

Department of State
Division of Publications
 312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower
 Nashville, TN 37243
 Phone: 615.741.2650
 Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 07-15-16
 Notice ID(s): 2544
 File Date: 7/8/16

Notice of Rulemaking Hearing

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

Agency/Board/Commission:	Tennessee Department of Mental Health & Substance Abuse Services
Division:	Division of Administration and Legislation
Contact Person:	Kurt Hippel
Address:	5th Floor, Andrew Jackson Building, 500 Deaderick Street, Nashville, TN 37243
Phone:	615-532-6520
Email:	Kurt.Hippel@tn.gov

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:	6 th Floor, Andrew Jackson Building, 500 Deaderick Street, Nashville, TN 37243
Phone:	615-532-6510
Email:	Gwen.Hamer@tn.gov

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

Address 1:	Andrew Jackson Building, Ground Floor Hearing Room		
Address 2:	500 Deaderick Street		
City:	Nashville		
Zip:	37243		
Hearing Date :	08/30/2016		
Hearing Time:	9:30 a.m.	<input checked="" type="checkbox"/> CST/CDT	<input type="checkbox"/> EST/EDT

Additional Hearing Information:

Please allow enough time to go through security upon entry to the building. Identification is required.
 All written comments re: these proposed rules are due by COB (4:30 p.m. CST) on 8/30/2016 to Kurt.Hippel@tn.gov.

Revision Type (check all that apply):

- Amendment
- New
- Repeal

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

Chapter Number	Chapter Title
0940-05-35	Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities

Rule Number	Rule Title
0940-05-35-.01	Purpose
0940-05-35-.02	Definitions
0940-05-35-.03	Application of the Rules
0940-05-35-.04	Licensing Procedures
0940-05-35-.05	Policy and Procedures
0940-05-35-.06	Admissions and Discharges and Best Practices Utilized
0940-05-35-.07	Patient Record Requirements
0940-05-35-.08	Patient Transfers
0940-05-35-.09	Individualized Treatment Plan and Best Practices Utilized
0940-05-35-.10	Special Populations
0940-05-35-.11	Counseling
0940-05-35-.12	Medication Management
0940-05-35-.13	Drug Screens
0940-05-35-.14	Detoxification and Medically Supervised Withdrawal
0940-05-35-.15	Diversion Control Plan
0940-05-35-.16	Reporting Requirements
0940-05-35-.17	Patient Rights
0940-05-35-.18	Community Relations
0940-05-35-.19	Personnel and Staffing Requirements

(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>)

0940-05-35-.01 Purpose.

The rules in this chapter implement the law relative to licensure and regulation of nonresidential office-based opiate treatment facilities pursuant to Chapter 912 of the Public Acts of 2016.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.02 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) "Nonresidential office-based opiate treatment facility" or "Facility" or "OBOT" is a service entity that includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate use disorder by preventing symptoms of withdrawal to fifty percent (50%) or more of its patients and one hundred fifty (150) or more patients. An association by contract, fee for service, business arrangement, or two or more unaffiliated physicians with a DATA 2000 waiver operating at the same physical location shall be considered an OBOT.
 - (b) "Buprenorphine" means a semi-synthetic opioid partial agonist that activates the opioid receptors but not to the same degree as full agonists such as morphine and heroin.
 - (c) "Case Management/Care Coordination" means a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes.
 - (d) "Controlled Substance Monitoring Database" or "CSMD" means a program administered by the Tennessee Department of Health to monitor the prescribing and dispensing of Schedule II, III, IV and V controlled substances as set forth by T.C.A. Title 53, Chapter 10, Part 3.
 - (e) "Counseling" or "Counseling Session" means a face-to-face individual therapeutic counseling session lasting not less than twenty (20) minutes with a qualified provider, or a group educational session of no more than twenty (20) patients and lasting not less than fifty (50) minutes facilitated by a qualified provider. Counseling shall be focused on issues related to the patient's opioid use disorder and shall not include discussions related to administrative procedures. Telehealth, pursuant to the Tennessee Code Annotated, may be utilized to facilitate counseling. Attendance of a 12-step program, such as Narcotics Anonymous, shall not be considered counseling. The Facility shall document each counseling session in the patient's medical chart.
 - (f) "DATA 2000 Waiver" means the registered authority given to a qualified health care professional by the U.S. Drug Enforcement Administration to prescribe FDA-approved narcotic medication for opioid detoxification or maintenance treatment pursuant to 21 U.S.C. §823(g).
 - (g) "DEA" means the United States Drug Enforcement Administration.
 - (h) "Detoxification" or "Detoxification Treatment" means the dispensing of an opioid agonist treatment medication in decreasing doses to the patient 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 patient to a drug-free state within that period.

