioids. It is approved by the FDA for detoxification and maintenance treatment of opioid addiction.
- (r) "Multidisciplinary Treatment Team" or "Treatment Team" means professionals which may include a licensed physician, licensed physician assistant, licensed nurse, qualified alcohol and drug treatment personnel and/or mental health professionals who assess service recipient progress.
- (s) "Opiate/Opioid" means a drug that contains opium, derivatives of opium or any of several

semi-synthetic or synthetic drugs with opium-like activity.

- (t) "Opioid Dependent" means an individual who physiologically needs opioid or other opiate-like drugs to prevent the onset of signs of withdrawal.
- (u) "Opioid Replacement Treatment" means the substitution of a prescription drug which has been approved by the FDA for the treatment of addiction to opioids or opiate-like drugs.
- (v) "Observed Testing" means testing conducted and witnessed by a Facility staff person to ensure against falsification or tampering or results of a drug screen.
- (w) "Prescriber" means a physician or physician's assistant with prescribing privileges under the Tennessee Board of Medical Examiners Chapter 0880-02 or 0880-03, respectively, or an advanced practice nurse with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs under Tennessee Board of Nursing Rules Chapter 1000-04.
- (x) "Program Director" means the person designated by the Facility's governing body who is responsible for the operation of the Facility, for the overall compliance with federal, state and local laws and regulations regarding the operation of opioid treatment programs, and for all Facility employees including practitioners, agents, or other persons providing services at the Facility.
- (y) "Program Physician" means any physician, including the medical director, who is employed by an OTP to provide medical services to service recipients. Any Facility program physician who is not a medical director shall work under the supervision of the Facility's medical director.
- (z) "Prescription Monitoring Program" or "PMP" means a program established by the Tennessee Department of Commerce and Insurance to monitor the prescribing and dispensing of Schedule II, III, IV and V controlled substances.
- (aa) "Psychiatrist" means a physician, who specializes in the assessment and treatment of individuals having psychiatric disorders, is certified by the American Board of Psychiatry and Neurology or has the documented equivalent in education and training, and who is fully licensed to practice medicine in the State of Tennessee.
- (bb) "Random Testing" means drug screens conducted by the Facility that lack a definite pattern of who and when service recipients are selected for testing; indiscriminate testing.
- (cc) "Relapse" means the failure of a service recipient to maintain abstinence from illicit drug use verified through drug screen.
- (dd) "Service Recipient Transfer" means any service recipient who changes locations of their home clinic without receiving a discharge status or without a break in treatment between clinics.
- (ee) "State Board of Pharmacy" means the Board created to regulate the practice of pharmacy pursuant to T.C.A. § 63-10-301.
- (ff) "State Opioid Treatment Authority" or "SOTA" means any individual person designated by the commissioner to exercise the responsibility and authority for governing the treatment of opioid addiction in accordance with all applicable state and federal regulations. The individual also serves as a liaison with the appropriate federal agencies.
- (gg) "Supervising Physicians" means a licensed and actively practicing physician who has been identified as accepting the responsibility for supervising physician assistants and advanced practice nurses.
- (hh) "TDMH" means the Tennessee Department of Mental Health.

- (ii) "Treatment" means a broad range of services including outreach, identification, assessment, diagnosis, detoxification, therapy, medical services, lectures/seminars, group process social services, and follow-up or aftercare for individuals with alcohol and other drug problems. The overall goal is to eliminate the alcohol and drug use as a contributing factor to physical, psychological and social dysfunction and to arrest or reverse the progress of any associated problems.
- (jj) "Volunteer" means a person who is not paid by the licensee and whose varied skills are used by the licensee to support and supplement the efforts of the paid facility staff.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-404 and 33-2-407.

0940-05-42-.02 Application of Rules.

In addition to this chapter, the licensee of an OTP shall comply with the following rules:

- (1) Chapter 0940-05-02 Licensure Administration and Procedures;
- (2) Applicable Life Safety Rules for Business Occupancies (Rule 0940-05-04-.04);
- (3) If services are provided to mobile, non-ambulatory service recipients, then Mobile Non-Ambulatory Rule (Rule 0940-05-04-.09);
- (4) Rules for Adequacy of Program Environment and Ancillary Services found in Chapter 0940-05-05; and
- (5) Applicable Minimum Program Requirements for All Services and Facilities found in Chapter 0940-05-06.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-404 and 33-2-407.

0940-05-42-.03 Licensing Procedures.

- (1) As of the effective date of these rules, when making application for a license, the applicant shall submit an application on a form provided by the Department along with a copy of the Certificate of Need (CON) issued by the Tennessee Health Services Development Agency or any other applicable state agency along with a copy of the letter of support from the local governing body of the county or city in which the facility is proposed to be located. Any condition placed on the CON will also be placed on the license.
- (2) The written application for operation of an OTP shall be filed simultaneously with the Federal Substance Abuse and Mental Health Service Administration (SAMHSA) and the DEA, and/or any other applicable federal agencies.
- (3) Service recipients shall not be admitted to the OTP until a license has been issued.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-404 and 33-2-407.

0940-05-42-.04 Designation of State Opioid Treatment Authority (SOTA) and Powers and Duties of SOTA.

- (1) The commissioner shall designate an individual within the department to serve as the SOTA to facilitate oversight and technical assistance to opioid treatment programs. The individual designated shall have demonstrated education and background evidencing comprehensive knowledge of opioid drugs and their effects.
- (2) The powers and duties of the SOTA include, but are not limited to, the following:
 - (a) Facilitating the development and implementation of rules, regulations, standards and best

practice guidelines to assure the quality of services delivered by opioid treatment programs;

- (b) Acting as a liaison between relevant State and federal agencies;
- (c) Reviewing opioid treatment guidelines and regulations developed by the federal government;
- (d) Assuring delivery of technical assistance and informational materials to opioid treatment programs as needed;
- (e) Performing both scheduled and unscheduled site visits to opioid treatment programs in cooperation with department licensure office or other governmental oversight agencies, or as designated by the SOTA, when necessary and appropriate and preparing reports as appropriate to assist department licensure or other governmental oversight agencies;
- (f) Consulting with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate;
- (g) Reviewing and approving exceptions to federal and state dosage policies and procedures;
- (h) Receiving and addressing service recipient appeals and grievances;
- (i) Monitoring of performance outcomes. The following performance indicators may be used to evaluate the impact of the program on service recipients and the community:
 - 1. Service recipient satisfaction.
 - 2. Service recipient employment status.
 - 3. Improvement in medical conditions.
 - 4. Drop-out rate.
 - 5. Recidivism rates.
 - 6. Alcohol use.
 - 7. Criminal arrests.
 - 8. Illicit drug use, as indicated by drug screens.
 - 9. Improvement in social and living standards; and
- (j) Working cooperatively with other relevant state agencies to determine the service need in the location of a proposed program.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.05 Policy and Procedures.

The governing body of the facility shall ensure it is administered and operated in accordance with written policies and procedures in the below-listed subject areas and in accordance with these rules. Each facility shall clearly identify the governing body, as defined in Rule 0940-05-01-.01, in its policies and procedures manual including the name and contact information of the governing body.

- (1) Intake, Admissions, and Discharges (0940-05-42-.06);
- (2) Service Recipient Records (0940-05-42-.07);

- (3) Multiple Enrollment (0940-05-42-.08);
- (4) Orientation (0940-05-42-.09);
- (5) Service Recipient Transfers (0940-05-42-.10);
- (6) Individual Program Plan (0940-05-42-.11);
- (7) Special Populations (0940-05-42-.12);
- (8) Professional Services (0940-05-42-.13);
- (9) Counseling (0940-05-42-.14);
- (10) Concurrent Alcohol and Polysubstance Abuse (0940-05-42-.15);
- (11) Medication Management (0940-05-42-.16);
- (12) Pharmacotherapy Guidelines (0940-05-42-.17);
- (13) Detoxification and Medically Supervised Withdrawal (0940-05-42-.19);
- (14) Diversion Control Plan (0940-05-42-.20);
- (15) Central Registry (0940-05-42-.21);
- (16) Reporting Requirements (0940-05-42-.22);
- (17) Quality of Care (0940-05-42-.23);
- (18) Infectious Hazardous Waste (0940-05-42-.24);
- (19) Infection Control (0940-05-42-.25);
- (20) Managing Disruptive Behavior (0940-05-42-.26);
- (21) Hours of Operation (0940-05-42-.27);
- (22) Service Recipients' Rights (0940-05-42-.28);
- (23) Community Relations (0940-05-42-.29); and
- (24) Personnel and Staffing Requirements (0940-05-42-.30).

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.06 Intake, Admissions, and Discharges.

