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# Rulemaking Hearing Rule(s) Filing Form

*Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205*

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___ Amendment
X New
X Repeal

**Rule(s) Revised** (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. 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 |
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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" (also be referred to herein as "Facility" or "Program") 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.

(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 dependence.

(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 and Substance Abuse Services (TDMHSAS 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 that is 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 treated 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 from opioid drugs and opioid 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 laws and rules regarding medical treatment of opioid addiction. The medical director shall have the experience and credentials specified in paragraph 0940-05-42-.29(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 which has been 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) "Office of Licensure" means the Tennessee Department of Mental Health and Substance

Abuse Services (TDMHSAS) Office of Licensure.

(t) "Opiate/Opioid" means a drug that contains opium, derivatives of opium or any of several semi-synthetic or synthetic drugs with opium-like activity.

(u) "Opioid Dependent" means an individual who physiologically needs opioid or other opiate-like drugs to prevent the onset of signs of withdrawal.

(v) "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.

(w) "Observed Testing" means testing conducted and witnessed by a Facility staff person to ensure against falsification or tampering or results of a drug screen.

(x) "Prescriber" means a physician or physician 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.

(y) "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.

(z) "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.

(aa) "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.

(bb) "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.

(cc) "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.

(dd) "Relapse" means the failure of a service recipient to maintain abstinence from illicit drug use verified through drug screen.

(ee) "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.

(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 Physician" means a licensed and actively practicing physician who has been identified as accepting the responsibility for supervising physician assistants and advanced practice nurses.

(hh) "TDMHSAS" means the Tennessee Department of Mental Health and Substance Abuse

Services.

(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.

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

(a) Chapter 0940-05-02 Licensure Administration and Procedures;

(b) Applicable Life Safety Rules for Business Occupancies (Rule 0940-05-04-.04);

(c) If services are provided to mobile, non-ambulatory service recipients, then Mobile Non-Ambulatory Rule (Rule 0940-05-04-.09);

(d) Rules for Adequacy of Facility Environment and Ancillary Services found in Chapter 0940-05-05; and

(e) Applicable Minimum Program Requirements for All Services and Facilities found in Chapter 0940-05-06.

(2) If any provision of these rules or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of these rules which can be given effect without the invalid provision or application, and to that end the provisions of these rules are declared severable.

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) When making application for a new 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. 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 the 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 the department's licensure office 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.

(1) 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(18), in its policies and procedures manual including the name and contact information of the governing body.

(a) Intake, Admissions, and Discharges (0940-05-42-.06);

(b) Service Recipient Record Requirements (0940-05-42-.07);

(c) Multiple Enrollments (0940-05-42-.08);

(d) Orientation (0940-05-42-.09);

(e) Service Recipient Transfers (0940-05-42-.10);

(f) Individual Program Plan (0940-05-42-.11);

(g) Special Populations (0940-05-42-.12);

(h) Professional Services (0940-05-42-.13);

(i) Counseling (0940-05-42-.14);

(j) Medication Management (0940-05-42-.15);

(k) Pharmacotherapy Guidelines (0940-05-42-.16);

(l) Drug Screens (0940-05-42-.17);

(m) Detoxification and Medically Supervised Withdrawal (0940-05-42-.18);

(n) Diversion Control Plan (0940-05-42-.19);

(o) Central Registry (0940-05-42-.20);

(p) Reporting Requirements (0940-05-42-.21);

(q) Quality of Care (0940-05-42-.22);

(r) Infectious Hazardous Waste (0940-05-42-.23);

(s) Infection Control (0940-05-42-.24);

(t) Managing Disruptive Behavior (0940-05-42-.25);

(u) Hours of Operation (0940-05-42-.26);

(v) Service Recipients' Rights (0940-05-42-.27);

(w) Community Relations (0940-05-42-.28); and

(x) Personnel and Staffing Requirements (0940-05-42-.29).

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) Prior to admission to the Facility, each potential service recipient 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 or detoxification 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 licensed program purpose and description and applicable federal and state 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 an initial assessment. 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:

(a) A physical examination;

(b) Relevant health history (e.g., determination of chronic or acute medical conditions such as diabetes, renal disease, hepatitis, sickle cell anemia, tuberculosis (TB), HIV exposure, sexually transmitted disease, chronic cardiopulmonary disease and pregnancy);

(c) A personal and family medical and mental health history;

(d) A determination of currently prescribed medications;

(e) Personal and family history of substance abuse;

(f) An evaluation of other substances of abuse;

(g) Determination of current opioid dependence;

(h) Determination of length of addiction;

(i) A full toxicology screen to identify use of drugs including, but not limited to, opioids, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and THC;

(j) A tuberculosis screen;

(k) A screening test for syphilis;

(l) Other tests as necessary or appropriate (e.g., CBC, EKG, chest x-ray, hepatitis B surface antigen and hepatitis B antibody, HIV testing). Tests not directly conducted by the Facility at admission shall be conducted within seven days after admission. 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.

(9) Comprehensive Assessment. Within 30 days of admission, the Facility shall have completed a comprehensive assessment to include the following items. It shall be attached to the service recipient's chart no later than five days after it is developed. It 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 initial assessment. The Facility shall obtain complete medical records from other providers with service recipient's written consent.

(a) Whenever possible and with service recipient consent, the intake process shall include a 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 and 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; and

(viii) Inappropriate use of prescribed substances;

5. Urgent needs, including suicide risk;

6. Previous behavioral health services, including:

(i) Diagnostic information;

(ii) Treatment information; and

(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) Within 72 hours of admission, the Facility shall conduct an inquiry with the Central Registry in accordance with Rule 0940-05-42-.20.

(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 documentation that the Facility's counseling and/or medical staff has discussed with the service recipient an individualized detoxification program appropriate to the service recipient as required in section 0940-05-42-.18 herein.

(c) The service recipient's discharge planning shall include the development of a menu of treatment resources available to the service recipient in his or her community. This menu shall be developed in consultation with the service recipient. And shall be in writing and made available to the service recipient upon discharge. The Facility shall assist the service recipient in obtaining the appropriate referral.

(d) 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 TDMHSAS. 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 TDMHSAS 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.

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 or verification of one year of opioid dependence and one documented unsuccessful attempt at clinical treatment. If clinically appropriate, the program physician may waive these dependency and detoxification requirements 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.

10. If a prospective service recipient is under 18 years of age, verification of two documented unsuccessful attempts at detoxification within a twelve month period. Additionally, 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-.27);

(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) Documentation that the service recipient was informed about 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;

(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; and

(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 75 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. The orientation shall be designed to educate the service recipient and ensure that the service recipient understands the Facility's program.

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

(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 vocational, educational, 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 shall include, but is not limited to, an increase in individual or group counseling session(s) and 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 the service recipient wishes to enter medically-supervised withdrawal, the plan of care shall reflect that choice.

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-.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 consent.

(b) If the service recipient refuses consent 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, an increase in counseling, 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 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 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.

(4) The OTP shall address abuse of alcohol and other non-opioid substances within the context of the medication-assisted therapy effort.

(a) The Facility shall ensure that staff is trained and knowledgeable regarding current effective strategies for treating abuse of alcohol, opioids, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and other drugs.

(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 the service recipient's condition and address the situation from an individualized clinical perspective.

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-.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.

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-.14 Counseling.

(1) 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. 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 30 days of treatment, counseling session(s) shall take place at least two times per week;

(b) During the next 90 days of treatment (day 31 to day 120), counseling session(s) shall take place at least one time per week;

(c) During the following 90 days of treatment (day 121 to day 210), counseling session(s) shall take place at least two times per month;

(d) For subsequent 90 day periods of treatment (day 211 forward), 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 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 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 licensed nurse or physician assistant, qualified by training and experience, and categorically approved by the medical staff of the Facility. 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. Only in extraordinary circumstances may the total dose for the first day exceed 40 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)(x). Additional dosage may be dispensed in the first day where the prescriber documents that the initial dose 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. 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;

(iii) The Facility shall provide detoxification treatment services either directly or through referral to another provider of detoxification treatment services;

(iv) 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;

(v) 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; and

(vi) 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. The 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. 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.

2. 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 upon admission of the service recipient, at least every six months to determine if controlled substances other than methadone are being prescribed for the service recipient, and thereafter as clinically indicated. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred.

(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. Service recipients enrolled less than 30 days at the home clinic shall be eligible for guest dosing only if approved by the SOTA.

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-.16 Pharmacotherapy Guidelines.

(1) 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:

(a) 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;

(b) 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

(c) 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-.17 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 at least weekly random drug screens for newly admitted service recipients during the first 30 days of treatment and at least 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 synthetics 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;

(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 drugs 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 that urine collected from service recipients is unadulterated. Such collection and testing may include random direct observation conducted professionally, ethically and in a manner which respects service recipients' privacy.

(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 that is illegal or for which the service recipient cannot provide a valid prescription or any drug or substance prohibited by the opioid treatment program or SOTA; the presence of medication which is documented as 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 qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision; and

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days;

(b) Upon a second positive drug test result within six months of 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 qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory documented treatment team meetings with the service recipient;

(c) Upon a third positive drug test result within six months of the second 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 qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive 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 the service recipient may be discharged for continued positive drug tests; and

(d) Upon a fourth positive drug test result within six months of the third positive drug test result, opioid treatment program shall:

1. Through an assessment of the service recipient's IPP, address the on-going multi-drug use through increased group and individual counseling, 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;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. If the service recipient refuses recommended, more intensive levels of care, the service recipient shall be immediately enrolled in an individualized, medically supervised detoxification plan for up to two weeks, 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, barbiturates 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 access the PMP:

(a) Upon admission of a service recipient;

(b) Before the initial administration of methadone or other treatment in an opioid treatment program;

(c) After any positive drug test for prescription medication;

(d) Every six months to determine if controlled substances other than methadone are being prescribed for the service recipient. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred; and

(e) Each PMP 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-.18 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 ensure onsite medical supervision and oversight of the detoxification program.

(4) For persons projected to be involved in detoxification for six months or less, except as described in 0940-05-42-.17(9)(d), the Facility must offer the service recipient counseling as described in 0940-05-42-.14(3).

(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-.26) shall not allow take-home unsupervised-medications. This section shall not apply to detoxification programs conducted pursuant to Rule 0940-05-42-.17(9)(d) or administrative detoxification as defined in 0940-05-42-.18(12).

(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 if deemed medically necessary;

(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, the service recipient shall begin participation in a medically-supervised detoxification program for up to two weeks or as deemed medically necessary;

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 a copy of which shall be given to the service recipient 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-.19 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, including sanctions for a service recipient's 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 an 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-.20 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 75 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 75 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 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-.21 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 Office of Licensure and the SOTA 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 that caused or had the potential to cause harm to the service recipient;

(b) Criminal acts;

(c) Suicide or attempted suicide;

(d) Rape;

(e) Neglect of a service recipient;

(f) Service recipient altercations;

(g) Service recipient abuse;

(h) Misappropriation of service recipient funds;

(i) Restraint related incidents; or

(j) Poisoning occurring within the Facility.

(4) Specific incidents that might result in a disruption of the delivery of health care services at the Facility shall be reported to the Office of Licensure and the SOTA within seven days after the Facility learns of the incident. These specific incidents include the following:

(a) Strike by the staff at the Facility;

(b) External disaster impacting the Facility;

(c) 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;

(d) 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; and

(e) Improper disclosure of a service recipient's protected health information.

(5) Within seven days of any event described in (3), the Facility shall file a report with the Office of Licensure 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-.22 Quality of Care.

(1) The Facility shall develop and implement a plan for continuous quality improvement. At a minimum, the plan shall include:

(a) Structured assessment of the program which addresses Facility program management, staffing, policies and procedures and general operations.

(b) 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).

(c) An assessment of the aggregate cost of services per service recipient per week for services rendered.

(d) An assessment of medication-related issues including take-home procedures, security, inventory and dosage issues.

(e) 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.

(f) 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-.23 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 of 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-.24 Infection Control.

(1) The Facility shall have policies and procedures to be followed for infection control, including:

(a) 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; 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.

(b) Management of service recipients who are infected with Hepatitis B or C virus, HIV/AIDS or other STD.

(c) Nondiscrimination of employees and service recipients regarding their HIV/AIDS status.

(d) Use of standard precautions for prevention of transmission of HIV/AIDS, Hepatitis B or C Virus, and other blood borne pathogens.

(e) 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.

(f) 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.

(g) 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.

(h) Informed consent of service recipients before screening and treatment.

(i) 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.

(j) 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, including:

1. Counseling the service recipients about TB;

2. 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;

3. Providing for or referring the service recipients infected with TB for appropriate medical evaluation and treatment; and

4. 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-.25 Managing Disruptive Behavior.

(1) 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:

(a) 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:

1. The service recipient shall have given prior written consent to any restrictive measures taken with him/her by the staff;

2. 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;

3. Only qualified personnel may use restrictive procedures and shall be adequately trained in their use; and

4. The adaptive or desirable behavior shall be taught to the service recipient in conjunction with the implementation of the restrictive procedures.

(b) 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-.26 Hours of Operation.

(1) A Facility's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work.

(a) Dosing and counseling shall be available at least six hours per day from Monday through Friday and at least three hours on Saturday. On Sundays, dosing shall be available at least three hours and counseling may be provided in order to accommodate a service recipient's schedule.

(b) 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.

(c) Any Facility may also be closed for one mandatory training day, if required by the SOTA.

(d) Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, and referral services, at least six days per week. Medical exams shall be provided on days when new admissions to the clinic occur.

(e) 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.

(f) Facilities shall provide the SOTA with at least two weeks' notice prior to any change in Facility hours.

(g) A Facility that intends to voluntarily close shall notify TDMHSAS 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 TDMHSAS regarding the orderly transfer of service recipients and their records.

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 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 from the Facility, upon written request, a copy of the Facility's most recent completed report of licensing compliance inspection. The Facility is not required to release a report until the Facility has had the opportunity to file a written plan of compliance for any 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-.28 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 or act in a manner that would constitute disorderly conduct or harassment by loitering on the Facility's property.

(2) Each Facility shall provide TDMHSAS, 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.

0940-05-42-.29 Personnel and Staffing Requirements.

(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 one hour per week for every 35 service recipients. At least 12.5% of the required prescriber services per week shall be provided by a physician.

(d) Physician Assistants and Advanced Practice Nurses. Licensed physician 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.

(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; 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; or

3. Certification as an addiction medicine specialist by the American Society of Addiction Medicine (ASAM) or Board certification as an addiction medicine specialist.

(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 TDMHSAS Office of Licensure for a waiver. The TDMHSAS Office of Licensure, 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 TDMHSAS Office of Licensure for a waiver. The TDMHSAS Office of Licensure, 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 the Facility notifies the Office of Licensure and the SOTA in writing that within two years from the effective date of these rules the physician serving as medical director or program physician will obtain 50 hours of continuing education in addiction medicine approved by the SOTA. 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 two years' experience in addiction treatment under appropriate clinical supervision in order to provide addiction counseling services. All unlicensed counselors should be encouraged to complete the process of obtaining appropriate licensure and/or certification.

(h) Program Directors. All Facility program directors shall have at least one year of supervisory or administrative experience in the field of addiction treatment.

(i) Professional Practice. All professional staff including, but not limited to, physicians, physician 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.

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.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

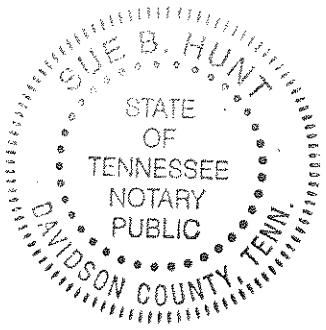
| Board Member | Aye | No | Abstain | Absent | Signature (if required) |
|---|---|---|---|---|---|
| | | | | | |

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Department of Mental Health and Substance Abuse Services (board/commission/ other authority) on 05/22/2012 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *(11/15/11)*

Rulemaking Hearing(s) Conducted on: (add more dates). *(01/05/12)*




Date: 5/22/12

Signature:

Name of Officer: E. Douglas Varney

Title of Officer: Commissioner

Subscribed and sworn to before me on: May 22, 2012

Notary Public Signature: Sue B. Hunt

My commission expires on: July 8, 2013

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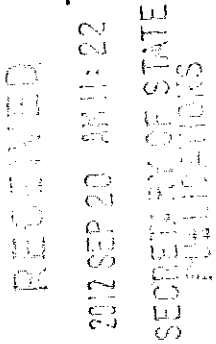
All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

RE Cooper

Robert E. Cooper, Jr.
Attorney General and Reporter

9-19-12
Date

**Department of State Use Only**




Filed with the Department of State on: 9/20/12

Effective on: 12/19/12

Tre Hargett
Secretary of State

**Public Hearing Comments**

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

TDMHSAS Responses to Comments about
Rules Chapter 0940-05-42 Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities made prior to, during, or after the
Rulemaking Hearing Held on January 5, 2012

GENERAL COMMENTS

**BEHAVIORAL HEALTH GROUP (BHG)**

On behalf of our client, Behavioral Health Group, we write to convey our opposition to several of the above referenced Department's proposed rules that were the subject of public hearing on January 5, 2012 and to comment on certain other rules. While our specific objections to the proposed rules are set forth separately below, it is appropriate to begin by expressing our surprise and disagreement with the Department's express purpose for the proposed rules as announced at the beginning of the January 5 public hearing. At that time, the Department stated its "summary of factual information" as required by T.C.A. § 4-5-204(a)(4). In essence, the Department stated that it is philosophically opposed to the long-term treatment provided by non-residential opioid treatment centers, which treatment modality it sees as contrary to the Department's "primary mission" of "encouraging patients to become drug-free." With all due respect, that philosophy is fundamentally flawed, scientifically unfounded and contrary to long-established best practice standards of medical care with respect to patients suffering from the disease of opioid addiction. The Department's position in this matter is at odds with that of the Center for Disease Control and Prevention (CDC), the Drug Enforcement Administration (DEA), the National Institutes of Health (NIH), the Center for Substance Abuse Treatment (CSAT) and the Substance Abuse and Mental Health Services Administration (SAMHSA) and with voluminous medical and scientific research, some of which is noted in this letter.

I. EFFECTIVENESS OF METHADONE MAINTENANCE TREATMENT

The opening comments at the hearing, as required by statute to provide the factual basis for the published rules, acknowledged that the major sentiment underlying these rules is opposition toward opioid treatment programs' (OTPs') "emphasis on maintenance effort," and referenced becoming "drug-free" as the "commonly accepted philosophy and belief of . . . drug abuse treatment." By use of the phrase "commonly accepted," the Department appears to be adopting "long-standing myths and misconceptions about opioid-based medications" in the general public, which "misinformation has the potential to discourage the appropriate use of these medications even though, properly administered, they have demonstrated efficacy and safety in millions of patients worldwide." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 8 (2004). (attached as Exhibit A); see also *Effective Medical Treatment of Opiate Addiction,* NIH Consensus Statement, Nov. 17-19, 1997 at 18 (noting that "[m]any of the barriers to effective use of MMT in the treatment of opiate dependence stem from misperceptions and stigmas attached to opiate dependence, the people who are addicted, those who treat them, and the settings in which services are provided") (attached as Exhibit B).

Contrary to the Department's stated position, detoxification is *not* "commonly accepted" among the scientific or medical community as being the best or most effective treatment for opioid addiction. In a study published in the Journal of the American Medical Association, researchers found, based on an extensive five-year investigation, that, as compared to detoxification, methadone maintenance therapy (MMT) resulted in greater treatment retention, lower heroin use, lower severity score for legal status and was equally effective with regard to employment and family functioning scores. Karen L. Sees, Kevin L. Delucchi, et al, *Methadone Maintenance vs. 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence. A randomized controlled trial,* 283 J. Am. Med. Ass'n. 1303-1310 (2000) (attached as Exhibit C). An overview of 5 meta-analyses summarizing 52 studies demonstrated that "methadone maintenance treatment was more effective than detoxification, no treatment, buprenorphine, LAAM, and heroin plus methadone. NIDA International Program

Methadone Research Web Gide, Part B, Question 1: Is methadone maintenance treatment effective for opioid addiction?, available at http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b. (attached as Exhibit D); see also M Connock, A Juarez-Garcia, et al, *Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation*, Health Tech. Assessment, March 2007 at 1 (attached as Exhibit E). Researchers confirm the effectiveness of long-term methadone maintenance:

> The benefits of long-term methadone maintenance are borne out by data. Two years of MMT appears to be the minimum duration before attempting withdrawal. Even patients receiving maintenance for long periods with substantial lifestyle changes often relapse after leaving treatment, and death rates are much higher than for individuals who remain in treatment. For many patients, therefore, years or even lifetime maintenance may be needed . . . . Ultimately, the problem of interminable maintenance vs. relapse may require learning how to reverse the brain changes associated with addiction. Until then, long-term agonist treatment remains a reasonable alternative.

Vincent P. Dole & Marie Nyswander, *Methadone Maintenance 4 Decades Later: Thousands of Lives Saved But Still Controversial.* 300 J. Am. Med. Ass'n. 2303-2305 (2008) (attached as Exhibit F). The National Center for Substance Abuse and Treatment has noted in its guidelines that "[s]tudies suggest that the duration of retention in treatment is directly related to success in outcome. For patients who drop out of treatment, the outcome is usually negative, whereas patients who remain in treatment, despite continued excessive use of alcohol or illicit drugs, tend to benefit from the treatment experience." CSAT Guidelines for the Accreditation of Opioid Treatment Programs, http://www.dpt.samhsa.gov/pdf/draft_accred_uidelines.pdf, Note 8 at 40 (attached as Exhibit G).

The Centers for Disease Control and Prevention (CDC) reports that the benefits of methadone include:

- Reduced or stopped use of injection drugs;
- Reduced risk of overdose and of acquiring or transmitting diseases such as HIV, hepatitis B or C, bacterial infections, endocarditis, soft tissue infections, thrombophlebitis, tuberculosis, and STDs;
- Reduced mortality – the median death rate of opiate-dependent individuals in MMT is 30 percent of the rate of those not in MMT;
- Possible reduction in sexual risk behaviors, although evidence on this point is conflicting;
- Reduced criminal activity;
- Improved family stability and employment potential; and
- Improved pregnancy outcomes.

Centers for Disease Control and Prevention – IDU HIV Prevention. Methadone Maintenance Treatment, February 2002, *available at* http://www.cdc.gov/idu/facts/methadonefin.pdf (attached as Exhibit H). See also NIDA International Program Methadone Research Web Guide, Part B, Question 4: Does methadone maintenance treatment reduce criminal activity?, available at http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit I). Several studies confirm increased employment rates among patients on methadone maintenance programs. NIDA International Program Methadone Research Web Guide, Part B, Question 5: Does methadone maintenance treatment improve the likelihood of obtaining and retaining employment?, available http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit J). Others show reduction in suicide rates and lethal overdoses, and improved health and productivity. NIDA International Program Methadone Research Web Guide, Part, Question 1: Is methadone maintenance treatment effective for opioid addiction?, available at http://international.drubabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide-part-b (attached as Exhibit D). The benefits of methadone maintenance therapy are so clear and compelling that a panel of experts convened by the National Institutes of Health concluded as follows:

> Opiate dependence is a brain-related medical disorder that can be effectively treated with significant benefits for the patient and society, and society must make a commitment to offer effective treatment for opiate dependence to all who need it. All opiate-dependent persons under legal supervision should have access to methadone maintenance therapy, and the U.S. Office of National Drug Control Policy and the U.S. Department of Justice should take the necessary steps to implement this recommendation . . . . The unnecessary regulations of methadone maintenance therapy and other long-acting opiate agonist treatment programs should be reduced, and coverage for these programs should be a required benefit in public and private insurance programs.

*Effective Medical Treatment of Opiate Addiction*, NIH Consensus Statement, Nov. 17-19, 1997 at 2 (attached as Exhibit B).

Thus, to the extent that the Department is equating methadone maintenance therapy with continued illegal drug use, it fundamentally misunderstands the effects of methadone at clinical levels. Researchers have observed that "[f]rom the beginning of MMT, the program has been stigmatized by the belief that methadone treatment merely substitutes one drug for another. This belief blurs the crucial differences between an active heroin addiction and the use of methadone in a maintenance program." Herman Joseph, Sharon Stancliff, & John Langrod, *Methadone Maintenance Treatment (MMT): A Review of Historical and clinical Issues,* 67 Mt. Sinai J. Med. 347-364 at 358 (2000) (attached as Exhibit K). At proper levels, methadone not only does not cause intoxication itself but significantly reduces the rate of other drug use by relieving the craving for and blocking the "high" caused by other opiates. The CDC has stated that methadone:

- blocks the euphoric and sedating effects of opiates;
- relieves the craving for opiates that is a major factor in relapse;
- relieves symptoms associated with withdrawal from opiates;
- does not cause euphoria or intoxication itself (with stable dosing), thus allowing a person to work and participate normally in society;
- is excreted slowly so it can be taken only once a day.

Centers for Disease Control and Prevention – IDU HIV Prevention. Methadone Maintenance Treatment, February 2002, *available* at http://www.cdc.gov/idu/facts/methadonefin.pdf (attached as Exhibit H).

The Department's obvious and inexplicable opposition to maintenance therapy notwithstanding, science supports the use of long-term maintenance therapy for opioid addiction:

> Studies have shown that good outcomes from substance abuse treatment are unequivocally contingent on adequate length of treatment. A research-based guide on the principles of substance abuse treatment, released in 1999 by the National Institute on Drug Abuse (NIDA), notes that "For methadone maintenance, 12 months of treatment is the minimum, and some opiate-addicted individuals will continue to benefit from methadone maintenance treatment over a period of years." . . . Most of those who discontinue MMT later relapse. . .

*Id.* Further, there is no scientific distinction between addiction to heroin and addiction to prescription painkillers or in the effectiveness of MMT to treat such addictions.