- (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) "Facility 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 a non-residential office-based opiate treatment facility, and for all Facility employees including practitioners, agents, or other persons providing services at the Facility.
- (k) "FDA" means the United States Food and Drug Administration.
- (l) "Governing Body" means the person or persons with primary legal authority and responsibility for the overall operation of the OBOT 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.
- (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) "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 Facility to be responsible for the administration of all medical services offered by the Facility, including compliance with all federal, state and local laws and rules regarding medical treatment of opioid use disorder.
- (o) "Medical Record" or "Medical Chart" 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 patients.
- (p) "Medication Assisted Treatment" means use of a medication approved by the federal Food and Drug Administration (FDA), in combination with counseling and behavioral therapies, for the treatment of an opioid related substance use disorder.
- (q) "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 patient progress.
- (r) "Office of Licensure" means the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Office of Licensure.
- (s) "Opiate/Opioid" means a drug that contains opium, derivatives of opium or any of several semi-synthetic or synthetic drugs with agonist activity at the opioid receptor.
- (t) "Observed Drug Screen" or "Observed Urine Drug Screening" means a test used to determine the presence of illicit drugs in an individual's body conducted by and in the presence of a Facility staff person so as to ensure against the tampering with or falsification of the results.
- (u) "Patient" or "Service Recipient" shall refer to an individual receiving treatment for opiate use disorder at an OBOT.

- (v) "Physical Location" means real property on which is located a physical structure, whether or not that structure is attached to real property, containing one (1) or more units and includes an individual apartment, office, condominium, cooperative unit, mobile or manufactured home, or trailer, if used as a site for prescribing or dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate use disorder by preventing symptoms of withdrawal.
- (w) "Phases of Treatment" means the induction, stabilization and maintenance phases associated with office-based opioid treatment as described in the Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Intervention Protocol published by the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT).
- (x) "Program Physician" means any physician, including the medical director, who is employed by the Facility to provide medical services to patients.
- (y) "Qualified Provider" means a qualified mental health professional as defined in T.C.A. §33-1-101(20), qualified alcohol and drug abuse treatment personnel as defined in 0940-05-01-.16(7), or treatment staff operating under the direct supervision of either a qualified mental health professional or qualified alcohol and drug abuse treatment personnel.
- (z) "Relapse" means the failure of a patient to maintain abstinence from illicit drug use verified through drug screen.
- (aa) "TDMHSAS" or "department" means the Tennessee Department of Mental Health and Substance Abuse Services.
- (bb) "Treatment", or "substance abuse treatment" means a broad range of services intended to assess status, reduce symptoms, or mitigate the effects of substance misuse, substance use disorders, or co-occurring disorders; reduce risk of relapse and associated harm; or restore or establish well-being for individuals and families; provided, that said practice shall include, but not be limited to, care coordination, case management, medical, pharmacological, psychological, psycho-educational, rehabilitative or social services and therapies. The overall goals are to eliminate the substance abuse as a contributing factor to physical, psychological and social dysfunction and to arrest or reverse the progress of any associated problems.
- (cc) "Treatment program" or "substance abuse treatment program" means an organized system of services containing a mission, philosophy and model of substance use disorder treatment designed to address the needs of clients.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.03 Application of Rules.

- (1) The licensee of an OBOT shall comply with the following rules:
 - (a) Chapter 0940-05-02 Licensure Administration and Procedures;
 - (b) Applicable Minimum Program Requirements for All Services and Facilities found in Chapter 0940-05-06; and
 - (c) Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities.
- (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.

0940-05-35-.04 Licensing Procedures.

- (1) An OBOT, as defined in 0940-05-35-.02(2)(a) and T.C.A. § 33-2-402, shall be licensed by the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS or Department).
- (2) An OBOT shall include, as part of its ownership structure, a physician who is licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination and holds an active DATA 2000 waiver registered in Tennessee. "Ownership Structure" means any entity, group, or individual(s) having legal ownership of the OBOT, directing its functions and operations. This includes, but is not limited to, a sole proprietor, general partner, board member of a non-profit or for-profit corporation, or managing member of a limited liability company. Final determination as to whether ownership structure requirements for an OBOT are being met is in the sole discretion of the Department.
- (3) A public benefit non-profit/charitable corporation, registered with the Tennessee Secretary of State, shall have the Facility's medical director on its Board of Trustees.
- (4) A corporate entity doing business as an OBOT in the State of Tennessee shall not provide, hold itself out as providing, or advertise that it provides substance use disorder treatment for opioid use disorder in the form of opioid agonist therapy, or office-based opiate treatment, unless it complies with the following requirements:
 - (a) Is appropriately registered with the Tennessee Secretary of State to operate in the State of Tennessee and/or is and remains current with corporate or non-profit/charitable registration requirements of the Tennessee Secretary of State; and
 - (b) Includes, as a member of its Board of Trustees, the Facility's medical director.
- (5) The OBOT shall make application with the Department's Office of Licensure by providing the following information, at a minimum:
 - (a) Application on the Office of Licensure's designated forms to include the:
 1. Initial Application;
 2. Fact Sheet; and
 3. Financial Statement;
 - (b) Applicable fees as defined in Tennessee Administrative Procedures Rule 0940-05-02-.05;
 - (c) Evidence of a contracted and/or currently employed physician registered in Tennessee with a DATA 2000 waiver;
 - (d) Evidence of all physicians contracted and/or currently employed at the Facility holding a license from the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination;
 - (e) Comprehensive listing of all members of the organization's ownership structure; and
 - (f) Any other item the Department believes is necessary and proper for application purposes.