- (1) Each service recipient admitted to the Facility shall be evaluated by the medical director or program physician and clinical staff who have been determined to be qualified by education, training, and experience to perform or coordinate the provision of such assessments. The purpose of such assessments shall be to determine whether opioid substitution, short-term detoxification, or drug free treatment will be the most appropriate treatment modality for the service recipient. No prospective service recipient shall be processed for admission until it has been verified that the service recipient meets all applicable criteria.
- (2) Except as otherwise authorized by law, no person shall be admitted for treatment without written authorization from the service recipient and, if applicable, parent, guardian or responsible party. The following information shall be explained by a trained staff person to the service recipient and other consenters and documented, in writing, in the service recipient's file:

- (a) The Facility's services and treatment;
 - (b) The specific conditions that will be treated;
 - (c) Explanation of treatment options, detoxification rights, and clinic charges, including the fee agreement, signed by the prospective service recipient or the service recipient's legal representative; and
 - (d) The facility's rules regarding service recipient conduct and responsibilities.
- (3) No standardized routines or schedules of increases or decreases of medications may be established or used.
 - (4) A facility physician shall document that treatment is medically necessary. The admissions and initial dosing decision ultimately rests with the medical director or his or her designated program physician.
 - (5) A facility shall only admit and retain service recipients whose known needs can be met by the facility in accordance with its program purpose and description and applicable federal statutes, laws and regulations.
 - (6) Drug dependent pregnant females shall be given priority for admission and services when a facility has a waiting list for admissions and it is determined that the health of the mother and/or unborn child is more endangered than is the health of other service recipients waiting for services.
 - (7) No facility shall provide a bounty, free services, medication or other reward for referral of potential service recipients to the clinic.
 - (8) Initial Assessment. Within seven days of admission the facility shall complete:
 - (a) An initial assessment and an initial plan of care. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if admission is determined appropriate. The initial assessment shall include:
 - 1. A brief physical examination;
 - 2. Immediately relevant health history (e.g., determination of chronic or acute medical conditions such as diabetes, renal disease, hepatitis, sickle cell anemia, tuberculosis, HIV exposure, sexually transmitted disease, chronic cardiopulmonary disease and pregnancy);
 - 3. A determination of currently prescribed medications;
 - 4. An evaluation of other substances of abuse;
 - 5. Determination of current opioid dependence;
 - 6. Determination of length of addiction;
 - 7. A toxicology screen to determine immediate use of opioids;
 - 8. An initial drug test to determine whether an individual is either opioid addicted or presently receiving methadone for an opioid addiction from another opioid treatment program; and
 - 9. A full toxicology screen to identify use of other drugs including, but not limited to, opioids, methadone, amphetamines, cocaine, barbituates, benzodiazepines and THC.
 - (b) A more comprehensive medical evaluation shall be completed and shall include:

1. A comprehensive physical evaluation;
 2. A comprehensive psychiatric evaluation, including mental status examination and psychiatric history;
 3. A personal and family medical history;
 4. A comprehensive history of substance abuse, both personal and family;
 5. A tuberculosis skin test and chest x-ray, if skin test is positive;
 6. A screening test for syphilis;
 7. Other tests as necessary or appropriate (e.g., CBC, EKG, chest x-ray, pap smear, hepatitis B surface antigen and hepatitis B antibody, HIV testing);
 8. A repeat full toxicology screen at 14 days to identify use of other drugs including, but not limited to, opioids, methadone, amphetamines, cocaine, barbituates, benzodiazepines and THC; and
 9. The Facility shall obtain complete medical records from other providers with service recipient permission.
 10. Laboratory tests that are not directly conducted by the Facility may be provided:
 - (i) By the person's primary care physician;
 - (ii) By other healthcare providers; or
 - (iii) By a medical clinic.
 11. The Facility is responsible for obtaining and maintaining documentation of required laboratory tests performed by an alternative provider. Alternative providers may not supply toxicology screens unless they meet the required quality guidelines, content and timelines.
 12. Tests not directly conducted by the Facility at admission shall be conducted within seven days after admission.
- (9) Comprehensive Assessment. Within 30 days of admission the Facility shall have completed a comprehensive, biopsychosocial evaluation to include the following items. The comprehensive evaluation shall be attached to the service recipient's chart no later than five days after the plan is developed. The comprehensive plan shall reflect that detoxification is an option for treatment and supported by the facility's program and has been discussed with the service recipient. It shall also integrate information obtained in the comprehensive medical evaluation.
- (a) Whenever possible and with service recipient permission, the intake process shall include a non-addicted family member or significant other to assist in provision of accurate information and a full understanding and retention of instructions given to the service recipient.
 - (b) The evaluation shall include information obtained from:
 1. The service recipient;
 2. Family members, when applicable or permitted;
 3. Friends and peers, when appropriate and permitted; and
 4. Other appropriate and permitted collateral sources.

- (c) The psychosocial evaluation shall include information about the service recipient's:
1. Personal strengths;
 2. Individualized needs;
 3. Abilities and/or interests;
 4. Presenting problems including a thorough analysis of the service recipient's addictive behaviors such as:
 - (i) Licit and illicit drugs used, including alcohol;
 - (ii) Amount(s) and method(s) used;
 - (iii) Frequency of use;
 - (iv) Duration of use;
 - (v) Symptoms of physical addiction;
 - (vi) History of treatment for addictive behaviors;
 - (vii) Adverse consequences of use;
 - (viii) Inappropriate use of prescribed substances;
 5. Urgent needs, including suicide risk;
 6. Previous behavioral health services, including:
 - (i) Diagnostic information;
 - (ii) Treatment information;
 - (iii) Efficacy of current or previously used medication;
 7. Physical health history and current status;
 8. Diagnoses;
 9. Mental status;
 10. Current level of functioning;
 11. Pertinent current and historical life situation information, including his or her:
 - (i) Age;
 - (ii) Gender;
 - (iii) Employment history;
 - (iv) Legal involvement;
 - (v) Family history;
 - (vi) History of abuse; and
 - (vii) Relationships, including natural supports.

12. Use of alcohol and tobacco;
 13. Need for, and availability of, social supports;
 14. Risk-taking behaviors;
 15. Level of educational functioning;
 16. Medications prescribed that are not a target of treatment or concern;
 17. Medication allergies or adverse reactions to medications;
 18. Adjustment to disabilities/disorders; and
 19. Motivation for treatment.
- (d) The psychosocial assessment shall result in the preparation of a concise interpretive multidisciplinary summary that:
1. Is based on the assessment data;
 2. Describes and evaluates the level and severity of the individual's addictive behaviors;
 3. Is used in the development of the individual plan of care; and
 4. Identifies any co-occurring disabilities or disorders that should be addressed in the development of the individual plan of care.
- (10) The following behavioral signs which support the diagnosis shall be discussed and documented in the service recipient's file, although none are required for admission:
- (a) Unsuccessful efforts to control use;
 - (b) Time spent obtaining drugs or recovering from the effects of abuse;
 - (c) Continual use despite harmful consequences;
 - (d) Obtaining opioids illegally;
 - (e) Inappropriate use of prescribed opioids;
 - (f) Giving up or reducing important social, occupational or recreational activities;
 - (g) Continuing use of the opioids despite known adverse consequences to self, family or society; and
 - (h) One or more unsuccessful attempts at gradual removal of physical dependence on opioids (detoxification) using methadone or other appropriate medications.
- (11) No person shall be admitted unless the facility conducts an inquiry with the Central Registry within 72 hours of admission, in accordance with Rule 0940-05-42-.21.
- (12) Non-Admissions. The facility shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs shall identify the reasons why the persons were not admitted and what referrals were made for them by the facility.
- (13) Discharge and Aftercare Plans. A facility shall complete an individualized discharge and aftercare plan for service recipients who complete their course of treatment.

- (a) Upon admission a facility shall begin development of a service recipient's discharge plan.
- (b) All discharge and aftercare plans shall include documented discussion between the service recipient and facility counseling and/or medical staff about an individualized detoxification program appropriate to the service recipient as required in section 0940-05-42-.19 herein.
- (c) The discharge plan shall be completed within seven days of discharge by the person who has primary responsibility for coordinating or providing for the care of the service recipient. It shall include a final assessment of the service recipient's status at the time of discharge and aftercare planning. If applicable, parents or guardian, or responsible persons may participate in discharge and aftercare planning. The reason for any service recipient not participating in discharge and aftercare planning shall be documented in the service recipient's record.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.07 Service Recipient Record Requirements.

- (1) Facilities shall organize and coordinate service recipient records in a manner which demonstrates that all pertinent service recipient information is accessible to all appropriate staff and to the SOTA and TDMH. The service recipient Central Registry I.D. Number shall be shown on each page of the service recipient's record.
 - (a) Records shall be preserved for not less than 10 years even if the facility discontinues operations. The records may be generated, maintained, or transferred in whole or in part to any recording medium that assures accurate preservation of the record.
 - (b) The facility shall discuss final storage or disposition of the facility's records with TDMH 90 days in advance of the closing of a facility.
- (2) The facility shall document that the following assessments are completed prior to the development of the Individualized Program Plan (IPP).
 - (a) Screening. The sources and methods of verification shall have been recorded in the prospective service recipient's case folder. The screening process shall include:
 1. Verification, to the extent possible, of a prospective service recipient's identity, including name, address, date of birth and other identifying data.
 2. Drug history and current status, including determination and substantiation, to the extent possible, of the duration of substance dependence, determination by medical examination performed by a program physician of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group, and determination of current Diagnostic and Statistical Manual (DSM) diagnosis.
 3. Medical history, including past and family medical history, HIV status, pregnancy, a six-month history of prescriber medications, over-the-counter medications used frequently, and the patterns of specific usage of alcohol or other drugs for the past 30 days, and active medical problems.
 4. Verification of other prescribed controlled medications through the PMP run by the Board of Pharmacy of the Tennessee Department of Health.
 5. Psychiatric history and current mental status exam.
 6. Within 14 days of admission, physical assessment and laboratory tests, including drug screens, HIV status, if the prospective service recipient consents to be tested, pregnancy, sexually transmitted diseases, Mantoux tuberculosis tests, Hepatitis C, and others as directed by the SOTA.