Moreover, this treatment for Tennesseans currently costs the State nothing, as OTPs in Tennessee receive no state funding or reimbursement whatsoever. Patients in Tennessee pay for treatment with their own funds or, in rare cases, through private insurance. Additionally, the treatment is extremely cost-effective compared to alternatives. As Dr. Rachel Farmer, owner and medical director of the Dyersburg OTP, testified at the rulemaking hearing, an OTP patient receives an entire year of comprehensive treatment, including physical examination, counseling, medication and referrals, for the cost of 4 days of treatment in an inpatient setting. As a practical matter, OTP treatment is the *only* treatment available to the overwhelming majority of patients receiving

it in Tennessee, as there are no other accessible, affordable programs offered. The State of Tennessee, of course, offers no financial assistance or in-patient programs.

To the benefit of taxpayers, OTP programs actually provide cost-savings to state and local governments. In 1997 the National Institutes of Health estimated the financial costs of untreated opiate addiction to be $20 billion per year. *Id.* As the Centers for Disease Control has stated, "[t]hese costs, combined with the social costs of destroyed families, destabilized communities, increased crime, increased disease transmission, and increased health care costs, mean that opiate addiction is a major problem for affected individuals and society." *Id.* Methadone maintenance treatment reduces those costs in many ways. It decreases funds spent on law enforcement and incarceration by drastically reducing criminal activity among addicts receiving treatment. One study has shown a 70% reduction in crime days per year among narcotics addicts on methadone maintenance. Vincent P. Dole & Marie Nyswander, *Methadone Maintenance 4 Decades Later: Thousands of Lives Saved But Still Controversial.* 300 J. Am. Med. Ass'n 2303-2305 (2008) (attached as Exhibit F). The public savings from reduced criminal activity alone amounts to $4 for every $1 spent on methadone treatment. Harwood HJ, Hubbard RL, Collins JJ, Rachal, JV. The Costs of Crime and the Benefits of Drug Abuse Treatment: A Cost-Benefit Analysis Using TOPS Data, NIDA Research Monograph, Number 86, 1988, *available at* http://archives.drugabuse.gov/pdf/monographs/86.pdf (attached as Exhibit L); see also NIDA International Program Methadone Research Web Guide, Part B, Question 15: Are there cost benefits to methadone maintenance treatment?, *available at* http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit M). Effective addiction treatment also results in lower unemployment and lower healthcare costs for the medical problems associated with active illegal drug use. The National Institute on Drug Abuse (NIDA) states unequivocally that "when all costs to society are considered, methadone maintenance treatment is extremely cost-effective and beneficial to society." *Id.* Accordingly, an expert panel convened by the National Institutes of Health has "strongly recommended expanding access to methadone treatment by eliminating excessive Federal and State regulations and increasing funding for methadone treatment." Mathias, R. NIH Panel Calls for Expanded Methadone Treatment for Heroin Addiction. NIDA Notes 1997; 12 (6), *available at* http://archives.drugabuse.gov/NIDA_Notes/NNVol12N6/NIHPanel.html (attached at Exhibit N); See also Herman Joseph, Sharon Stancliff, & John Langrod, *Methadone Maintenance Treatment (MMT: A Review of Historical and Clinical Issues,* 67 Mt. Sinai J.Med. 347-364 (2000) (noting reduction in property crime, drug arrests, hepatitis and addiction-related deaths and going on to state that "[a]vailability of MMT should be increased and made more affordable") (Exhibit K).

To the extent that the Department believes its rules are necessitated by a concern about the risk of mortality associated with methadone, that concern manifestly does *not* warrant tighter restrictions on OTPs or their patients. "[M]ethadone is among the most thoroughly studied drugs in modern medicine" and has been proven to be safe when used as indicated. U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 10-11 (2004); see also NIDA International Program Methadone Research Web Guide, Part B, Question 12: Is the long-term use of methadone medically safe, and is it well tolerated by patients?, available at http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit O). As SAMHSA has noted, "[m]ethadone is a medication valued for its effectiveness *in reducing the mortality associated with opioid addiction* as well as the various medical and behavioral morbidities associated with addictive disorders." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 3 (2004) (emphasis added) (Exhibit A). Specifically, SAMHSA reported that "[m]ortality from all causes is many-fold lower in methadone-treated patients than in untreated opioid addicts." *Id.* at 11.

The federal Drug Enforcement Administration's Office of Diversion Control noted in April 2007 that a recent increase in methadone distribution "is primarily associated with increased use for pain management not narcotic treatment," and that "[c]urrent data suggest that medication from pain management is likely the source of methadone for illicit use." Methadone: Methadone Mortality Working Group, Drug Enforcement Administration, Office of Diversion Control, April 2007, *available at* http://www.deadiversion.usdoj.gov/drugs_concern/methadone/methadone_presentation_0407_revised.pdf at 8 and 41 (attached as Exhibit P). (Note: Page numbers were added to the presentation for citation purposes and did not appear in the original document.) The increase in the amount of methadone distributed by pharmacies has far outpaced that of OTPs, to the point that by 2002, "pharmacies accounted for 88 percent of all purchases of methadone tablets." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 21 (2004) (Exhibit A). While it is true that methadone-related deaths have been reported, SAMHSA has conducted an expert national assessment of all available relevant data and announced that "[e]xamination of the data available to the National Assessment

participants indicates that OTP's and the 2001 regulatory changes {permitting more take home doses of methadone in OTP treatment] *did not* have a significant effect on rates of methadone-associated mortality." *Id.* at 22 (emphasis in original). "In the cases in which the sources of methadone associated with deaths could be traced, OTPs did not appear to be involved." *Id.* Rather, "participants concurred that methadone tablets and/or diskettes that have become available through channels *other than OTPs* are most likely the central factor in recent increases in methadone-associated mortality." *Id.* (emphasis in original). Accordingly, cases of methadone-related mortality do not justify tighter regulations targeted at limiting access to OTPs.

Given the demonstrated safety, effectiveness and cost-savings to the State associated with the treatment provided by OTPs, there is no scientific or even logical basis for the Department to treat OTPs or their patients more harshly than any other treatment setting. As discussed above, OTPs are not the only sources of methadone, and the federal Drug Enforcement Administration data show that, by 2006, pharmacies, hospitals and other practitioners accounted for approximately the same about of methadone distribution as OTPs (Methadone: Methadone Mortality Working Group, Drug Enforcement Administration, Office of Diversion Control, April 2007, available at http://www.deadiversion.usdoj.gov/drugs_concern/methadone/methadone_presentation0407_revised.pdf at 13, Exhibit P), and yet the Department's rules target only OTPs for restriction.

In this regard, the Tennessee Attorney General has opined, the "state may not invidiously discriminate, and may not rely upon a classification whose relationship to an asserted goal is so attenuated as to render the distinction arbitrary or irrational." Op. Tenn. Atty. Gen. No. 99-221, at * 4 (Nov. 4, 1999) attached as Exhibit Q). Accordingly, the Attorney General has repeatedly cautioned that prohibitions and limitations targeted at OTPs are "constitutionally suspect" as a violation of the right to equal protection and "also raise substantial legal concerns" about violations of the Americans with Disabilities Act and § 504 of the Rehabilitation Act. *See id.* (evaluating proposed legislation that would prohibit OTPs); Op. Tenn. Atty. Gen. No. 98-087 (Apr. 15, 1998) (finding proposed legislation requiring local government support for an OTP as prerequisite to a certificate of need to be "constitutionally suspect") (attached as Exhibit R); Op. Tenn. Atty. Gen. No. 97-099 (July 1, 1997) (finding proposed state agency rule preventing an OTP from locating within 100 miles of another OTP to be "constitutionally suspect") (attached as Exhibit S). There is, quite simply, no justification for the perception of OTPs embodied in these misinformed, illogical, illegal and arbitrary proposed rules.

**CONTINUUM HEALTH PARTNERS (CONTINUUM)**

The Regulations seem directed only at "programs" that provide methadone and/or buprenorphine. However, they address concerns that presumably apply to office-based opioid treatment (OBOT) providers as well: the risk of diversion, the need for monitoring patients, dosage issues, verification of medication prescribed by other providers, etc. Furthermore, many of the specific provisions that are proposed would be applicable all addiction treatment service providers, regardless of setting and whether medication is or is not utilized. Thus, the requirement that applicants for and recipients of "opioid treatment programs" be given "explanation of treatment options . . ." (page 9) is one I applaud, but it is equally imperative that applicants for drug-free care and for community-based buprenorphine treatment be informed of all options, including medication-assisted treatment and "programs," and that referral be facilitated upon request.

Comprehensive assessment" (page 10) would seem relevant to all care providers, and not just to medication-assisted treatment programs. (I note in passing that the "assessment," as described, includes many elements that would prove both time-consuming and expensive, and for which there is no evidence that they are essential.)

To the extent the requirements for "screening" applicants (pages 13 – 14) might be considered justified, why would they be less relevant to applicants seeking treatment other than in an OTP setting?

The proposed regulations would assign responsibility to state officials for decisions that should be entirely within the purview of the clinical care provider: determination of need for and appropriateness of a particular treatment modality; dosages; type and frequency of laboratory tests; response to less than optimal therapeutic results; justification for take-home medication; etc. It is not clear if the SOTA staff to whom these medical-clinical decisions are to be left are physicians – let alone whether they meet the various qualifications demanded of "program" medical directors (e.g., board eligibility in psychiatry and two years documented experience in the treatment of persons who are addicted" page 37), and other program physicians. Regardless of the academic and clinical qualifications of the authority staff, however, they presumably will be totally unfamiliar with the patients and may well never have had any contact with their healthcare providers other than through submission of

documents. In sum, this would seem to be a totally inappropriate system for reaching decisions with potentially life-and-death consequence.

* * *

*Informed consent*: this is –appropriately – required prior to beginning treatment and for release of confidential patient information under almost any circumstances. it is most strongly urged that informed consent, in writing, *also* be obligatory prior to initiation of voluntary *discharge*. The provider should be obligated to inform the patient of the consistent evidence that following detoxification (for any reason) relapse to illicit drug use is the rule rather than the exception, and that such relapse is associated with a very marked increase in likelihood of fatal overdose. Indeed, providing this information to applicants and patients should be mandatory *at the time of admission* to treatment as well, and mentioned explicitly in the "consent to treatment."

There are a great many additional criticisms that I believe the proposed rules merit, but I have limited myself to what I consider to be the most important. I urge that each and every provision be assessed from the standpoint of likely consequences – good and bad – for applicants and patients, providers, and the community as a whole. it is my conviction that with respect to every aspect of the proposal the question should be asked: would this be appropriate if applied to any other chronic, notoriously relapsing, incurable – but treatable – medical condition? From that perspective I am confident the right answers will be forthcoming and benefit all concerned.

**SOLUTIONS OF SAVANNAH & RECOVERY OF COLUMBIA (SOS)**

My business partner, Beverly Jones, and I own and operate two Opioid Treatment Programs in Tennessee. Solutions of Savannah and Recovery of Columbia are both small programs, and Solutions of Savannah is located in a rural area. We both live in Savannah and work in the clinics daily. We operate very clinical and ethical programs. We are able to see the difference medication-assisted treatment makes in the lives of individuals, families, and our community.

Many of the proposed new regulations are standards that we have always adhered to, and will continue to do so regardless. We understand that there have been changes in the field of medication-assisted treatment in the past few years, and that the regulations need to be updated. However, we feel that many of the proposed regulations are heavy-handed and punitive to the programs and clients.

Some of the proposed regulations will have a significant financial impact on programs, especially smaller ones, like ours. If the proposed regulations are approved, as written, they have the potential to force small clinics out of business. This will force people out of work and out of treatment. We are concerned about this impact as business owners, members of the community, and taxpayers.

We would like explanations as to the reasoning behind the changes in many of the regulations. The research that we follow recommends, in many instances, the opposite of what is being proposed here. We would like to see the Department's research behind the proposed changes.

Methadone Maintenance Treatment is one the most researched forms of treatment available. Please consider this research, when making your decision.

**VOLUNTEER TREATMENT CENTER (VOLUNTEER)**

First, the rules, as proposed by the Commissioner of the Department of Mental Health (Commissioner), exceed the Commissioner's authority by undermining the fundamental purpose of the legislature in enacting legislation to establish a statutory framework for regulating OTPs. It is well established that an administrative agency does not have the power to thwart the purpose of a statute enacted by the legislature. Deweese v. Board of Funeral Directors and Embalmers, 1994 WL 137873. The Tennessee legislature has authorized the establishment and licensure of OTP Facilities for the purpose of addressing the state's opiate abuse crisis. The cost of many of the requirements set forth in the Proposed Rules will make it almost impossible for OTP Facilities to continue to operate and provide much needed services for their patients. By making it unreasonably costly for OTP Facilities to operate, the Commissioner has promulgated rules that conflict with the intent and purpose of the statute.

Second, many of the Proposed Rules are unsupported by any clinical evidence that they will improve the efficiency or effectiveness of treatment, and are simply arbitrary and capricious. The actions of any administrative agency must not be arbitrary and should be supported by substantial and material evidence. Jackson Mobile

Phone Company, Inc. vs. Tennessee Public Service Commission, 876 S.W. 2d 106 (1994). The Proposed Rules as drafted do not meet this standard. Instead, they require actions and processes that are inconsistent with well-established standards of care in the industry which will not only limit access to treatment but will often eliminate the effectiveness of that treatment.

Further, the Proposed Rules are vague and in many instances will be impossible to implement. In order to meet the standards of both the Tennessee and United States Constitution, the Proposed rules must be in a form so that it is possible for a facility to know whether or not it in compliance. Williams v. State Department of Health and Environment, 880 SW2d 995 (Tenn. App. 1994). The Proposed Rules do not meet this standard. Often the requirements of the Proposed rules are so vague that reasonable men could easily differ in interpretation of the Proposed rules. In many instances, OTP Facilities will not know what steps they will be required to take in order to meet the requirements of the Proposed Rules and in other instances will not be able to take the actions that are mandated.

**TDMHSAS Response:** The Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS or Department) believes that Non-residential Opioid Treatment Program Facilities (OTPs) are an integral component in Tennessee's mission to curb and eliminate drug abuse of all kinds in this state and the Department recognizes that some of the practices of these facilities are indispensable for that purpose. However, in light of the prescription drug epidemic confronting our state and the vulnerable nature of the individuals served by OTPs, the Department believes that OTPs are in need of clearer operational guidelines and better reporting mechanisms in order to ensure the safety and health of their service recipients and to track the nature and scope of the medications the OTPs dispense. It is in the spirit of ensuring the safety and sobriety of our Tennessee citizens that the changes to 09040-05-42 have been promulgated.

The new rules have benefited from the extensive research done by TDMHSAS' Policy and Planning Division, particularly as it relates to the administrative procedures relative to OTPs in other states, especially those of nearby states with issues similar to Tennessee's relative to opioid addiction. Additionally, TDMHSAS considered other information gathered regarding the regulation and operation of OTPs, including: 1.) Information gathered during site visits by the State Opioid Treatment Authority (SOTA) and Licensure staff to OTPs in Illinois, New York, Maryland, Kentucky, and Texas; 2.) Meetings and telephone conferences with DEA personnel; 3.) Consultation with OTP regulators in other states; 4.) an overview of federal OTP regulations and various publications; 5.) Tennessee statutes and operating procedures; 5.) Federal regulations, particularly those regarding guidelines for the accreditation of OTPs; and 6.) Research regarding Tennessee's increasing opioid-addicted population and its unique characteristics. Furthermore, TDMHSAS has considered the concerns and comments presented by stakeholders (OTP service recipients, owners, operators, and employees) at the rulemaking hearing for these rules held on January 5th, 2012, the concerns and comments submitted by the stakeholders during the extended written comment period granted by TDMHSAS from January 5th to January 19th, 2012, and the arguments offered by the stakeholders during a meeting with TDMHSAS Commissioner Varney held pursuant to T.C.A. § 4-5-204(c)(1) on February 13, 2012. Based on those stakeholders' concerns and comments, TDMHSAS made appropriate changes to the rule.

All in all, TDMHSAS has been diligent in researching these rules and responsive in reacting to stakeholders' concerns and comments. As a result, it is TDMHSAS' belief that these new rules capture the best practices in the area of opioid treatment and represent a positive step forward in the area of OTP regulation which will allow Tennessee citizens to continue to access this important treatment option while benefitting from increased safety and public health accountability measures.

**SPECIFIC COMMENTS**

**All citations referenced by the stakeholders in this section refer to the version of the rule as it appeared in the Notice of Rulemaking Hearing document filed by TDMHSAS with the Secretary of State on November 15, 2011.*

(A) 0940-05-42-.01(2)(e)

**VOLUNTEER:** This proposed definition of "no less than thirty (30) minutes" is arbitrary. It assumes, with no medical basis, that therapy delivered for a short duration, such as in unscheduled crisis situations, is ineffective.

**BHG:** This provision defines a counseling session as a "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 . . ." The effect of this definition is to limit documentation credit for therapy provided via a crisis phone call or for face-to-face

conversations lasting less than 30 minutes. This essentially negates the opportunity to provide those forms of therapy, and may have the effect of causing patients to abandon treatment if they are required to submit to lengthy face-to-face conversations for every counseling session. We would ask that the definition be modified to include counseling via telephone and for shorter periods of time as appropriate to the patient's needs.

**TDMHSAS Response:** We disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. SAMHSA TIP 43, pages 124-125, provides: "Studies have found that OTPs providing regular, structured, substance abuse-focused counseling had better outcomes than OTPs providing little or no counseling (Kidorf et al. 1999; Magura et al. 1999)." SAMHSA TIP 43, page 125, lists the elements of a "typical individual counseling session" at an OTP. In order for the OTP to effectively address each elements of a typical individual counseling session, it is TDMHSAS' belief that a minimum of 30 minutes per counseling session is needed.

(B) 0940-05-42-.01(2)(n)

**BHG**: This subsection defines a maintenance dose as one that 'suppress[es] signs and symptoms of withdrawal and drug cravings for individuals with opioid addiction.' This definition is technically incorrect as methadone does not reduce cravings for *all* drugs. That sentence should be modified to read 'signs and symptoms of withdrawal from opioid drugs and opioid drug cravings.'

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholder.

(C) 0940-05-42-.01(2)(q)

**BHG:** This subsection defines methadone as an "opioid agonist with actions similar to those of morphine and heroin." This is scientifically inaccurate. Among other critical distinctions, in contrast to morphine and heroin, methadone is long-acting and non-tolerance forming. The definition should be modified to provide that "Methadone is in a class of medications called opiate (narcotic) analgesics. Methadone works as a therapeutic replacement agent for drugs of abuse by preventing withdrawal symptoms in people who have stopped using these drugs."

**VOLUNTEER**: The comparison of methadone to heroin is arbitrary and inappropriate. VTC suggests using a definition similar as that for Buprenorphine. Any definition for methadone should not include a comparison to an illicit drug.

**SOS**: This definition seems to set the tone for the following proposed regulations. Treatment providers and clients are in a constant battle to fight the stigma of substance dependence and methadone treatment. We work in the community to improve relations and increase understanding and acceptance of medication-assisted treatment. This definition, with the Department comparing methadone to heroin, is a slap in the face to every treatment provider and client in the State of Tennessee.

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholders and returned to the earlier definition of methadone found in the current version of these rules.

(D) 0940-05-42-.01(2)(y)

**VOLUNTEER**: This definition should not include medical director, another defined term. Including the term medical director as part of a separate defined term creates confusion.

**TDMHSAS Response:** We disagree. No change has been made from the existing rule. Therefore, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(E) 0940-05-42-.01(2)(ee)

**VOLUNTEER**: The Board of Pharmacy regulates pharmacists, and has no jurisdiction to regulate OTPs. This definition is not needed and should be deleted. OTPs do not employ pharmacists. Only two (2) drugs are used at OTPs, and those drugs are properly dispensed through an automated dispensing system. Including this definition in these rules creates confusion and a perception that the Board of Pharmacy has some authority over OTPs.

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholder.

(F) 0940-05-42-.03

**BHG**: This subsection imposes new requirements on OTPs "when making application for a license." This language should be modified in order to make clear that these requirements apply only to those "making application for a *new* license," as opposed to those simply seeking renewals of existing licenses. More importantly, the proposed rule will require applicants for an opioid treatment program ("OTP") license to submit, in addition to the Certificate of Need ("CON") issued by the Tennessee Health Services Development Agency ("HSDA"), "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." This requirement exceeds, and directly conflicts with State law, governing community input into the licensing of healthcare facilities. When any such proposed facility applies for a CON, any interested party may require the HSDA to conduct "a fact-finding public hearing on the application" in the community in which it is to be located. Tenn. Code Ann. § 68-11-1608(b). Additionally, within ten days of filing an application for a CON, OTPs must "send a notice to the county mayor of the county in which the facility is proposed to be located, the member of the house of representatives and the senator of the general assembly representing the district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential methadone treatment facility has been filed with the agency by the applicant." Tenn. Code Ann. § 68-11-1607(c)(3). Any person may appear before the HSDA and express opposition to an application, Tenn. Code Ann. § 68-11-1609(g)(2), and any person who so objects to an application may petition the HSDA to hold a contested case hearing on the matter if the application is approved. Tenn. Code Ann. § 68-11-1610(a). Finally, any person who is aggrieved by the outcome of a contested case hearing may seek judicial review of that decision in the Davidson County Chancery Court. Tenn. Code Ann. § 4-5-322. Thus, there is ample opportunity for communities and government officials to have their opinions about a proposed OTP heard by both the agency and the courts responsible for reviewing CON proceedings. This proposed rule, however, goes much further. By requiring a letter of local government support as part of an application for an OTP license, this rule would essentially give local governments veto power over the establishment of an OTP within their jurisdictions. That power is expressly prohibited by State law, which provides that while local government input is to be heard, local government support is not required for the establishment of OTPs:

> At a hearing conducted by the HSDA for a nonresidential substitution-based treatment center for opiate addiction, if a local governing body requests to participate in such hearing, the officials of such governing body shall have the opportunity to appear before the agency and express support or opposition to the granting of a certificate of need to the applicant. The testimony of such officials shall be informational and advisory to the agency, and **the support of the local governing body shall not be a requirement** for the granting of a certificate of need by the agency. Tenn. Code Ann. § 68-11-1624 (emphasis added).

In 1998 the Tennessee Attorney General opined that proposed legislation designed to give local governments a veto over OTPS would be "unconstitutional as a violation of equal protection of the laws," and noted that it would likely also violate the Americans with Disabilities Act and the Rehabilitation Act. *See* Op Tenn. Atty. Gen. No. 98-087 at *14 (attached as Exhibit R). Specifically the Attorney General cited case law to the effect that "irrational prejudice" and fears of property owners and residents are insufficient support for a legislative classification between various types of facilities or populations, *Id.* at *10-11, and concluded that the disparate treatment of nonresidential methadone treatment facilities were 'insufficiently and concluded that the disparate treatment of nonresidential methadone treatment facilities was "insufficiently narrow in scope and insufficiently grounded in fact" to be rationally related to any legitimate state interest. *Id.* at *14. Accordingly the proposed requirement of a letter of support from local government is unlawful.

Rather than giving credence and power to local misconceptions about OTPs, the Department should be acting in its role as a public health agency to educate the public about many societal and individual benefits provided by methadone maintenance treatment. As SAMHSA has announced, "public misperceptions about methadone must be addressed," and "[t]here is an immediate need for professional organizations and regulatory agencies to present scientific evidence and credible data to counter misinformation about methadone and 'methadone clinics' (OTPs) presented in the mass media." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin, Methadone-Associated Mortality: Report of a National Assessment 26 (2004).

**VOLUNTEER**: This rule should be deleted because it is confusing and exceeds the authority of the Commissioner to impose such a requirement. First, "as of the effective date of these rules" is not specific and will not give adequate notice to those who seek to comply. Second, the requirement of a "letter of support from the local governing body" is vague and confusing. Finally, such a requirement is an inappropriate delegation of authority to a separate government body not contemplated by the statute.

**TAADAS**: TAADAS recommends the deletion of the language "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," and substituting instead the language, "The application shall include a resolution adopted by the city governing body and the county legislative body where the facility is proposed to be located stating that the facility's proposed land use is appropriate under the local government's land use regulations." The explanation for this revision is that a local governing body acts by its resolutions and ordinances. Procedurally, a governing body does not draft letters, unless of course the rule may have intended for the letter of support and statement of compliance with land use regulations to be drafted by the city mayor and the county mayor.

**SOS**: The Tennessee Health Services Development Agency does not require a letter of support from the local governing body of the county or city in which the facility is proposed to be located. How can one State agency re-write the requirements of another State agency?

**TDMHSAS Response**: TDMHSAS has removed the licensure provision requiring OTPs to submit a letter of support from the local governing body of the county or city in which the facility is proposed to be located.

(G) 0940-05-42-.05

**BHG**: This section requires in part that "[e]ach 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." The effect of this rule will be to require BHG facilities to provide personal contact information of their board members, a requirement that addresses no legitimate state interest and impinges on the privacy rights of the members of the board. This rule should be modified to allow for the provision of corporate office/CEO contact information only or to require that the documents containing personal contact information for board members or other individuals are to be accessible only by the proper regulatory authorities. This same objection applies to 0940-05-42.27(7), which is additionally objectionable as redundant.

**VOLUNTEER**: It is appropriate to require each OTP to identify its governing body and to submit such information to the Department of Mental Health. It is beyond the scope of the Commissioner's authority to dictate the terms of an OTP's policy and procedure manual and to require information about the governing body be contained therein. Further, name and address information is not a policy or procedure.