- (6) Prior to renewal of the license, the OBOT shall be required to formulate policies and procedures that substantially comply with the provisions of this Rule, as well as with Administrative Chapter 0940-05-06.
- (7) The Department may release to and/or gather information from the TDOH Board of Medical Examiners (BME) as is necessary for licensing and/or investigation of complaints against an OBOT.
- (8) With or without notice, the Department, or its representatives, shall have the right to enter upon or into the premises of an OBOT in order to make inspections and/or investigations deemed necessary to determine compliance with applicable law. The OBOT shall comply with all reasonable requests of the Department and allow it to obtain information from third parties as is necessary.
- (9) The Department shall be given the authority to enter upon the premises of an unlicensed facility prescribing buprenorphine type products to better determine that facility's' need for TDMHSAS oversight. The Department shall attempt to conduct inspections and investigations in the least intrusive manner needed in order to obtain necessary information. The facility shall be required to provide reasonable amounts of information to the Department for this determination.
 - (a) "Reasonable amounts of information," in this context, may be considered aggregate, non-patient identifying information to include, but not be limited to:
 - 1. Patient de-identified identifiers;
 - 2. Lists of medications prescribed to that de-identified patient; and
 - 3. The total number of patients seen at the physical location in question.
- (10) The governing body of an OBOT shall designate a facility director (as defined in 0940-05-35-.02(2)(j)), who is responsible for the operation of the Facility.
 - (a) Should a Facility operate in such a fashion that the physicians working at the same physical location are unassociated and/or unaffiliated to one another in some type of business arrangement, then the unassociated and/or unrelated physicians shall designate a facility director.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.05 Policy and Procedures.

- (1) The governing body of the Facility shall ensure the OBOT 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) and Rule 0940-05-35-.02(2)(l), in its policies and procedures manual including the name and contact information of the governing body.
 - (a) Admissions and Discharges and Best Practices Utilized (0940-05-35-.06);
 - (b) Patient Record Requirements (0940-05-35-.07);

- (c) Patient Transfers (0940-05-35-.08);
- (d) Individualized Treatment Plan and Best Practices Utilized (0940-05-35-.09);
- (e) Special Populations (0940-05-35-.10);
- (f) Counseling (0940-05-35-.11);
- (g) Medication Management (0940-05-35-.12);
- (h) Drug Screens (0940-05-35-.13);
- (i) Detoxification and Medically Supervised Withdrawal (0940-05-35-.14);
- (j) Diversion Control Plan (0940-05-35-.15);
- (k) Reporting Requirements (0940-05-35-.16);
- (l) Patient Rights (0940-05-35-.17);
- (m) Community Relations (0940-05-35-.18); and
- (n) Personnel and Staffing Requirements (0940-05-35-.19).

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.06 Admissions and Discharges and Best Practices Utilized.

- (1) Prior to admission to the Facility, each potential patient 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, and document, whether the patient meets the diagnostic criteria for an opioid use disorder as defined in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) and whether the Facility will be the most appropriate treatment modality for the service recipient. No prospective patient shall be processed for admission until it has been verified that the patient meets all applicable criteria.
 - (a) The Facility shall use standardized assessment and evaluation tools as approved by the Department. Examples include American Society of Addiction Medicine (ASAM) placement criteria, the Addiction Severity Index, SAMHSA's TIP 40, or any other assessment and evaluation tools approved by the Department.
- (2) Prior to receiving treatment at the Facility, the patient shall acknowledge in writing having received education on the following:
 - (a) Treatment options, including detoxification, and the benefits and risks associated with each treatment option;
 - (b) The risk of neonatal abstinence syndrome and use of voluntary long-acting reversible contraception for all female patients of child-bearing age and potential;
 - (c) Prevention and treatment of chronic viral illnesses, such as HIV and hepatitis C;
 - (d) Expected therapeutic benefits and adverse effects of treatment medication;