7. Pregnancy tests for females at admission and at least annually thereafter, unless otherwise indicated.
 8. Determination if the prospective service recipient needs special services, such as treatment for alcoholism or psychiatric services, and determination that the facility is capable of addressing these needs either directly or through referral.
 9. If a prospective service recipient is 18 years of age or older, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years.
 10. If clinically appropriate, the program physician may waive the requirement of a two-year history of addiction for service recipients released from penal institutions (within six months after release), for pregnant service recipients with a verified pregnancy and for previously treated service recipients up to two years after discharge.
 11. Verification shall be obtained that the service recipient has had two documented unsuccessful attempts at detoxification or drug-free treatment within a 24-hour period.
 12. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the SOTA consents in writing to such treatment.
- (3) A voluntary, written, program-specific informed consent to treatment from each service recipient at admission to include:
- (a) Information about all treatment procedures, services and other policies and regulations throughout the course of treatment, including clinic charges in the form of a fee agreement signed by the service recipient.
 - (b) Consent to the individualized, prescribed therapy before dosing begins, including information about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures and food;
 - (c) Information to each service recipient that the goal of opioid treatment is stabilization of functioning;
 - (d) Information that detoxification from opioids over 30 to 180 days is a treatment alternative to long-term maintenance;
 - (e) Acknowledgement that the service recipient has been informed of the facility's rules regarding service recipient conduct and responsibilities and continuing documentation of the service recipient's compliance with the facility's policies;
 - (f) Acknowledgement that the service recipient has been informed of his or her rights (0940-05-42-.28);
 - (g) Information that at regular intervals, in full consultation with the service recipient, the program shall discuss the service recipient's present level of functioning, course of treatment and future goals; and
 - (h) Information that the service recipient may choose to withdraw from or be maintained on the medication as s/he desires unless medically contraindicated.
- (4) A narrative biopsychosocial history completed within 30 days of the service recipient's admission;
- (5) Medical reports including results of the physical examination; past and family medical history;

review of systems; laboratory reports, including results of required toxicology screens; and progress notes, including documentation of current dose and other dosage data. Information in the medical record shall be entered by physicians and other licensed health professionals;

- (6) Dated case entries of all significant contacts with service recipients, including a record of each counseling session in chronological order;
- (7) Dates and results of case conferences for service recipients;
- (8) The initial treatment plan, any amendments to the plan, reviews of the plan and the long-term, individualized treatment plan, including any amendments to that document and reviews of the plan;
- (9) Documentation that services listed in the plan are available and have been provided or offered;
- (10) A written report of the process and factors considered in decisions impacting service recipient treatment (for example, take-home medication privileges, changes in counseling sessions, changes in frequency of toxicology screens) or any other significant change in treatment, both positive and negative;
- (11) A record of correspondence with the service recipient, family members and other individuals and a record of each referral for services and its results;
- (12) Documentation that the service recipient was provided a copy of the Facility's rules and regulations and a copy of the service recipient's rights and responsibilities and that these items were discussed with her or him; and
- (13) A closing summary, including reasons for discharge and any referral. In the case of death, the reported cause of death shall be documented.
- (14) A written fee agreement as detailed in Rules Chapter 0940-05-42-.06 dated and signed by the service recipient (or the service recipient's legal representative) prior to provision of any services. This fee agreement shall include an explanation of the financial aspects of treatment and the consequences of nonpayment of required fees, including the procedures for medically supervised withdrawal in the event the service recipient (or service recipient's legal representative) becomes unable to pay for treatment.
- (15) Documentation of Central Registry clearance as required under these rules.
- (16) All other information and documents as required by the SOTA and these rules.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.08 Multiple Enrollments.

- (1) The Facility shall have a procedure which shall ensure that no service recipient is enrolled in more than one opioid treatment program.
- (2) The procedure shall take into account requirements for service recipient confidentiality.
- (3) The Facility shall obtain a release of information from the service recipient in order to check the records by telephone or fax of every opioid treatment program within Tennessee and those opioid treatment programs within 125 miles of the Facility site so as to ensure that the service recipient is not currently enrolled in those programs as well. The release of information shall state that its purpose is to obtain information and records developed during prior admission(s) not contacts with admission. Results of that check shall be contained in the clinical record. This check shall be duplicated if the service recipient is discharged and readmitted at any time.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.09 Orientation.

- (1) The facility shall provide orientation to service recipients within 24 hours of admission for treatment and again within 30 days following the admission date to ensure service recipient understanding and emphasize education.
- (2) Orientation shall be done by a designated staff person who has been determined to be qualified by education, training and experience to perform the task.
- (3) Facilities shall ensure that each service recipient signs a statement confirming that the following information has been explained to the service recipient:
 - (a) The expected benefits of the treatment that the service recipient is expected to receive;
 - (b) The service recipient's responsibilities for adhering to the treatment regimen and the consequences of non-adherence; and
 - (c) An explanation of individualized program planning.
- (4) Facilities shall ensure that each service recipient signs a statement confirming that he or she has been offered detoxification services as an admission alternative and that the following has been discussed with the service recipient:
 - (a) An explanation of the types of detoxification services offered by the facility, including administrative detoxification; and
 - (b) An individualized assessment of the medical risks and benefits of detoxification for the service recipient.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.10 Service Recipient Transfers.

- (1) If a prospective service recipient has previously been discharged from treatment at another methadone clinic or Facility, the admitting facility shall initiate an investigation into the prospective service recipient's prior treatment history, inquiring of the last program attended and the reasons for discharge from treatment.
- (2) Service recipients who were terminated from a prior Facility or program due to non-compliance shall be admitted as a new service recipient.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.11 Individualized Program Plan.

- (1) A facility shall develop an Individualized Program Plan (IPP) for each service recipient within 30 days of admission. Each service recipient shall be involved in the development and review of his/her IPP. IPPs shall document the following:
 - (a) A consistent pattern of substance abuse treatment services and medical care appropriate to individual service recipient needs;
 - (b) Detoxification as an option for treatment that is supported by the facility; and
 - (c) A discharge plan that has been discussed with the service recipient.

The initial IPP and all reviews shall be signed by the service recipient and program physician.

- (2) The admission requirements of 0940-05-42-.06 shall first be completed prior to the development of an IPP.
- (3) Medical care, including referral for necessary medical service, and evaluation and follow-up of service recipient complaints shall be compatible with current and accepted standards of medical

practice. All service recipients shall receive a medical examination at least annually. All other medical procedures performed at the time of admission shall be reviewed by the medical staff on an annual basis, and all clinically indicated tests and procedures shall be repeated. The medical director or program physician shall record the results in this annual medical examination and review of service recipient medical records in each service recipient's record.

- (4) In recognition of the varied medical needs of service recipients, the case history, IPPs, detoxification plan and discharge planning shall be reviewed at least every 90 days for service recipients in treatment less than one year and at least annually for service recipients in treatment more than one year. This review will be conducted by the medical director or program physician along with the primary counselor and other appropriate members of the treatment team for general quality controls and evaluation of the appropriateness of continuing the form of treatment on an ongoing basis. This review shall also include an assessment of the current dosage and schedule and the rehabilitative progress of the individual, as part of a determination that additional medical services are indicated. If this review results in a determination that additional or different medical services are indicated the facility shall ensure that such services are made available to the service recipient, either at the facility or by referral to the appropriate medical professional.
- (5) When the program physician prescribes other controlled substances to service recipients in the facility, the facility shall ensure that such prescription is in accord with all applicable statutes and regulations and with current and accepted standards of medical practice. Such prescriptions shall not be issued to any service recipient unless the physician first sees the service recipient and assesses the service recipient's potential for abuse of such medications.
- (6) As part of the rehabilitative services provided by the facility, each service recipient shall be provided with individual and group counseling appropriate to his/her needs. The frequency and duration of counseling provided to service recipients shall be in conformity with 0940-05-42-.14 and be consistent with the Individualized Program Plan. Individualized Program Plans shall indicate a specific level of counseling services needed by the service recipient as part of the rehabilitative process.
- (7) All service recipients shall receive HIV and hepatitis risk reduction education appropriate to their needs.
- (8) When appropriate, each service recipient shall be enrolled in an education program, or be engaged in vocational activity (vocational evaluation, education or skill training) or make documented efforts to seek gainful employment. Deviations from compliance with these requirements shall be explained in the service recipient's record. Each facility shall take steps to ensure that a comprehensive range of rehabilitative services, including vocation, education, legal, mental health, alcoholism and social services are made available to the service recipients who demonstrate a need for such services. The facility can fulfill this responsibility by providing support services directly or by appropriate referral. Support service recommended and utilized shall be documented in the service recipient's record. Each facility shall have policies for matching service recipient's needs to treatment.
- (9) All facilities will develop and implement policies for matching service recipient's needs to treatment. These policies may include treatment phasing in which the intensity of medical, counseling and rehabilitative services provided to a service recipient are individualized for each service recipient depending upon the service recipient's phase of treatment.
- (10) If the service recipient experiences a relapse, his/her IPP shall document evidence of intensified services provided. Such evidence may include, but is not limited to, an increase in individual or group counseling session(s) and/or a reduction in the service recipient's take-home privileges.
- (11) Discussion shall be held with the service recipient regarding his or her continued desire to remain in the program for maintenance treatment. Alternatives such as medically-supervised withdrawal shall be presented to the service recipient at the time of the discussion and documented in the service recipient's record. The service recipient shall sign and date a statement indicating that she or he wishes to remain within the program in a maintenance format. If s/he wishes to enter medically-supervised withdrawal, the plan of care shall reflect that choice.

0940-05-42-.12 Special Populations.

- (1) The OTP shall ensure that physicians are knowledgeable in the management of opioid dependence in a context of chronic pain and pain management. The OTP may not prohibit a service recipient diagnosed with chronic pain from receiving medication-assisted therapy for either maintenance or withdrawal in a program setting.
 - (a) The OTP shall ensure continuity of care and communication between programs or physicians regarding service recipients receiving treatment in both an opioid treatment program and a facility or physician's office for purposes of pain management, with service recipient permission.
 - (b) If the service recipient refuses permission for the two entities to communicate and coordinate care, the OTP shall document refusal and may make clinically appropriate decisions regarding take-home medication privileges and continuation in treatment.
- (2) The OTP shall ensure that service recipients with mental health needs are identified through the evaluation process and referred to appropriate treatment.
 - (a) The OTP shall monitor service recipients during withdrawal to identify the emergence of symptoms of mental illness.
 - (b) The OTP shall establish linkages with mental health providers in the community.
- (3) The OTP shall address abuse of alcohol and other non-opioid substances within the context of the medication assisted therapy effort.
 - (a) The OTP shall ensure that staff is trained and knowledgeable regarding current effective strategies for treating alcohol, cocaine and other drug abuse.
 - (b) Ongoing multi-drug use is not necessarily a reason for discharge unless the service recipient refuses recommended, more intensive levels of care, to include but not be limited to intensive outpatient and residential clinical treatment. The treatment team shall consider each service recipient's condition and address the situation from an individualized clinical perspective.
 - (c) The OTP shall have a policy regarding treatment of co-morbid disorders such as psychiatric and medical disorders. The goal of treatment shall be to provide treatment for these disorders in as seamless a fashion as possible, maximizing service recipient convenience and compliance with appointments and recommendations. The OTP shall establish linkages with mental health and other appropriate providers in the community to ensure smooth referral processes and interchange of information.