**TDMHSAS Response:** TDMHSAS clarified the citation as suggested by the stakeholders. TDMHSAS disagrees with regard to the remainder of the comments. The governing body is the licensee and the name and contact information for the governing body shall be provided. TDMHSAS will make no further change to the rule as proposed in its November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. See also TDMHSAS' Response to Comment regarding 0940-05-42-.27(7).

(H) 0940-05-42-.06

**BHG**: Subsection (1) of this rule provides a list of treatment options for new patients. The language should be modified to include "long-term detoxification" among those options, in order to be consistent with other provisions of the rules (i.e., Rule 0940-05-42-.19(1)) and to ensure that patients are apprised of and screened for all potentially appropriate treatment options.

**VOLUNTEER**: This rule arbitrarily limits the medical judgment of the physician to three (3) treatment options, "opioid substitution, short-term detoxification or drug-free treatment." These limitations should be deleted and the physician should be allowed to determine the appropriate treatment plan for the patient. The statute does not confer on the Commissioner or the State Opioid Treatment Authority (SOTA) authority to make treatment decisions. No such limitations are imposed in other care settings. In fact, to impose such authority on the Commissioner or SOTA would be an unauthorized and illegal practice of medicine.

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholders and deleted the term "short-term" from 0940-05-42-.06(1). TDMHSAS clarified that certain evaluations need to be

completed prior to admission.

(I) 0940-05-42-.06(3)

**BHG**: This subsection (.06(3)) provides that "[n]o standardized routines or schedules of increases or decreases of medications may be established or used." BHG supports and follows an individualized approach to treatment for patients suffering from addiction. However, as it is currently written, this rule would prohibit best practice protocols such as starting all patients at an initial 20 mg dose (in the absence of any factors indicating the need for a higher initial dose). Just as general practitioners and over-the-counter drug labels prescribe standard doses of medications based on a person's size, OTP providers must be able to rely on that same approach when appropriate to care for their patients.

**TDMHSAS Response:** We disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(J) 0940-05-42-.06(5)

**BHG**: As written, this subsection (.06(5)) provides that an OTP may only admit and retain patients "whose known needs can be met by the facility." Construed strictly, this would prevent an OTP from treating a patient who suffers from *any* known ailment in addition to his drug dependency, which is impractical in any patient population but especially not possible or practical among those suffering from addiction. In fact, the likelihood of addicted patients presenting health problems in addition to their addiction is implicitly acknowledged by subsection (8) of this same rule. This language should be modified to provide for admission of patients "whose known needs can be met by the facility directly or indirectly through coordination of care."

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholder and amended the proposed rule to include the suggested language.

(K) 0940-05-42-.06(8)(a)

**SOS**: What is an initial plan of care?

**TDMHSAS Response:** TDMHSAS concurs that the rule was unclear as to the reference to "initial plan of care". Therefore, TDMHSAS amended the proposed rule by deleting the term "initial plan of care".

(L) 0940-05-42-.06(8)(a)7

**BHG**: This subsection 0940-05-42-.06(8)(a)(7) requires a "toxicology screen to determine *immediate* use of opioids" as part of the initial assessment to determine a patient's eligibility and need for treatment. Because "immediate" use of opioids is not necessary in order for a patient to be addicted, and many patients present in full withdrawal, this provision should be modified to make clear that evidence of "immediate" use is not a pre-requisite to eligibility for treatment. The Department's use of the term "immediate" is ambiguous and should be clarified or replaced with "recent" or some other more definite modifier.

**TDMHSAS Response:** TDMHSAS concurs that the rule was unclear with regard to toxicology screening. Therefore, TDMHSAS amended the proposed rule by deleting subsection (7).

(M) 0940-05-42-.06(8)(a)8

**BHG**: As part of the same initial assessment, this subsection (.06(8)(a)(8) requires 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." This provision is quite simply nonsensical. Drug tests indicate the presence of drugs in the body; they do not establish whether or not a person is *addicted* to those drugs. Additionally, while a drug test can reveal a patient's use of methadone within a particular time frame, it obviously cannot determine the source of that methadone, whether "from another opioid treatment program" or elsewhere. Because the toxicology screen required by subsection (8)(a)(9) will already reveal the presence of opioids and/or methadone in a patient's body, this subsection service no purpose and should be eliminated entirely as redundant, or it should be re-written to clarify what feasible additional requirement is being imposed.

**SOS**: How does a drug test determine if a person is receiving methadone for an opioid addiction from another opioid treatment program?

**TDMHSAS Response:** TDMHSAS concurs that the rule was unclear with regard to initial drug test. Therefore, TDMHSAS amended the proposed rule by deleting subsection (8).

(N) 0940-05-42-.06(8)(a)9

**BHG**: This subsection requires a "full toxicology screen" as part of the initial assessment. We ask that the subsection be modified to clarify that it is satisfied by a CLIA waived on-site (instant) drug test.

**TDMHSAS Response:** The rule requires a full toxicology screen but does not specify the need for specific lab certification. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(O) 0940-05-42-.06(9)a

**BHG**: This subsection requires that "[w]henever possible and with the 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." In order to mirror HIPAA and other applicable regulatory language, the word 'permission' in this provision should be changed to 'consent.' Furthermore, because whether or not a family member or significant other is 'non-addicted' is not immediately apparent in the absence of a thorough evaluation, the term 'non-addicted' is unenforceable and should be eliminated from this requirement.

**TDMHSAS Response:** We concur. The term "non-addicted" was removed from the proposed rules.

(P) 0940-05-42-.06(9)(c)1-4

**SOS**: Is this supposed to be referring to the SNAP (Strengths, Needs, Abilities, Preferences)?

**TDMHSAS Response:** Regardless of the specific instrument used for the psychosocial evaluation (SNAP, etc.), the provisions stated in the rule must be achieved by the psychosocial evaluation.

(Q) 0940-05-42-.06(11)

**BHG**: This subsection requires an inquiry with the Central Registry in connection with a patient's admission to an OTP, but as written it is unclear whether such inquiry must be made prior to admission or within 72 hours after admission. It should be modified or stricken entirely as redundant, as the requirement at issue is already adequately and more clearly covered by Rule 0940-05-42-.21(3).

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholder's comment and clarified that the OTP must notify the SOTA within 72 hours of the admittance of a new patient.

(R) 0940-05-42-.06(13)(b)

**BHG**: This provision requires that a discharge and aftercare plan for patients who complete their course of treatment '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.' The reference to a long-term detoxification option offered as an alternative to admission is confusing in the context of documentation related to discharge of a patient who has already completed a course of treatment. This provision should be modified to clarify what, if any, additional discussion of long-term detoxification is required by this subsection, and to correct the apparent typographical error in the first word of the subsection.

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholder's comment.

(S) 0940-05-42-.07(2)(a)9

**AMERICAN ASSOCIATION FOR THE TREATMENT OF OPIOID DEPENDENCE, INC. (AATOD)**: The regulations require that all patients be screened through a Central Registry System before the first dose of methadone can be dispensed and the patient is formally admitted to treatment. What protections will be guaranteed as OTPs are registering patients with such systems? States that have such systems in place have gone to considerable effort to ensure that patient confidentiality is not compromise in any way that the Central Registry Services are completely compliant with Federal Confidentiality Regulations 42 CFR 2.

**BHG**: This rule requires that, prior to development of an Individualized Program Plan, a provider must verify that a prospective adult patient has been dependent on opioids for at least two years. The effect of this rule is to require OTPs to deny treatment to patient who cannot prove that they have been addicted for two years or more. This requirement exceeds the applicable federal guideline, which requires only one year of addiction prior to admission, which can be waived in some circumstances. 42 CFR Section 8.12(e); CSAT Guidelines for the Accreditation of Opioid Treatment Programs (draft), http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pef 2(f)(4) at 12 (attached as Exhibit G). It creates an artificial barrier to treatment for individuals who are without doubt in need of it, which is all the more arbitrary in light of the Department's recognition of the 'drug epidemic co9nfronting our state.' This rule will force OTPs to turn away people who are suffering from addiction and have taken the step of voluntarily seeking treatment for which they are willing to pay with no assistance from the State. Preventing people from receiving medically necessary treatment for their illness serves only to prolong the negative consequences of drug addiction that the state seeks to address. This proposal is clearly against the best interests of the patient, is arbitrary and irrational, and should be eliminated from the rule. Nor does this proposed rule serve the public interest and, in fact, perpetuates activities that increase both economic and non-economic costs to society.

Perhaps this is best illustrated by the following description of a patient from one of BHG's managers:

"After working in OMT for over 11 years, I have witnessed many patient who took several years to finally achieve a negative urine screen. I remember one male patient in particular who became very discouraged because he was consistently positive for opiates – heroin in his case. He insisted that he was 'cutting down' but unfortunately his urine screens did not indicate that. His counselor recommended that he keep a 'using journal.' At his highest use, he reported using heroin every couple of hours. As he began documenting his use, he saw that he decrease to a couple of times a day, to once a day to a couple of days a week. Even that amount of use would result in a positive urine screen monthly, but he was able to see his own progress. He was finally able to go for longer and longer periods without using and began getting negative urine screens and finally earned take home privileges. It took several years for this patient to get that first negative urine screen; yet after he did, he remained drug free until a successful discharge from the program."

**CONTINUUM**: Neither evidence nor logic supports such a criterion for "eligibility." To demand prior treatment "failure" before admission to what is widely acknowledged to be the "gold standard" care for opioid dependence is no more justified than insisting that a deeply depressed patient demonstrate two prior unsuccessful attempts at suicide before permitting the prescription of anti-depressant medication.

**NATIONAL ALLIANCE FOR MEDICATION ASSISTED RECOVERY, INC. (NAMA)**: Requiring admissions to have two documented treatment failures. It can take time and in the meantime an individual needing treatment is made to wait. It has been our experience that when individuals seeking services are denied or delayed services, they do not return. Some will go to another state if they do not have the required documentation and have the funds. Those without the funds will continue their addiction because they have been denied the most effective treatment for their opiate addiction. Neither of these options is positive for the state.

**MIDSOUTH**: Requires 2 Years addiction – formerly 1 year. DSM criteria specify 1 year, does not conform to standards of care, will limit access to care for those with the disease of addiction.

**VOLUNTEER**: The requirement to verify the patient's addiction for a period of two (2) years is arbitrary, not based on medical standards or protocol and should be deleted.

**TDMHSAS Response:** After consideration, TDMHSAS made a change to this section as suggested by the stakeholders. The rule now requires either two years of addiction or one year of addiction and one unsuccessful documented attempt at clinical treatment.

(T) 0940-05-42-.07(2)(a)10

**SOS**: The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) states the criteria for dependency "must occur at any time in the same 12-month period". The DSM-IV-TR is the manual recognized and used universally for diagnosing individuals with mental health and substance disorders. It is considered standard of care to use DSM criteria for diagnoses.
The Federal Regulations 42 CFR Part 8. *8.12 Federal opioid treatment standards*
*(e) Patient admission criteria. – (1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment.* Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005. Refers to the Federal regulations and states "opioid pharmacotherapy is appropriate for persons who currently are addicted to an opioid drug and became addicted at least 1 year before admission".

We are required to be accredited. Our accreditation body is the Commission of Accreditation of Rehabilitation Facilities (CARF). In the CARF Standards Manual 2010, it states
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5. The opioid treatment program has admission criteria that are consistent with those outlined in the definition of opioid dependence in *Diagnostic and Statistical Manual of Mental Disorders.*

Our concern is if we refuse admission to someone, that person then overdoses and dies, or hurts someone else; we could be sued for not following standard of care. We feel that this regulation will open our facilities to more liability.

**TDMHSAS Response:** After consideration, TDMHSAS revised the language originally proposed in 0940-05-42-.07(2)(a)(10) and deleted and combined some, but not all, of those requirements with that proposed in 0940-05-42-.07(2)(a)(9). As amended, 0940-05-42-.07(2)(a)(9) states: "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 or verification of one year of opioid dependence and one documented unsuccessful attempt at clinical treatment. If clinically appropriate, the program physician may waive these dependency and detoxification requirements for service recipients released from penal institutions (within 6 months after release), for pregnant service recipients with a verified pregnancy and for previously treated service recipients."

(U) 0940-05-42-.07(2)(a)11

**BHG**: The proposed rule as published and as distributed at the January 5 hearing reads: "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." There was discussion at the hearing about the apparent typographical error in this provision, in that two attempts at detoxification in a 24-hour period is a factual impossibility. However even assuming the language is corrected to specify some other period of time, the effect of this rule is to deny treatment to patients who cannot demonstrate repeated failures at other forms of treatment that have scientifically proven to be less effective. One major problem with this requirement is that the State does not provide an facilities or support for those attempts at detoxification that the Department is mandating, which is fundamentally unfair to the patient. But perhaps even more significant is the fact that there is absolutely no logical, medical, scientific or other sound rationale for requiring patients to fail at other treatments before allowing them access to the most effective treatment ever utilized for their illness. The State should not dictate the use of a treatment known to be relatively ineffective for an illness before permitting the use of the most effective treatment, and it does not do so in any other circumstance. This 'fail-first' requirement increases the likelihood of harm to patients and should be eliminated.

**MIDSOUTH**: "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. "The speed of getting responses from other treatment centers, if we can obtain correct contact information, and if they still exist, is not under OTP's control. Many patients do not have insurance, cannot afford the money or the time away from their job and family to attend other treatment programs. Many areas of the state do not have other appropriate treatment facilities

available, and many low or no cost facilities such as Grace House or Serenity House do not have openings for patients. For these and other reasons, this will deny access to care.

**SOS**: Again this is not a standard requirement in the field. There are no such requirements in the Federal Regulations. Ethics and morality dictate that treatment providers refer a person to another treatment provider, if the person is not eligible or appropriate for services. With the limited resources in Tennessee for persons with no insurance, which describes the majority of our clients/perspective clients, referrals for these individuals will be difficult at best. Again if we refuse admission based on the proposed regulation, which is not standard of care, and something happens to the perspective client. Would we not, as well as the State, be held liable for not adhering to standard of care?
"Treatment needs to be readily available. Because drug-addicted individuals may be uncertain about entering treatment, taking advantage of available services the moment people are ready for treatment is critical. Potential patients can be lost if treatment is not immediately available or readily accessible. As with other chronic diseases, the earlier treatment is offered in the disease process, the greater the likelihood of positive outcomes". National Institute on Drug Abuse (NIDA)
Requiring two previous unsuccessful attempts in a 24-month period is going to limit greatly the access to treatment for many people. Research has shown that once a person relapses, after a treatment episode, the time period to seek treatment again is greater than two years. This is even truer for a person, who has relapsed twice, after treatment. This regulation will deny treatment to many people, who are in desperate need.

**VOLUNTEER**: The required verification of prior unsuccessful attempts at detoxification or drug-free treatment is arbitrary and should be deleted. Such requirement, by rule, imposes a medical judgment regarding appropriate treatment options which is beyond the scope of the Commissioner's authority.

**TDMHSAS Response:** TDMHSAS has deleted 0940-05-42-.07(2)(a)(11). See TDMHSAS's Response to Comment regarding 0940-05-42-.07(2)(a)(9) and (10) above. TDMHSAS feels that the comment for (T) was handled in the changes made to 0940-05-42-07(2)(a)(9).

(V) 0940-05-42-.07(3)

**Continuum**: This is – appropriately – required prior to beginning treatment and for release of confidential patient information under almost any circumstances. It is most strongly urged that informed consent, in writing, *also* be obligatory prior to initiation of voluntary *discharge*. The provider should be obligated to inform the patient of the consistent evidence that following detoxification (for any reason) relapse to illicit drug use is the rule rather than the exception, and that such relapse is associated with a very marked increase in likelihood of fatal overdose. Indeed, providing this information to applicants and patients should be mandatory *at the time of admission* to treatment as well, and mentioned explicitly in the "consent to treatment."

**TDMHSAS Response:** We disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(W) 0940-05-42-.07(10)

**SOS**: We have policies and procedures that are in place (and in writing) that covers all of these situations. Is this "written report" something else? If so, why?

**TDMHSAS Response:** After consideration, TDMHSAS deleted the language "[a] written report" and inserted the language "[d]ocumentation that the service recipient was informed about".

(X) 0940-05-42-.08(3)

**VOLUNTEER**: The requirement to verify that the service recipient is not receiving similar services from another OTP within a one hundred and twenty-five (125) mile radius is arbitrary and overly burdensome, and should this be deleted. The cost of compliance with this single requirement would be significant and would add no real value to patient care.

**TDMHSAS Response:** We agree. TDMHSAS changed the radius from 125 miles to 75 miles.

(Y) 0940-05-42-.10(2)

**VOLUNTEER**: Requiring service recipients to be treated as new patients when they transfer to a new OTP, or re-enroll is an arbitrary burden of unnecessary paperwork. This requirement should be deleted or revised into a more reasonable requirement based on a valid regulatory purpose.

**TDMHSAS Response:** TDMHSAS disagrees that requiring service recipients to be treated as new patients when transferring to a new OTP or re-enrolled is a burden of unnecessary paperwork. TDMHSAS feels that such a service recipient should be treated as a new service recipient so that the new facility can gain the requisite knowledge about the terminated service recipient. A terminated service recipient should not be instantly eligible for take-home doses when they move to a new facility. Therefore, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(Z) Rule 0940-05-42-.12(3)b

**MIDSOUTH**: "Drug use is not necessarily a reason for discharge", conflicts with .18(9)(d), which requires discharge after a 4th positive UDS. Patients must be treated on an individualized basis, and treatment planning should be the purview of the medical provider and treatment team.

**TDMHSAS Response:** After consideration, TDMHSAS made a revision to reflect the need to treat service recipients on an individualized basis. As amended, "[t]he treatment team shall consider each service recipient's condition and address the situation from an individualized clinical perspective.

(AA) 0940-05-42-.14(3)(a-d)

**MIDSOUTH**: 2 times per week counseling for 90 days is a significant increase, and may pose a hardship for patients who are employed, or have family responsibilities. Counseling is already conducted according to the current regulations, and is conducted more frequently on an individualized basis.

**SOS**: Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005. Page 88 "Ideally, service intensity should depend on the level of care required to help patients achieve and maintain successful treatment outcomes".
Page 125 "Usually, individual sessions during the acute phase are more intensive than those that follow, although individual needs should dictate the frequency and duration of counseling".
Comment also referred reader to pages 88 and 125 of TIP 43.

**TDMHSAS Response:** TDMHSAS recognized that this rule needed clarification. Therefore, TDMHSAS revised the rule to state as follows:

(a) During the first 30 days of treatment, counseling sessions shall take place twice a week.
(b) During the next 90 days of treatment (day 31-120), counseling sessions shall take place at least once a week.
(c) During the following 90 days of treatment (day 121-210), counseling sessions shall take place at least two times per month.
(d) For subsequent 90 day periods of treatment (day 211 forward), counseling sessions 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.

(BB) 0940-05-42-.16(1)(a)(1)

**MIDSOUTH**: "Pharmacy". OTP's do not have pharmacies; they have dispensaries for 1-2 medicines. See comments on section .30(3)9.

**TDMHSAS Response:** TDMHSAS has removed the "pharmacy" provision.

(CC) 0940-05-42-.16(1)(a)(3)

**VOLUNTEER**: The Commissioner has authority to regulate mental health facilities. He/she does not have authority to direct the activities of physicians and pharmacists. Thus, the Commissioner may not specify how physicians and pharmacists transmit and respond to verbal orders. This provision is void and should be deleted.

**TDMHSAS Response:** TDMHSAS has removed the language regarding the pharmacy requirements. Additionally, the subject of this comment was already contemplated in existing OTP rule (0940-05-42-.06).

(DD) 0940-05-42-.16(1)(a)(5)

**BHG**: The first proposed rule (0940-05-42-.16(1)(a)5) refers to a dosage's being "dispensed by the pharmacist," and the second (0940-05-42-.30(3)(g)) provides than an "OTP shall provide on-site pharmacist services for the dispensing of opioid drugs." this rule violates applicable State law governing the practices of both physicians and pharmacists and would unlawfully discriminate against physicians operating in OTPs. Rules governing the practice of pharmacy are promulgated by the Tennessee Board of Pharmacy and are beyond the scope of this Department. *See* Tenn. Code Ann. § 63-10-304. The Board of Pharmacy's rules provides provide that "[a] pharmacist may compound and dispense prescription drugs and devices and related materials *only in a pharmacy practice site which is duly licensed by the board [of pharmacy]* and which operates in compliance with Tennessee and federal laws and rules governing the practice of pharmacy." Tenn. Comp. R. & Regs. 1140-03-.02 (emphasis added). Because OTPs are not licensed pharmacies, it would constitute a violation of State law for a pharmacist to be employed to dispense medication on-site. Rather, OTPs are able to deliver medication to patients under the legal authority of all physicians to dispense medication as part of their practice, either personally or through a "licensed supervisee pursuant to appropriate protocols or medical orders." *See* Tenn. Comp. R & Regs. 0880-02-.14. The Department's proposal to carve out an exception to that legal authority for physicians practicing in OTPs is arbitrary, exceeds its authority and violates the constitutional right to equal protection of the law.

**SOS**: This regulation is unclear. If additional milligrams are ordered by the physician on the first day, nurses can legally administer the medication. All medications are administered in the clinic on the first day, there is no take home medication given.

**VOLUNTEER**: The Commissioner does not have authority to dictate treatment instructions to a pharmacist. This provision is arbitrary and should be deleted.

**TDMHSAS Response:** TDMHSAS recognized the need for clarity in this rule. Therefore, TDMHSAS made revisions (changed the word "dispense" to "administer" to clarify that medication does not leave with the patient on the first day of treatment, and took out the provision requiring a pharmacist). However, TDMHSAS respectfully disagrees that these provisions violate state law.

(EE) Rules No. 0940-05-42-.16(1)(a)8, (1)(a)9, (1)(a)10 and (1)(i)1

**AATOD**: How will the SOTA make determinations with regard to the prescribing of dosages of 100 mgs or greater? What are the special medical qualifications of the SOTA in order to make the appropriate dosage evaluations in view of the fact that the Tennessee regulations are so specific with regard to the expertise of physicians or other licensed service providers? One would assume that the SOTA has equal or greater medical knowledge in making such an assessment. If not, AATOD suggested that this requirement be removed from the regulatory proposal.

**BHG**: Each of these provisions, both old and new, interjects the State Opioid Treatment Authority ("SOTA") into individual medical treatment decisions that are the province of patients and their healthcare providers, and exceed the scope of the SOTA's authority and expertise. The rules define the SOTA simply as "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." Rule 0940-05-42-.01. There is no requirement that the SOTA be a licensed healthcare provider in Tennessee. Accordingly, having the SOTA in a position to make decisions with respect to the dosage or quantity of medication ordered by a lawful prescriber for a patient would not only unreasonably intrude upon the provider-patient relationship and unnecessarily delay care, but could constitute the unlicensed practice of medicine or professional nursing. *See* Tenn. Code Ann. § 63-6-204(a)(1) (defining the practice of medicine to include treating or prescribing for any physical ailment of another); 63-7-123 (authorizing certified nurse practitioners to prescribe, order and issue medication). Another problem with this proposal is that it embodies a presumption that higher dosage levels of methadone are somehow suspect and inherently to be avoided or limited. Such a presumption is arbitrary and is contradicted by the available data. The CIDE has addressed this issue:

Most patients require a dose of 60-120 mg/day to achieve optimum
therapeutic effects of methadone. Compared to those on lower doses, patients on higher doses are shown to stay in treatment longer, use less heroin and other drugs, and have lower incidence of HIV infection. Some patients need even higher doses for fully effective treatment. Studies of methadone, effectiveness have shown a dose-response relationship, with higher doses more effective in reducing heroin use, helping patients stay in treatment, and reducing criminal activity.

Centers for Disease Control and Prevention – IDU HIV Prevention, Methadone Maintenance Treatment, February 2002, *available at* http://www.cdc.gov/idu/facts/methadonefin.pdf (Exhibit H); see also Eric C. Donny, Susan M. Brasser, et al, *Methadone doses of 100 mg or greater are more effective than lower doses at suppressing heroin self-administration in opioid –dependent volunteers*, 100 Addiction 1496-1509 (2005) (attached as Exhibit T). Accordingly, national guidelines expressly provide that "[t]here are no limits on the duration or the dosage level of medication, unless clinically indicated." CSAT Guidelines for the Accreditation of Opioid Treatment Programs (Draft), http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pdf (2)(m)(2)(d) at 18 (Exhibit G). Moreover these rules unfairly target prescribers practicing in OTPs for additional and unwarranted state oversight of their orders, to which prescribers –even prescribers of methadone – and their patients in other settings are not subjected. This requirement is arbitrary and illegal.

**CONTINUUM**: See comments above regarding shifting the responsibility for critical medical decisions, including those that determine dosage, from the treating physician to government appointees whose credentials and experience are unspecified, and who have never seen the patient (and who will probably refuse to acknowledge liability if their decisions have serious adverse consequences). In addition, there appears to be a misunderstanding regarding the significance of "peak and trough" blood concentrations of methadone; such measurements are not utilized to justify need for higher doses, but rather to identify the possibility that *divided* dosages might be more efficacious (though even if split-dosing were found to be indicated, it would probably be precluded by regulatory restrictions on dispensing of "take-home" doses).

**NAMA**: Reporting dose to the state. The federal government had a similar requirement and found that it was counterproductive to quality treatment. This regulation raises a number of issues:
(1) it sends a message to clinicians that doses over 100 mgs are not good;
(2) most clinicians will not want to report doses over 100 mgs to the state and therefore patients needing a dose over 100 mgs will be left with three decisions:
(a) remain in withdrawal half the day resulting in reduced health;
(b) purchase methadone illegally; or
(c) purchase other narcotics illegally;
(3) quality clinicians begin to leave the state treatment system because they are being forced to practice bad medicine; and
(4) patients will leave the state for treatment elsewhere because they cannot get an adequate dose.