- (e) Risks for overdose, including drug interactions with CNS depressants, such as alcohol and benzodiazepines and relapsing after periods of abstinence from opioids; and
 - (f) Overdose prevention and reversal agents.
- (3) A Facility shall only admit and retain patients 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.
 - (4) 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 patients waiting for services.
 - (5) No Facility shall provide a bounty or other reward to a third party for referral of potential patients to the clinic.
 - (6) Initial Screening. Upon admission, the Facility shall complete a patient's initial screening in accordance with peer reviewed medication assisted treatment guidelines developed by nationally recognized organizations, such as SAMHSA or the American Society of Addiction Medicine. The initial screening shall focus on the individual's eligibility and need for treatment.
 - (7) Comprehensive Assessment. Within thirty (30) days of admission, the Facility shall have completed a comprehensive assessment in accordance with peer reviewed medication assisted treatment guidelines, developed by nationally recognized organizations, such as SAMHSA and the American Society of Addiction Medicine. The comprehensive assessment shall be attached to the patient's medical 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 patient. It shall also integrate information obtained in the initial screening. If necessary, the Facility shall obtain complete medical records from other providers with patient's written consent.
 - (8) Discharge and Aftercare Plans. A Facility shall complete an individualized discharge and aftercare plan for patients who complete their course of treatment.
 - (a) All discharge and aftercare plans shall include documentation that the Facility's counseling and/or medical staff has discussed with the patient an individualized medically supervised withdrawal plan appropriate to the patient.
 - (b) The patient's discharge planning shall include the development of a menu of appropriate treatment resources available to the patient in his or her community. This menu shall be developed in consultation with the patient. And shall be in writing and made available to the patient upon discharge. The Facility shall assist the patient in obtaining the appropriate referrals, as necessary.
 - (c) The discharge plan shall be completed within seven days of discharge by the person who has primary responsibility for coordinating or providing for the care of the service recipient. It shall include a final assessment of the patient'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 patient not participating in discharge and aftercare planning shall be documented in the patient'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, 33-2-402, 33-2-403

0940-05-35-.07 Patient Record Requirements.

- (1) Each Facility shall have a specific policy and procedure outlining the Facility's duties and responsibilities regarding any service recipient record requirements that are listed herein and in the minimum requirements of Chapter 0940-05-06.

- (2) Facilities shall organize and coordinate patient medical and billing records in a manner which demonstrates that all pertinent patient information is accessible to all appropriate staff and to TDMHSAS surveyors.
- (a) Should the licensee plan to close its operations, written notice shall be given to the patient or the new provider prior to the planned closure of the Facility. Patient records shall be transferred to the patient or to the new provider within fourteen (14) business days of the last scheduled visit of the patient.
- (3) The qualifying facility and/or private practitioner site shall ensure that adequate billing and medical records are maintained in accordance with T.C.A. § 33-2-403(e), (f), and (g).
- (4) Except as otherwise authorized by law, no person shall be admitted for treatment without written consent from the patient and, if applicable, parent, guardian or responsible party. A documented, voluntary, written, program-specific informed consent to treatment from each patient at admission to include:
- (a) Information about all treatment procedures, services and other policies and regulation throughout the course of treatment, including clinic charges in the form of a fee agreement signed by the patient.
1. 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 the patient (or patient's legal representative) in the event they are unable to pay for treatment.
- (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 patient that the goal of opioid treatment is stabilization of functioning;
- (d) Acknowledgement that the patient has been informed of the Facility's rules regarding patient conduct and responsibilities.
- (e) Acknowledgement that the patient has been informed of his or her rights (0940-05-35-.17);
- (f) Information that at regular intervals, in full consultation with the patient, the program shall discuss the patient's present level of functioning, course of treatment and future goals; and
- (g) Information that the patient may choose to withdraw from or be maintained on the medication as he or she desires unless medically contraindicated.
- (5) The patient's medical chart shall also include documentation of the following:
- (a) Documentation that the patient's initial screening and comprehensive assessment are completed and documented in the patient's record prior to the development of the Individualized Treatment Plan;
- (b) The individualized treatment plan, including any reviews, changes or amendments to the plan;
- (c) Documentation that services listed in the individualized treatment plan are available and have been provided or offered;
- (d) A record of correspondence with the patient, family members and other individuals and a record of each referral for services and its results;

- (e) A discharge plan, including reasons for discharge and any referral. In the case of death, the reported cause of death shall be documented; and
- (f) Documentation that the facility has provided coordination of care with the patient's other providers, including but not limited to: primary care provider, hospitalist, OB/GYN, gastroenterologist, surgeon, dentist or any other healthcare provider that has a legitimate patient-provider relationship with the patient.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.08 Patient Transfers.