0940-05-42-.13 Professional Services.

- (1) In addition to the alcohol and drug treatment service provided, the facility shall provide a continuum of services to service recipients to address the needs as indicated in the assessment and history in the areas of social, family and peer interactions; employment and educational needs; financial status; emotional and psychological health; physical health; legal issues; and community living skills and housing needs. Such services may be provided directly by the agency or indirectly by referral to other service providers. Referral agreements with frequently used providers shall be documented. The provision of such services to individual service recipients must be documented in the service recipient record.
- (2) Facilities shall be able to document a referral agreement with a local hospital health care facility or licensed health care professional.

0940-05-42-.14 Counseling.

Counseling is essential to promote and guide the service recipient to a more productive life style of abstinence from illicit medications or drugs due to so many opioid addicted service recipients also abusing other illicit or prescription substances.

- (1) The primary counselor is responsible for developing and implementing the service recipient's plan of care, in coordination with the medical staff. The plan of care shall address the social, environmental, psychological and familial issues maintaining the service recipient's maladaptive patterns of drug consumption and other high risk and/or destructive behaviors. The counselor is responsible for assisting the service recipient to alter life styles and patterns of behavior in order to improve the service recipient's ability to function adaptively in his or her family and community.
- (2) The clinical staff caseload ratio shall:
 - (a) Reflect an appropriate clinical mix of sex, race and ethnicity representative of the population served;
 - (b) Allow the Facility to provide adequate:
 1. Psychosocial assessment;
 2. Treatment planning; and
 3. Individualized counseling;
 - (c) Allow for regularly scheduled counseling sessions; and
 - (d) Allow service recipients access to their primary counselor if more frequent contact is merited by need or is requested by the service recipient.
- (3) For all service recipients the following counseling schedule shall be followed:
 - (a) During the first 90 days of treatment, counseling session(s) shall take place at least twice weekly;
 - (b) During the second 90 days of treatment, counseling session(s) shall take place at least three times per month;
 - (c) During the third 90 days of treatment, counseling session(s) shall take place at least two times per month;
 - (d) For subsequent 90 day periods of treatment, counseling session(s) shall take place as needed or indicated in the service recipient's IPP, but not less frequently than monthly as long as the service recipient is compliant.
- (4) Exceptions to frequency of counselor to service recipient contact shall be clearly justified by Facility program documentation. The program physician or prescribing professional evaluating the service recipients eligibility for take-home doses shall carefully consider the service recipient's participation in the counseling sessions as a factor in his or her decision although justified lack of participation (such as for reasons of employment) shall not be held against the service recipient in the take-home decision.
- (5) The primary counselor or medical staff is responsible for documentation of significant contact with each service recipient, which shall be filed in the service recipient record.
- (6) The documentation shall include a description of:
 - (a) The reason for or nature of the contact;

- (b) The service recipient's current condition;
 - (c) Significant events occurring since prior contact;
 - (d) The assessment of the service recipient's status; and
 - (e) A plan for action or further treatment that addresses the goals of the treatment plan.
- (7) Each entry shall be completed within 24 hours of the contact and shall be clearly dated and initialed or signed by the staff person involved.
 - (8) Opportunities for family involvement in counseling shall be provided and documented.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.15 Concurrent Alcohol and Polysubstance Abuse.

- (1) The Facility shall address abuse of alcohol and other non-opioid substances within the context of the medication-assisted therapy effort.
- (2) The Facility shall ensure that staff is trained and knowledgeable regarding current effective strategies for treating alcohol and other drug abuse.
- (3) Ongoing multi-drug use is not necessarily a reason for discharge unless the service recipient refuses recommended, more intensive levels of care. The treatment team shall consider the service recipient's condition and address the situation from a clinical perspective.
- (4) The Facility shall have a policy regarding treatment of co-morbid disorders such as psychiatric and medical disorders. The goal of the treatment shall be to provide treatment for these disorders. The goal of the treatment shall be to provide treatment for these disorders in as seamless a fashion as possible, maximizing service recipient convenience and compliance with appointments and recommendations. The Facility shall ensure a smooth referral process and interchange of information.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.16 Medication Management.

- (1) Opioid Drugs. Facilities shall develop and implement written policies and procedures for prescription, dispensing and administration of opioid drugs and their security. No standardized routines or schedules of increases or decreases of medications may be established or used. These policies and procedures shall include the following:
 - (a) Administration.
 - 1. A program physician shall perform a medical assessment to determine the service recipient's initial dose and schedule. The physician shall communicate the initial dose and schedule to the pharmacy or the person supervising medication.
 - 2. The proper initial dose shall be based on the clinical judgment of the program physician who has examined the service recipient and who has considered all available relevant information, including, but not limited to, drug screens, quantitative methadone levels, service recipient interview, and specific circumstances pertaining to the individual service recipient.
 - 3. A physician may assign such dose and schedule by verbal order only on an emergency basis. If a verbal order is given, the physician shall examine the service recipient within 72 hours. Both the verbal order and the results of the physical examination shall be documented in the service recipient's record. Verbal orders must be taken by a pharmacist, licensed nurse or physician

assistant, qualified by training and experience, and categorically approved by the medical staff of the facility/program. Upon hearing the order, the receiver shall record the order in the service recipient's record, and then shall read back the written order to the issuing professional to assure that the order is understood clearly. "Oral" and "Telephone" orders must be documented as such and staff recording must sign their name and title. "Oral" and "Telephone" orders must be countersigned by the physician no later than 72 hours.

4. The initial dose of methadone may not exceed 30 milligrams. A transferring service recipient may receive an initial dosage of no more than the last daily dosage authorized at the former facility unless in the clinical judgment of the medical director, there are extenuating circumstances documented in the records which justify an initial dosage that is greater than the last daily dosage authorized at the former facility.
5. Subsequent doses shall be authorized by a prescriber, as defined by Rule 0940-05-42-.01(2)(v). Additional dosage may be dispensed by the pharmacist in the first day where the prescriber documents that 30 milligrams does not suppress withdrawal symptoms. Service recipients are stabilized on methadone when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the service recipient comfortable for at least 24 hours with no need to resort to illicit opioids to satisfy opioid cravings.
6. No dosage increases shall occur on the days that the facility is closed.
7. No methadone may be administered unless the prospective service recipient has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the records. In that case, intake procedures shall be completed on the next working day. No take-home medication may be given in such an emergency.
8. The administration of greater than 100 milligrams of methadone to a service recipient requires written notification to the SOTA within 10 working days, signed by the program physician, which details clinical justification for exceeding 100 milligrams.
9. No dose of methadone in excess of 120 milligrams may be ordered or administered without the prior approval of the SOTA.
10. Any requests for approval for a dose of methadone in excess of 140 milligrams shall be submitted with a peak and trough for SOTA approval.
11. Benzodiazepine Use. If a service recipient has a positive benzodiazepine screen:
 - (i) The treatment team shall meet with the service recipient within 14 days of receiving the results of the screen, to develop a benzodiazepine action plan in the service recipient's record. The plan shall be reviewed and signed by the medical director.
 - (ii) If the plan requires the service recipient to become clean from benzodiazepines a time period for detoxification shall be established. The plan must contain a justification for any time period longer than 90 days; and
 - (iii) The facility shall provide detoxification treatment services either directly or through referral to another provider of detoxification treatment services.
12. If the plan calls for the continued use of benzodiazepines, the facility shall coordinate the care with a qualified prescriber and document this coordination in the service recipient's record.

13. The plan shall contain requirements for counseling, frequency of urine drug screens, and the consequences for failing to comply with the action plan on take-home privileges, and continued treatment at the OTP.
 14. The plan and weekly progress notes about plan implementation shall be documented in the service recipient's record.
- (b) Any opioid drug prescribed and administered shall be documented on an individual medication administration record that is filed with the IPP. The record shall include:
1. Name of medication;
 2. Date prescribed;
 3. Dosage;
 4. Frequency of administration;
 5. Route of administration;
 6. Date and time administered; and
 7. Documentation of staff administering medication or supervising self-administration.
- (c) Take-home doses of methadone or buprenorphine shall be handled in accordance with applicable rules of the Substance Abuse and Mental Health Administration or other applicable federal agency.
1. All requests for take-home exceptions shall be reviewed and approved by the SOTA and any other applicable federal agency.
 2. The facility shall check the PMP database prior to requesting any take-home or dosing exceptions and shall submit this report to the SOTA with the exception request.
 3. The facility shall provide counseling prior to providing take-home doses to any service recipient. Progress notes in the service recipient's record shall document the counseling provided.
 4. The facility shall document in the service recipient's record the basis for approving "take-home" medication for the service recipient. The following criteria shall be considered in determining the service recipient's eligibility for "take-home" medications.
 - (i) Cessation of illicit drug use;
 - (ii) Regularity of program attendance;
 - (iii) Length of time and level of treatment in medication therapy (ability to responsibly self-medicate);
 - (iv) Absence of known recent criminal activity (especially drug dealing);
 - (v) Absence of serious behavioral problems;
 - (vi) Absence of abuse of drugs including excessive use of alcohol;
 - (vii) Other special needs of the service recipient, such as split dosing, physical health needs, pain treatment, etc.;