Over time, reporting of dose results in poor quality treatment and low dose clinics. Pain patients are prescribed doses three times the amount of opiate treatment programs and yet only opiate treatment clinicians are required to report doses.

**SOS**: The current State Opioid Treatment Authority (SOTA) is a pharmacist. This regulation allows the SOTA to practice medicine without a medical license. The SOTA is going to approve a dose of medication for a person that he/she has not ever laid eyes on, has not examined, and has no license to do so. Does this not open the State up for liability? If a person's dose is approved by the SOTA, and the person overdoses and dies, what is the responsibility of the SOTA?
The Federal Regulations puts no cap on the dosage of methadone. We are not opposed to there being a cap and guidelines, but the program physician should have final approval.

**VOLUNTEER**: The statute does not confer on the Commissioner or the SOTA authority to make treatment decisions. Dictating medication dosage is tantamount to dictating treatment decisions and medical judgment by rule. This exercise of such administrative authority is void and should be deleted. The Commissioner does not have authority to confer upon the SOTA authority to make medical judgments. Treatment decisions should be made by physicians. This rule is arbitrary, not authorized by law and should be completely rewritten or deleted.

**TDMHSAS Response:** With regard to (1)(a)(8), we disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. This requirement is in the existing OTP rule (0940-05-42-.11) - written notification to the SOTA is required for dose

increases greater than 100 mgs.

**TDMHSAS Response:** With regard to (1)(a)(9), we disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. This requirement is in the existing OTP rule (0940-05-42-.11) - no dose of methadone in excess of 120 mgs may be ordered or administered without the prior approval of the SOTA.

**TDMHSAS Response:** With regard to (1)(a)(10), we agree. TDMHSAS has deleted this section.

**TDMHSAS Response:** With regard to (1)(i)(1), we disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. The 14 day provision prevents abuse by a patient guest dosing for an extended period of time without receiving the required non-medication treatment (i.e.-counseling or drug screens).

(FF) 0940-05-42-.16(1)(c)

**BHG**: This subsection requires that "[a]ll medications shall be stored in a locked safe when not being administered or self- administered." This provision should be modified to account for the fact that OTP staff must be able to unlock and access the medication supply for other purposes besides administering medications, including stocking, counting and otherwise physically managing the medication supply.

**TDMHSAS Response:** We disagree in part. The strictness of this provision is designed to prevent diversion of these medications. However, TDMHSAS recognized the need for clarification: TDMHSAS modified the rule so that the supply of medication could be managed without staff violation of the rule.

(GG) 0940-05-42-.16(1)(g)(1)

**BHG**: This requirement includes terminology, such as "refill instructions" and "prescription order data" that is not appropriate for OTPs and appears geared toward regulation of pharmacies. For the reasons explained above in connection with Rules 0940-05-42-.16(1)(a)5 and 0940-05-42-.30(3)(g), this type of regulation is not appropriate for OTPs. Additionally, this subsection requires prescribers using a computerized system for medication or dosing orders to certify that such information is correct *daily* by either printing and signing each day's medical or prescription data or by maintaining a log attesting that each day's dosing information is correct. This rule as written is both unclear and unduly burdensome. Printing all daily data for signature would defeat the cost and space-saving purpose of electronic record-keeping. Moreover, even the proposed rules do not require prescribers to be on-site daily, so this rule would add a burden that even the Department does not believe is necessary to provide optimal care for OTP patients. This rule is unnecessary and arbitrary. At a minimum, the rule should be modified to clarify that the prescriber is only required to attest to the accuracy of his or her own orders as recorded, and not to the actual dosing that is carried out and recorded by another staff according to those orders. In fact, OTPs are required by 21 CFR Section 1304.24 to maintain a dispensing log detailing all medication activity conducted (dispensed and administered) that indicates which specific licensed practitioner actually dispensed or administered the medication – either by signature or by electronic record that can be reproduced if requested.

**VOLUNTEER**: The Commissioner has authority to regulate mental health facilities. He/she has no authority over prescribers or the prescribing of medication. Thus, these provisions are overly broad and exceed the authority of the Commissioner and are, therefore, void and should be deleted.

**TDMHSAS Response:** After consideration, TDMHSAS agrees with the stakeholders' comments and has removed section (g)(1) from the proposed rules.

(HH) 0940-05-42-.16(1)(h)

**MIDSOUTH**: Checking PMP at random, about 1-2 times per year is reasonable, requiring more often is not. Over the past 3 years or so, I have been checking it on a random basis, and it can very occasionally be a therapeutic tool.

**TDMHSAS Response:** We concur. TDMHSAS has revised this section of the proposed rules to require the Facility to check the PMP database upon admission of the service recipient, at least every six months to determine if controlled substances other than methadone are being prescribed for the service recipient, and

thereafter as clinically indicated. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred.

(II) 0940-05-42-.16(1)(i)1-3

**BHG**: This rule (.16(1)(i)(2)) provides that patients are ineligible for guest doses treatment for the first thirty days of treatment. The effect of this rule is that newly enrolled patients will be prohibited from traveling away from their home facilities for more than a day. In essence, the rule penalizes patients for beginning treatment for their addiction, which is a decision that both the State and healthcare providers should, instead, be supporting and encouraging. While likely intended to ensure safety, this requirement is not supported by any factual or medical rationale and should be modified to provide OTP Medical Directors with the ability to approve guest dosing privileges to newly enrolled patients with a documented justification for doing so.

**VOLUNTEER**: The administration of medication to a patient is a medical decision requiring medical expertise and judgment. The statute does not confer upon the Commissioner or the SOT authority to make medical judgments for patients through the regulatory process. Thus, this rule is void and should be deleted.

**TDMHSAS Response:** We disagree. TDMHSAS feels that the proposed rule, as written, will help ensure that service recipients are clinically stable before participation in guest dosing. OTPs can request that the SOTA approve guest dosing for service recipients enrolled at the home clinic for less than thirty days. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(JJ) 0940-05-42-.17

**BHG**: Subsection (2) of this rule may be read to require that OTPs revoke a patient's take-home privileges any time a patient fails to report information about prescriptions from outside physicians. This type of punitive measure is often not warranted by the circumstances and should be considered on an individualized basis rather than dictated without exception by the Department. National guidelines recognize that take-home privileges are a key component of OTP treatment plans and should be left within sound professional judgment of the patient's physician and treatment team staff in accordance with the criteria set forth in the applicable federal regulation, 42 CFR 8.12(h):

Providing medication for unsupervised use is a reflection of the physician's judgment and staff's assessment of a patient's behavior while in treatment. Time in treatment is also an important factor. Take-home medication is a valuable therapeutic tool and is part of an individualized treatment plan. Program policies that do not permit take-homes for any patients are unacceptable as these policies would preclude individualized patient care. Take-home medication often becomes a critical issue with patients who are deciding whether to enter and remain in treatment. CSAT Guidelines for the Accreditation of Opioid Treatment Programs, http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pdf 2(v)(1)(a) at 32 (Exhibit G). This rule should be modified to clarify that loss of take-home privileges is one option to be included in the OTP's guidelines, but that it is not mandatory in every instance of failure to report.

**TDMHSAS Response:** We disagree. TDMHSAS would like to clarify that that the section concerning the failure to report prescriptions from outside physicians only requires that the loss of take-home privileges be included in the program's procedures for dealing with the failure to report. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(KK) 0940-05-42-.18(2)(a) and (b)

**BHG**: This subsection provides that "[d]rug screen procedures shall be individualized", then proceeds to mandate a schedule of drug screens, while the remainder of section .18 dictates both the substance and the OTP responses to the screens. National guidelines provide that after admission, "the frequency of toxicological testing is determined by the clinical appropriateness for each individual patient and related to the stage of treatment." *Id.* 1(s)(8) at 26. This subsection should be amended to clarify what is meant by "individualized" drug screening procedures, as the proposed rules are internally inconsistent on this point.

**SOS**: (2)(a) Requires **weekly** random drug screens for new recipients during the first 30 days of treatment. (2)(b) Requires new recipients be tested upon admission and at approximately **14 days** of treatment. What is the requirement here, weekly or at 14 days? This needs clarification.

**VOLUNTEER**: The language in (a) and (b) are in conflict. VTC recommends retaining the language in (b) and deleting the language in (a).

**TDMHSAS Response:** We concur. TDMHSAS has revised this section of the proposed rules to state as follows: "Drug screening procedures shall be individualized and shall include at least weekly random drug screens for newly admitted service recipients during the first 30 days of treatment and at least monthly thereafter."

(LL) 0940-05-42-.18(6)

**BHG**: Subsection (c) specifically requires that the screen for benzodiazepines include detection of diazepam, clonazepam, alprazolam and lorazepam. A test for clonazepam is not included in the typical benzodiazepine panel, and its addition would be both costly and unnecessary in the vast majority of cases. Clonazepam is used far less frequently in our patient population than other drugs for which we routinely screen, and OTP practitioners are in the better position to determine when screening for this drug is necessary in light of a patient's drug abuse history and other indicators than is the Department National guidelines provide that "Drug testing should be determined by community drug use patterns and individual medical indications." *Id.* 2(s)(4) at 26. This requirement should be eliminated in favor of the individualized approach to care that underlies the provider-patient relationship and the majority of the proposed rules at issue.

**VOLUNTEER**: This list of drug screens that shall be performed is overly broad and arbitrary. Discretion should be left to the treatment professional working with the service recipient. Further, the added expense for the costly new screens may not yield any benefit to the patient. This language should be deleted.

**TDMHSAS Response:** After reviewing the comments to this section, TDMHSAS made a revision to provide that each sample collected shall be screened to include, but not be limited to, opioids including synthetics and the broad category of benzodiazepines.

(MM) 0940-05-42-.18(7)

**BHG**: This subsection requires that "[c]ollection 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." This provision should be modified to clarify exactly what is required. Given the volume of drug screens required by OTPs, it is impracticable to maintain a urine sample for every on-site (instant) test conducted, and the expense associated with attempting to do so would increase operating costs and patient fees.

**TDMHSAS Response:** We agree. TDMHSAS has revised this section of the proposed rules to follow the existing OTP rule (0940-05-42-.06). As amended, this section of the proposed rules states: "Collection and testing shall be done in a manner that assures that urine collected from service recipients is unadulterated. Such collection and testing may include random direct observation conducted professionally, ethically and in a manner which respects service recipients' privacy."

(NN) 0940-05-42-.18(9)

**AATOD**: According to AATOD, the provisions in this section are generally reasonable until you get to the section of responding to positive drug test results. The regulations set forth the idea that the fourth positive drug test results within a six month period of time would require the patient to be immediately discharged. This recommendation runs counter to federal Treatment Improvement Protocols on this topic as published by SAMHSA in 2005 (TIP #43), Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. AATOD goes on to quote the following from Chapter 9 within the TIP, Drug Testing as a Tool: "For patients who continue to abuse drugs or test negative for treatment medication, the consensus panel recommends that OTPs institute more frequent, random tests. Increased testing provides greater protection to patients vulnerable to relapse because only short periods pass before a therapeutic intervention can be initiated. However, as emphasized throughout this chapter, programs should avoid making treatment decisions affecting patients' lives that are based solely on drug test reports." The chapter goes on to state that "OTP directors should ensure that results are not used to force patients out of treatment and that no treatment decisions are based on a single test result." Basically, the federal recommended guidelines underscore the fact that OTPs should use the drug testing results clinically and not punitively. Such drug tests results should be used as a guidance to intervene more frequently with the patient and to make appropriate therapeutic dosage determinations. According to AATOD, in

view of the long-term literature with regard to patient relapse once treatment has ended (greater than 80% of this patient population), this requirement should be eliminated.

**BHG**: This subsection requires that patients with positive drug test results participate in weekly counseling meetings "with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules." This provision should be amended to conform to the qualifications for counselors provided in Rule 0940-05-42-.30(4)(g). But far more importantly, this subsection goes on to mandate increasingly proscriptive treatment for patients suffering from relapse of their illness, including mandatory discharge upon a fourth positive drug screen. this punitive approach to a patient's illness is contrary to the standard of care and evidences a fundamental misunderstanding of addiction and its treatment. National guidelines provide that "clinical decisions about take home or discharge are not based on toxicology test reports solely." *Id.* 2(s)(9) at 26. In its Treatment Improvement Protocols, the National Center for Substance Abuse Treatment counsels that numerous studies indicate that involuntary discharge leads to serious negative consequences for patients:

[P]atients who were discharge from medical maintenance or long-term detoxification treatment had consistently worse outcomes than patients who remained in treatment. Zanis and Woody (1998) found substantial increases in death rates among those involuntarily discharged for continued drug use. The consensus panel strongly recommends that involuntary discharge be avoided if possible, especially when patients would like to remain in and might benefit from [methadone-assisted treatment]. Center for Substance Abuse treatment, TIP 43 Chapter 8, Approaches to Providing Comprehensive Care and Maximizing patient Retention. SAMHSA/CSAT Treatment Improvement Protocols. Rockville (MD): Substance Abuse and Mental Health Services Administration (US): 1993, *available at* http://www.ncbi.nlm.nih.gov/books/nbk25994/ (attached as Exhibit U). The panel particularly cautions against discharge for continued substance abuse:

The consensus panel recommends that patients receive every chance to continue treatment and that treatment last as long as it is effective. Program effectiveness may be determined by comparing a patient's substance use and overall adjustment at admission with his or her current status. . . . Studies have shown significant improvement in patients even when complete abstinence was not achieved (e.g., Strain et al. 1999); therefore, caution should be used in judging patients' progress in MAT based solely on drug tests.

*Id.* Similarly, the CDC has advised that "[r]ealistic expectations of treatment reflect the understanding that recovery is a day-to-day process with occasional relapses." Centers for Disease Control and Prevention – IDU HIV Prevention. Methadone Maintenance Treatment, February 2002, *available at* http://www.cdc.gov/idu/facts/methadonefin.pdf (Exhibit H). National guidelines, therefore, provide that "It is not uncommon for a patient to relapse. there is both an individual and public health advantage to maintaining a patient on medication, even when psycho-social treatment may not be yielding optimum results," and that "A major goal for programs is to retain patients for as long as they can benefit from treatment and express a desire to continue it." CSAT Guidelines for the Accreditation of Opioid Treatment Programs (Draft), http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pdf 2(m)(1) at 18 and 2(n) at 19 (Exhibit G). Contrary to the advice of these experts and voluminous scientific studies underlying their guidance, the Department would have OTPs arbitrarily discharge upon a fourth positive drug testing six months a patient whose pre-treatment drug use may have been chronic and debilitating. And significantly, the Department would do so with the full knowledge that the patient as *no other alternative* for treatment in this State.

Drug addiction, by its very nature, is a "chronic, relapsing disease of the brain," and "[r]elapses are more the norm." Alan I. Leshner, *Addiction Is a Brain Disease, and It Matters*, 1 Focus 190-193 (2003) (reprinted with permissionfrom278 Science 45-47 (1997) (attached as Exhibit V). Accordingly, as with other chronic illnesses such as diabetes and chronic hypertension, "a reasonable standard for treatment success [is] the management of the illness, not a cure." *Id.* OTPs help patients suffering from addiction manage their illness by addressing the causes and appropriate treatments for relapse on an individualized case-by-case basis, just as an endocrinologist would treat a diabetic patient with blood sugar spikes despite insulin therapy or a cardiologist would treat a hypertensive patient with blood pressure spikes despite antihypertensive medication therapy. Requiring OTPs effectively to punish their patients and even discontinue treatment based on their exhibiting a symptom of their disease is the equivalent of requiring a physician to discontinue insulin treatment to a diabetic patient. The results can be deadly. SAMHSA reports that "research shows that patients in whom methadone therapy is discontinued have mortality rates three to four times higher than patients in whom methadone therapy is continued." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment (2004)(Exhibit A). The State does not enforce this "cure or give up" approach to any other illness or healthcare provider in the State. Requiring these proscriptive responses

regardless of individual needs and circumstances would be disastrous to patients, arbitrary and a violation of the rights of both patients and providers.

**CONTINUUM**: This provision is inappropriate and counter-intuitive, and another example of seeking to impose by *fiat* clinical decisions that should be left to healthcare providers. Patients whose laboratory and/or clinical findings confirm the diagnosis (and the severity!) of the condition being treated are those who obviously most *need* the treatment being provided. This provision would be analogous to requiring discontinuation of anti-tuberculosis treatment for patients who suffer persistent hemoptysis, or refusing further insulin to diabetics whose blood sugar for whatever reason(s) – including patient non-compliance with a prescribed diet regimen – repeatedly exceeds a stipulated threshold.

**NAMA**: Requiring patients to lose their home privileges for a single positive urine. Drug screens are not perfect and false positives do exist and in numbers enough for the federal government to require a warning at the first positive drug screen with no loss of privilege. It was also decided that this would be using the medication as a behavioral tool without first taking some sort of intervention in case of a relapse. A working patient that has a false positive drug screen could be placed in a stressful position having to go daily. We believe that guidelines can be made but not regulated for such decisions.

**MIDSOUTH**: In total [this section] is an example of a possible method of "upping the ante" or increasing consequences for patients who relapse repeatedly. If it were a law they were breaking, like speeding, having a predetermined sequence of penalties might be fair. However, we are dealing with persons who have a disease that cannot always be controlled by rules or willpower. Addiction treatment professionals will agree that relapse is part of the natural history of addiction. We agree that guidelines for helping motivate addicts to not use their substance of choice are helpful. We also agree that sometimes discharge of a patient is helpful or necessary. We do not agree, however, that mandated discharge of those we are trying to serve is always therapeutic. We must remember that the treatment philosophy of opiate replacement therapy is reduction of harm, and "ongoing multi-drug use is not necessarily a reason for discharge."

**SOS**: 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 months 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.

Tennessee is not recognizing Dependency as a chronic, recurring disease. This regulation goes against what years of research recommend for the treatment of Opioid Dependency. The State is redefining what Substance Dependency is, and treatment.

Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005.

On page 154, "programs should avoid making treatment decisions affecting patients' lives that are based solely on drug test reports".

Page 155, "OTP directors should ensure that results are not used to force patients out of treatment and that no treatment decisions are based on a single test result". "OTPs should use drug test results clinically – not punitively – for guidance, treatment planning, and dosage determination".

Page 156, "Again, the consensus panel emphasizes that results should be used to explore different treatment interventions and treatment plans that will reduce and eliminate substance use and improve treatment compliance".

Page 122 "Studies of patients who left MAT prematurely have determined that length of retention was the most important indicator of treatment outcomes. Patients who stayed in treatment a year or longer abused substances less and were more likely to engage in constructive activities and avoid criminal involvement than those who left treatment earlier".

Page 139 "In their review of numerous studies, Magura and Rosenblum (2001) concluded that patients who were discharged from medical maintenance or long-term detoxification treatment had consistently worse outcomes than patients who remained in treatment.

"Zanis and Woody (1998) found substantial increases in death rates among those involuntarily discharged for continued drug use".

"The consensus panel recommends that patients receive every chance to continue treatment and that treatment last as long as it is effective".

"Studies have shown significant improvement in patients even when complete abstinence was not achieved; therefore, caution should be used in judging patients' progress in MAT based solely on drug tests".

Page 186 "Some have argued for early treatment discharge if patients continue using multiple substances. In addition, some State regulations set specific timetables for compliance, although the requirement is unsupported by research".

"Policies favoring treatment termination for patients who use substances negate a fundamental principal- that longer retention in treatment is correlated highly with increased treatment success".

"Consensus panel members have found that, if patients with secondary substance use problems remain in MAT and staff members address overall substance abuse patterns for these patients, many patients stop using nonopioid and nonprescribed substances".

"Without treatment, a person with these problems may continue criminal activity; remain obsessed with substance use; experience severe financial, vocational, and personal problems; and be at increased risk of overdose death".

"Given the importance of retention in MAT for positive outcomes, the consensus panel agrees that a policy of discharge for other substance use is seldom appropriate".

CARF Standards Manual:

Page 109-110.

23. b. Drug screening procedures, including:

(4) Procedures to ensure that drug screening results are not used:
(a) As the sole basis for treatment decisions
(b) As the sole basis for termination from treatment.

23. d. That ongoing drug abuse is not, in and of itself, a reason for discharge unless the person served refuses recommended levels of intensive treatment.

National Institution on Drug Abuse (NIDA): Unfortunately, when relapse occurs many deem treatment a failure. This is not the case: successful treatment for addiction typically requires continual evaluation and modification as appropriate, similar to the approach taken for other chronic diseases. For example, when a patient is receiving active treatment for hypertension and symptoms decrease, treatment is deemed successful, even though symptoms may recur when treatment is discontinued. For the addicted patient, lapses to drug abuse do not indicate failure—rather, they signify that treatment needs to be reinstated or adjusted, or that alternate treatment is needed.

Ethics and morality dictate that a treatment provider refers a person to another treatment provider, if the person is discharged from the facility. We are being forced to discharge a client, who is obviously in a relapse, and we have very limited (if any) place to refer. Again, if this client overdoses and dies, we could be found liable for not adhering to the standard of care. We are being asked by the State to go against Federal regulations and our Accrediting body's recommendations and standards.

**VOLUNTEER**: Setting forth specific procedures for the result of a positive drug test is overly broad, arbitrary and should be revised or deleted. Treatment decisions should be based on the needs of the individual patient. This one-size fits all approach will negatively impact patient care. Clinical staff should make treatment decisions for each patient.

**TDMHSAS Response:** We concur. Upon review, TDMHSAS has revised this section of the proposed rules by removing the mandatory detoxification and discharge at the 4th positive drug test; stating that for each positive drug test, the opioid treatment program shall immediately revoke the take-home privilege for a minimum of 30 consecutive days; and modifying the qualifications required for a counselor. As amended, this section of the proposed rules states:

(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 qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision; and

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days;

(b) Upon a second positive drug test result within six months of 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 qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory documented treatment team meetings with the service recipient;

(c) Upon a third positive drug test result within six months of the second 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 qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive 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 the service recipient may be discharged for continued positive drug tests; and

(d) Upon a fourth positive drug test result within six months of the third positive drug test result, opioid treatment program shall:

1. Through an assessment of the service recipient's IPP, address the on-going multi-drug use through increased group and individual counseling, 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;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. If the service recipient refuses recommended, more intensive levels of care, the service recipient shall be immediately enrolled in an individualized, medically supervised detoxification plan for up to two weeks, followed by immediate discharge from the opioid treatment program.

(OO) 0940-05-42-.18(9)a

**MIDSOUTH**: [This section] requires licensed, certified, or in process counselors. [Section] .30(4) g recommends that counselors shall be qualified by training, education and/or experience, and is more reasonable. Finding counselors at all, much less licensed, certified, or in process trainees in some parts of Tennessee is difficult to impossible. Some clinics already employ counselors qualified under .30(4)g, but not .18(9)a(1). This would force unemployment for some who have been working with patients in a competent manner, when unemployment and staffing are pervasive issues.

**TDMHSAS Response:** We agree. TDMHSAS has modified this section of the proposed rules to reflect the change suggested by the stakeholders.

(PP) 0940-05-42-.18(17)(a) thru (d)

**BHG**: For clarity, this subsection (.18(17)(a)) should be revised to read "Before the *initial* administration of methadone . . .These provisions (.18(17)(b) – (d)) require an OTP to query the Prescription Drug Monitoring Program (PMP) after any positive drug test, at every 90-day treatment review, and every six months for each patient. This volume of PMP query is unduly burdensome, particularly in light of the limited personnel access to the PMP, the frequency of drug screening required by OTPs and the fact that the PMP itself is only updated by the State on a monthly basis. This requirement will be unproductive and costly and result in no benefit to patients. It should be eliminated or modified to require PMP query "when clinically indicated" or on some far less frequent basis than the current proposed rule would require.

**VOLUNTEER**: This provision is confusing, unnecessary, and overly broad. The "Prescription Monitoring Program" is defined in the Proposed Rule 0940-05-42-.01 as a program that is part of the Department of Commerce and Insurance. It is unclear if this reference is to the same or if a similar program exists at the

Tennessee Board of Pharmacy. Notwithstanding clarification on that point, the Commissioner does not have authority to force mental health facilities to comply with programs administered by other departments without specific authority from the legislature.

**TDMHSAS Response:** We agree. TDMHSAS accepted the change suggested by the stakeholders.

(QQ) 0940-05-42-.19(1)

**SOS**: Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005.

Page 64 "Control of withdrawal symptoms often is insufficient treatment to prevent a relapse to opioid abuse, and detoxification alone may yield only short-term benefits. Research has shown that retention in treatment over an extended period is key to successful outcomes for opioid addiction in many patients, just as it is for other chronic diseases like hypertension, diabetes, and asthma" (McLellan et al. 2000).

"Comprehensive, long-term opioid agonist maintenance remains the treatment with the best track record of controlling opioid use and saving lives".

**TDMHSAS Response:** We disagree. Although TIP 43 (p. 64) states that long-term detoxification gives service recipients the best chance at not relapsing, service recipients should still have the option of participating in a short-term detoxification program. This provision is not in conflict with TIP 43 (pg. 102), which states: "Although the phases of treatment model is structured for patients admitted for comprehensive maintenance treatment, some patients may be admitted specifically for detoxification from opioids." This provision simply allows a facility the option of providing short-term detoxification services as well as long-term detoxification services. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(RR) 0940-05-42-.19(3)

**BHG**: This subsection provides that the "program physician shall provide onsite medical supervision and oversight of the detoxification program." OTP Physicians control detoxification by ordering medically appropriate dose changes during their onsite hours. This provision should be modified to clarify that the physician need not be onsite for every clinic visit by a patient undergoing detoxification.

**TDMHSAS Response:** We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholder.

(SS) 0940-05-42-.19(4)

**VOLUNTEER**: Standards for detoxification and medically supervised withdrawal should be the same as those for maintenance programs. Less counseling for patients in a detoxification program than they receive in a maintenance program does not promote patient recovery.