- (1) If a prospective patient has previously been discharged from treatment at another clinic or facility, the admitting Facility, after having patient sign a release of information, shall initiate an investigation into the prospective patient's prior treatment history, inquiring of the last program attended and the reasons for discharge from treatment.
- (2) Patients who were terminated from a prior Facility or program due to noncompliance or violation of the program's patient responsibilities shall be admitted as a new patient.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.09 Individualized Treatment Plan and Best Practices Utilized.

- (1) The admission requirements of 0940-05-35-.06 shall first be completed prior to the development of an Individualized Treatment Plan (ITP).
- (2) A Facility shall develop an ITP for each patient within thirty (30) days of admission. The ITP shall be developed in accordance with peer reviewed medication assisted treatment guidelines, developed by nationally recognized organizations, such as SAMHSA and the American Society of Addiction Medicine.
- (3) Medical care, including referral for necessary medical service, and evaluation and follow-up of patient complaints, shall be compatible with current and accepted standards of medical practice. All patients 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 patient medical records in each service recipient's record.
- (4) Requirements for services according to phases of treatment:
 - (a) A patient in the induction or stabilization phases of treatment shall:
 - 1. Have weekly office visits scheduled
 - 2. Receive appropriate counseling sessions at least twice a month
 - 3. Be subject to one (1) observed drug screen at least weekly
 - 4. Receive case management services weekly
 - (b) A patient in the maintenance phase of treatment shall:
 - 1. Have a scheduled office visit every two (2) to four (4) weeks
 - 2. Receive counseling sessions at least monthly

3. Be subject to a random observed drug screen at least eight (8) times annually
 4. Receive case management services at least monthly
- (5) 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 patients who demonstrate a need for such services. The Facility can fulfill this responsibility by providing support services directly or by appropriate referral. Support services that are recommended and/or utilized shall be documented in the patient's record. Each Facility shall have policies for matching patient's needs to treatment.
 - (6) If the patient experiences a relapse, his or her ITP 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) or more frequent drug screens.
 - (7) When an ITP is reviewed, discussion shall be held with the patient 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 patient at the time of the discussion and documented in the patient's record. The patient shall sign and date a statement indicating that she or he wishes to remain within the program in a maintenance phase. If the patient 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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.10 Special Populations.

- (1) Pregnant women. The facility will ensure that pregnant women shall be treated using nationally recognized best practice guidelines and within all applicable federal and state rules and regulations. If the facility does not provide their prenatal care, the facility shall ensure that there is coordination of care between the facility and the patient's prenatal care provider.
 - (a) The facility shall document, in the patient record, that the facility has informed all pregnant patients, initially and at regular intervals throughout the pregnancy, the risks and benefits of the utilization of voluntary, reversible, long-acting contraception, the risks and benefits of medication assisted treatment and detoxification treatment with buprenorphine containing products, and the risks associated with the continued use of illicit opioids. The information provided to pregnant patients shall be based on current best practices and research.
- (2) Pain Management. The Facility shall ensure that employed physicians are knowledgeable in the management of opioid use disorder in a context of chronic pain and pain management. Individuals being treated with opioids for chronic or acute pain, who have become physically dependent in the course of their medical treatment, should be treated in a medical or surgical setting due to the possibility that this type of patient may need a higher dosage of pain medication to achieve adequate pain control. Individuals who are addicted to opioids, demonstrating drug-seeking behavior, or performing illegal drug-related activity, and who also need treatment for pain may be enrolled in the Facility but the Facility shall ensure continuity of care and communication between treatment programs or physicians regarding patients receiving treatment in both non-residential office-based opiate treatment facility and a facility or physician's office for purposes of pain management, with patient consent.
- (3) Co-occurring disorders. The Facility shall ensure that patients with mental health needs are identified through the initial screening and comprehensive assessment processes and are referred to appropriate treatment.
 - (a) The Facility shall monitor patients during treatment to identify the emergence of symptoms of mental illness.
 - (b) The Facility shall establish linkages with mental health providers in the community.

- (4) Polysubstance Abuse. The Facility shall address abuse of alcohol and other non-opioid substances within the context of the medication-assisted therapy effort. Ongoing polysubstance abuse is not necessarily a reason for discharge, however, the patient may be offered a referral to more intensive levels of care, to include but not be limited to, intensive outpatient or residential alcohol and drug abuse treatment.
- (5) Criminal justice. The department encourages each facility to work with local law enforcement, probation officers, and courts, including drug courts, to act as a resource for individuals in the criminal justice system to receive the necessary treatment services including medications and counseling.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.11 Counseling.