- (viii) Capacity to safely store "take-home" medication within the service recipient's home;
 - (ix) Stability of the home environment and social relationships;
 - (x) Service recipient's work, school, or other daily-life activity schedule; and
 - (xi) Hardship experienced by the service recipient in traveling to and from the Facility.
- (d) Adverse drug reactions and errors shall be reported to a program physician immediately and corrective action initiated. The adverse reaction or error shall be recorded in the drug administration record, the nurse progress notes and the IPP, and all persons who are authorized to administer medication or supervise self-medication shall be alerted.
- (e) All medications shall be stored in a locked safe when not being administered or self-administered.
- (f) Medication orders and dosage changes shall be written or printed on a form which clearly displays the physician's signature. Dosage dispensed, prepared or received shall be recorded and accounted for by written or printed notation in a manner which achieves a perpetual and accurate inventory at all times. Every dose shall be recorded in the service recipient's individual medication record at the time the dose is dispensed or administered. If initials were used, the full signature and credentials of the qualified person administering or dispensing shall appear at the end of each page on the medication sheet. The perpetual inventory shall be totaled and recorded in milligrams daily.
- (g) Computer-based Recording.
 1. Where computer-based recording is utilized, the computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of the original medication or dosage order information and the complete dosing history. These data shall include the date of issuance of the medication and dosage order, service recipient's name and address and DEA registration number; product name, strength, dosage form, and quantity ordered; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and identity of the qualified prescriber for the original medication order and subsequent dosing orders. Each individual prescriber using a computerized system for medication or dosing orders shall certify that the information entered into the computer is correct by verifying, dating, and signing a hard-copy printout of each day's medical or prescription order data, or in lieu of such a printout, by signing a statement in a book or file each day attesting that the dosing information entered that day has been reviewed by the prescriber and is correct as shown. Such documentation shall be separately maintained at the OTP for at least two years from the date of the last dispensing.
 2. Any such computerized system shall have the capability of producing a hard-copy printout of any medical or dosing order data which the OTP is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. Any computerized system shall, upon the request of the SOTA, send or provide such a printout within 48 hours excluding weekends.
 3. In the event that an OTP which utilizes such a computerized system experiences system down-time, the OTP must have a written or readily retrievable auxiliary policy and procedure for documentation of all medical and dosing orders. The auxiliary procedure shall ensure that each medical or dosing order is authorized, and that all appropriate data are retained for on-line data entry as soon as the computer system is available for use again.
- (h) The facility shall check the PMP database at least every six months to determine if controlled substances other than methadone are being prescribed for the service

recipient. The results of this check shall be included in the service recipient's record.

(i) Guest Dosing.

1. Guest dosing shall be provided for a maximum of 14 days. Anything beyond 14 days shall be approved by the SOTA before dosing occurs.
2. Service recipients shall have been enrolled at the home clinic for a minimum of 30 days before being eligible for a guest dose. Guest dosing of service recipients enrolled less than 30 days at the home clinic shall only occur if approved by the Department.
3. Service recipients shall have two consecutive clean urine drug screens before being eligible for a guest dose unless the medical director determines that the benefits of guest dosing outweigh the risks and documents the justification for granting guest dosing privileges in the service recipient's record.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.17 Pharmacotherapy Guidelines.

The facility shall develop pharmacotherapy guidelines for opioid replacement treatment for service recipients covering the Facility's own prescribing and review of prescriptions from other physicians. These shall minimally include:

- (1) Procedures to ensure that service recipients' prescriptions from outside physicians will be reported to the medical staff and reviewed by the program physician at admission and annually thereafter;
- (2) Procedures describing the Facility's response when information about prescriptions from outside physicians is not reported including, but not limited to, the loss of take-home privileges, to ensure compliance with this rule; and
- (3) If a Facility is unable to acquire information about a service recipient's prescriptions, the Facility shall document efforts made to obtain information about prescriptions from outside physicians in the service recipient's record.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-302, and 33-2-404.

0940-05-42-.18 Drug Screens.

- (1) Random urine drug screening and other adequately tested toxicological procedures shall be used for the purposes of assessing the service recipient's abuse of drugs and evaluating a service recipient's progress in treatment.
- (2) Drug screening procedures shall be individualized and shall include:
 - (a) At least weekly random drug screens for new service recipients during the first 30 days of treatment and at least monthly thereafter.
 - (b) New service recipients shall be tested upon admission and at approximately 14 days of treatment, then weekly through the remainder of the first 30 days, then monthly thereafter.
- (3) Service recipients on a monthly schedule whose drug screen reports indicate drug abuse shall be returned to a weekly schedule for at least two weeks, or longer, if clinically indicated.
- (4) More frequent collection and analysis of samples during medically-supervised or other types of withdrawal may occur.
- (5) Collection of observed specimens on an unannounced basis when using urine as a screening

mechanism may occur if the staff believes that observation is necessary based on service recipient behavior or need.

- (6) Each sample collected shall be screened to include, but not be limited to:
 - (a) Opioids including oxycodone at common levels of dosing;
 - (b) Methadone or any other medication used by the Facility's program as an intervention for that service recipient;
 - (c) Benzodiazepines (including testing procedures that detect diazepam, clonazepam, alprazolam and lorazepam);
 - (d) Cocaine;
 - (e) Meth-amphetamine/amphetamines;
 - (f) Tetrahydrocannabinol (THC); and
 - (g) Other drugs as indicated by individual service recipient use patterns, community standards, regional variation or clinical indication (e.g., carisoprodol, barbituates) or that are heavily used in the locale of the service recipient or as directed by the SOTA.
- (7) Collection and testing shall be done in a manner that assures a method of confirmation for positive results and documents the chain of custody of the collection.
- (8) Positive Test. Any refusal to participate in a random drug test shall be considered a positive test. A positive test is a test that results in the presence of any drug or substances listed in section (6) of this rule or any drug or substance prohibited by the opioid treatment program or SOTA; provided that the presence of medication which is part of the service recipient's treatment plan shall not be considered a positive test.
- (9) A positive drug test result after the first six months in an opioid treatment program shall result in the following:
 - (a) Upon the first positive drug test result, the opioid treatment program shall:
 - 1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program; and
 - 2. Immediately revoke the take-home privilege for a minimum of 30 days;
 - (b) Upon a second positive drug test result within six months of a previous positive drug test result, the opioid treatment program shall:
 - 1. Provide mandatory and documented weekly counseling which shall include weekly meetings with a counselor who is licensed, certified, or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;
 - 2. Immediately revoke the take-home privilege for a minimum of 60 days; and
 - 3. Provide mandatory documented treatment team meetings with the service recipient;
 - (c) Upon a third positive drug test result within a period of six month the opioid treatment program shall:
 - 1. Provide mandatory and documented weekly counseling, which shall include

weekly meetings with a counselor who is licensed, certified, or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;

2. Immediately revoke the take-home privilege for a minimum of 120 days; and
 3. Provide mandatory and documented treatment team meetings with the service recipient which shall include, at a minimum: the need for continuing treatment; a discussion of other treatment alternatives; and documentation that the service recipient has been advised that s/he shall be discharged for continued positive drug tests; and
- (d) Upon a fourth positive drug test within a six month period, the service recipient shall be immediately discharged from the opioid treatment program, or, at the option of the service recipient, shall immediately be provided the opportunity to participate in a medically-supervised detoxification plan, followed by immediate discharge from the opioid treatment program.
- (10) The Facility shall document both the results of toxicological tests and the follow-up therapeutic action taken in the service recipient record.
 - (11) Treatment programs shall work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards are not appropriate for urine testing.
 - (12) The Facility shall ensure that its physicians demonstrate competence in interpretation of "false negative" and "false positive" laboratory results as they relate to physiological issues, differences among laboratories, and factors that impact absorption, metabolism and elimination of opioids.
 - (13) The program physician shall thoroughly evaluate a positive toxicological screen for any potentially licit substance such as benzodiazepines, carisoprodol, barbituates and amphetamines. The Facility shall verify with appropriate releases of information that:
 - (a) The service recipient has been prescribed these medications by a licensed prescriber for a legitimate medical purpose; and
 - (b) The prescribing physician is aware that the service recipient is enrolled in an opioid treatment program.
 - (14) If the service recipient refuses the release of information to contact his or her physician but can produce prescriptions and/or other evidence of legitimate prescription (such as current medication bottles, fully labeled), the team shall consider the service recipient's individual situation and the possibility that he or she may be dismissed from the care of his or her physician if the physician discovers that the service recipient is in medication-assisted treatment. The program physician shall make the ultimate decision as to the service recipient's continuing care in the clinic and the circumstances of that care.
 - (15) Absence of methadone or other medications prescribed by the Facility for the service recipient shall be considered evidence of possible medication diversion and evaluated by the physician accordingly.
 - (16) As appropriate and necessary, the SOTA shall develop guidelines for frequency of toxicological screening for alternative treatment modalities such as buprenorphine.
 - (17) The Facility shall comply with policies and procedures developed by the Department and the Tennessee Board of Pharmacy to allow access to the Prescription Drug Monitoring Program (PMP) maintained by the Tennessee Board of Pharmacy:
 - (a) Before the administration of methadone or other treatment in an opioid treatment program;
 - (b) After any positive drug test;

- (c) At each 90-day treatment review;
 - (d) Every six months to determine if controlled substances other than methadone are being prescribed for the service recipient. The results of the check shall be included in the service recipient's record; and
 - (e) Each Prescription Drug Registry access shall confirm that the service recipient is not seeking prescription medication from multiple sources.
- (18) Nothing contained in this rule shall preclude any opioid treatment program from administering any additional drug tests it determines necessary.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.19 Detoxification and Medically Supervised Withdrawal.