**TDMHSAS Response:** We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholder.

(TT) 0940-05-42-.19(10)(b)

**BHG**: The word "possible" in this subsection is awkward and not clearly related to medical necessity; it should be replaced with "if deemed medically necessary."

**VOLUNTEER**: The language contained in this section is so confusing it is impossible to know how to comply. Thus, this provision is void for vagueness.

**TDMHSAS Response:** We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholders.

(UU) 0940-05-42-.19(12)(a)(1)

**AATOD**: The proposed regulations recommend that OTPs provide an administrative withdrawal schedule that will not be less than a six month period of time for patients who have been maintained for a two year period. A detoxification schedule is considered at 90 days or less in a number of other state regulations. In this particular case, if the state does have an interest in establishing this six month period of time in order to maintain a long-term tapering schedule, there should be some consideration in developing a fund for patient care so that programs will be able to sustain such treatment, in addition to providing other counseling and medical services. Such regulations need to be balanced against the need to ensure that when a patient loses his or her ability to pay for treatment that the withdrawal schedule should not be precipitous and should be related to the length of time the patient has been in treatment in addition to the maintenance dosage and other medical conditions.

**BHG**: This subsection requires OTPs to provide detoxification treatment for a period of six months or more, free of charge, to a non-paying patient. As discussed above, the decision to discharge a patient involuntarily is extremely serious and is considered by an OTP only as a last resort. However, like all healthcare providers, OTPs must be paid for service rendered in order to keep their doors open and continue to provide care to their patients. Mandating six months of free treatment to nonpaying patients could severely impair the financial viability of OTPs. It is also subject to abuse by patients who may be nearing administrative discharge for other reasons and would stop paying in order to benefit from the continued treatment that is free and mandatory for the OTP under this provision, but no so if the patient is pursuing detoxification or being discharged for other reasons. Moreover, this blanket requirement is contrary to the goal of providing individualized healthcare decision based on each patient's circumstances. Finally and perhaps most importantly for the purposes of this proceeding, this rule if implemented would constitute a regulatory taking without just compensation in violation of the Fifth Amendment of the Constitution of the United States and Article 1, Section 21 of the Constitution of Tennessee.

**MIDSOUTH**: We agree with the possible underlying motivation of the Department. Rather than summarily discharging patients who do not pay for services and incur large balances, a variety of ways to discontinue MMT are used in our clinic. We work with them as they work with us. Methadone Maintenance clinics are private clinics, for profit. The significant financial losses that will be incurred will have to be offset by increased fees. Word of the policy will spread rapidly, and patients will begin to "game the system". These and other consequences of this requirement will increase the financial burden on patients in this sagging economy, and decrease access to care for other potential patients. As a private provider receiving no state or federal funding, OTP's should not be forced to provide free services.

**SOS**: The detoxification schedule is considered at 90 days or less in a number of other state regulations and Section 0940-05-42-.01(g) defines "Administrative withdrawal" as usually relatively brief.

We work with clients on an individual basis and take many things into consideration, not just time in treatment. As business owners, we must take into consideration the financial impact of certain decisions. As well intended as the department may be in this, this can and will put a financial hardship on clinics. Clients will quickly learn to manipulate the system and take advantage of this regulation.

Being a private, for-profit business, we are inquiring about the legality of this regulation.

**VOLUNTEER**: This requirement is excessive and inappropriate and should be withdrawn. Part of compliance with the patient's treatment plan is demonstration of financial responsibility. The proposed provision would create a situation where many patients would leave treatment with enormous bills that they could never pay back. This would result in the patient not being able to afford reentry into an OTP if relapse occurs. Such a broad overreach of authority is void and unconstitutional as it dictates the terms of an agreement between two private parties.

**TDMHSAS Response:** We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholders.

(VV) 0940-05-42-.20(1)(b)

**VOLUNTEER**: This rule creates an unnecessary burden on the patient. We agree with the current call back requirements of six (6) or more take-homes are sufficient.

**TDMHSAS Response:** We disagree. The more frequent the amount of take home doses distributed, the higher the possibility of diversion of those take home doses. This change was made to minimize the potential for diversion. With the rise of methadone related deaths in TN and the emphasis the state is focusing on prescription

drug abuse, TDMHSAS, through this provision, is attempting to clamp down on the amount of doses that could be potentially diverted. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(WW) 0940-05-42-.20(1)(c)

**AATOD**: AATOD recommends that the State work with the Drug enforcement Administration and SAMHSA in order to best understand current regulations/policies concerning diversion control plans and call back medication programs. There are recent developments at the federal level concerning the procedures in how such call back programs are used. More careful consideration is needed in developing this policy and certainly a longer time period than the proposed hearing schedule of January 5, 2012 allows.

**BHG**: This subsection mandates "uniform sanctions for violating take-home policies." This requirement is in direct conflict of the concept of individualized treatment inherent in the provider-patient relationship and underlying many of the Department's own rules. An OTP's response to apparent tampering should be based on the patient's individual circumstances, including the patient history and any explanation provided. The entire notion of "uniform sanctions" should be eliminated from the rules.

**TDMHSAS Response:** We disagree. The rule simply requires the OTPs to establish written procedures to impose sanctions for a service recipient tampering with take home doses. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(XX) 0940-05-42-.21(5) and (6)

**BHG**: These provisions require contact with every OTP in an adjoining state within 125 miles upon admission of a new patient in order to avoid dual enrollment. At a minimum, these provisions must be modified to provide that such contact is subject to the patient's written consent, pursuant to the requirements of HIPPA. Moreover, the mileage requirement should be reduced, as the current requirement would force some facilities to contact dozens of out of state OTPs for every patient admission, which is simply infeasible and unnecessary.

**CONTINUUM**: Federal regulations (CFR 42) clearly specify that central registries containing information about patients receiving methadone maintenance treatment are permitted – but *exclusively* for the purpose of preventing multiple simultaneous enrollment. Any proposed state regulation establishing such a registry should clearly acknowledge this strict and unqualified limitation and specify the key procedures that shall minimize the likelihood of violation. For example, there should be explicit reference to the fact that notification to the registry will be required within a matter of days *after discharge* (for any and all reasons), and that upon such notification all identifying information of the (former!) patient will be expunged. It should also be stated that applicants for treatment who are not actually enrolled will not be included in the registry.

**TDMHSAS Response:** TDMHSAS accepts the change suggested by the stakeholders and decreased the radius from 125 miles to 75 miles. The issue of written consent is already addressed in .19(2).

(YY) 0940-05-42-.21(7)

**SOS**: According to the proposed regulations, the IPP is a detailed document. IPP is required to contain both medical and psychological health information that is protected by law. This is too much information to be sent to the Department. How will the Department store this information to maintain confidentiality, and who will have access to it? What if a client refuses consent to release this information to the Department? What is the purpose of the Department having this information?

The following is a list of Code of Ethics regarding disclosure of information:

- American Psychiatric Association. *The Principals of Medial Ethics with Annotations Especially Applicable to Psychiatry 2010 Edition.*

*Section 4*
*A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.*

Psychiatric records, including even the identification of a person as a patient, must be protected with extreme care. Confidentiality is essential to psychiatric treatment. This is based in part on the special nature of psychiatric therapy as well as on the traditional ethical relationship between physician and patient. Growing concern regarding the civil rights of patients and the possible adverse effects of computerization, duplication equipment, and data banks makes the dissemination of confidential information an increasing hazard. Because of the sensitive and private nature of the information with which the psychiatrist deals, he or she must be circumspect in the information that he or she chooses to disclose to others about a patient. The welfare of the patient must be a continuing consideration.

- American Medical Association. Code of Medical Ethics.

Opinion 5.05 – Confidentiality
When the disclosure of confidential information is required by law or court order, physicians generally should notify the patient. Physicians should disclose the minimal information required by law, advocate for the protection of confidential information and, if appropriate, seek a change in the law. (III, IV, VII, VIII)

- American Counseling Association. Code of Ethics.

Section B
**Confidentiality, Privileged Communication, and Privacy**
**B.2.d. Minimal Disclosure**

To the extent possible, clients are informed before confidential information is disclosed and are involved in the disclosure decision-making process. When circumstances require the disclosure of confidential information, only essential information is revealed.

- Code of Ethics *of the National Association of Social Workers*

1.07 Privacy and Confidentiality
(c) Social workers should protect the confidentiality of all information obtained in the course of professional service, except for compelling professional reasons. The general expectation that social workers will keep information confidential does not apply when disclosure is necessary to prevent serious, foreseeable, and imminent harm to a client or other identifiable person. In all instances, social workers should disclose the least amount of confidential information necessary to achieve the desired purpose; only information that is directly relevant to the purpose for which the disclosure is made should be revealed.

- American Psychological Association. Ethical Principles of Psychologists and Code of Conduct

2010 Amendments
**4.04 Minimizing Intrusions on Privacy**
(a) Psychologists include in written and oral reports and consultations, only information germane to the purpose for which the communication is made.
(b) Psychologists discuss confidential information obtained in their work only for appropriate scientific or professional purposes and only with persons clearly concerned with such matters.

**TDMHSAS Response:** In response to the stakeholder's comment, TDMHSAS revised the type of information required to be submitted by the stakeholders.

(ZZ) 0940-05-42-.22(3)(a)

**BHG**: This subsection requires a facility to report "[m]edication errors" to the Department and SOTA. This provision should be revised to clarify that the errors included in this requirement are limited to those that cause or had the potential to cause harm to a patient, such as medication dosing errors, and do not include immaterial medication errors such as patient spills or emesis, etc.

**TDMHSAS Response:** We agree. TDMHSAS accepts the change suggested by the stakeholder.

(AAA) 0940-05-42-.23(3)

**BHG**: Subsection (3) requires the facility's quality improvement plan to include an "assessment of the average cost of services per service recipient per week and the average charge per service recipient per week." Essentially, this provision requires a facility to include details about its profit margin as part of its plan for quality improvement. This information has absolutely no bearing on the quality of the care provided or how best to improve it, and its inclusion in the quality improvement plan is not supported by any rationale. The requirement would constitute an unwarranted intrusion by the State in the operations of a private entity.

**VOLUNTEER**: Assessment of the average cost of services is proprietary business information. The Commissioner does not have authority to require submission of such information. It serves no statutory or regulatory purpose to require submission of this information. Thus, the provision is void.

**TDMHSAS Response:** After review, TDMHSAS revised the language in this section of the proposed rule to reflect the suggestion by the stakeholders.

(BBB) 0940-05-42-.27

**SOS**: As business owners, who rely on client payments for revenue, it is in the best interest of the clinics to accommodate their clients' needs. We already offer a crisis number for clients 24 hours a day, seven day per week. We do not agree that the state should mandate hours of operation. Hours should be based on the size and needs of each clinic individually. We operate small clinics and can adequately provide the services needed in less time than larger clinics. We do not feel that mandating hours will enhance client care, only the opposite. Clinics will have to increase fees to pay additional salaries to employees to sit idle.
Sunday Dosing – I can only guess that the rationale behind this regulation would be diversion risk. We live and operate a clinic in a small town. We take diversion very seriously and are constantly working on ways to prevent it. However, we feel that requiring clients to come to the clinic on Sundays and holidays will not decrease diversion. Many studies have found that methadone diversion is mainly from prescriptions, not OTP's.

In a report published by the Government Accountability Office in March 2009, on methadone associated overdose deaths, the study concluded that the growing availability of methadone through its increased use for pain management is a contributing factor to the rise in methadone-associated overdose deaths and addiction treatment in OTP's was not related to increased deaths.

We feel this regulation will force more clients out of OTP's and into pain clinics. Pain clinics prescribing methadone is already a problem in Tennessee. This will be a financial burden on clients as many have to travel long distances to get treatment. This requirement takes away a person's ability to spend time with family and their ability to participate in religious activities. It will be much easier and affordable to obtain a 30 day prescription from a pain clinic than being required to be at an OTP seven days a week.

Section 0940-05-42-.27 states that "A facility's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care, and variable shift work." How does requiring additional days in the clinic accommodate any of these?

**TDMHSAS Response:** Service recipients who are new to OTP treatment and service recipients who have been found to be diverting medication need to be dosed daily so that the service recipient can be properly assessed and so that the OTP can ensure that the service recipient's medication is not being diverted. TDMHSAS continues to believe that services should be available to service recipients seven days a week; therefore, no change was made to this part.

(CCC) 0940-05-42-.27(1)

**BHG**: This section begins by requiring that a "facility's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work." It further requires OTPs to "make dosing and counseling available at least six hours per day from Monday through Friday" and "at least three hours on Saturday." It requires three hours of dosing on Sundays, and provides that "[c]ounseling may be provided on Sunday to accommodate a service recipient's schedule." Subsection (3) mandates that every facility offer comprehensive services including counseling and medical exams at least six days per week. these requirements are wholly arbitrary, as they bear no relationship to the needs of the population served by an individual facility. the proposal requires OTPs to be open 365 days a year, except for 4 nonconsecutive holidays an one training day. This is completely unnecessary and is *not required of any other non-emergent healthcare provider in this State.* In addition to the unwarranted burden placed on the OTPs by dictating this schedule, the effect of this rule

would have serious negative consequences for the patients being served. Bringing patients into the clinic on Sundays, for example, disrupts the patient's sense of freedom of movement and worship and the normal social structure that contributes to successful treatment. The Center for Substance Abuse Treatment has encouraged facilities to improve patient retention by "*[r]educ[ing]* the attendance burden":

Attendance requirements can exert powerful effects on retention.
Rhoades and colleagues (1998) found that patients who were
required to visit an OTP less frequently were less likely to drop out of treatment and no more likely to use other drugs than patients on
a daily attendance schedule.

Center for Substance Abuse Treatment, Chapter 8, Approaches to Providing Comprehensive Care and Maximizing Patient Retention. SAMHSA/CSAT Treatment Improvement Protocols. Rockville (MD): Substance Abuse and Mental Health Services Administration (US): 1993, *available at* http://www.ncbi.nlm.nih.gov/books/nbk25994/(Exhibit U). Increasing the patients' attendance burden where no medically indicated, as required by this and other proposed rules under consideration, would result in increased drop-out rates and more untreated drug addicts in this State. These requirements should be eliminated and left to the discretion of the program and treatment team based on the parameters of 42 CFR 8.

**MIDSOUTH**: Must be open 365 days per year and close only 4 nonconsecutive days. We oppose this new requirement. Being allowed to close the same amount of holidays as State facilities and other private outpatient treatment facilities is equitable. Limiting to 4 holidays is no safer, does not increase access to care or positive outcomes, and does not minimize diversion. Requiring patients to travel to the clinic on Sundays and holidays decreases important family time and poses a travel hardship for some. Public transportation is not available in northwest Tennessee.

**VOLUNTEER**: VTC vigorously opposes the requirement to operate seven (7) day per week. Mediation and clinical services are currently offered six (6) days per week. Opening Sundays will not increase admissions. There is no evidence that seven (7) day operation improves any aspect of treatment. Seven (7) day operation creates the need for the patient to travel an extra day to the clinic every week for the first nine (9) months in treatment compared to what they do now. This extra cost to the patient provides no benefit and will reduce access to care. No studies have been provided which demonstrate that seven (7) day operation improves treatment outcomes. If this is being done to prevent diversion, the DEA in multiple reports have declared that the vast majority of diverted methadone on the street is from prescriptions out of pain management and private practices.

**TDMHSAS Response:** Service recipients who are new to OTP treatment and service recipients who have been found to be diverting medication need to be dosed daily so that the service recipient can be properly assessed and so that the OTP can ensure that the service recipient's medication is not being diverted. TDMHSAS continues to believe that services should be available to service recipients seven days a week; therefore, no change was made to this part.

(DDD) 0940-05-42-.27(3)

**SOS**: (3) Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical exams and referral services, at least six day per week.

This regulation is excessive. There is no reason to offer medical exams on Saturdays. Clinics open very early to accommodate patient schedules. We begin appointments at 5:30 a.m. This should be based on size and need of each clinic. We currently have no need to offer medical exams on Saturdays. No other outpatient treatment providers, including mental health agencies, offer any type of medical services on Saturdays.

**TDMHSAS Response:** After consideration, TDMHSAS made revisions to this section of the proposed rules as suggested by the stakeholder: Medical exams shall be provided on days when new admissions to the clinic occur.

(EEE) 0940-05-42-.27(7)

**VOLUNTEER**: As previously stated, VTC objects to putting information about the governing body into the Policies and Procedures as contact information has nothing to do with policies and procedures.

**TDMHSAS Response:** After consideration, TDMHSAS deleted this section of the proposed rules. However, TDMHSAS disagrees with the stakeholder's characterization of the request for governing body information. The governing body is the licensee and the name and contact for the governing body is already required to be provided pursuant 0940-05-42-.05.

(FFF) 0940-05-42-.29

**BHG**: This section makes OTPs responsible for ensuring that its patients do not "act in a manner that would constitute disorderly conduct or harassment," and requires them to "assure responsiveness to community needs," including "soliciting . . . community ideas about medication assisted treatment." As discussed above, communities already have an opportunity to raise their concerns about OTPs and the treatment they provide during public CON proceedings. The issuance of a CON constitutes a determination by the State that the OTP is "necessary to provide needed health care in the are to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities or services," despite any misgivings by members of the community. *See* Tenn. Code Ann. § 68-11-1609(b). Once that express determination has been made, to require OTPs – and no other CON-holders – to continually respond to community complaints about the nature of their operations is unfair, arbitrary and clearly designed to raise the burden to OTPs of providing a treatment that the Department has admitted it opposes on a philosophical basis. Beyond its legal invalidity, the Department's attempt to task OTPs with "***ensuring***" that their patients do not commit disorderly conduct or harassment raises an absolute impossibility. OTPs are no more able to control their patients' off-site behavior than any other health care provider or business establishment. Ironically, however, studies indicate that the most effective means of reducing the incidence of criminal activity in opioid addicts is to provide the very treatment that the Department seems intent on eliminating –methadone maintenance treatment.

Additionally, this entire section suffers from a grammatical awkwardness that makes it difficult to understand exactly what burdens are being imposed. For example, BHG is unable to decipher what is meant by "[i]nclude policies and procedures or resolve community problems" ((2)(b)) or "addressing community concerns and the Facility's presence in the community." ((2)(c)). For the reasons discussed above, the section should be stricken in its entirety. At the very least, it must be complete re-written in order to be decipherable.

**TDMHSAS Response:** After consideration, TDMHSAS revised this section of the proposed rules to require that OTPs are only responsible for the actions of service recipients while on the OTP's property.

(GGG) 0940-05-42-.30(3)(b)

**BHG**: This existing rule generally prohibits physicians from serving as medical director of more than one OTP. This prohibition does nothing to improve the quality of care provided to OTP patients, and serves only to make it more difficult for OTPs to find physicians who are qualified and willing to serve in this position. The rule is arbitrary.

**VOLUNTEER**: This requirement is overly burdensome, arbitrary and provides no benefit to patient care. As long as each facility has adequate physician coverage, the use of one (1) physician in multiple clinics should be allowed. An excellent Medical Director should be allowed to train and lead multiple clinics.

**TDMHSAS Response:** We disagree. The subject of this comment was already contemplated in existing OTP rule (0940-05-42-.04). Therefore, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(HHH) 0940-05-42-.30(3)(c) and (3)(c)(2)

**AATOD**: According to AATOD, there needs to be a better understanding of the basis for requiring the physician time and its relation to the use of approved physician extenders (physician assistants, nurse practitioners) or other clinical personnel, who are approved to provide services in OTPs under Tennessee law. Once again, staffing ratios need to be based on the reality of what patients will need as opposed to regulations that have arithmetic calculations without connection to patient outcome.

**BHG**: This rule requires OTPs to "provide on-site prescriber services of two hours per week for every 15 service recipients," at least 12.5% of which must be provided by a physician. Once again, this requirement evidences an underlying misunderstanding about the nature of OTP treatment. The fundamental nature and work-flows of

addiction treatment in OTPs are centered around counselors, not around physicians. Only on occasion do a small subset of OTP patients require a non-routine level of attention that can only be provided by a physician, and then only for short periods of time. As Dr. Farmer explained at the rulemaking hearing, this proposal is so excessive that it would require her to be present in her facility almost twice as many hours per week as there are actually patients in the facility. Requiring the proposed level of coverage by physicians has shown to be unnecessary to patient care, would not improve patient care, and would serve only to increase the costs of operating an OTP so dramatically that it would create an obstacle to treatment among patients who could not afford the increase and have nowhere else to turn. The proposed rule will ultimately increase the number of individuals not engaged in treatment and actually increase costs to the communities in the form of increased criminality, drug abuse, and acute hospital/ER visits. This requirement should be eliminated or greatly revised. For example, the Department's proposal dated March 31, 2010 reflected requirements that are more consistent with actual OTP medical coverage requirements.

**MIDSOUTH**: Requires 2 hrs/wk medical provider per every 15 pts. This appears arbitrary and not related to clinical needs. OTP's are more driven by counseling time than by medical provider time. Face to face time with a medical provider is several times per week right after admission, then yearly for annual exams. Some patients request a change in their dose, and this may necessitate a visit. Most patients who must come into the clinic are usually present the first 5 hours of operation. Many patients only come to the clinic every 1-3 weeks. There simply is no clinical need to have a medical provider present 40 hours per week for a 300 patient base. A clinic that size would be required to have a medical provider present 40 hours per week when patients are present in the clinic only 24 hours per week. We recommend that, as in any other medical office, each clinic be allowed to determine staffing hours needed.

**VOLUNTEER**: The requirements in this section are arbitrary and do not make sense. The level of medical coverage required by this provision is not medically necessary and is not required by any other state in the United States. The primary purpose of these facilities is to provide counseling centered treatment. The on-site physician requirement will not improve patient care and will be possible for only the largest facilities to meet. This will reduce services and access to care.

**TDMHSAS Response:** After consideration, TDMHSAS revised this section of the proposed rules: An on-site physician will now be required to provide services at the OTP a minimum of one hour per week for every 35 services recipients.

(III) 0940-05-42-.30(3)(g)

**MIDSOUTH**: Nurses are clinically trained to assess patients for signs of intoxication, withdrawal, and other medical conditions before dispensing medications and pharmacists are not. In clinics and hospitals, nurses dispense medications, and insure that counts of medications are correct. In some diet clinics, 5 to 10 controlled medications are dispensed, and they are not required to have a pharmacist on staff. In dental and surgical clinics, several medications, including controlled drugs may be dispensed without a pharmacist. Most OTP's dispense one medication, and are strictly monitored by the DEA for accountability. In the state of Tennessee, it is within the scope of practice of physicians to dispense. Medicines are dispensed legally and safely without a required pharmacist. Requiring the use of a pharmacist for something a physician is licensed in Tennessee to do is restricting the scope of practice for only selected physicians. This appears to be an arbitrary decision, and we question its legality.

**SOS**: We do not agree that the addition of a pharmacist to staffing requirements will enhance client care. Physicians and nurses can legally dispense medication in Tennessee. Nurses assess patients every time they dose. Pharmacists are not qualified to make medical assessments. We use automated Sci-Log dispensing pumps in our clinics. We have documentation to support the accuracy of these pumps. We are regulated and inspected by the DEA. We would like to see the department's research on how they feel this will improve patient care. We are not aware of any problems that would have prompted this change?
This proposed regulation adds operating cost with no obvious benefits.

**VOLUNTEER**: VTC vehemently objects to this arbitrary requirement. OTPs do not operate pharmacies and oversight by a pharmacist is not necessary. This requirement presents an additional, costly financial burden which will reduce access to treatment with no additional benefit to patient outcome or safely.

**TDMHSAS Response:** After consideration, TDMHSAS removed the pharmacist requirement from this section of the proposed rules.

(JJJ) 0940-05-42-.30(4), (4)(a) and (4)(h)

**BHG**: Both of these provisions set the credentials required for an OTP medical director and program director unreasonably high. Few physicians have two years of addiction experience, and even fewer have treated opioid addiction with a replacement medication. The American Society of Addiction Medicine does not require board eligibility in psychiatry in order to be certified as an addiction medicine specialist, so the Department's requirement of such eligibility in addition to ASAM certification is unreasonable and clearly unwarranted. The Department has not cited any evidence that patient outcomes have been negatively impacted by current credentialing standards or that the proposed standards would have any beneficial effect on patient care. Given the already limited pool of professionals willing and able to serve in these roles, the proposed requirements will have a significant negative impact on OTP's ability to hire qualified medical directors in order to stay in business. [See also comment re: Rule 0940-05-42-.16(1)(a)(5) herein.]

**VOLUNTEER**: Requiring one (1) year of supervisory or administrative experience for all program directors is arbitrary and will limit the field of potential candidates at a time when there is great need for the services provided by OTPs. VTC recommends replacing "behavioral healthcare" where "substance abuse" now appears.

**TDMHSAS Response:** After consideration, TDMHSAS reverted back to the requirements of the existing OTP rule (0940-05-42-.05). Additionally, TDMHSAS revised the medical director qualifications to include board certification as an addiction medicine specialist as an alternative, thereby expanding the pool from which OTPs can choose.

**Regulatory Flexibility Addendum**
Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

The agency shall consider, but not be limited to, each of the following methods of reducing the impact of the proposed rule on small businesses while remaining consistent with health, safety, and well-being:

(1) The extent to which the rule may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

Rules Chapter 0940-05-42 has been written to conform to federal guidelines and regulations for Opioid Treatment Programs (OTPs), incorporating best practices for the treatment of service recipients.

(2) Clarity, conciseness, and lack of ambiguity in the rule.

As indicated in the comments section, TDMHSAS made several changes suggested by stakeholders participating in the rulemaking hearing to improve rule clarity and conciseness.

