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Sequence Number: 03-51-10
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File Date: 03/31/2010

Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Tennessee Department of Mental Health and Developmental Disabilities
Division:	Office of Licensure
Contact Person:	Karen Edwards
Address:	425 Fifth Avenue North 5th Floor, Cordell Hull Building Nashville, TN 37243
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Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	Gwen Hamer
Address:	425 Fifth Avenue North 5th Floor, Cordell Hull Building Nashville, TN 37243
Phone:	615-532-6510
Email:	Gwen.Hamer@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	425 Fifth Avenue North		
Address 2:	Cordell Hull Building, Third Floor		
City:	Nashville, TN		
Zip:	37243		
Hearing Date :	05/25/2010		
Hearing Time:	1:30 p.m.	_X_ CST ___ EST	

Additional Hearing Information:

TDMHDD Large Conference Room

Revision Type (check all that apply):

___ Amendment
_X_ New
_X_ Repeal

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

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

Rule Number	Rule Title
0940-05-42-.01	Definitions
0940-05-42-.02	Application of Rules
0940-05-42-.03	Licensing Procedures
0940-05-42-.04	Policy and Procedures
0940-05-42-.05	Financial Management
0940-05-42-.06	Personnel and Staffing Requirements
0940-05-42-.07	Admissions, Discharges and Transfers
0940-05-42-.08	Professional Services
0940-05-42-.09	Basic Services
0940-05-42-.10	Service Recipient Record Requirements
0940-05-42-.11	Medication Management
0940-05-42-.12	Infectious and Hazardous Waste
0940-05-42-.13	Records and Reports
0940-05-42-.14	Service Recipients' Rights

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

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)" means a non-residential opioid treatment facility for treating opioid-dependent service recipients with the goal of the service recipient becoming free from any drug which is not medically indicated.

(b) "Advanced Practice Nurse" means a nurse licensed in Tennessee who meets the Tennessee Board of Nursing requirements for an advanced practice nurse.

(c) "Buprenorphine" means a synthetic opioid agonist which has been approved by the FDA for detoxification in maintenance treatment of opioid addiction.

(d) "Central Registry" means an electronic system used to register service recipients currently receiving opioid replacement treatment at an OTP. The Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) or State Opioid Treatment Authority (SOTA) may require OTP's 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) "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.

(f) "Counseling Session" means therapeutic discussion between service recipient(s) and a facility counselor for a period of no less than thirty (30) minutes designated to address service recipient addiction issues or coping strategies and Individualized Program Plans.

(g) "DEA" means the United States Drug Enforcement Administration.

(h) "FDA" means the United States Food and Drug Administration.

(i) "Guest Dose" means any dose provided on a temporary basis at a program other than the service recipient's home clinic.

(j) "Home Clinic" means the program where an individual is admitted and primarily treated as a program service recipient.

(k) "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.

(l) "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 opiate-like drugs.

(m) "Medical Director" means a physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who has been designated by the governing body of the OTP to be responsible for the administration of all medical services performed by the OTP, including compliance with all federal, state

and local law and rules regarding medical treatment of opiate addiction. The medical director shall have the experience and credentials specified in paragraph 0940-05-42-.06(4) of these rules.

(n) "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 confinement or services rendered to service recipients.

(o) "Methadone (trade name Dolophine)" means a synthetic opioid agonist approved by the FDA for detoxification and maintenance treatment of opiate addiction.

(p) "Multidisciplinary Treatment Team (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.

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

(r) "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.

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

(t) "Plan of Compliance" means a report filed with the Department by the facility if the facility is found to be out of compliance with rules contained in this chapter. The plan shall indicate:

1. How the deficiency will be corrected;

2. The date upon which each deficiency will be corrected;

3. What measures or systematic changes will be put in place to ensure that the deficient practice does not recur; and

4. How the corrective action will be monitored to ensure that the deficient practice does not recur.

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

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

(w) "Program Physician" means any physician, including the medical director, who is employed by an OTP to provide medical services to service recipients. Any program physician who is not a medical director shall work under the supervision of the program's medical director.

(x) "Prescription Monitoring Program" 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.

(y) "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.

(z) "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.

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

(bb) "Reputable and Responsible Character" means that the applicant or licensee can be trusted with responsibility for persons who are particularly vulnerable to abuse, neglect, and financial or sexual exploitation. Personal, professional and/or business histories and practices containing evidence of the operation of substandard facilities or violation of applicable federal, state, and local laws, ordinances, rules, and regulations are presumed innocent with a "reputable and responsible character."