- (1) The facility shall offer detoxification services as an admission alternative. All potential service recipients shall be offered long-term detoxification as an admission alternative; however, a Facility may choose to offer short-term detoxification for those service recipients who desire such a service.
- (2) No standardized routines or schedules of increases or decreases of medications may be established or used.
- (3) The program physician shall provide onsite medical supervision and oversight of the detoxification program.
- (4) For persons projected to be involved in detoxification for six months or less, the Facility must offer the service recipient:
 - (a) A minimum of two counseling sessions per week for the first month; and
 - (b) A minimum of two counseling sessions each month thereafter.
- (5) Exceptions or refusal to participate in the detoxification program shall be documented and tracked by the Facility.
- (6) The program physician shall determine on an individualized basis the appropriate dosage of opioid agonist medication to ensure stabilization during detoxification.
- (7) Urine and/or other toxicological screening instruments shall be used by Facility staff during detoxification in order to demonstrate the absence of use of alternative licit and/or illicit drugs.
- (8) In detoxification programs of 30 days or less duration, the Facility shall have a policy that does not allow more than one unsupervised or take-home medication per week for persons served. A Facility operating on a seven day per week basis (pursuant to 0940-05-42-.27) shall not allow take-home unsupervised-medications.
- (9) In detoxification programs of more than 30 days duration, the Facility shall have a policy that allows the persons served to have the opportunity for take-home medications.
- (10) The Facility shall have a policy regarding detoxification from opioid agonist medication that shall include:
 - (a) Individualized determination of a schedule of detoxification that is:
 - 1. Well tolerated by the service recipient; and
 - 2. Consistent with sound medical practices;
 - (b) Implementation of a higher stabilizing dose possible;

- (c) Assurances that voluntary detoxification shall be discontinued in the event of relapse and that provisions for maintenance treatment shall be made;
 - (d) Evaluation and/or testing for pregnancy prior to detoxification; and
 - (e) Provision for continuing care after the last dose of methadone or other treatment medication.
- (11) Counseling services provided in conjunction with detoxification services shall be designed to:
- (a) Explore other modalities of care including drug and alcohol treatment following detoxification or discharge;
 - (b) Motivate the service recipient to continue to receive services or to develop a plan for recovery following discharge; and
 - (c) Identify triggers for relapse and a coping plan for dealing with each, detailed and in writing and given to the service recipient prior to discharge. The plan shall be developed in conjunction with the service recipient.
- (12) In the event the service recipient becomes unable to pay for treatment, the facility shall develop procedures for administrative detoxification or medically supervised withdrawal, including an appropriate time frame over which the procedure would take place. The schedule of withdrawal may be brief, less than 30 days if necessary. Such procedures shall include documentation of referral of the service recipient to alternative treatment resources. For persons involved in detoxification for 14 days or less, the Facility must offer a minimum of four counseling sessions per week.
- (a) The facility shall develop policies and procedures clearly describing under what circumstances a service recipient may be subject to administrative withdrawal. Administrative withdrawal may result from:
 1. Non-payment of fees. The Facility shall make every effort to consider all clinical data including service recipient participation and compliance with treatment prior to initiating administrative withdrawal for non-payment. If the service recipient has a history of compliance and cooperation with treatment, the Facility shall document every effort to explore alternatives to administrative withdrawal with the service recipient prior to onset of withdrawal. If a service recipient has been in maintenance treatment for two years or more and subsequently cannot pay, administrative withdrawal under this section shall not be less than six months;
 2. Disruptive conduct or behavior considered to have an adverse effect on the Facility, staff or service recipient population of such gravity as to justify the involuntary withdrawal and discharge of a service recipient. Such behaviors may include violence, threat of violence, dealing drugs, diversion of pharmacological agents, repeated loitering, and/or flagrant noncompliance resulting in an observable, negative impact on the Facility, staff and other service recipients; or
 3. Other reasons as determined by the facility and approved by the SOTA.
 - (b) Medically supervised withdrawal occurs as a voluntary and therapeutic withdrawal agreed upon by staff and service recipient. In some cases the withdrawal may be against the advice of clinical staff (against medical advice).
 1. The Facility shall supply a schedule of dose reduction well tolerated by the service recipient.
 2. The Facility shall offer supportive treatment including increased counseling sessions and referral to a self-help group or other counseling provider as appropriate.

3. If the service recipient leaves the Facility's program abruptly against medical advice, the Facility may readmit the service recipient within 30 days without a formal reassessment procedure. The Facility shall document attempting to assist the service recipient in any issues which may have triggered his or her abrupt departure.
 4. The Facility shall make provisions for continuing care for each service recipient following the last dose of medication and for re-entry to maintenance treatment if relapse occurs or if the service recipient should reconsider withdrawal.
 5. Female service recipients shall have a negative pregnancy screen prior to the onset of either administrative or medically-supervised withdrawal.
- (13) For detoxification or withdrawal, the Facility shall have in place a detailed relapse prevention plan developed by the counselor in conjunction with the service recipient and given to the service recipient in writing prior to the administration of the final dose.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.20 Diversion Control Plan.

- (1) Each clinic shall prepare a Diversion Control Plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate medical treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control functions described in the Diversion Control Plan.

The Diversion Control Plan shall contain, at a minimum, a random call-back program with mandatory compliance.

- (a) This call-back shall be in addition to the regular schedule of clinic visits.
 - (b) Each service recipient receiving three or more consecutive take-home medications shall be called back randomly within the three-month period immediately following the previous call-back.
 - (c) Upon call back a service recipient shall report to the clinic within 24 hours of notification, with all take-home medications. The quantity and integrity of packaging shall be verified for all doses. If a take-home dose shows evidence of tampering, the clinic shall impose uniform sanctions for violating take-home policies prohibiting a service recipient from tampering with a take-home dose.
 - (d) Service recipients shall be informed of consequences for violating the take-home policy.
 - (e) The facility shall maintain individual call-back results in the service recipient record.
- (2) Diversion control plans shall minimize the diversion of methadone or other opioid treatment medications to illicit use. The plan shall include:
 - (a) Clinical and administrative continuous monitoring of the potential for and actual diversion including and investigation, tracking and monitoring system of incidents of diversion; and
 - (b) Proactive planning and procedures for problem identification, correction and prevention signed by the facility medical staff and the service recipient.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.21 Central Registry.

- (1) All facilities shall participate in the Department's Central Registry.
- (2) Service recipients shall be informed of the facility's participation in the Central Registry; and, prior

to initiating a central registry inquiry, the facility shall obtain the service recipient's written consent.

- (3) To prevent simultaneous enrollment of a service recipient in more than one OTP, within 72 hours of admission the facility shall initiate a clearance inquiry by submitting to the approved Central Registry the name, date of birth, anticipated date of admission or discharge and any other relevant information required for the clearance procedure or as required by the SOTA. No person who is reported by the Central Registry to be participating in another such facility shall be admitted to an OTP, or in the event a dual enrollment is found, the service recipient shall be discharged from one OTP in order to continue enrollment at another OTP. The SOTA shall be notified within 24 hours of any service recipient who is found by an OTP to be simultaneously enrolled in another OTP.
- (4) Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed facility or its designated legal representative or as approved by the SOTA, or as required by law. Information made available by the Central Registry to facilities or their designated legal representatives or as approved by the SOTA shall also be treated as confidential.
- (5) If a facility operates within 125 miles of an OTP in an adjoining state, the SOTA may direct the facility to share service recipient information with the OTP in the other state to prevent simultaneous enrollment of persons in more than one OTP facility.
- (6) The facility shall develop policies and procedures to address a service recipient's multiple enrollment and cumulative time in all prior opioid replacement treatment episodes with other opioid treatment programs or Facilities in Tennessee as well as procedures for contacting opioid treatment programs or Facilities in an adjoining state if within 125 miles of a Tennessee OTP.
- (7) Within five days of completion of the service recipient's IPP, the OTP shall submit to the Central Registry such information regarding the service recipient and his or her IPP as is required by the SOTA and the Department.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.22 Reporting Requirements.

- (1) The facility shall submit the following information to the Department:
 - (a) All reports, forms and correspondence submitted to or received from the FDA, DEA, any other applicable federal agencies or accreditation organizations shall be provided to the SOTA within five business days of sending or receiving such documents.
 - (b) Such reports and information which may be required by the Department to conduct evaluations of opioid replacement treatment effectiveness or monitor service delivery.
- (2) The OTP shall report each case of communicable disease to the local county health officer in the manner provided by T.C.A. § 68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health. Repeated failure to report communicable diseases shall be cause for revocation of a facility license.
- (3) The facility shall report within 24 hours to the Department of Mental Health Office of Licensure and Review and SOTA the identification of the abuse of a service recipient or an unexpected occurrence or accident that results in death or serious injury to a service recipient or any action taken against the Facility by the DEA, accrediting body or other state, local or federal agency. Additionally, the following are examples of events that should be reported:
 - (a) Medication errors;
 - (b) Criminal acts;
 - (c) Suicide or attempted suicide;

- (d) Rape;
- (e) Service recipient altercation;
- (f) Service recipient abuse, service recipient neglect, or misappropriation of resident/service recipient funds;
- (g) Restraint related incidents; or
- (h) Poisoning occurring within the facility.
- (i) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall be reported to the Department within seven days after the facility learns of the incident. These specific incidents include the following:
 - 1. Strike by the staff at the facility;
 - 2. External disaster impacting the facility;
 - 3. Disruption of any service vital to the continuous, safe operation of the facility or to the health and safety of its service recipients and personnel; and
 - 4. Fires at the facility which disrupt the provision of service recipient care services or cause harm to service recipients or staff, or which are reported by the facility to any entity, including, but not limited to, a fire department charged with preventing fires.
- (4) Within seven days of any event described in (3), the facility shall file an event report with the Office of Licensure and Review and the SOTA on the incident consisting of the following:
 - (a) The actions implemented to prevent the reoccurrence of the event;
 - (b) The time frames for the action(s) to be implemented;
 - (c) The person(s) designated to implement and monitor the action(s); and
 - (d) The strategies for the measurements of effectiveness to be established.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.23 Quality of Care.