(3) The establishment of flexible compliance and reporting requirements for small businesses.

The Department deleted requirements for financial reporting, reverting to its current requirements for reporting of serious incidents and other matters to the TDMHSAS Office of Licensure and the SOTA, including reporting findings by federal agencies such as the DEA and FDA and accrediting bodies, such as the Joint Commission.

(4) The establishment of friendly schedules or deadlines for compliance and reporting requirements for small businesses.

Timeframes for laboratory testing were lengthened to conform to federal guidelines. Otherwise, no changes were made to current compliance and reporting requirements.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses;

The proposed rules impose no new reporting requirements of costs for reporting on the OTPs. The OTPs will continue to report information impacting the health, safety and well-being of its service recipients to the SOTA and TDMHSAS Office of Licensure.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These rules are designed to provide the operational standards necessary to safeguard the health, safety and well-being of service recipients receiving opioid replacement treatment services.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

Federal and state law requires entry requirements prior to obtaining a license for operation of an opioid treatment program (e.g., TCA §68-11-1607(a)(4)(requires a certificate of need prior to obtaining a Tennessee license)).

**Economic Impact Statement**

(1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule.

These rules apply to non-residential opioid treatment programs (OTPs) in Tennessee. One-half

of the twelve OTPs currently operating in Tennessee qualify as small businesses with fewer than 50 employees. All OTPs will bear the costs associated with the proposed rules.

(2) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The proposed rules impose no new substantive reporting requirements or costs for reporting on the OTPs. The rules envision that the OTPs will continue with current electronic reporting to the SOTA and the TDMHSAS Office of Licensure. The rules further envision that the OTPs will follow current federal law that requires 1) that OTPs be approved by the FDA, DEA and SOTA before beginning operation; and 2) that they obtain and maintain accreditation by a nationally recognized accrediting body. See 42 CFR §8.4.

(3) A statement of the probable effect on impacted small businesses and consumers.

The new rules will have three primary impacts on small businesses. First, OTPs will be required to be open 7 days per week and 365 days per year. Second, OTPs will be required to test service recipients for HIV status (if the prospective service recipient consents to be tested), pregnancy, STDs, tuberculosis, and Hepatitis C. And, third, the OTP will be required to provide on-site prescriber services of 1 hour per week for every 35 service recipients. At least 12.5% of the required prescriber services per week must be provided by a physician.

All of these changes were made to safeguard the health and safety of service recipients. Service recipients currently taking methadone have a higher incidence of infection from TB, HIV, Hepatitis B and C, thereby requiring additional monitoring by a qualified prescriber. Because the half-life of methadone is extremely variable, the effects of methadone accumulate over time and adverse effects can be delayed one to two weeks. These safety concerns resulted in the development of rules allowing for daily monitoring when clinically indicated. The requirement that there be on-site prescriber services of 1 hour per week for every 35 service recipients will allow prescriber (e.g., physician, physician assistant, nurse practitioner) monitoring of service recipients with complex and multiple medical disorders in addition to physical and emotional issues. The proposed rules will increase the quality of care provided to service recipients. The Department developed these rules through extensive research, recognizing the need to protect the health, safety and well-being of the service recipients.

(4) A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business.

Because of the safety issues associated with methadone replacement treatment, the Department finds that increased prescriber time is necessary to ensure the safety and well-being of service recipients. In response to cost concerns, the Department allowed up to 87.5% of physician services to be provided by physician assistants or advanced practice nurses with a certificate of fitness for prescribing legend drugs.

(5) A comparison of the proposed rule with any federal or state counterparts.

The proposed rules conform to federal guidelines and regulations governing non-residential opioid treatment programs.

(6) Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.

The effect of exempting small businesses from all or any part of the requirements contained in the new OTP rule would be inequitable, considering one-half of the total number of OTPs currently operating in Tennessee qualify as small businesses (six of twelve OTPs). More importantly, an exemption would create an environment in which the safety and public health accountability measures contemplated by the new OTP rule would be unevenly applied to the already small number of OTPs currently providing services in Tennessee.

**Impact on Local Governments**

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://state.tn.us/sos/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

TDMHSAS estimates that this rule will have a minimal fiscal impact on state and local government revenues and expenditures.

**Additional Information Required by Joint Government Operations Committee**

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

**(A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Brief summary of the rule:

In light of the prescription drug epidemic confronting our state and the vulnerable nature of the individuals served by Non-residential Opioid Treatment Program Facilities (OTP), the department believes that OTPs are in need of clearer operational guidelines and better reporting mechanisms in order to ensure the safety and health of their service recipients and to track the nature and scope of the medications the OTPs dispense. The new OTP rules capture the best practices in the area of opioid treatment and represent a positive step forward in the area of OTP regulation. They provide Tennessee citizens continued access to an important treatment option with increased safety and public accountability measures.

The following is a description of the relevant changes in previous regulations effectuated by this rule:

**All citations referenced below refer to the version of the rule contained in this document.*

1. The most evident change to the rules is the formatting of the rules. The previous version of the rules was based on the original Department of Health (DOH) rules. The DOH rules were self-contained with rule sections encompassing many issues. The new OTP rules are re-formatted to mirror other Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Licensing rules. For example, the former Policy and Procedures section (0940-5-42.04) was "taken apart", with each subsection being made into a stand-alone section.

2. The new OTP rules make various housekeeping/technical/stylistic changes that update/synch rule language with proper terminology and definitions.

3. The new OTP rules incorporate new/modified definitions (0940-05-42-.01):

   A. Adds a definition for *buprenorphine* (commercial name *Suboxone)* and more scientifically descriptive language to expand coverage to generic forms of drugs as well as commercial forms (0940-05-42-.01(2)(c)).

   B. Changes the definition of *counseling session* to require a counseling session to be at least 30 minutes, face-to-face in a private location (0940-05-42-.01(2)(e)).

   C. Changes the definition of *detoxification* to add additional forms of detoxification, which should address more than just use of methadone (0940-05-42-.01(2)(g)).

   D. Adds term *opiate/opioid* to the definitions to include more than just Methadone (0940-05-42-.01).

4. The new OTP rules provide for the designation of the State Opioid Treatment Authority (SOTA) and the duties of that office (0940-05-42-.04). These rules:

   A. Designates a SOTA position (0940-05-42-.04(1)).

   B. Gives general overview of the authority of the SOTA, leaving open the ability for the SOTA to develop rules and policies regarding the operations, including best practices, for these agencies (0940-05-42-.04(2)).

5. The new OTP rules revise regulations regarding patient intake, admission and discharge (0940-05-42-.06). Highlights include:

   A. Clarifies the responsibility of the medical director or program physician (0940-05-42-.06(1) and (4));

B. Imposes a prohibition on any standardized routines or schedules of medication, emphasizing the need for individualized treatment) (0940-05-42-.06(3));

C. Develops specific requirements for an initial assessment of a potential patient (0940-05-42-.06(8));

D. Develops specific requirements for a comprehensive assessment of a potential patient (0940-05-42-.06(9));

E. Develops additional requirements for information to be gathered from the potential patient prior to admissions (0940-05-42-.06(2)); and

F. Develops specific timelines for completion of the assessments and adds the requirement that the information required by Section 0940-05-42-.06 be attached to the patient's file (0940-05-42-.06(2),(8) and (9)).

6. The new OTP rules require a prospective adult service recipient at an OTP (18 years of age of older) to verify his or her dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years OR verify one year of opioid dependence and one documented unsuccessful attempt at clinical treatment. These requirements can be waived for service recipients released from penal institutions, for pregnant service recipients with a verified pregnancy, and for previously treated service recipients (0940-05-42-.07(2)(a)(9)).

7. The new OTP rules require a prospective juvenile service recipient at an OTP (under 18 years of age) to verify two documented unsuccessful attempts at detoxification within a twelve month period (0940-05-42-.07(2)(a)(10)).

8. The new OTP rules require that the patient acknowledge in writing that s/he has been offered detoxification services as an admission alternative and that certain issues have been discussed with the patient (0940-05-42-.06(2)(c) and -.18(1)).

9. The new OTP rules require that attention be given to those patients with pain management/chronic pain issues as well as those with mental health needs (0940-05-42-.12(1) and (2)).

10. The new OTP rules require counselors to document in more detail their counseling encounters and increase the number and frequency of counseling sessions (0940-05-42-.14(3) and (6)).

11. The new OTP rules revise the requirements for addressing a situation in which a patient receives a positive drug screen, increases the frequency of additional drug screening after a positive drug screening, and provides for the possibility of discharging a patient if the patient receives a 4$^{th}$ positive screen within a 6 month period (0940-05-42-.17(9)).

12. The new OTP rules expand OTP hours of operation for dosing to seven (7) days a week (0940-05-42-.26).

13. The new OTP rules add the requirement that all OTP staff be trained in the areas of chronic pain and pain management (0940-05-42-.29(5)(b)(11)).

**(B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a), 300y-11; 42 C.F.R. §8.1, *et seq.* (Federal statutes and rules regarding controlled substances, substance abuse services, etc.).

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 (Tennessee statutes creating TDMHSAS and granting TDMHSAS and its commissioner certain authority, including the authority to promulgate rules regarding licensure, compliance, etc.).

**(C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

As of May 22nd, 2012, Twelve (12) Non-Residential Opioid Treatment Program Facilities (OTPs) operate in the state of Tennessee and these facilities will be the entities most directly affected by these Rulemaking Hearing Rules. The twelve (12) OTPs have participated in the rulemaking process by: appearing and making oral comments at the rulemaking hearing held by TDMHSAS on January 5th, 2012; submitting written comments regarding these rules (as presented at the January 5th, 2012 rulemaking hearing) during the extended written comments period held between January 5th and January 19th, 2012; and meeting with TDMHSAS Commissioner Varney on February 13th, 2012 (pursuant to TCA 4-5-204(c)(1) wherein they presented their concerns directly to TDMHSAS Commissioner Varney. Although TDMHSAS has made appropriate changes to these rules based on the comments received from the twelve (12) OTPs, the OTPs may still urge the rejection of these rules.

**(D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

TDMHSAS has no knowledge of any opinions of the attorney general and reporter and/or any judicial ruling that directly relates to this rule.

**(E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

TDMHSAS estimates that this rule will have a minimal fiscal impact on state and local government revenues and expenditures.

**(F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Kurt Hippel
TDMHSAS
Director of the Office of Legislation and Rules

Cynthia Tyler
TDMHSAS
Director of the Office of Licensure

Ty Thornton
TDMHSAS
Assistant General Counsel

Rodney Bragg
TDMHSAS
Assistant Commissioner for the Division of Substance Abuse Services

Jason Carter
TDMHSAS
Chief Pharmacist and State Opioid Treatment Authority (SOTA)

**(G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Kurt Hippel
TDMHSAS
Director of the Office of Legislation and Rules

Cynthia Tyler
TDMHSAS
Director of the Office of Licensure

Ty Thornton
TDMHSAS
Assistant General Counsel

Rodney Bragg
TDMHSAS
Assistant Commissioner for the Division of Substance Abuse Services

Jason Carter
TDMHSAS
Chief Pharmacist and State Opioid Treatment Authority (SOTA)

**(H)** Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

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**(l)** Any additional information relevant to the rule proposed for continuation that the committee requests.

NA

# RULES
# OF
# THE TENNESSEE DEPARTMENT OF MENTAL HEALTH
# AND DEVELOPMENTAL DISABILITIES

## CHAPTER 0940-5-42
## MINIMUM PROGRAM REQUIREMENTS FOR ALCOHOL AND DRUG ABUSE NON-RESIDENTIAL OPIATE TREATMENT FACILITIES

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### ~~0940-5-42-.01 DEFINITIONS.~~

~~(1) Abuse. The infliction of physical pain, injury, or mental anguish on a client by a caretaker. Abuse includes "exploitation" as defined by these rules.~~

~~(2) A.D.A. The Americans with Disabilities Act.~~

~~(3) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.~~

~~(4) Aftercare Plan. A plan which specifies, as appropriate, referral for further counseling and/or treatment services at another level of care, the type of contact, planned frequency of contact and the staff responsible for referrals. The focus of the aftercare phase is to ensure the maintenance of gains made and the ongoing achievement of long term goals.~~

~~(5) Alcohol and Other Drugs of Abuse Services:~~

~~(a) Treatment Services. Formal, organized services for persons who have abused alcohol and/or other drugs. These services are designed to alter specific physical, mental or social functions of persons under treatment by reducing client disability or discomfort, and ameliorate the signs or symptoms caused by alcohol and/or other drug abuse.~~

~~(b) Rehabilitation or Habilitation Services. A range of services for persons who have abused alcohol and/or other drugs. These services may include an array of counseling, vocational, social and/or educational services aimed at restoring overall well being, health and ability to engage in rewarding and/or productive activities.~~

~~(6) Assessment. A documented evaluation of a client for the purpose of determining treatment and/or rehabilitation or habilitation needs. An assessment may, but does not necessarily, include examination and tests determined to be necessary by the treatment staff, based on the presenting problems and symptoms of the individual client.~~

~~(7) Board. The Board for Licensing Health Care Facilities.~~

~~(8) Business Occupancies. Those facilities used for the transaction of business (other than that covered under mercantile), for the keeping of accounts and records, and similar purposes.~~

(Rule 0940-5-42-.01, continued)

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a resident, whether by mechanical devices, chest compressions, mouth to mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(10) Case Management. A series of actions based on the relationship between a person and a case manager, which assist the person and his/her family to access clinical treatment, housing, education, employment, financial, medical, and other support services that the person and the case manager deem necessary for his/her successful community living.

(11) Central Registry. An electronic system used to register clients currently receiving opioid replacement treatment at a NRNTF. The Department or SNA may require NRNTFs to initiate a clearance inquiry and client registration into an approved central registry for the purpose of gathering program information, performance data and to prevent simultaneous enrollment in other NRNTFs.

(12) Chief Executive Officer or Director. The person appointed, designated, or hired by the governing body to be responsible for the day to day operation of the facility or facilities operated by the licensee.

(13) Civil Rights. The rights of personal liberty guaranteed to citizens by the Constitutions of the United States and the State of Tennessee, and by federal and state statutes.

(14) Client. The individual who is the direct recipient of the services provided by the facility subject to the licensure jurisdiction of the Tennessee Department of Health.

(15) Commissioner. The Commissioner of Health or his/her designee.

(16) Counseling Session. Therapeutic discussion between client(s) and a facility counselor for a period of no less than thirty (30) minutes designed to address client addiction issues or coping strategies and treatment plans.

(17) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual 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.

(18) DEA. The United States Drug Enforcement Agency.

(19) Department. The Tennessee Department of Health.

(20) Detoxification. Medical and non-medical procedures resulting in the systematic reduction of the amount of a toxic agent in the body or the elimination of a toxic agent from the body.

(21) Do Not Resuscitate (DNR) Order. An order entered by the client's treating physician in the client's medical records which states that in the event the client suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain

(Rule 0940-5-42-.01, continued)

limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(22) Drug Abuse. A condition characterized by the continuous or episodic use of a drug or drugs resulting in impairment of the user's physical, mental, emotional, or social well-being, vocational impairment, psychological dependence or pathological patterns of use as defined in currently accepted diagnostic nomenclature.

(23) DSM. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV is the fourth edition of the manual).

(24) Exploitation. The improper use by a caretaker of funds which have been paid by a governmental agency to a patient or client or to the caretaker for the use or care of the patient or client; the "borrowing" or improper solicitation, use or conversion of any monies or property paid by a person or entity to a patient or client or to the caretaker for the use of or care of the client; engaging in sexual contact or sexual penetration with a patient or client by the caretaker; coercion, conspiring with or aiding a patient or client to engage in any criminal activity by the caretaker.

(25) Facility. A treatment resource, counseling center, or other entity providing alcohol and drug abuse services.

(26) FDA. The United States Food and Drug Administration.

(27) Governing Body. The person or persons with primary legal authority and responsibility for the overall operation of the facility and to whom a director/chief executive officer is responsible. Depending upon the organizational structure, this body may be an owner or owners, a board of directors or other governing members of the licensee, or, state, city or county officials appointed by the licensee, etc. The Governing Body maintains and controls the program and is legally responsible for the operation.

(28) Inspection. 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.

(29) LAAM. The acronym for levo alpha acetyl methadol or levomethadyl acetate hydrochloride (trade name ORLAAM). LAAM is a synthetic opioid agonist which has been approved by the FDA for the maintenance treatment of opiate addiction.

(30) Licensee. The proprietorship, partnership, association, governmental agency or corporation which operates a facility under the licensure jurisdiction of the Department.

(31) Licensure. The process by which an agency of government grants permission, to persons or health care facilities meeting qualifications, to engage in a given occupation and/or use a particular title.

(32) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(33) Maintenance Treatment. The dispensing of a narcotic drug, at relatively stable dosage levels, for a continuous, open ended period deemed medically necessary by a program

(Rule 0940-5-42-.01, continued)

~~physician or medical director, in the treatment of an individual for dependence on heroin or other opiate like drugs.~~

~~(34) Medical Director. 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 NTF to be responsible for the administration of all medical services performed by the NTF, including compliance with all federal, state, and local laws and rules regarding medical treatment of narcotic addiction. The medical director shall have the experience and credentials specified in subparagraph 0940-5-42-.04 (5) (a) of these rules.~~

~~(35) Medically Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident.~~

~~(36) Medical Record. 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 confinement or services rendered to residents, patients or clients.~~

~~(37) Methadone. A synthetic narcotic agonist which has been approved by the FDA for detoxification and maintenance treatment of narcotic addiction (trade name Dolophine).~~

~~(38) Multidisciplinary Treatment Team (Treatment Team). Professionals which may include a physician, nurse, alcohol and drug abuse counselor and mental health professionals who assess client progress.~~

~~(39) Narcotic Dependent. An individual who physiologically needs heroin or other opiate like drugs to prevent the onset of signs of withdrawal.~~

~~(40) Narcotic Treatment Facilities (NTF). Any program for chronic heroin or other opiate like drug users that administers narcotic drugs under physicians' orders either for detoxification purposes or for maintenance treatment in a rehabilitative context; the term facility includes any program or clinic licensed by the Department to operate as a Non-Residential Narcotic Treatment Facility (NRNTF).~~

~~(41) Non-Residential Narcotic Treatment Facility (NRNTF). A non-residential narcotic treatment facility which provides a combination of medical, mental health, and social services for treating the opiate dependent client with the goal of the individual becoming free from any drug which is not medically indicated. Non-residential narcotic treatment services in Tennessee consist of three (3) treatment modalities as follows: Thirty (30) Day Detoxification Treatment, Long-Term Detoxification Program (180 day program), and Narcotic Replacement Maintenance Treatment Program. Clients are admitted to the various modalities based upon client requests and admission criteria defined in the state and federal rules, as medically appropriate. Each modality is further defined as follows:~~

~~(a) Thirty (30) Day Detoxification Treatment. A period of continuous detoxification treatment with narcotic replacement therapy not to exceed thirty (30) days in length for the purpose of assisting the opiate dependent client in reaching a drug-free state. There must be at least thirty (30) days between thirty (30) day treatment episodes. An episode of thirty (30) day detoxification is any length of time in which the client receives narcotic replacement therapy for three (3) or more days.~~

(Rule 0940-5-42-.01, continued)

(b) Long-Term Detoxification Program. A period of narcotic replacement therapy services or programs in Tennessee not to exceed 180 days. Clients who have completed the 180 day detoxification must wait seven (7) days between Long-Term Detoxification Program episodes.

(c) Narcotic Replacement Maintenance Treatment Program. That period of continuous open-ended narcotic replacement treatment services as deemed necessary by the program physician/medical director. Clients will be admitted or re-admitted to this modality only after careful clinical evaluation by a multidisciplinary team.

(42) Narcotic Replacement Treatment. The substitution of a prescription drug which has been approved by the FDA for the treatment of opiate addiction to heroin or other opiate-like drugs.

(43) Neglect. The deprivation of services, including adequate and nutritious food and drink, by a caretaker, which are necessary to maintain the health and welfare of the client. Neglect includes "exploitation" as defined by these rules.

(44) Observed Testing. Testing conducted and witnessed by a facility staff person to ensure against falsification or tampering of results of a drug screen.

(45) On Duty/On Site. A staff person who is on the facility's premises and has the obligation to carry out any job responsibilities designated in his/her job description.

(46) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(47) Philosophy of Opiate Dependence and Treatment. A narrative overview as to why persons become opiate dependent which addresses the social, emotional, physiological, and spiritual aspects of dependency. The overview must further address how narcotic treatment and its ancillary services help the opiate dependent person in their recovery.

(48) Physical Holding. The use of body contact by staff to prevent the client's behavior from becoming dangerous to self, others, or property.

(49) Physician. A physician is a person who is duly licensed in Tennessee to practice medicine by the Tennessee Board of Medical Examiners or by the Tennessee Board of Osteopathic Examination.

(50) Policies and Procedures Manual. A document that describes the philosophy, services, organization, policies, and procedures for implementing services to the clients of a facility.

(51) Program Director (or "Sponsor"). The person designated by the program's governing body who is responsible for the operation of the program, for overall compliance with federal, state and local laws and regulations regarding the operation of narcotic treatment programs, and for all program employees including practitioners, agents, or other persons providing services at the program.

(52) Program Physician. Any physician, including the medical director, who is employed by a NTF to provide medical services to clients. Any program physician who is not a medical director must work under the supervision of the program's medical director.

~~(53) Psychiatrist. 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.~~

~~(54) Qualified Alcohol and Other Drugs of Abuse Personnel. Persons who meet the criteria described in items (a), (b) and (c) as follows:~~

~~(a) Currently meet one (1) of the following conditions:~~

~~1. Licensed or certified by the State of Tennessee as a physician, registered nurse, practical nurse, clinical or counseling psychologist, psychological examiner, social worker, alcohol and other drugs of abuse counselor, teacher, professional counselor, or marital and family therapist, or, if there is no applicable licensure or certification by the state, has a bachelor's degree or above in a behavioral science or human development related area; or~~

~~2. Actively engaged in a recognized course of study or other formal process for meeting the criteria of part (1) of subparagraph (a) above, and directly supervised by a staff person who meets the criteria in part (1) of subparagraph (a) above, who is trained and qualified as described in subparagraphs (b) and (c) below, and who has a minimum of two (2) years experience in his/her area of practice; and~~

~~(b) Are qualified by education and/or experience for the specific duties of their position; and~~

~~(c) Are trained in alcohol or other drug specific information or skills. (Examples of types of training include, but are not limited to, alcohol or other drug specific services, workshops, substance abuse schools, academic coursework and internships, field placement, or residencies).~~

~~(55) Random Testing. Drug screens conducted by the facility that lack a definite pattern of who and when clients are selected for testing; indiscriminate testing.~~

~~(56) Relapse. The failure of a client to maintain abstinence from illicit drug use verified through drug screen.~~

~~(57) Reputable and Responsible Character. Possession of a personal, professional and/or business history and practice that recommends the licensed owner or operator or applicant be entrusted with the responsibility for persons with mental illness and those particularly susceptible to participation in illegal, medically dangerous, unhealthy practices and financial and sexual and other forms of exploitation. Personal, professional and/or business histories and practices containing evidence of the operation of substandard facilities, violation of the professional and business licensing laws and regulations of the State of Tennessee and the United States of America are presumed inconsistent with a "reputable and responsible character".~~

~~(58) State Board of Pharmacy. The Board created to regulate the practice of pharmacy pursuant to T.C.A. §63-10-501.~~

~~(59) State Narcotic Authority (SNA). The Tennessee Department of Health or any agency that has been designated in Tennessee to exercise the responsibility and authority for governing~~

(Rule 0940-5-42-.01, continued)

~~the treatment of narcotic addiction with a narcotic drug in accordance with all applicable state and federal regulations.~~

~~(60) Treatment. 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.~~

~~(61) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

~~(62) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

~~(63) Volunteer. 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. §§4-5-202 through 4-5-206, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Amendment filed April 11, 2003; effective June 25, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.02 LICENSING PROCEDURES.**~~

~~(1) No person, partnership, association, corporation, or state, county or local government unit, or division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any NRNTF, as defined, without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the NRNTF.~~

~~(2) In order to make application for a license:~~

~~(a) The applicant shall submit an application on a form provided by the Department along with a copy of the Certificate of Need (CON), if necessary, issued by the Tennessee Health Facilities Commission or any other applicable state agency. Any condition placed on the CON will also be placed on the license. The written application for operation of a NRNTF must be filed simultaneously with the Substance Abuse and Mental Health Services Administration and the DEA, and/or any other applicable federal agencies.~~

~~(b) Each initial and renewal application for licensure shall be submitted with the appropriate fee or fees. All fees submitted are nonrefundable. The fee rate is based on the number of distinct facility categories to be operated at each non residential site. Any applicant who files during the fiscal year must pay the full license fee. A fee must be submitted for each facility at each site for which licensure is being sought under the following schedule:~~

~~1. The Annual License Fee for each NRNTF is $600.00~~

(Rule 0940-5-42-.02, continued)

2. An additional fee of $150.00 is required for each additional distinct facility category to be licensed in conjunction with the above.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Clients shall not be admitted to the NRNTF until a license has been issued. Providing narcotic replacement treatment services without a license is unlawful and will result in civil and/or criminal sanctions pursuant to T.C.A. §68-11-213. A license shall not be issued until the facility is in substantial compliance with these rules and regulations.

(d) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and the review process.

(e) The applicant must prove the ability to meet the financial needs of the facility.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.

(a) For the purposes of licensing, the licensee of a NRNTF has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the NRNTF's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the NRNTF is owned and operated.