- (1) Counseling is essential and the Facility shall determine the best counseling option for each individual patient based upon the patient's history and assessments, agreeance with the patient, and the goals of the patient's individualized treatment plan.
- (2) The Facility shall be responsible to determine and document that counseling is being received and the patient is progressing towards meeting the goals listed in the individualized treatment plan. The Facility shall review and modify the individualized treatment plan if it is determined that a patient is not following through with counseling referrals.
- (3) If the Facility utilizes their own staff to provide counseling:
 - (a) The Facility staff shall be sufficient in number and in training to:
 - 1. Allow the Facility to provide adequate:
 - (i) Psychosocial assessment;
 - (ii) Treatment planning; and
 - (iii) Individualized counseling.
 - 2. Allow for regularly scheduled counseling sessions; and
 - 3. Allow patients access to their counselor if more frequent contact is merited by need or is requested by the patient.
- (4) For Facilities referring patients for counseling, the Facility shall provide the patient, with the patient's consent, a list of available licensed treatment providers in the community and assist the patient in receiving these services by making appointments on the patients' behalf and coordinating care.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.12 Medication Management.

- (1) Opioid Drugs. Facilities shall develop and implement written policies and procedures for the prescription of opioid drugs. No standardized routines or schedules of increases or decreases of medications may be established or used. Any changes to these policies and procedures shall be done in consultation with the Facility's medical director. These policies and procedures shall include the following:
 - (a) Prescribing.

1. The proper initial dose, medication type and dosage form shall be based on the clinical judgment of the program physician who has examined the patient and who has considered all available relevant patient-specific information including, but not limited to, drug screens, initial screenings, medication availability and cost, and in consultation with the patient.
 2. No standardized routines or schedules of increases or decreases of medication doses may be established or used.
 3. A copy of all prescriptions written for a patient at the Facility shall be documented in the patient's medical chart.
- (2) CSMD Check. The Facility shall check the CSMD upon every visit of the patient. The patient's record shall include documentation of the check of the CSMD and the date upon which it occurred.
 - (3) Preventing Multiple Enrollments. The Facility shall have a procedure which shall endeavor to ensure that no patient is enrolled in more than one Facility, treatment program, or any other medical practice for treatment of opioid use disorder unless the other Facility, treatment program or other medical practice is fulfilling a service need for the patient that cannot be fulfilled by the Facility (i.e. behavioral counseling, holistic treatments, or other therapies deemed necessary), in which case, there must be a coordination of care between all of the patient's providers.
 - (4) Benzodiazepine Use. Benzodiazepines should only be prescribed to a patient after careful evaluation while utilizing caution and good judgement. Benzodiazepines may be prescribed to a patient on buprenorphine or a buprenorphine and naloxone combination under the following conditions:
 - (a) Benzodiazepines may not be initiated on a patient with opiate use disorder or the disease of addiction who has never been prescribed these products or has a history of misusing or abusing these products, except in extreme circumstances for severe anxiety or panic disorder, and only after evaluation by a board certified psychiatrist.
 - (b) Patients who present with a longstanding prescription for benzodiazepines for a legitimate medical condition from another prescriber may be prescribed buprenorphine products by a physician with a DATA 2000 waiver. Contact should be initiated with the prescriber of the benzodiazepine to coordinate care and clear documentation should be recorded in the patient's medical chart.
 - (c) A physician with a DATA 2000 waiver working at an OBOT may assume management of a patient's benzodiazepine prescribing from another physician if the patient is willing to initiate a program of tapering.
 - (d) If a patient presents at an OBOT with a dual diagnosis of opiate use disorder and a clear history of benzodiazepine use disorder, the duration and extent of the abuse should be clearly documented in the medical record. A physician with a DATA 2000 waiver may prescribe a long acting benzodiazepine, such as clonazepam or its equivalent, under the following conditions:
 1. A patient may continue on benzodiazepine therapy as medically indicated as long as there is an ongoing effort to taper the patient to the lowest effective dose in order to prevent benzodiazepine withdrawal syndrome and clear documentation of this effort is made in the patient's medical record.
 - (i) Prescribing more than two (2) milligrams of clonazepam or its equivalent twice daily is considered "high dose therapy".
 - (ii) Patients receiving high dose therapy should have justification for the dosing clearly documented in the patient's medical record.