The facility shall develop and implement a plan for continuous quality improvement. At a minimum, the plan shall include:

- (1) Structured assessment of the program which addresses Facility program management, staffing, policies and procedures and general operations.
- (2) A service delivery assessment which, at a minimum, shall evaluate appropriateness of the IPP and services delivered, completeness of documentation in service recipients' records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out-of-program services, and availability of services and medications for other conditions (e.g. prenatal, tuberculosis, HIV).
- (3) An assessment of the average cost of services per service recipient per week and the average charge per service recipient per week.
- (4) An assessment of medication-related issues including take-home procedures, security, inventory and dosage issues.
- (5) Such process shall serve to continuously monitor the Facility's compliance with the requirements

set forth in these rules. Responsibility for administering and coordinating the quality improvement process shall be delegated to a staff person who has been determined to be qualified by education, training and experience to perform such tasks. The medical director shall be actively involved in the process.

- (6) A Facility shall participate in additional quality improvement outcome studies as directed by the SOTA.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.24 Infectious Hazardous Waste.

- (1) Each facility shall develop, maintain and implement written policies and procedures for the definition and handling of its infectious wastes. These policies and procedures shall comply with the standards of this section and all other applicable state and federal regulations.
- (2) The following waste shall be considered to be infectious waste:
 - (a) Waste contaminated by service recipients who are isolated due to communicable diseases, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals."
 - (b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures.
 - (c) Waste human blood and blood products such as serum, plasma, and other blood components.
 - (d) All discarded sharps (e.g., hypothermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) used in service recipient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories.
 - (e) Other waste determined to be infectious by the facility in its written policy.
- (3) Infectious and hazardous waste shall be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.
- (4) Waste shall be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging shall provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging shall be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.25 Infection Control.

The facility shall have policies and procedures to be followed for infection control, including:

- (1) Reporting all suspected or diagnosed cases of infectious disease including tuberculosis, AIDS, and sexually transmitted disease (STD) promptly to the regional health department in accordance with 42 CFR, Part 2 and T.C.A. §§ 68-10-101 et seq., 68-9-201 and 68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health.
- (2) Management of service recipients who are infected with Hepatitis B or C virus, HIV/AIDS or other STD.

- (3) Nondiscrimination of employees and service recipients regarding their HIV/AIDS status.
- (4) Use of standard precautions for prevention of transmission of HIV/AIDS, Hepatitis B or C Virus, and other blood borne pathogens.
- (5) Infectious disease skin or blood testing will be made on a voluntary basis for any service recipient who requests it, and be documented in appropriate records. If a clinic does not have the capacity to conduct pelvic exams, the clinic shall establish and document a relationship with a community health care provider so that referrals can be made and care can be coordinated.
- (6) Assurance that a service recipient's HIV, other STD, and tuberculosis status will be kept confidential in accordance with T.C.A. § 33-3-103; Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 Code of Regulations (CFR) Parts 160 and 164, Subparts A and E; and Confidentiality of Alcohol and Drug Abuse Service Recipient Records regulations at 42 CFR Part 2.
- (7) Documentation on the establishment of linkages between the facility and the local health department to ensure service recipients receive appropriate medical care relative to their infection and/or exposure to tuberculosis, Hepatitis B or C; and STD (including HIV), i.e., establish contact between the health department and the facility to communicate appropriate information to assure that the service recipient receives appropriate care.
- (8) Informed consent of service recipients before screening and treatment.
- (9) Conducting case management activities to ensure that individuals receive appropriate treatment services for HIV/AIDS, Hepatitis B or C Virus and other sexually transmitted diseases.
- (10) Procedures to ensure that the facility, either directly or through arrangements with other public or private non-profit entities, will make available tuberculosis (TB) services in accordance with current Tennessee TB Guidelines for Alcohol and Drug Treatment Facilities (TB Guidelines), established by the Department of Health TB Elimination Program and the Department of Mental Health Division of Alcohol and Drug Abuse, including:
 - (a) Counseling the service recipients about TB;
 - (b) Screening all service recipients for TB and, if applicable, testing service recipients at high risk for TB to determine whether the service recipients have been infected with TB;
 - (c) Providing for or referring the service recipients infected with TB for appropriate medical evaluation and treatment; and
 - (d) Conducting case management activities to ensure that service recipients receive such services.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.26 Managing Disruptive Behavior.

The facility shall develop policies and procedures which address the methods for managing disruptive behavior. If restrictive procedures are used to manage disruptive behaviors, written policies and procedures shall govern their use and shall minimally address the following:

- (1) Any restrictive procedure shall be used by the facility only after all less restrictive alternatives for dealing with the problem behavior have been systematically tried or considered and have been determined to be inappropriate or ineffective:
 - (a) The service recipient shall have given prior written consent to any restrictive measures taken with him/her by the staff;
 - (b) The restrictive procedure(s) shall be documented in the IPP, be justifiable as part of the plan, and meet all requirements that govern the development and review of the plan;

- (c) Only qualified personnel may use restrictive procedures and shall be adequately trained in their use; and
 - (d) The adaptive or desirable behavior shall be taught to the service recipient in conjunction with the implementation of the restrictive procedures.
- (2) A policy which states physical holding shall be implemented in such a way as to minimize any physical harm to the service recipient and may only be used in an emergency situation to assure the physical safety of the service recipient or others nearby or to prevent significant destruction of property that puts the service recipient or persons nearby in danger.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.27 Hours of Operation.

A facility's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work. Each OTP shall make dosing and counseling available at least six hours per day from Monday through Friday. Dosing and counseling shall be available at least three hours on Saturday. Dosing shall be available at least three hours on Sunday. Counseling may be provided on Sunday to accommodate a service recipient's schedule.

- (1) All clinics shall be open seven days per week and 365 days per year with the exception of being closed on four nonconsecutive days for holidays. Facilities shall notify the SOTA and service recipients of the date of any holiday when the facility will be closed at least 14 days in advance of the holiday.
- (2) Any facility may also be closed for one mandatory training day, if required by the SOTA.
- (3) Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical exams and referral services, at least six days per week.
- (4) Any service recipient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, such as holidays, not to exceed two consecutive days.
- (5) Facilities shall provide the SOTA with at least two weeks notice prior to any change in Facility hours.
- (6) A facility that intends to voluntarily close shall notify TDMH no later than 90 days prior to closure. In order to assure continuity of care, any facility which closes, either voluntarily or involuntarily, shall comply with all directions received from the TDMH regarding the orderly transfer of service recipients and their records.
- (7) Each licensee shall clearly identify the governing body, as defined in Rule 0940-05-01-.01, in its policies and procedures manual including the name and contact information of the governing body.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.28 Service Recipients' Rights.

- (1) All applications, certificates, records, reports and all legal documents, petitions and records made or information received pursuant to treatment in an OTP directly or indirectly identifying a service recipient shall be kept confidential and shall not be disclosed by any person except the individual identified.
- (2) Nothing in this rule shall prohibit disclosure, upon proper inquiry, of information as to the current medical condition of a service recipient to any member of the facility of a service or to the service recipient's relatives or friends in accordance with T.C.A. § 33-3-103; Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 Code of Regulations (CFR) Parts 160 and 164, Subparts A and E; and Confidentiality of Alcohol and Drug Abuse Service Recipient

Records regulations at 42 CFR Part 2.

- (3) Service recipients shall not be abused or neglected.
- (4) Facilities shall develop and implement written policies and procedures regarding the rights and responsibilities of service recipients under Rules 0940-05-06-.07 and 0940-05-06-.08 and the handling and resolution of complaints.
- (5) Other service recipient rights include:
 - (a) Right to a humane treatment environment that affords reasonable protection from harm, exploitation, and coercion;
 - (b) Right to be informed about the IPP and to participate in the planning, as able;
 - (c) Right to be promptly and fully informed of any changes in the plan of treatment;
 - (d) Right to accept or refuse treatment;
 - (e) Right to receive a written notice of the address and telephone number of the state licensed authority, i.e. the Department; and
 - (f) Right to obtain a copy of the Facility's most recent completed report of licensing inspection from the facility upon written request. The facility is not required to release a report until the facility has had the opportunity to file a written plan of compliance for the violations as provided for in these rules.
- (6) The written policies and procedures shall include provisions for service recipients and others to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.29 Community Relations.