(cc) "Service Recipient Transfer" means any service recipient who changes locations of their home clinic without receiving a discharge status or has a break in treatment.

(dd) "State Board of Pharmacy" means the Board created to regulate the practice of pharmacy pursuant to T.C.A. § 63-10-301.

(ee) "SOTA" or "State Opioid Treatment Authority" means the Tennessee Department of Mental Health and Developmental Disabilities or any individual person designated by the Commissioner to exercise the responsibility and authority for governing the treatment of opioid addiction with a responsibility and authority for governing the treatment of opioid addiction with an opioid drug in accordance with all applicable state and federal regulations.

(ff) "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.

(gg) "TDMHDD" means the Tennessee Department of Mental Health and Developmental Disabilities.

(hh) "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.

(ii) "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. §§ 4-4-103, 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 Program 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.

Authority: T.C.A. §§ 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 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. The written application for operation of an OTP shall be filed simultaneously with the federal Substance Abuse and Mental Health Services Administration (SAMSHA) and the DEA, and/or any other applicable federal agencies.

(2) Service recipients shall not be admitted to the OTP until a license has been issued.

(3) A proposed change of ownership, including a change in a controlling interest, shall 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 governing body of an OTP 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 OTP's operation is transferred.

(b) A change of ownership occurs as defined in 0940-05-02 Licensure Administration and Procedures.

Authority: T.C.A. §§ 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 Policy and Procedures.

(1) The governing body of the facility shall ensure it is administered and operated in accordance with written policies and procedures including the following:

(a) The facility shall maintain written policies and procedures governing the intake and assessment process and specify the following:

1. The information to be obtained on all prospective service recipients or referrals for admission;

2. The procedures for accepting referrals from outside agencies or organizations;

3. The records to be kept on all prospective service recipients;

4. Any prospective service recipient data to be recorded during the intake process; and

5. The procedures to be followed when a prospective service recipient or a referral is found ineligible for admission.

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

(c) Pharmacotherapy guidelines for opioid replacement treatment for service recipients covering the program's own prescribing and review of prescriptions from other physicians which shall minimally include assurance that service recipient's prescriptions from outside physicians will be reported to the medical staff and reviewed by the program physician.

(d) 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 service recipient's chart detailing why a service recipient is to remain in treatment as determined by multidisciplinary treatment team evaluation and signed by the program physician or medical director of the program.

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

(f) Procedures for medically supervised withdrawal in the event the service recipient becomes unable to pay for treatment, including an appropriate time frame over which the procedure would take place.

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

1. Any restrictive procedure shall be used by the facility only after all less restrictive alternatives for dealing with the problem behavior have been systematically tried or considered and have been determined to be inappropriate or ineffective:

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

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

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

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

2. A policy which states physical holding shall be implemented in such a way as to minimize any physical harm to the service recipient and may only be used in an emergency situation to assure the physical safety of the service recipient or others nearby or to prevent significant destruction of property that puts the service recipient or persons nearby in danger.

(h) Hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work.

1. All clinics shall be open seven (7) days per week and three hundred sixty-five (365) days per year.

2. Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical exams and referral services, at least six (6) days per week.

3. 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 State and Federal holidays, not to exceed two (2) consecutive days.

4. Facilities shall provide the SOTA with at least two (2) weeks notice prior to any change in program hours.

5. A facility that intends to voluntarily close shall notify TDMHDD no later than thirty (30) 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 TDMHDD regarding the orderly transfer of service recipients and their records.

(i) Each licensee shall clearly identify the governing body in its policies and procedures manual.

(j) Each clinic shall prepare a Diversion Control Plan for service recipients receiving more than four (4) take-home medications. The Diversion Control Plan shall contain, at a minimum, the following:

1. A random call back program with mandatory compliance.

(i) This call back shall be in addition to the regular schedule of clinic visits.

(ii) Each service recipient receiving take-home medications shall randomly be called back within the three (3) month period immediately following the previous call back.

(iii) Upon call back a service recipient shall 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 for all doses. If a liquid take-home dose shows evidence of tampering, one dose shall be replaced and sent for analysis to verify strength and contents.

(iv) The facility shall maintain individual callback results in the service recipient record.

(k) Procedures for community relations to include the following:

1. A facility shall be responsible for assuring that its service recipients 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.

2. Each facility shall provide TDMHDD, 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. The TDMHDD 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.