- (iii) Patients receiving high dose therapy should be tapered as rapidly as possible to two (2) milligrams or less of clonazepam or its equivalent, and if the taper is unsuccessful, the reason(s) shall be clearly documented in the patient's medical record.
 - (iv) Patients receiving high dose therapy for a period of longer than six (6) weeks shall be managed by a physician who is board certified in addiction medicine or who is board certified or fellowship trained in addiction psychiatry, or by a physician with a DATA 2000 waiver who has obtained a formal consult from a physician who is board certified in addiction medicine or who is board certified or fellowship trained in addiction psychiatry. The formal consult shall be clearly documented in the patient's medical record.
- (5) The Facility shall develop guidelines for review of prescriptions from other providers. These shall include:
- (a) Procedures to ensure that patients' 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 to ensure compliance with this rule; and
 - (c) Documentation of the Facility's efforts to obtain information about prescriptions from outside physicians in the patient's record, if a Facility is unable to acquire information about a patient's prescriptions.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.13 Drug Screens.

- (1) Random observed urine drug screening and other adequately tested toxicological procedures shall be used for the purposes of assessing the patient's abuse of drugs and evaluating a patient's progress in treatment.
- (2) Drug screening procedures shall be individualized and shall follow the required drug screen frequency described in 0940-05-35-.09.
- (3) More frequent collection and analysis of drug samples during episodes of relapse or medically-supervised or other types of withdrawal may occur.
- (4) Collection and testing shall be done in a manner that assures that urine collected from patients is unadulterated. Such collection and testing shall include random direct observation that is conducted professionally, ethically, and in a manner which respects service recipients' privacy.
- (5) A positive test is a test that results in the presence of any drug or substances that is illegal or for which the patient cannot provide a valid prescription or any drug or substance prohibited by the Facility. Any refusal to participate in a random drug test assigned by the Facility shall also be considered a positive result.
- (6) The Facility shall document both the results of toxicological tests and the follow-up therapeutic action taken in the patient record.
- (7) Absence of medications prescribed by the Facility for the service recipient shall be considered evidence of possible medication diversion and evaluated by the physician accordingly.
- (8) Nothing contained in this rule shall preclude any Facility from administering any additional drug tests it determines necessary.

Authority: T.C.A. §§ 4-3-1601, 4-1-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.14 Detoxification and Medically Supervised Withdrawal.

- (1) Medically supervised withdrawal occurs as a voluntary and therapeutic withdrawal agreed upon by staff and patient. In some cases, the withdrawal may be initiated against the advice of clinical staff (against medical advice).
 - (a) The Facility shall work with the patient to taper the patient's dose at a rate that is well tolerated by the patient.
 - (b) The Facility may offer supportive treatment including increased counseling sessions or referrals to a self-help group or other counseling provider as appropriate during a medically-supervised withdrawal.
 - (c) The Facility shall make provisions for continuing care (i.e. referral to other community resources for counseling, etc.) for each patient completing care at the Facility and for re-entry to the Facility if relapse occurs or if the patient should reconsider treatment at the Facility.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.15 Diversion Control Plan.

- (1) Each Facility 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 Facility for carrying out the diversion control functions described in the Diversion Control Plan. These measures may include patient call backs. The Diversion Control Plan shall address, at a minimum, the following scenarios that may indicate diversion:
 - (a) The patient has been reported to be diverting medication.
 - (b) The patient's recent drug screen results show an absence of the treatment medication.
 - (c) The patient's urine drug screen is identified as not belonging to the patient or is otherwise adulterated.
 - (d) Results from the patient's CSMD check demonstrate significant variation from the patient's treatment plan.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.16 Reporting Requirements.

- (1) Upon request or inspection, the Facility shall submit the following information to the Department:
 - (a) All reports, forms, and correspondence submitted to or received from the health-related boards of the Tennessee Department of Health, FDA, DEA, SAMHSA or any other applicable federal agencies, or accreditation organizations shall be provided to the Office of Licensure 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 medication assisted treatment effectiveness or monitor service delivery.
- (2) The Facility shall report any significant occurrence, as defined in the TDMHSAS Office of Licensure Reportable Incident Form Instructions, to the Office of Licensure. This shall include any unexpected occurrence or accident that results in death or serious injury to a patient or any action

taken against the Facility by the DEA, accrediting body or other state (not to exclude any state related boards and/or commissions), local or federal agency. Additional reporting requirements may be found in Chapter 0940-05-02-.20.

- (3) The Facility shall be required to respond in writing following the citation of the Office of Licensure or other State entity. The Facility will be given an appropriate amount of time to respond and their response should encapsulate at least the following:
 - (a) The actions implemented to prevent the recurrence 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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.17 Patient Rights.

- (1) Patients shall have a right to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.
- (2) All applications, certificates, records, reports and all legal documents, petitions and records made or information received pursuant to treatment in a Facility directly or indirectly identifying a patient shall 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.
- (3) Patients have the right to a humane treatment environment that affords reasonable protection from harm, exploitation, and coercion.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.18 Community Relations.