The facility shall have policies and procedures for community relations to include the following:

- (1) A facility shall be responsible for ensuring that its service recipients do not cause unnecessary disruption to the community by loitering in an area directly adjacent to the facility such as a parking lot or acting in a manner that would constitute disorderly conduct or harassment.
- (2) Each facility shall provide TDMH, when requested, with a specific plan describing the efforts it will make to avoid disruption of the community by its service recipients and the actions it will take to assure responsiveness to community needs. This plan shall, at a minimum:
 - (a) Identify Facility personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan.
 - (b) Include policies and procedures or resolve community problems, including service recipient loitering and medication diversion, to ensure that facility operations do not affect community life adversely.
 - (c) Include procedures for soliciting service recipient and community ideas about medication assisted treatment, addressing community concerns and the Facility's presence in the community.
- (3) Each facility shall document community relations efforts and community contacts, including the resolution of issues identified by community members or service recipients.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

- (1) A personnel record for each staff member of a facility shall include an application for employment and/or resume and a record of any disciplinary action taken. A licensee shall maintain written records for each employee and each individual file shall include:
 - (a) Identifying information including name, current address, current telephone number, and emergency contact person(s).
 - (b) A 10-year employment history or a complete employment history if the person has not worked in 10 years.
 - (c) Records of educational qualifications, if applicable.
 - (d) Date of employment.
 - (e) Documentation of training and orientation of the person's duties and responsibilities.
 - (f) Any records relevant to the employee's performance.
 - (g) Evidence that any professional license required as a condition of employment is current and in good standing.
 - (h) Annual verification of basic skills and annual evaluation of personnel performance. Included shall be written verification that the employee has reviewed the evaluation and has had an opportunity to comment on it.
 - (i) Training and development activities designed to educate the staff in meeting the needs of the service recipients being served, including STD/HIV education.
- (2) Tuberculosis.
 - (a) All new employees, including volunteers who have routine contact with service recipients, shall be tested within three business days of employment for latent tuberculosis infection utilizing the two-step Mantoux method or a single interferon-gama release blood assay (IGRA).
 - (b) Employees shall have a test for tuberculosis annually and at the time of exposure to active tuberculosis and three months after exposure. Annual tuberculosis testing of previously TST-negative employees and volunteers shall be performed by the one-step Mantoux method.
 - (c) Employee records shall include the date and type of annual tuberculin tests given to the employee, date of tuberculin test results, and, if applicable, date and results of chest x-ray and any drug treatment for tuberculosis.
- (3) Staffing.
 - (a) Program Director. The governing body of each facility shall designate in writing a program director who is responsible for the operation of the facility and overall compliance with federal, state and local laws and regulations regarding the operation of opioid treatment programs, and for all employees including practitioners, agents, or other persons providing services at the facility. Facilities shall notify the SOTA in writing within 10 calendar days whenever there is a change in program director.
 - (b) Medical Director. The governing body of each facility shall designate in writing a medical director to be responsible for the administration of all medical services, including compliance with all federal, state and local laws and regulations regarding the medical treatment of opioid addiction. No physician may serve as medical director of more than one OTP without the prior written approval of the SOTA. Facilities shall notify the SOTA in writing within 10 calendar days whenever there is a change in medical director.

- (c) Program Physician. Facilities are required to provide sufficient physician services to provide the medical treatment and oversight necessary to serve service recipient needs.
 - 1. Physician services include, but are not limited to, performing medical history and physical exams, determining a diagnosis under current DSM criteria, determination of opioid dependence, ordering take-home privileges, discussing cases with the treatment team and issuing any emergency orders.
 - 2. The OTP shall provide on-site prescriber services of two hours per week for every 15 service recipients. At least 12.5% of the required prescriber services per week shall be provided by a physician.
- (d) Physician's Assistants and Advanced Practice Nurses. Licensed physician's assistants and advanced practice nurses with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs may perform any functions under Tennessee law or regulations.
- (e) Nurses. Facilities shall ensure that adequate nursing care is provided at all times the facility is in operation and that a nurse is present at all times medication is administered at the facility. Facilities that do not employ a registered nurse to supervise the nursing staff shall ensure that licensed practical nurses adhere to written protocols and are properly supervised consistent with Rules Chapter 1000-02 Rules and Regulations of Licensed Practical Nurses.
- (f) Counselors. There shall be sufficient group and individual counseling available to meet the needs of the service recipient population.
- (g) Pharmacist. The OTP shall provide on-site pharmacist services for the dispensing of opioid drugs.
- (4) Staff Qualifications.
 - (a) Medical Director. All medical directors shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain their licenses in good standing and shall have the following experience and/or credentials:
 - 1. Three years of documented experience in the provision of services to persons who are addicted to alcohol or other drugs, including at least one year of experience in the treatment of opioid addiction with an opioid drugs; or
 - 2. Board eligibility in psychiatry and two years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; and
 - 3. Certification as an addiction medicine specialist by the American Society of Addiction Medicine (ASAM).
 - (b) Waiver from Medical Director Qualifications. Facilities that are unable to secure the services of a medical director who meets the requirements of subparagraph (a) above may apply to the TDMH Office of Licensure and Review for a waiver. The TDMH Office of Licensure and Review, in consultation with the SOTA, may grant such a waiver when there is showing that:
 - 1. The facility has made good faith efforts to secure a qualified medical director, but has failed;
 - 2. The facility can secure the services of a licensed physician who is willing to serve as medical director and participate in the training plan;
 - 3. A training plan has been developed which is acceptable to the SOTA and which consists of a combination of continuing education in addiction medicine and in-service training by a medical consultant who meets the qualifications specified in

subparagraph (a) above; and

4. A medical consultant who meets the requirements of subparagraph (a) above shall be available, consistent with a training plan approved by the SOTA, to oversee the training of the medical director and the delivery of medical services at the Facility requesting the waiver.
- (c) Program Physician. All Facility physicians shall be licensed to practice medicine in Tennessee, shall maintain their licenses in good standing and shall have at least one year of documented experience in the treatment of persons addicted to alcohol or other drugs.
- (d) Waiver from Program Physician Qualifications. Facilities seeking to employ a program physician, in addition to the medical director, but are unable to secure the services of a program physician who meets the requirements of subparagraph (c) above may apply to the TDMH Office of Licensure and Review for a waiver. The TDMH Office of Licensure and Review, in consultation with the SOTA, may grant such a waiver when there is a showing that:
 1. The facility has made good faith efforts to secure a qualified program physician, but has failed;
 2. The facility can secure the services of a licensed physician who is willing to serve as program physician and participate in the training plan;
 3. A training plan has been developed which is acceptable to the SOTA and which consists of a combination of continuing education in addiction medicine and in-service training by the Facility's medical director; and
 4. The facility employs a qualified medical director who has the experience and credentials specified in subparagraph (a) above, has completed the training program specified in subparagraph (b) above or has completed the continuing education specified in subparagraph (e) below.
- (e) Current Medical Directors and Program Physicians. All physicians serving as medical director or program physicians as of the effective date of these rules who do not meet the criteria specified above will be deemed qualified provided that they obtain 50 hours of continuing education in addiction medicine approved by the SOTA within two years from the effective date of these rules. At least 25 hours of this continuing education shall be obtained within one year from the effective date of these rules.
- (f) Nurses. All registered nurses and licensed practical nurses shall be licensed to practice in Tennessee and shall maintain their license in good standing.
- (g) Counselors. All counselors shall be qualified by training, education and/or experience in addiction treatment to provide addiction counseling services.
- (h) Program Directors. All Facility program directors shall have at least one year of supervisory or administrative experience in the field of substance abuse treatment.
- (i) Pharmacist. All pharmacists shall be licensed to practice in Tennessee and shall maintain their license in good standing.
- (j) Professional Practice. All professional staff including, but not limited to, physicians, pharmacists, physicians' assistants, nurses and counselors may perform only those duties that are within the scope of their applicable professional practice acts and Tennessee licenses.
- (5) Staff Training and Orientation. Prior to working with service recipients, all staff providing treatment or services shall be oriented in accordance with these rules and shall thereafter receive additional training with these rules.

- (a) Orientation shall include instruction in:
 - 1. The facility's written policies and procedures regarding its purposes and description; service recipient rights, responsibilities, and complaints; confidentiality; and other policies and procedures that are relevant to the employee's range of duties and responsibilities;
 - 2. The employee's assigned duties and responsibilities; and
 - 3. Reporting service recipient progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services.
- (b) Additional training consisting of a minimum of eight clock hours of training or instruction shall be provided annually for each staff member who provides treatment or services to service recipients. Such training shall be in subjects that relate to the employee's assigned duties and responsibilities, and in subjects about current clinical practice guidelines for opioid replacement treatment. In-house training for staff may be substituted for external training with the approval of the SOTA. The following areas shall receive emphasis during training:
 - 1. Dosage level as determined through a physician's clinical decision-making and the individual service recipient's needs;
 - 2. Counseling;
 - 3. Drug screens and urinalysis;
 - 4. Phases of treatment;
 - 5. Treating multiple substance abuse;
 - 6. Opioid treatment during pregnancy and diseases;
 - 7. HIV and other infectious diseases;
 - 8. Co-morbid psychiatric conditions;
 - 9. FDA-approved drugs for the treatment of opioid addiction, including methadone and buprenorphine;
 - 10. Take-home medication practices;
 - 11. Chronic pain and pain management; and
 - 12. Referring service recipients for primary care or other specialized services.
- (c) The SOTA may require facilities to attend mandatory training in addition to any other training required by these rules.
- (d) Facilities shall maintain records documenting that each staff member has received the required annual training.
- (6) Employee Drug Screening. Facilities shall establish and implement written policies and procedures for pre-employment and ongoing random drug screening of all facility employees. Each sample collected shall be screened for opioids, methadone, amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by the SOTA.
- (7) A minimum of one on-duty staff member certified in cardiopulmonary resuscitation (CPR) and trained in the Abdominal Thrust Technique and First Aid shall be maintained.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

0940-05-42-.31 Posted Information.

All facilities shall post the following information required by T.C.A. § 71-6-121 in the main public entrance:

- (1) Contact information, including the statewide toll-free number of the Division of Adult Protective Services, and the number for the local District Attorney's office;
- (2) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the Department concerning abuse, neglect and exploitation; and
- (3) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one-half inches (8 ½") in width and eleven inches (11") in height.
- (4) Postings of (1) and (2) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

Repeals

Chapter 0940-05-42 Minimum Program Requirements for Alcohol and Drug Abuse Non-Residential Opiate Treatment Facilities is repealed in its entirety.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, and 33-2-404.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: 11-14-2011

Signature: [Signature]

Name of Officer: Zachary S. Griffith

Title of Officer: General Counsel, Office of Legal Counsel

Subscribed and sworn to before me on: 11/14/2011

Notary Public Signature: [Signature]

My commission expires on: 6/3/2012

Department of State Use Only

My Commission Expires

Filed with the Department of State on: 11/15/11

[Signature]
Tre Hargett
Secretary of State

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