(l) Policies and procedures to be followed for infection control, including:

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

2. Management of service recipient's who are infected with Hepatitis B or C virus, HIV/AIDS or other STD;

3. Nondiscrimination of employees and service recipient's regarding their HIV/AIDS status;

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

5. Infectious diseases testing will be made on a voluntary basis for any service recipient who requests it, and be documented in appropriate records;

6. Assurance that a service recipient's HIV, other STD, and tuberculosis status will be kept confidential in accordance with T.C.A. § 33-3-103; Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 Code of Regulations (CFR) Parts 160 and 164, Subparts A and E; and Confidentiality of Alcohol and Drug Abuse Patient Records regulations at 42 CFR Part 2;

7. Documentation on the establishment of linkages between the facility and the local health department to ensure service recipients receive appropriate medical care relative to their infection and/or exposure to tuberculosis, Hepatitis B or C, and STD (including HIV), i.e., establish contact between the health department and the facility to communicate appropriate information to assure that the service recipient receives appropriate care;

8. Informed consent of service recipients before screening and treatment; and

9. Conducting case management activities to ensure that individuals receive appropriate treatment services for HIV/AIDS, Hepatitis B or C Virus and other sexually transmitted diseases, and tuberculosis.

(m) Policies and procedures for random drug screens for the purposes of assessing the service recipient's abuse of drugs and making decisions about the service recipient's treatment. These policies and procedures shall include the following provisions:

1. Urine drug screens shall be conducted on a random basis weekly for new service recipients during the first thirty (30) days of treatment and at least monthly thereafter; however, service recipients on a monthly schedule whose drug screen reports indicate drug abuse will be returned to a weekly schedule for at least two (2) weeks, or longer, if clinically indicated.

2. Each sample collected shall be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, tetrahydrocannabinol (THC) and other drugs as indicated by individual service recipient use patterns or that are heavily used in the locale of the service recipient or as directed by the SOTA.

3. Policies and procedures shall ensure that urine collected from service recipients is unadulterated. Such policies may include random drug observation which shall be conducted professionally, ethically, and in a manner which respects service recipients' privacy.

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

(a) Contact information, including the statewide toll-free number of the Division of Adult Protective Services, and the number for the local District Attorney's office;

(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 Department 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 (8 ½") in width and eleven inches (11") in height.

(d) 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. §§ 4-4-103, 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-.05 Financial Management.

(1) 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 shall be available upon request by the Department for examination and review by the TDMHDD.

Authority: T.C.A. §§ 4-4-103, 33-1-305, 33-2-301, 33-2-403, 33-2-404 and 33-2-407.

0940-05-42-.06 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 ten-year employment history or a complete employment history if the person has not worked in ten 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 (3) 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 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 opiate 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 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 service recipient 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 opioid dependence, ordering take-home privileges, discussing cases with the treatment team and issuing any emergency orders. Facilities shall 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 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.

(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 (3) years of 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 opiate addiction with an opioid 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; and

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 TDMHDD for variance. The TDMHDD has the discretion to grant such a variance 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 will be available to oversee the training of the medical director and the delivery of medical services at the program requesting the variance.

(c) Program Physician. All program physicians shall be licensed to practice medicine in Tennessee, shall maintain their licenses in good standing and shall 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 TDMHDD for a variance. The TDMHDD 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 SOTA 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 physicians as of the effective date of these rules who do not meet the criteria specified above will be deemed qualified provided that they obtain 50 hours of continuing education in addiction medicine approved by the SOTA within two years from the effective date of these rules. At least 25 hours of this continuing education shall be obtained within one year from the effective date of these rules.

(f) Nurses. All registered nurses and licensed practical nurses shall be licensed to practice in Tennessee and shall maintain their license in good standing.

(g) Counselors. All counselors shall be qualified by training, education and/or experience in addiction treatment to provide addiction counseling services.

(h) Program Directors. All program directors shall 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.

(5) Staff Training and Orientation. Prior to working with service recipients, all staff who provide treatment and services shall be oriented in accordance with these rules and shall thereafter receive additional training in accordance 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 (8) 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. 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. Referring service recipients for primary care or other specialized services.

(c) 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 opiates, methadone, amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by the SOTA.

(7) Staff Ratios and Responsibilities. For every 400 service recipients enrolled in services, the program physician shall provide at least 10 hours of on-site service per week. A certified nurse practitioner or physician's assistant may perform a maximum of 30% of the required physician time. However, all dosing and administration decisions shall be made by the program physician.