(c) Transactions constituting a change of ownership include, but are not limited to, the following:

1. Transfer of the facility's legal title;

2. Lease of the facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;

6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate facility owner with one or more corporations; or

8. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

(Rule 0940-5-42-.02, continued)

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally licensed corporation survives;

3. Changes in the membership of a non profit corporation;

4. Transfers between departments of the same level of government; or

5. Corporate stock transfers or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.

(4) To be eligible for a license or renewal of a license, each NRNTF shall be periodically inspected for compliance with these rules. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the Department.

(5) Every facility owner or operator shall designate a distinctive name for the facility which shall be on the application for a license. The name of a facility shall not be changed without first notifying the Department in writing. The change will be made when renewal of license is due.

(6) A separate license shall be required for each facility when more than one facility is operated under the same management or ownership.

***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-213, and 68-11-216 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

**0940-5-42-.03 DISCIPLINARY PROCEDURES.**

(1) The board may suspend or revoke a license for:

(a) Violation of federal statutes or rules.

(b) Violation of state statutes or the rules as set forth in this chapter.

(c) Permitting, aiding or abetting the commission of any illegal act in the NRNTF.

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the clients of the NRNTF.

(e) Failure to renew the license.

(Rule 0940-5-42-.03, continued)

~~(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:~~

~~(a) The degree of sanctions necessary to ensure immediate and continued compliance;~~

~~(b) The character and degree of impact of the violation on the health, safety and welfare of the clients of the facility;~~

~~(c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,~~

~~(d) Any prior violations by the facility of statutes, regulations or orders of the board.~~

~~(3) When a NRNTF is found by the Department to have committed a violation of this chapter, the Department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a plan of correction indicating the following:~~

~~(a) How the deficiency will be corrected;~~

~~(b) The date upon which each deficiency will be corrected;~~

~~(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and~~

~~(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.~~

~~(4) Either failure to submit a plan of correction in a timely manner or a finding by the Department that the plan of correction is unacceptable shall subject the NRNTF's license to possible disciplinary action.~~

~~(5) Any licensee or applicant for a license, aggrieved by a decision or action of the Department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §4-5-101, et seq.~~

~~(6) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-4-1-.18 regarding petitions for reconsiderations and stays in that case.~~

~~***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206 through 68-11-209, and 68-11-213 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed March 1, 2007; effective May 15, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.04 ADMINISTRATION.**~~

~~(1) The governing body shall ensure the following:~~

~~(a) The facility complies with all applicable federal, state and local laws, ordinances, rules, regulations and accreditation requirements.~~

(Rule 0940-5-42-.04, continued)

~~(b) The facility is administered and operated in accordance with written policies and procedures.~~

~~(c) There is general direction over the facility and policies established governing the operation of the facility and the welfare of the individuals served.~~

~~(d) A responsible individual is designated for operation of the facility.~~

~~(e) The licensed facility serves only persons whose placement will not cause the facility to violate its licensed status and capacity based on the facility's distinct licensure category, the facility's life safety occupancy classification, and the required staffing ratios.~~

~~(f) A written policies and procedures manual is maintained. The manual shall include the following elements:~~

~~1. A description of each facility service provided by the licensee. The description must include the hours of operation, and admission and discharge criteria.~~

~~2. An organizational chart or a statement which clearly shows or describes the lines of authority between the governing body, the chief executive officer, and the staff.~~

~~3. Policy and procedures which ensure that someone is delegated the authority to act in the absence of the individual responsible for the operation of the facility.~~

~~4. A schedule of fees, if any, currently charged to the client for all services provided by the licensee. The schedule must identify all fees which are chargeable to clients and a copy of the schedule shall be provided to the client, or to a parent, guardian or responsible party during the admission process.~~

~~5. A statement of client rights and a policy which establishes a definite procedure by which grievances presented by the client, his/her physician, relative (friends in some instances), staff or administrator may be handled.~~

~~6. Policy and procedures which ensure the confidentiality of client information and which include the following provisions:~~

~~(i) The facility staff shall comply with applicable confidentiality laws and regulations;~~

~~(ii) The client shall not be required to make public statements which acknowledge gratitude to the licensee or for the licensee's facility services;~~

~~(iii) The client shall not be required to perform in public gatherings;~~

~~(iv) Identifiable photographs of the client shall not be used without the written and signed consent of the client or the client's guardian; and~~

~~(v) A medication administration policy and control procedures for facilities involved in the administration of medication to clients.~~

~~This policy and procedures must include a written notice of rights and responsibilities provided to each client at orientation.~~

(Rule 0940-5-42-.04, continued)

7. The plans and procedures to be followed in the event of fire evacuation, bomb threat and natural disaster emergencies evidenced by a record that the clients and staff have been informed of the procedures.

8. The plans and procedures to be followed in the event of an emergency involving client care which will provide for emergency CPR and initial care at the facility, emergency transportation of clients, emergency medical care, and staff coverage in such events.

9. A policy which prohibits clients from having any of the following responsibilities:

   (i) Responsibility for the care of other clients;

   (ii) Responsibility for the supervision of other clients unless on duty/on site staff are present; and

   (iii) Responsibilities requiring access to confidential information.

10. Policy and procedures to be followed in the reporting and investigation of suspected or alleged abuse or neglect of clients, or other critical incidents. The procedures must include provisions for corrective action to be taken as a result of such reporting and investigation.

11. Policy and procedures which ensure that volunteers, if used by the facility, are in a supportive capacity, are under the supervision of appropriate designated staff members, and understand confidentiality and privacy of the client.

12. Policy and procedures for the purpose of admitting and assessing deaf and hard of hearing individuals which shall include a mechanism for providing sign language interpreters for all clients whose primary means of communication is through manual communication. Interpreters shall be qualified.

13. A policy regarding the use of human subjects in research, if the facility is involved or planning to be involved in such research, which includes procedures for the following:

   (i) Identification of subjects, projects, and staff;

   (ii) Provisions to protect the personal and civil rights of the subjects;

   (iii) Obtaining informed consent of the subjects prior to research;

   (iv) Assurance that all research projects are conducted under the direction and supervision of professional staff qualified by education and experience to conduct research;

   (v) Emergency guidelines for problems that may develop during research activities;

   (vi) Appointment of a facility representative to act as coordinator of the research activities; and

   (vii) An identified individual and phone number for a client/guardian to call if there are any problems that develop during research activities.

(Rule 0940-5-42-.04, continued)

14. Monitoring procedures for multiple enrollment and cumulative time in all prior narcotic replacement treatment episodes with other narcotic treatment programs in Tennessee and participation in the central registries of adjoining states, if the programs are within 125 miles of the adjoining states' boundaries.

15. Pharmacotherapy guidelines for narcotic replacement treatment clients covering the program's own prescribing and review of prescriptions from other physicians which shall minimally include assurance that clients' prescriptions from outside physicians will be reported to the medical staff and reviewed by the program physician.

16. Evaluation criteria, clinical justification process, and ongoing review procedures will be in the form of an annual justification form and a six month update form, completed by the primary counselor, included in the client's chart detailing why a client is to remain in treatment as determined by multidisciplinary team evaluation and signed by the program physician or medical director of the program.

17. Procedures for providing non narcotic replacement treatment detoxification services to opiate dependent clients who are no longer eligible for further narcotic replacement treatment services. Such services may be provided directly by the agency or indirectly through referrals based on written agreements with other service providers.

18. Procedures for medically supervised withdrawal in the event the patient becomes unable to pay for treatment, including an appropriate time frame over which the procedure would take place.

19. Policy and procedures which address the methods for managing disruptive behavior. If restrictive procedures are used to manage disruptive behaviors, written policies and procedures must govern their use and must minimally address the following:

    (i) 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;

    (ii) The client shall have given prior written consent to any restrictive measures taken with him/her by the staff;

    (iii) The restrictive procedure(s) shall be documented in the Individual Treatment Plan, be justifiable as part of the plan, and meet all requirements that govern the development and review of the plan;

    (iv) Only qualified personnel may use restrictive procedures and shall be adequately trained in their use; and

    (v) The adaptive or desirable behavior shall be taught to the client in conjunction with the implementation of the restrictive procedures.

20. A policy which states physical holding shall be implemented in such a way as to minimize any physical harm to the client and may only be used when the client poses an immediate threat under the following conditions:

(Rule 0940-5-42-.04, continued)

(i) The client poses an immediate danger to self or others; and/or

(ii) To prevent the client from causing substantial property damage.

21. Hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work. Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical exams and referral services, at least five days per week. Any patient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, including Sundays and State and Federal holidays, not to exceed two (2) consecutive days. Facilities shall provide the SNA with at least two weeks notice prior to any change in program hours.

22. A facility that intends to voluntarily close shall notify the SNA no later than thirty days prior to closure. In order to assure continuity of care, any facility which closes, either voluntarily or involuntarily, will comply with all directions received from the SNA regarding the orderly transfer of clients and their records.

23. Each licensee shall clearly identify the governing body in its policies and procedures manual.

24. A Diversion Control Plan shall be in place at each clinic. The Diversion Control Plan must contain, at a minimum, the following:

(i) The Diversion Control Plan shall apply to all clients receiving more than five (5) take home medications.

(ii) It will include a random call back program with mandatory compliance. This call back must be in addition to the regular schedule of clinic visits.

(iii) Each client receiving take home medications must be called back at a minimum of once per three (3) months.

(iv) Upon call back a client must report to the clinic within twenty four (24) hours of notification, with all take home medications. The quantity and integrity of packaging shall be verified. If take home medications are liquid or any take home dose shows evidence of tampering, one dose must be replaced and sent for analysis to verify strength and contents.

(v) The facility shall maintain individual callback results in the client record.

(vi) The facility must maintain a current log of all callbacks with the results of compliance.

(2) Financial Management.

(a) The licensee holding or receiving funds or property for the client as trustee or representative payee will adhere to all laws, state and federal, that govern his/her position and relationship to the client.

(b) The licensee must prohibit staff and proprietors from borrowing money from clients.

(c) The licensee must not take funds or property of the client for the facility's own use or gain.

(Rule 0940-5-42-.04, continued)

(d) The governing body shall provide for the preparation of an annual budget and approve such budget. Copies of the current year's budget and expenditure records must be available upon request by the Department for examination and review by the Department.

(3) Personnel.

(a) 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:

1. Identifying information including name, current address, current telephone number, emergency contact person(s);

2. A ten year employment history or a complete employment history if the person has not worked ten years;

3. Records of educational qualifications if applicable;

4. Date of employment;

5. The person's job description or statements of the person's duties and responsibilities;

6. Documentation of training and orientation required by these rules;

7. Any records relevant to the employee's performance; and

8. Evidence that any professional license required as a condition of employment is current and in good standing.

(b) Wage and salary information, time records, and authorization and record of leave, shall be maintained but may be kept in a separate location.

(c) A job description shall be maintained which includes the employment requirements and the job responsibilities for each facility staff position.

(d) A personnel record shall be maintained which verifies that each employee meets the respective employment requirements for the staff position held, including annual verification of basic skills and annual evaluation of personnel performance. This evaluation shall be in writing. There shall be documentation to verify that the employee has reviewed the evaluation and has had an opportunity to comment on it.

(e) Training and development activities which are appropriate in assisting the staff in meeting the needs of the clients being served shall be provided for each staff member including STD/HIV education. The provision of such activities shall be evidenced by documentation in the facility's records.

(f) Training and development activities which are appropriate in assisting volunteers (if volunteers are used by the facility) in implementing their assigned duties shall be provided for each volunteer. The provision of such activities shall be evidenced by documentation in the facility's records.

(Rule 0940-5-42-.04, continued)

(g) Direct services staff members shall be competent persons aged eighteen (18) years of age or older.

(h) All new employees, including volunteers, who have routine contact with clients shall have a current tuberculosis test prior to employment.

(i) Employees shall have a tuberculin skin test annually and at the time of exposure to active TB and three months after exposure.

(j) Employee records shall include date and type of tuberculin skin test used and date of tuberculin skin test results, date and results of chest x ray, and any drug treatment for tuberculosis.

(4) 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 narcotic treatment programs, and for all employees including practitioners, agents, or other persons providing services at the facility. Facilities must notify the Department in writing within ten (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 narcotic addiction. No physician may serve as medical director of more than one NTF without the prior written approval of the SNA. Facilities must notify the Department in writing within ten (10) calendar days whenever there is a change in medical director.

(c) Program Physician. Facilities are required to provide sufficient physician coverage to provide the medical treatment and oversight necessary to serve client needs. A program physician's responsibilities include, but are not limited to, performing medical history and physical exams, determination of diagnosis under current DSM criteria, determination of narcotic dependence, reviewing treatment plans, determining dosage and all changes in dosage, ordering take home privileges, discussing cases with the treatment team and issuing any emergency or verbal orders relating to client care. At all times a facility is open and a physician is not present, a program physician must be available for consultation and emergency orders. Facilities must be able to document a referral agreement with a local hospital or health care facility.

(d) Physician's Assistants and Nurse Practitioners. Licensed physician's assistants and certified nurse practitioners may be employed by facilities and perform any functions permitted under Tennessee law.

(e) Nurses. Facilities shall insure 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 must ensure that licensed practical nurses adhere to written protocols and are properly supervised.

(f) Counselors. There must be sufficient group and individual counseling available to meet the needs of the client population. At a minimum, the following counseling schedule shall be followed:

(Rule 0940-5-42-.04, continued)

1. During the first ninety (90) days of treatment, counseling session(s) shall take place at least one time a week;

2. During the second ninety (90) days of treatment, counseling session(s) shall take place at least three (3) times per month;

3. During the third ninety (90) days of treatment, counseling session(s) shall take place at least two (2) times per month;

4. For subsequent ninety (90) day periods of treatment, counseling session(s) shall take place as needed or indicated in the client's treatment plan, but no less frequent than monthly as long as the client is compliant;

5. If the client experiences a relapse, his/her individualized treatment plan must document evidence of intensified services provided. Such evidence may include, but is not limited to, increase in individual or group counseling session(s) and/or a reduction in the client's take home privileges.

(5) 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 (3) years documented experience in the provision of services to persons who are addicted to alcohol or other drugs, including at least one (1) year of experience in the treatment of narcotic addiction with a narcotic drug; or

2. Board eligibility in psychiatry and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or

3. Certification as an addiction medicine specialist by the American Society of Addiction Medicine (ASAM).

(b) Variance 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 SNA for a variance. The SNA has the discretion to grant such a variance when there is a 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 SNA 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 will be available to oversee the training of the medical director and the delivery of medical services at the program requesting the variance.

(Rule 0940-5-42-.04, continued)

~~(c) Program Physician. All program physicians must be licensed to practice medicine in Tennessee, must maintain their licenses in good standing and must have at least one (1) year of documented experience in the treatment of persons addicted to alcohol or other drugs.~~

~~(d) Variance 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 SNA for a variance. The SNA has the discretion to grant such a variance 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 SNA and which consists of a combination of continuing education in addiction medicine and in-service training by the program'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 physician 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 SNA within two years from the effective date of these rules. At least 25 hours of this continuing education must be obtained within one year from the effective date of these rules.~~

~~(f) Nurses. All registered nurses and licensed practical nurses must be licensed to practice in Tennessee and must maintain their licenses in good standing.~~

~~(g) Counselors. All counselors must be qualified by training, education and experience to provide addiction counseling services as required by these rules.~~

~~(h) Program Directors. All program directors must have at least one year of supervisory or administrative experience in the field of substance abuse treatment.~~

~~(i) 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.~~

~~(j) Staff Training and Orientation. Prior to working with clients, all staff who provide treatment and services must be oriented in accordance with these rules and must thereafter receive additional training in accordance with these rules. Orientation must include instruction in:~~

~~1. The facility's written policies and procedures regarding its purpose and description; client rights, responsibilities, and complaints; confidentiality; and~~

(Rule 0940-5-42-.04, continued)

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 client progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services.

(k) Additional training consisting of a minimum of eight (8) clock hours of training or instruction must be provided annually for each staff member who provides treatment or services to clients. Such training must be in subjects that relate to the employee's assigned duties and responsibilities, and in subjects about current clinical practice guidelines for narcotic treatment such as dosage, based on physician's clinical decision making and individual client needs; drug screens; take home medication practices; phases of treatment; treating abusers of multiple substances; narcotic treatment during pregnancy; HIV and other infectious diseases; co morbid psychiatric conditions; and referring clients for primary care or other specialized services. Facilities shall maintain records documenting that each staff member has received the required annual training.

(l) 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 must be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by the SNA.

(m) Staff Ratios and Responsibilities. The facility shall have sufficient types and numbers of staff to provide the treatment and services required by all applicable state and federal laws and regulations and as outlined in its program description and these rules.

(n) A minimum of one (1) on duty staff member trained in CPR, Heimlich Maneuver, and First Aid shall be maintained.

(6) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

(a) Contact information including statewide toll free number of the division of adult protective services, and the number for the local district attorney's office;

(b) 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 division concerning abuse, neglect and exploitation; and

(c) 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 (8½") in width and eleven inches (11") in height.

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-222, and 71-6-121 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18,*

(Rule 0940-5-42-.04, continued)
~~*2003; effective May 4, 2003. Amendment filed April 30, 2003; effective July 14, 2003. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.05 ADMISSIONS, DISCHARGES AND TRANSFERS.**~~

~~(1) The facility shall maintain written policies and procedures governing the intake and assessment process and specify the following:~~

~~(a) The information to be obtained on all applicants or referrals for admission;~~

~~(b) The procedures for accepting referrals from outside agencies or organizations;~~

~~(c) The records to be kept on all applicants;~~

~~(d) Any prospective client data to be recorded during the intake process; and~~

~~(e) The procedures to be followed when an applicant or a referral is found ineligible or admission.~~

~~(2) Screening, Admission, and Orientation of Clients.~~

~~(a) A facility may only admit and retain clients whose known needs can be met by the facility in accordance with its program purpose and description and applicable federal and state laws and regulations. Written policies and procedures for client referral, intake, assessment, and admission must be established and implemented and must include the following provisions or requirements:~~

~~1. Screening. All applicants for admission must be initially screened by facility staff to determine eligibility for admission. No applicant may be processed for admission until it has been verified that he or she meets all applicable criteria, and that the sources and methods of verification have been recorded in the applicant's case folder. The screening process must include:~~

~~(i) Verification, to the extent possible, of an applicant's identity, including name, address, date of birth and other identifying data;~~

~~(ii) 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 DSM diagnosis;~~

~~(iii) Medical history, including HIV status, pregnancy, current medications (prescription and nonprescription), and active medical problems;~~

~~(iv) Psychiatric history and current mental status exam;~~

~~(v) Physical assessment and laboratory tests, including drug screens and HIV status (if the applicant consents to be tested), pregnancy, STD, and Mantoux TB tests;~~

~~(vi) If an applicant has previously been discharged from treatment at another methadone clinic or program, the admitting facility must initiate an~~

(Rule 0940-5-42-.05, continued)

~~investigation into the applicant's prior treatment history, inquiring of the last program attended the reasons for discharge from treatment;~~

~~(vii) Determination if the applicant 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;~~

~~(viii) Explanation of treatment options, detoxification rights, and clinic charges, including the fee agreement, signed by the applicant;~~

~~(ix) If an applicant 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 one year; and~~

~~(x) If an applicant is under 18 years of age, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years.~~

~~2. Assessment. Each client admitted to the facility must 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 narcotic substitution, short term detoxification, long-term detoxification, or drug free treatment will be the most appropriate treatment modality for the client. The evaluation must include an assessment of the client's needs for other services including treatment, educational and vocational.~~

~~3. Admission.~~

~~(i) Consent. Except as otherwise authorized by law, no person may be admitted for treatment without written authorization from the client and, if applicable, parent, guardian or responsible party. The following information must be explained by a trained staff person to the client and other consenters, and documented in the client file:~~

~~(I) The program's services and treatment;~~

~~(II) The specific condition that will be treated;~~

~~(III) The expected charges for services including any charges that might be billed separately to the client or other parties; and,~~

~~(IV) The facility's rules regarding client conduct and responsibilities.~~

~~(ii) Admission Clearance. No person may be admitted unless the facility conducts an inquiry with the Central Registry in accordance with rule 0940-5-42-.05 (4).~~

~~(iii) Orientation. The facility shall provide orientation to clients within 24 hours of admission for treatment. Orientation must be done by a staff person who has been determined to be qualified by education, training, and experience to perform the task. Facilities shall ensure that each client signs a statement confirming that the following information has been explained to the client:~~

(Rule 0940-5-42-.05, continued)

(I) The expected benefits of the treatment that the client is expected to receive;

(II) The client's responsibilities for adhering to the treatment regimen and the consequences of non-adherence;

(III) An explanation of individualized treatment planning;

(IV) The identification of the staff person who is expected to provide treatment or coordinate the treatment;

(V) Facility rules including requirements for conduct and the consequences of infractions;

(VI) Client's rights, responsibilities, and complaint procedures;

(VII) Drug screening policies and procedures; and

(VIII) HIV information.

(b) Drug dependent pregnant females must 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 clients waiting services. Pregnancy tests for females must be conducted at admission and at least annually thereafter, unless otherwise indicated.

(c) No facility may provide a bounty, free services, medication or other reward for referral of potential clients to the clinic.

(d) 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 must identify the reasons why the persons were not admitted and what referrals were made for them by the facility.

(3) Discharge and Aftercare Plans. A facility must complete an individualized discharge and aftercare plan for clients who complete their course of treatment. This plan must be developed prior to discharge and must be completed within seven days of discharge by the person who has primary responsibility for coordinating or providing for the care of the client. It must include a final assessment of the client's status at the time of discharge and a description of aftercare plans for the client. The client must participate in discharge and aftercare planning and, if applicable, parents or guardian, or responsible persons should participate.

(4) Central Registry.

(a) To prevent simultaneous enrollment of a client in more than one facility, all facilities shall participate in a central registry approved by the Department. Clients must be informed of the facility's participation in the central registry and prior to initiating a central registry inquiry, the facility must obtain the client's signed consent. Within seventy two (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. No person shall be admitted to a facility who is reported by the central registry to be participating in another such facility, or in the event a dual enrollment is found, the client must be discharged from one facility in order to continue enrollment at

(Rule 0940-5-42-.05, continued)

another facility. Reports received by the central registry shall be treated as confidential and shall not be released except to a licensed facility, or as required by law. Information made available by the central registry to facilities shall also be treated as confidential.

(b) To prevent simultaneous enrollment of persons in different facilities located in different states, if a facility operates within 125 miles of any adjoining state and that state also has a central registry, the facility shall, at the direction of the SNA, also participate in the central registry of the adjoining state.

(5) The facility shall provide services, as available, to clients to address their needs as indicated on the assessment/ history in the areas of social/ family/ peer, employment/ education/ financial, emotional/ psychological health, physical health, legal, and community living skills/housing. Such services may be provided directly by the agency or indirectly by referral to other service providers. Referral agreements with frequently used providers must be documented. The provision of such services to individual clients must be documented in the client record. The facility shall ensure that clients are instructed in the proper storage and security of take home medications after they leave the facility.

***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

**0940-5-42-.06 BASIC SERVICES.**

(1) Quality of Care. The Narcotic Treatment facility will develop and implement a plan for continuous quality improvement. At a minimum, the plan shall include:

(a) Structured assessment of the program which addresses program management, staffing, policies and procedures and general operations.

(b) A service delivery assessment which at a minimum shall evaluate appropriateness of the treatment plan and services delivered, completeness of documentation in clients' 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, T.B., HIV).

(c) An assessment of utilization and cost effectiveness of the services delivered which shall examine treatment slot utilization and cost per slot, staff to client ratio and cost per counseling session and other support services.

(d) An assessment of medication related issues including take home procedure, security, inventory and dosage issues.

(e) Such process shall serve to continuously monitor the program's compliance with the requirements set forth in these rules. Responsibility for administering and coordinating the quality improvement process must 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.

(f) Programs shall participate in additional quality improvement outcome studies as directed by the Department or SNA.

(Rule 0940-5-42-.06, continued)

~~(2) Performance Outcome. The Narcotic Treatment Facility shall monitor performance outcome. The following performance indicators may be used to evaluate the impact of the program on clients and the community:~~

~~(a) Client receipt of needed program or out of program services.~~

~~(b) Client satisfaction.~~

~~(c) Client employment status.~~

~~(d) Improvement in medical conditions.~~

~~(e) Drop out rates.~~

~~(f) Recidivism rates.~~

~~(g) Alcohol use.~~

~~(h) Criminal arrests.~~

~~(i) Illicit drug use, as indicated by drug screens.~~

~~(j) Improvement in social and living standards.~~

~~(3) Staff Training. The Narcotic Treatment Facility shall promote, utilize and provide staff training on current clinical practice guidelines for narcotic replacement treatment. The following areas shall receive emphasis during training:~~

~~(a) Dosage.~~

~~(b) Counseling.~~

~~(c) Urinalysis.~~

~~(d) Phases of treatment.~~

~~(e) Treating multiple substance abuse.~~

~~(f) Narcotic treatment during diseases.~~

~~(g) HIV and other infectious diseases.~~

~~(h) Co-morbid psychiatric conditions.~~

~~(i) FDA approved drugs for the treatment of opiate addiction, including methadone and LAAM.~~

~~(4) Community Relations. The Narcotic Treatment Facility shall develop procedures for community relations to include the following:~~

~~(a) Identify community leaders (representatives within the area in which the clinic is situated as well as in the districts served) and establish interpersonal contact, liaison, education or proactive association in an advisory group with elected officials, health,~~

substance and human service directors, business leaders, law enforcement, religious and spiritual leaders and community grass-roots organizations.

(b) Develop a community relations plan specific to the configuration and needs of the facility within the community to include the following:

1. Liaison with community representatives.

2. Define the goals and procedures of the community relations plan.

3. Provide a mechanism to hear community concerns about the narcotic treatment facility's presence and operations in the community.

4. Develop policies and procedures to resolve community issues and problems to insure that program operations do not adversely affect community life.