- (1) The Facility shall have policies and procedures for community relations to include the following:
 - (a) The Facility shall identify Facility personnel who will function as community relations coordinators and define the goals and procedures for the community relations plan.
- (2) A Facility shall be responsible for ensuring that its patients 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.
- (3) 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 patients and the actions it will take to assure responsiveness to community needs.
- (4) Each Facility shall document community relations efforts and community contacts, including the resolution of issues identified by community members or patients.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.19 Personnel and Staffing Requirements.

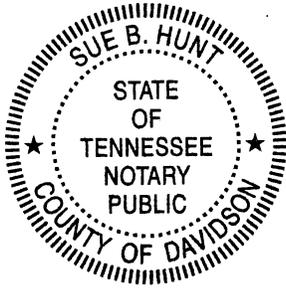
- (1) A personnel record for each staff member of a Facility shall include an application for employment and/or resume and a record of any disciplinary action taken. A licensee shall maintain written records for each employee.
- (2) Staffing.
 - (a) Facility Director. The governing body of each Facility shall designate in writing a Facility 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 non-residential office-based opiate treatment programs, and for all employees including practitioners, agents, or other persons providing services at the Facility. Facilities shall notify the TDMHSAS Office of Licensure in writing within 10 calendar days whenever there is a change in Facility director.
 - (b) Medical Director. The governing body of each Facility shall designate in writing a physician medical director to be responsible for the administration of all medical services at the Facility, including compliance with all federal, state and local laws and regulations regarding the medical treatment of opioid use disorder. The medical director shall be physically present at the Facility the equivalent of fifty (50) percent of the time the Facility is open to the public each week. No physician may serve as medical director of more than three Facilities without the prior written approval of the TDMHSAS Office of Licensure.
 - (c) Program Physician. Facilities are required to provide sufficient physician services to provide the medical treatment and oversight necessary to serve patient need. A Program Physician may be the same individual as the Medical Director, should the Facility so choose and all requirements are still met.
 - (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 Federal and Tennessee law or regulations.
 - (e) Case management/care coordination. Each Facility shall provide case management/care coordination services by a qualified professional.
- (3) Staff Qualifications.
 - (a) Staff Training. Prior to working with patients, all staff providing treatment or services shall be oriented in accordance with all applicable administrative rules, reporting requirements, and their individual position responsibilities. All staff shall receive ongoing training and development activities. Record of all staff training activities shall be noted in their personnel record.
 - (b) Medical Director. A medical director shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain his/her license as unrestricted and in good standing, hold an active DATA 2000 waiver from the DEA registered in Tennessee and shall have the following experience and/or credentials:
 1. Certification in addiction psychiatry by the American Board of Psychiatry and Neurology or exam eligible in psychiatry and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; and
 2. Certification as an addiction medicine specialist by the American Board of Addiction Medicine (ABAM) or exam eligible for certification as an addiction medicine specialist.
 - (c) Program Physician. A program physician shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain his/her license as unrestricted and in good standing, hold an active DATA 2000 waiver from the DEA registered in Tennessee and

shall have at least one (1) year of documented experience in the treatment of persons addicted to alcohol or other drugs.

- (d) Facility Directors. All Facility directors shall have at least one year of supervisory or administrative experience in the field of opioid use disorder treatment.
 - (e) Professional Practice. All professional staff including, but not limited to, physicians, physician assistants, nurses and counselors shall perform only those duties that are within the scope of their applicable professional practice acts and Tennessee licenses.
 - (f) Qualified Provider. A qualified provider shall be duly licensed, certified or registered as required by the State of Tennessee for the profession and shall only perform those duties that are within the scope of their applicable professional practice acts and Tennessee license. Those individuals operating under the direct supervision of a Qualified Provider must have at least one year of prior experience in the field of opioid use disorder treatment before assuming this position.
- (4) Employee Drug Screening. Facilities implement pre-employment and ongoing random drug screening of all Facility employees.

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, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

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: 7/6/16

Signature: [Handwritten Signature]

Name of Officer: Cynthia Tyler, Esq.

Title of Officer: Interim General Counsel

Subscribed and sworn to before me on: July 4, 2016

Notary Public Signature: [Handwritten Signature]

My commission expires on: **My Commission Expires**
May 8, 2017

Department of State Use Only

Filed with the Department of State on: 7/8/16

[Handwritten Signature]
Tre Hargett
Secretary of State

RECEIVED
2016 JUL -8 AM 9: 07
SECRETARY OF STATE
PUBLICATIONS