(8) A minimum of one (1) on-duty staff member certified in CPR and trained in the Abdominal Thrust Technique and First Aid shall be maintained.

Authority: T.C.A. §§ 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-.07 Admissions, Discharges and Transfers.

(1) Screening, Admission, and Orientation of Service Recipients.

(a) A facility shall only admit and retain service recipients whose known needs can be met by the facility in accordance with its program purpose and description and applicable federal and state laws and regulations.

(b) 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.

(c) No facility shall provide a bounty, free services, medication or other reward for referral of potential service recipients to the clinic.

(d) The facility shall document that the following assessments are completed prior to the development of the Individualized Program Plan (IPP).

1. Screening. All service recipients applying for admission shall be initially screened by facility staff to determine eligibility for admission. No prospective service recipient shall 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 prospective service recipient's case folder. The screening process shall include:

(i) Verification, to the extent possible, of a prospective service recipient'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) Verification of other prescribed controlled medications through the prescription monitoring program (PMP) run by the Board of Pharmacy of the Tennessee Department of Health;

(v) Psychiatric history and current mental status exam;

(vi) 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;

(vii) Pregnancy tests for females shall be conducted at admission and at least annually thereafter, unless otherwise indicated;

(viii) If a prospective service recipient has previously been discharged from treatment at another methadone clinic or program, the admitting facility shall initiate any investigation into the prospective service recipient's prior treatment history, inquiring of the last program attended and the reasons for discharge from treatment;

(ix) 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;

(x) 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 one year; and

(xi) If a prospective service recipient 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 service recipient admitted to the facility shall be evaluated by the medical director or program physician and clinical staff who have been determined to be qualified by education, training, and experience to perform or coordinate the provision of such assessments. The purpose of such assessments shall be to determine whether opioid substitution, short-term detoxification, long-term detoxification, or drug free treatment will be the most appropriate treatment modality for the service recipient. The evaluation shall include an assessment of the service recipient's needs for other services including treatment, education and vocational.

(e) Admission.

1. Consent. 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 the service recipient's file:

(i) The program's services and treatment;

(ii) The specific condition that will be treated;

(iii) Explanation of treatment options, detoxification rights, and clinic charges, including the fee agreement, signed by the prospective service recipient; and

(iv) The facility's rules regarding service recipient conduct and responsibilities.

2. Admission Clearance. No person shall be admitted unless the facility conducts an inquiry with the Central Registry in accordance with Rule 0940-05-42-.07(3).

(f) Orientation.

1. The facility shall provide orientation to service recipients within twenty-four (24) hours of admission for treatment. Orientation shall occur again within thirty (30) days following the admission date to ensure service recipient understanding and emphasize education. 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. Facilities shall ensure that each service recipient signs a statement confirming that the following information has been explained to the service recipient:

(i) The expected benefits of the treatment that the service recipient is expected to receive;

(ii) The service recipient's responsibilities for adhering to the treatment regimen and the consequences of non-adherence;

(iii) An explanation of individualized program planning:

(I) The identification of the staff person who is expected to provide treatment or coordinate the treatment;

(II) Facility rules including requirements for conduct and the consequences of infractions;

(III) Drug screening policies and procedures; and

(IV) Information about HIV, tuberculosis, and sexually transmitted diseases.

(g) 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.

(h) Service Recipient Transfers. Service recipients who were terminated from a prior program due to non-compliance shall be admitted as a new service recipient.

(2) Discharge and Aftercare Plans. A facility shall complete an individualized discharge and aftercare plan for service recipients who complete their course of treatment. This plan shall be completed within seven (7) 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 a description of aftercare plans for the service recipient. The service recipient shall participate in 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.

(3) Central Registry.

(a) To prevent simultaneous enrollment of a service recipient in more than one facility, all facilities shall participate in the Department's central registry. 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 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 service recipient shall be discharged from one facility in order to continue enrollment at 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 SOTA also participate in the central registry of the adjoining state.

Authority: T.C.A. §§ 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-.08 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 their 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.

Authority: T.C.A. §§ 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-.09 Basic Services.

(1) Quality of Care. The 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 Individualized Program Plan 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 utilization and cost effectiveness of the services delivered which shall examine treatment slot utilization and cost per slot, staff to service recipient ratio and cost per counseling session and other support services.

(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 program'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) Programs shall participate in additional quality improvement outcome studies as directed by the SOTA.