5. Document all community relations efforts, community contacts and resolutions, and evaluate these efforts and contacts over time.

(c) A facility shall be responsible for assuring that its clients do not cause unnecessary disruption to the community by loitering in the vicinity or acting in a manner that would constitute disorderly conduct or harassment. Clients who consistently cause disruption to the community or to the facility should be discharged from the program.

(d) Each facility shall provide the Department, when requested, with a specific plan describing the efforts it will make to avoid disruption of the community by its clients and the actions it will take to assure responsiveness to community needs. The Department may require that such plan include the formation of a committee to consist of representative members of the community. Such committee shall meet on a regular basis.

(5) Individual Treatment Planning. A facility must develop an individual treatment plan for each client within thirty (30) days of admission. Clients must be involved in the development of their treatment plans. Treatment plans must document a consistent pattern of substance abuse treatment services and medical care appropriate to individual client needs.

(a) Medical care, including referral for necessary medical service, and evaluation and follow up of client complaints must be compatible with current and accepted standards of medical practice. All clients must receive a medical examination at least annually. All other medical procedures performed at the time of admission must be reviewed by the medical staff on an annual basis, and all clinically indicated tests and procedures must be repeated. The medical director or program physician shall record the results of this annual medical examination and review of client medical records in each client's record.

(b) In recognition of the varied medical needs of clients, the case history and treatment plan must be reviewed at least every 90 days for clients in treatment less than a year and at least annually for clients in treatment more than a 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 must also include an assessment of the current dosage and schedule and the rehabilitative progress of the individual, as part of a determination of whether additional medical services are indicated. If this review results

~~in a determination that additional or different medical services are indicated, the facility must ensure that such services are made available to the client.~~

~~(c) When the program physician prescribes other controlled substances to clients 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 client unless the physician first sees the client and assesses the client's potential for abuse of such medications.~~

~~(d) As part of the rehabilitative services provided by the facility, each client must be provided with individual and group counseling appropriate to his/her needs. The frequency and duration of counseling provided to clients must be determined by appropriate program staff and be consistent with the treatment plan. Treatment plans must indicate a specific level of counseling services needed by the client as part of the rehabilitative process.~~

~~(e) All clients shall receive HIV risk reduction education appropriate to their needs.~~

~~(f) When appropriate, each client must be enrolled in an education program, or be engaged in a vocational activity (vocational evaluation, education or skill training) or make documented efforts to seek gainful employment. Deviations from compliance with these requirements must be explained in the client's record. Each facility shall take steps to ensure that a comprehensive range of rehabilitative services, including vocational, educational, legal, mental health, alcoholism and social services are made available to the clients who demonstrate a need for such services. The facility can fulfill this responsibility by providing support services directly or by appropriate referral. Support services recommended and utilized must be documented in the client record.~~

~~(g) All facilities will develop and implement policies for matching client needs to treatment. These policies may include treatment phasing in which the intensity of medical, counseling and rehabilitative services provided to a client varies depending upon the client's phase of treatment. Phases of treatment may include intensive stabilization for new clients and those in need of acute care, graduated rehabilitation phases, and for long-term stable clients, a medical maintenance or methadone tapering phase.~~

~~(h) Each client's individualized treatment plan must include the counseling needs, including both group and individualized counseling sessions as indicated by evaluation of the client's length of time in the program, drug screening results, progress notes, and social environment. The treatment plan must be reviewed at least every six (6) months.~~

~~(6) Infection Control. A facility must develop policies and procedures to be followed for infection control, including:~~

~~(a) 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 C.F.R., Part 2 and T.C.A. §§68-10-101, 68-9-201 and 68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health;~~

~~(b) Management of clients who are infected with Hepatitis B or C Virus, HIV/AIDS or other STD;~~

~~(c) Nondiscrimination of employees and clients regarding their HIV/AIDS status;~~

(d) Use of standard precautions for prevention of transmission of HIV/AIDS, Hepatitis B or C Virus, and other blood borne pathogens;

(e) Infectious disease testing will be made on a voluntary basis for any client who requests it, and be documented in appropriate records;

(f) Assurance that a client's HIV, other STD, and tuberculosis status will be kept confidential in accordance with "Confidentiality of Alcohol and Drug Abuse Patient Records" (42 C.F.R., Part 2);

(g) Documentation on the establishment of linkages between the facility and the local health department to ensure clients receive appropriate medical care relative to their infection and/or exposure to TB, 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 client receives appropriate care;

(h) Informed consent of clients before screening and treatment; and

(i) 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, and tuberculosis.

(7) Client Records.

(a) Facilities must organize and coordinate client records in a manner which demonstrates that all pertinent client information is accessible to all appropriate staff and to the Department. The client Central Registry I.D. number must be shown on each page of the client's record. Each client record must contain, at a minimum, the following:

1. The name of the client.

2. The address of the client.

3. The current telephone number of the client.

4. The sex of the client.

5. The date of the client's birth.

6. The date of the client's admission to the program.

7. The source of the client's referral to the facility.

8. The name, address, and telephone number of an emergency contact person.

9. If the facility charges fees for its services, a written fee agreement dated and signed by the client (or the client's legal representative) prior to provision of any services. This agreement shall include at least the following information:

(i) The fee or fees to be paid by the client;

(ii) The services covered by such fees;

(iii) Any additional charges for services not covered by the basic service fee; and

(iv) Procedures for medically supervised withdrawal in the event the patient becomes unable to pay for treatment.

10. Appropriate signed and dated informed consent and authorization forms for the release or obtainment of information about the client.

11. Documentation that the client or someone acting on behalf of the client has been informed of the client's rights and responsibilities and of the facility's general rules affecting the client.

12. Documentation of Central Registry clearance as required in paragraph 0940-5-42-.05 (4) of these rules.

(b) Records shall be retained for a minimum of five (5) years even if a facility discontinues operations.

(c) The Department must be notified in advance of a facility's closing.

(d) Upon the closing of any facility, a person of authority representing the facility may request final storage or disposition of the facility's records by the Department.

(8) Drug Screens. The facility shall develop and implement written policies and procedures for random drug screens. These policies and procedures will be for the purposes of assessing the client's abuse of drugs and making decisions about the client's treatment. These policies and procedures must include the following provisions:

(a) Urine drug screens must be conducted on a random basis weekly for new clients during the first thirty days of treatment and at least monthly thereafter. However, clients on a monthly schedule whose drug screen reports indicate drug abuse will be returned to a weekly schedule for at least two weeks, or longer if clinically indicated.

(b) Each sample collected must be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, THC and other drugs as indicated by individual client use patterns or that are heavily used in the locale of the client or as directed by the SNA.

(c) Facilities shall develop policies to ensure that urine collected from clients is unadulterated. Such policies may include random direct observation which shall be conducted professionally, ethically, and in a manner which respects clients' privacy.

(9) Narcotic Drugs. Facilities shall develop and implement written policies and procedures for prescription and administration of narcotic drugs and their security. These policies and procedures must include the following:

(a) Administration.

1. A program physician shall determine the client's initial and subsequent dose and schedule. If the physician did not perform the medical assessment required in these rules, the physician must consult with the person who performed the assessment before determining the client's initial dose and schedule. The physician shall communicate the initial and subsequent dose and schedule to the pharmacy or the person supervising medication. The physician may assign such

(Rule 0940-5-42-.06, continued)

dose and schedule by verbal order, however, all such orders must be confirmed in writing by the physician within 72 hours.

2. Proper dose should be based on the clinical judgment of the program physician who has examined the client and who has considered all available relevant information, including, but not limited to, drug screens, quantitative methadone levels, client interview, and specific circumstances pertaining to the individual client.

3. The initial dose of methadone may not exceed 30 milligrams. Additional dosage may be given in the first day where the physician documents that 30 milligrams does not suppress withdrawal symptoms. Only in extraordinary circumstances may the total dose for the first day exceed 40 milligrams. A transferring client 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 record which justify an initial dosage that is greater than the last daily dosage authorized at the former facility.

4. Clients are stabilized on methadone when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the client comfortable for at least 24 hours with no need to resort to illicit opiates to satisfy opiate cravings.

5. The dose must be administered by a professional authorized by law to do so. No methadone may be administered unless the applicant 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 must be completed on the next working day. No take home medication may be given in such an emergency.

6. No dose of methadone in excess of 120 milligrams may be ordered or administered without the prior approval of the SNA.

(b) Any narcotic drug prescribed and administered shall be documented on an individual medication administration record that is filed with the individual treatment plan. The record must 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 and LAAM shall be handled in accordance with applicable rules of the Substance Abuse and Mental Health Administration or other

(Rule 0940-5-42-.06, continued)

applicable federal agency. All requests for take home exceptions must be reviewed and approved by the SNA and any other applicable federal agency.

(d) Adverse drug reactions and errors must be reported to a program physician immediately and corrective action initiated. The adverse reaction or error must be recorded in the drug administration record, the nurse progress notes and the individual treatment plan, and all persons who are authorized to administer medication or supervise self-medication must be alerted.

(e) All medications must be stored in a locked safe when not being administered or self-administered.

(f) Medication orders and dosage changes must be written or printed on a form which clearly displays the physician's signature. Dosage dispensed, prepared or received must 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 must be recorded in the client's individual medication record at the time the dose is dispensed or administered. If initials are used, the full signature and credentials of the qualified person administering or dispensing must appear at the end of each page of the medication sheet. The perpetual inventory must be totaled and recorded in milligrams daily. Where computer based recording is utilized, the facility shall show that hard copy records are maintained for inspection.

***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-209, 68-11-222, 68-11-305, and 68-11-308 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

**0940-5-42-.07 RESERVED.**

**0940-5-42-.08 BUILDING STANDARDS.**

(1) The non-residential narcotic treatment facility must be constructed, arranged, and maintained to ensure the safety of the clients.

(2) The condition of the physical plant and the overall non-residential narcotic treatment facility environment must be developed and maintained in such a manner that the safety and well-being of clients are assured.

(3) When construction is planned by any facility for any building, additions to an existing building or substantial alterations to an existing building, two (2) sets of plans and specifications shall be submitted to the department to be approved. For the purpose of life safety, non-residential narcotic treatment facilities are required to meet business occupancies and all new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), and the National Electrical Code, as adopted by the Board for Licensing Health Care Facilities. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.).

(4) Flammable and combustible liquids such as gasoline, cleaning fluids, kerosene, turpentine etc., shall be stored in safety containers and stored at least 16 feet from the building or stored in a U.L. approved/listed cabinet and ventilated as prescribed by code requirement or manufacturers' recommendation.

(5) Mechanical

(Rule 0940-5-42-.08, continued)

(a) All units having a total of 2,000 cubic feet per minute (CFM) or greater in a zone shall shut down when the fire alarm panel is activated.

(6) Electrical

(a) The electrical system, components, equipment and appliances shall be kept in good repair at all times.

(b) Knob and Tube wiring is prohibited.

(c) Electrical cords shall not have splices.

(d) Electric circuit breaker panel boxes shall not have open slots exposing wiring.

(e) Circuit breakers shall be properly labeled.

(f) In all new facilities or renovations to existing electrical systems, the installation must be approved by an inspector or agency authorized by the State Fire Marshall.

(g) The electrical system shall not be overloaded.

(h) Ground Fault Circuit Interrupters (GFCI) are required in all wet areas, such as kitchens, laundries, janitor closets, bath and toilet rooms, etc. and within six (6) feet of any laboratory.

(7) Fire Alarm

(a) Manual pull stations shall be installed in paths of travel to exits and by each required exit.

(b) All alarm devices shall be connected to the fire alarm panel.

(c) The fire alarm panel shall have auxiliary power such as batteries or generators.

(d) All sprinkler systems are to be electrically supervised.

(e) Structures with atriums, vertical openings or monumental stairs open to another floor must have their fire alarm system automatically transmit an alarm to the municipal fire department or to an agency acceptable to this department with equipment which meets NFPA signaling and standard building codes. Fire protection systems and smoke evacuation systems must be on emergency power.

***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed June 21, 2007; effective September 4, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

**0940-5-42-.09 LIFE SAFETY.**

(1) Any non residential narcotic treatment facility which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(Rule 0940-5-42-.09, continued)

~~(2) The non-residential narcotic treatment facility shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the department within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Records which document and evaluate these incidents must be maintained for at least three (3) years.~~

~~(3) The non-residential narcotic treatment facility shall have a written emergency plan to document instructions to staff, upon employment, and clients, upon enrollment, in fire evacuation procedures. The plan shall include actions to be taken in inclement weather and internal and external emergencies. Evacuation plans shall be posted in prominent areas such as reception areas, near door in class rooms, etc. and shall designate meeting places outside the building in event of emergencies.~~

~~(4) Corridor doors shall not have louvers.~~

~~(5) Battery powered emergency lighting shall be installed in corridors, common areas and in stair ways.~~

~~(6) Corridors shall be lighted at all times, to a minimum of one foot candle.~~

~~(7) Corridors and exit doors shall be kept clear of equipment, furniture and other obstacles at all times. There shall be a clear passage at all times from the exit doors to a safe area.~~

~~(8) Corridors in multi-storied buildings shall have two exits remote from each other. At least one exit shall be directly to the outside.~~

~~(9) Storage beneath any stair is prohibited.~~

~~(10) Combustible finishes and furnishings shall not be used.~~

~~(11) Open flame and portable space heaters shall not be permitted in the facility. Cooking appliances other than microwave ovens shall not be allowed in the facility.~~

~~(12) All heaters shall be guarded and spaced to prevent ignition of combustible material and accidental burns. The guard shall not have a surface temperature greater than 120°F.~~

~~(13) Fireplaces and/or fireplace inserts may be used only if provided with guards or screens which are secured in place. Fireplaces and chimneys shall be inspected and cleaned annually and verified documentation shall be maintained.~~

~~(14) All electrical equipment shall be maintained in good repair and in safe operating condition.~~

~~(15) Electrical cords shall not be run under rugs or carpets.~~

~~(16) The electrical systems shall not be overloaded. Power strips must be equipped with circuit breakers. Extension cords shall not be used.~~

~~(17) Fire extinguishers, complying with NFPA 10, shall be provided and mounted to comply with NFPA 10. An extinguisher in the kitchen area shall be a minimum of 2-A:10-B:C and an extinguisher with a rating of 20-A shall be adjacent to every hazardous area. The minimum travel distance shall not exceed fifty (50) feet between the extinguishers.~~

(Rule 0940-5-42-.09, continued)

~~(18) Smoking and smoking materials shall be permitted only in designated areas. Ashtrays must be provided wherever smoking is permitted. The facility shall have written policies and procedures for smoking within the facility which shall designate a room or rooms to be used exclusively for clients who smoke. The designated smoking room or rooms shall not be the dining room or activity room.~~

~~(19) Trash and other combustible waste shall not be allowed to accumulate within and around the facility and shall be stored in appropriate containers with tight fitting lids. Trash containers shall be UL approved.~~

~~(20) All safety equipment shall be maintained in good repair and in a safe operating condition.~~

~~(21) Janitorial supplies shall not be stored in the kitchen, food storage area, dining area or client accessible areas.~~

~~(22) Emergency telephone numbers must be posted near a telephone accessible to the clients.~~

(Rule 0940-5-42-.09, continued)

~~***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed June 21, 2007; effective September 4, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.~~

~~**0940-5-42-.10 INFECTIOUS AND HAZARDOUS WASTE.**~~

~~(1) Each facility must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must 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 clients who are isolated due to communicable disease, 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., hypodermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) used in client care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories; and,~~

~~(e) Other waste determined to be infectious by the facility in its written policy.~~

~~(3) Infectious and hazardous waste must 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 must 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 must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must 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.~~

~~(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture-resistant containers which must then be tightly sealed;~~

~~(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;~~

~~(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste; and~~

(Rule 0940-5-42-.10, continued)

(d) Opaque packaging must be used for pathological waste.

(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind, and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents and does not create a nuisance.

(7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:

(a) Isolate the area from the public and all except essential personnel;

(b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of this section; and

(c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure must specify how this will be done.

(8) Except as provided otherwise in this section, a facility must treat or dispose of infectious waste by one or more of the methods specified in this paragraph.

(a) A facility may treat infectious waste in an on site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device is rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non infectious, unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation. Such ash shall be disposable as a (non hazardous) solid waste under current rules of the Department of Environment and Conservation.

(b) The facility may discharge liquid or semi liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §69 3 101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.

(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.

(Rule 0940-5-42-.10, continued)

(9) The facility may have waste transported off site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off site location is in Tennessee, the facility must ensure that it has all necessary state and local approvals, and such approvals shall be available for review. If the off site location is in another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) All garbage, trash and other non infectious waste shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily cleanable material and shall be kept on elevated platforms.

***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

**0940-5-42-.11 RECORDS AND REPORTS.**

(1) Reporting. The facility shall submit the following information to the Department:

(a) All reports, forms and correspondence submitted to the FDA, DEA, any other applicable federal agencies or required accreditation organizations.

(b) Written notification of the administration of greater than one hundred (100) milligrams of methadone to a client requires written notification within ten (10) working days, signed by the program physician, which details clinical justification for exceeding one hundred (100) milligrams.

(c) Such reports and information which may be required by the Department to conduct evaluations of narcotic replacement treatment effectiveness or monitor service delivery.

(2) The NRNTF 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) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

(Rule 0940-5-42-.11, continued)

2. ~~aspiration in a non-intubated patient related to conscious/moderate sedation;~~

3. ~~intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

4. ~~volume overload leading to pulmonary edema;~~

5. ~~blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;~~

6. ~~perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

7. ~~burns of a second or third degree;~~

8. ~~falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;~~

9. ~~procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:~~

   (i) ~~procedure related injury requiring repair or removal of an organ;~~

   (ii) ~~hemorrhage;~~

   (iii) ~~displacement, migration or breakage of an implant, device, graft or drain;~~

   (iv) ~~post operative wound infection following clean or clean/contaminated case;~~

   (v) ~~any unexpected operation or reoperation related to the primary procedure;~~

   (vi) ~~hysterectomy in a pregnant woman;~~

   (vii) ~~ruptured uterus;~~

   (viii) ~~circumcision;~~

   (ix) ~~incorrect procedure or incorrect treatment that is invasive;~~

   (x) ~~wrong patient/wrong site surgical procedure;~~

   (xi) ~~unintentionally retained foreign body;~~

   (xii) ~~loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;~~

   (xiii) ~~criminal acts;~~

   (xiv) ~~suicide or attempted suicide;~~

   (xv) ~~elopement from the facility;~~

(Rule 0940-5-42-.11, continued)

~~(xvi) infant abduction, or infant discharged to the wrong family;~~

~~(xvii) adult abduction;~~

~~(xviii) rape;~~

~~(xix) patient altercation;~~

~~(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;~~

~~(xxi) restraint related incidents; or~~

~~(xxii) poisoning occurring within the facility.~~

~~(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) 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 continued safe operation of the facility or to the health and safety of its patients and personnel; and~~

~~4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.~~

~~(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.~~

~~(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.~~

~~(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report,~~

(Rule 0940-5-42-.11, continued)

~~then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.~~

~~(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

~~(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.~~

~~(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(Rule 0940-5-42-.11, continued)

~~(4) The NRNTF shall retain legible copies of the following records and reports for thirty-six months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them. Each client must be fully informed of the availability of these reports to the public, of their location within the facility, and given an opportunity to inspect the file before entering into any monetary agreement with the facility:~~

~~(a) Local fire safety inspections;~~

~~(b) Local building code inspections, if any;~~

~~(c) Fire Marshall reports;~~

~~(d) Department licensure and fire safety inspections and surveys;~~

~~(e) Federal government surveys and inspections, if any;~~

~~(f) Orders of the Commissioner or Board, if any;~~

~~(g) Comptroller of the Treasury's audit reports and findings, if any; and~~

~~(h) Maintenance records of all safety equipment.~~

~~(5) Inspections.~~

~~(a) The Department is authorized to conduct on-site inspections of any facility to verify compliance with these rules and all relevant laws or regulations. A facility shall permit any authorized Department representative to enter upon and inspect any and all facility premises which, for the purposes of these rules, shall include access to all parts of the facility, staff, persons in care, and documents pertinent to initial and continued licensure. Failure to permit entry and inspection is a violation of this rule and may result in the denial of any license applied for or the suspension or revocation of a license.~~

~~(b) If, as a result of an inspection, violations of these rules are identified, the Department may issue a written inspection report that identifies the rules violated and requires the facility to submit a written plan of correction that states what the program will do to correct each of the violations identified. The Department will provide written inspection reports to the facility within 30 days after the on-site inspection, unless there is a determination by the SNA that the complexity of the issues or other extenuating circumstances require an extension of this time period. The facility may offer any explanation or dispute the findings of violations in the written plan of correction so long as an acceptable plan of correction is submitted within 30 days of receipt of the inspection report. Failure to submit an acceptable plan of correction may constitute cause for the Department to deny a license or suspend or revoke a license. Nothing in this paragraph will be interpreted to mean that facilities must be afforded an opportunity to correct all violations. Upon the discovery of any violation of these rules, the Department may proceed to suspend or revoke a facility's license in accordance with these rules. In determining the appropriate response to rule violations, the Department will consider whether the violations can be corrected, the facility's history of compliance, the nature and seriousness of the violations, the impact of the violations on the safety and welfare of the facility's clients and the surrounding community and any other relevant circumstances.~~

(Rule 0940-5-42-.11, continued)

~~***Authority:** T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213 and Executive Order 44 (February 23, 2007). **Administrative History:** Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed April 11, 2003; effective June 25, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.~~

~~**0940-5-42-.12 CLIENTS RIGHTS.**~~

~~(1) Confidential Records.~~

~~(a) All applications, certificates, records, reports and all legal documents, petitions and records made or information received pursuant to treatment in a NRNTF directly or indirectly identifying a client shall be kept confidential and shall not be disclosed by any person except the individual identified; and~~

~~(b) As a court may direct upon its determination that disclosure is necessary for the conduct of proceedings before it and that failure to make such disclosure would be contrary to the public interest or detrimental to either party to the proceedings, consistent with the provisions of 42 C.F.R. Part 2.~~

~~(2) Nothing in this rule shall prohibit disclosure, upon proper inquiry, of information as to the current medical condition of a client to any members of the family of a client or to his relatives or friends providing that conditions of 42 C.F.R. Part 2 have been met.~~

~~(3) Clients shall not be abused or neglected.~~

~~(4) Facilities shall develop and implement written policies and procedures regarding the rights and responsibilities of clients, and the handling and resolution of complaints.~~

~~(5) Other client rights include:~~

~~(a) Right to a humane treatment environment that affords reasonable protection from harm, exploitation, and coercion;~~

~~(b) Right to be free from physical and verbal abuse;~~

~~(c) Right to be informed about the individualized plan of treatment and to participate in the planning, as able;~~

~~(d) Right to be promptly and fully informed of any changes in the plan of treatment;~~

~~(e) Right to accept or refuse treatment;~~

~~(f) Right to confidentiality of client records;~~

~~(g) Right to be informed of the facility's complaint policy and procedures and the right to submit complaints without fear of discrimination or retaliation and to have them investigated by the program within a reasonable period of time;~~

~~(h) Right to receive a written notice of the address and telephone number of the state licensing authority, i.e. the Department; and~~

~~(i) 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~~

(Rule 0940-5-42-.12, continued)

~~report until the facility has had the opportunity to file a written plan of correction for the violations as provided for in these rules.~~

~~(6) The written policies and procedures shall include provisions for clients 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. §§4-5-202 through 4-5-206, 68-11-202, 68-11-209, 68-11-302, and 68-11-304 and Executive Order 44 (February 23, 2007).* ~~***Administrative History:***~~ *Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.13 REPEALED.**~~

~~***Authority:*** *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209 and Executive Order 44 (February 23, 2007).* ~~***Administrative History:***~~ *Original rule filed June 8, 1999; effective August 22, 1999. Repeal filed April 30, 2003; effective July 14, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.14 DISASTER PREPAREDNESS.**~~

~~(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans, for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans shall be readily available at all times in the telephone operator's position or at the security center. Each of the following plans shall be exercised annually prior to the month listed in each plan:~~

~~(a) Fire Safety Procedures Plan (to be exercised at any time during the year) shall include:~~

~~1. Minor fires.~~

~~2. Major fires.~~

~~3. Fighting the fire.~~

~~4. Evacuation procedures~~

~~5. Staff functions by department and job assignment.~~

~~(b) Tornado/Severe Weather Procedures Plan (to be exercised prior to March) shall include:~~

~~1. Staff duties by department and job assignment.~~

~~2. Evacuation procedures.~~

~~(c) Bomb Threat Procedures Plan (to be exercised at any time during the year):~~

~~1. Staff duties by department and job assignment.~~

~~2. Search team, searching the premises.~~

(Rule 0940-5-42-.14, continued)

3. Notification of authorities.

4. Location of suspicious objects.

5. Evacuation procedures.

(d) Flood Procedures Plan (to be exercised prior to March):

1. Staff duties by department and job assignment.

2. Evacuation procedures.

3. Safety procedures following the flood.

(e) Severe Cold Weather (to be exercised prior to November) and Severe Hot Weather (to be exercised prior to May) Procedures Plans:

1. Staff duties by department and job assignment.

2. Equipment failures.

3. Insufficient HVAC on emergency power.

4. Evacuation procedures.

5. Emergency food service.

(f) Earthquake Disaster Procedures Plan (to be exercised at any time during the year):

1. Staff duties by department and job assignment.

2. Evacuation procedures.

3. Safety procedures.

4. Emergency services.

(2) All facilities shall participate in the Tennessee Emergency Management local/county emergency plans on an annual basis. Participation includes but is not limited to filling out and submitting a questionnaire on a form to be provided by the Tennessee Emergency Management Agency. Documentation of participation must be maintained and shall be made available to survey staff as proof of participation.

***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*