(2) Performance Outcome. The OTP shall monitor performance outcome. The following performance indicators may be used to evaluate the impact of the program on service recipients and the community:

(a) Service recipient receipt of needed program or out-of-state services.

(b) Service recipient satisfaction.

(c) Service recipient 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) Individual Program Planning. A facility shall develop an Individualized Program Plan for each service recipient within thirty (30) days of admission. Service recipients shall be involved in the development of their Individualized Program Plans. Individualized Program Plans shall document

a consistent pattern of substance abuse treatment services and medical care appropriate to individual service recipient needs.

(a) 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 of this annual medical examination and review of service recipient medical records in each service recipient's record.

(b) In recognition of the varied medical needs of service recipients, the case history and Individualized Program Plans shall be reviewed at least every ninety (90) days for service recipients in treatment less than one (1) year and at least annually for service recipients 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 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.

(c) 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.

(d) 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 determined by appropriate program staff 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.

(e) All service recipients shall receive HIV risk reduction education appropriate to their needs.

(f) When appropriate, each service recipient shall 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 shall be explained in the service recipient's record. Each facility shall take steps to ensure that a comprehensive range of rehabilitative services, including vocation, 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 services 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.

(g) 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 varies depending upon the service recipient's phase of treatment. Phases of treatment may include intensive stabilization for new service recipients and those in need of acute care, graduated rehabilitation phases, and for long-term stable service recipients, a medical maintenance or methadone-tapering phase.

(h) Each service recipient's Individualized Program Plan shall include the counseling needs, including both group and individualized counseling sessions as indicated by evaluation of the service recipient's length of time in the program, drug screening results, progress notes, and social environment. The Individualized Program Plan shall be reviewed at least every six (6) months.

(i) If the service recipient experiences a relapse, his/her Individualized Program Plan shall document evidence of intensified services provided. Such evidence may include, but is not limited to, an increase in individual or group counseling session(s) and/or a reduction in the service recipient's take home privileges.

(4) Counseling.

(a) For all service recipients, except those receiving buprenorphine, the following counseling schedule shall be followed:

1. During the first ninety (90) days of treatment, counseling session(s) shall take place at least one (1) time per 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 service recipient's Individualized Program Plan, but not less frequently than monthly as long as the service recipient is compliant.

(b) For all service recipients on buprenorphine, counseling shall occur monthly or more often if indicated in the Individualized Program Plan.

Authority: T.C.A. §§ 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-.10 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 TDMHDD. The service recipient Central Registry I.D. number shall be shown on each page of the service recipient's record.

(2) A written fee agreement as detailed in Rules Chapter 0940-05-06 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 procedures for medically supervised withdrawal in the event the service recipient becomes unable to pay for treatment.

(3) Documentation of Central Registry clearance as required in paragraph 0940-05-42-.07(3) of these rules.

(a) Records shall be retained for a minimum of ten (10) years even if a facility discontinues operations.

(b) The TDMHDD shall be notified ninety (90) days in advance of a facility's closing.

(c) 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.

Authority: T.C.A. §§ 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.

(1) 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 shall include the following:

(a) Administration.

1. A program physician shall perform a medical assessment to determine the service recipient's initial and subsequent 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 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 twenty-four (24) hours. Both the verbal order and the results of the physical examination shall be documented in the service recipient's record.

2. Proper dose should 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. 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. 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. No dosage increases shall occur on the days that the facility is closed.

4. 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 opiates to satisfy opiate cravings.

5. The dose shall be administered by a professional authorized by law to do so. 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.

6. The administration of greater than one hundred (100) milligrams of methadone to a service recipient requires written notification to the SOTA within ten (10) working days, signed by the program physician, which details clinical justification for exceeding one hundred (100) milligrams.

7. No dose of methadone in excess of one hundred twenty (120) milligrams may be ordered or administered without the prior approval of the SOTA.

8. Any request for approval for a dose of methadone in excess of one hundred forty (140) milligrams shall be submitted with a peak and trough for SOTA approval.

9. Benzodiazepine use.

(i) The facility shall initiate coordination of care with a qualified prescriber, who is authorized to prescribe medications by the Tennessee Board of Medical Examiners or the Tennessee Board of Nursing, within fourteen (14) days if a service recipient has a positive benzodiazepine screen.

(ii) The service recipient shall have ninety (90) days from the positive screen to:

(I) Become clean from benzodiazepines; or

(II) Medically withdraw from the program; or

(III) Have a qualified prescriber send a letter, updated annually, stating that the service recipient requires long-term use of benzodiazepines; and

(IV) Receive counseling regarding the effects of and use of benzodiazepines and opioids. Counseling shall be documented in the service recipient's record.

(iii) Monthly drug screens of all long-term users of benzodiazepines shall determine the type of benzodiazepine used.

(b) Any narcotic drug prescribed and administered shall be documented on an individual medication administration record that is filed with the Individualized Program Plan. 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 burprenorphine 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 prescription monitoring database prior to providing a take-home dose to any service recipient. The results of the check shall be documented in the service recipient's record.

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.

(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 Individualized Program Plan, and all persons who are authorized to administer medication or supervise self-medication shall be alerted.

(e) All medications shall be stored in a locked safe when not being administered or self-administered.

(f) Medication orders and dosage changes shall be written or printed on a form which clearly displays the physician's signature. Dosage dispensed, prepared or received shall be recorded and accounted for by written or printed notation in a manner which achieves a perpetual and accurate inventory at all times. Every dose shall be recorded in the service recipient's individual medication record at the time the dose is dispensed or administered. If initials were used, the full signature and credentials of the qualified persons 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. Where computer-based recording is utilized, the facility shall show that hardcopy records are maintained for inspection.

(g) The facility shall check the prescription monitoring database, at least on a quarterly basis and whenever a dose increases, to determine if controlled substances other than methadone are being prescribed for the service recipient. The results of this check shall be included in the service recipient's record.

(h) Guest Dosing.

(i) Guest dosing shall be provided for a maximum of fourteen (14) days. Anything beyond fourteen (14) days shall be approved by the SOTA before dosing occurs.

(ii) Tennessee service recipients shall have been enrolled at the home clinic for a minimum of thirty (30) days before being eligible for a guest dose. Guest dosing of service recipients enrolled less than thirty (30) days at the home clinic shall only occur if approved by the Department.

(iii) Tennessee service recipients shall have two (2) consecutive clean urine drug screens before being eligible for a guest dose.

Authority: T.C.A. §§ 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-.12 Infectious Hazardous Waste.

(1) Each facility shall develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous 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 is 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 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. §§ 4-4-103, 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-.13 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) 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 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 twenty-four (24) hours to the Department of Mental Health and Developmental Disabilities Office of Licensure and Review the identification of the abuse of a service recipient or an unexpected occurrence or accident that results in death or serious injury to a service recipient. The following are examples of events that should be reported:

(a) Medication errors;

(b) Criminal acts;

(c) Suicide or attempted suicide;

(d) Rape;

(e) Service recipient altercation;

(f) Service recipient abuse, service recipient neglect, or misappropriation of resident/service recipient funds;

(g) Restraint related incidents; or

(h) Poisoning occurring within the facility.

(i) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall be reported to the Department within seven (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 service recipients and personnel; and

4. Fires at the facility which disrupt the provision of service recipient care services or cause harm to service recipients or staff, or which are reported by the facility

to any entity, including, but not limited to a fire department, charged with preventing fires.

(j) Within seven (7) days of any event described in (a) or (b), the facility shall file an event report on the incident consisting of the following:

1. The actions implemented to prevent the reoccurrence of the event;

2. The time frames for the action(s) to be implemented;

3. The person(s) designated to implement and monitor the action(s); and

4. The strategies for the measurements of effectiveness to be established.

Authority: T.C.A. §§ 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-.14 Service Recipients' 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 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 members of the facility of a service or to his relatives or friends in accordance with Tennessee Code Annotated § 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 Patient 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 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 Individualized Program Plan 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 received a written notice of the address and telephone number of the state licensed authority, i.e. the Department; and

(f) Right to obtain a copy of the facility's most recent completed report of licensing inspection from the facility upon written request. The facility is not required to release a report until the facility has had the opportunity to file a written plan of compliance for the violations as provided for in these rules.

(6) The written policies and procedures shall include provisions for service recipients and others to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

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

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. §§ 4-4-103, 33-1-302, 33-1-305, 33-1-309; 33-2-301, 33-2-302, 33-2-404 and 33-2-407.

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

Date: 3/31/2010

Signature:

Name of Officer: Zachary S. Griffith

Title of Officer: General Counsel

Subscribed and sworn to before me on: March 31, 2010

Notary Public Signature: Rebecca Calvert

My commission expires on: 6/3/2012

REBECCA CARLS CALVERT STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY TENN My Commission Expires

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Tre Hargett
Secretary of State

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