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Sequence Number: 10-22-23  
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File Date: 10/20/2023

# 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.*

<b>Agency/Board/Commission:</b>	Department of Mental Health and Substance Abuse Services
<b>Division:</b>	Division of Administrative and Regulatory Services
<b>Contact Person:</b>	Krysten Velloff
<b>Address:</b>	500 Deaderick Street, 5th Floor, Andrew Jackson Building, Nashville, TN 37243
<b>Phone:</b>	615-881-5280
<b>Email:</b>	<a href="mailto:Krysten.Velloff@tn.gov">Krysten.Velloff@tn.gov</a>

*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:*

<b>ADA Contact:</b>	Austin Nichols
<b>Address:</b>	500 Deaderick Street, 5th Floor, Andrew Jackson Building, Nashville, TN 37243
<b>Phone:</b>	615-426-2689
<b>Email:</b>	<a href="mailto:Austin.L.Nichols@tn.gov">Austin.L.Nichols@tn.gov</a>

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

Address 1:	500 Deaderick Street		
Address 2:	Ground Floor Hearing Room, Andrew Jackson Building		
City:	Nashville		
Zip:	37243		
Hearing Date:	12/18/2023		
Hearing Time:	10:00 AM	X CST/CDT	EST/EDT

**Additional Hearing Information:**

Please allow enough time to go through security upon entering the building. A state-issued ID is required.

All written comments from the public re: this proposed rulemaking activity may be sent to [Krysten.Velloff@tn.gov](mailto:Krysten.Velloff@tn.gov) and are due by close of business (4:30 PM CDT) on Thursday, 12/28/2023.

**Revision Type (check all that apply):**

- ☒ Amendment  
☐ New  
☐ Repeal

**Rule(s)** (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. 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
0940-05-35-.10	Phases of Treatment
0940-05-35-.11	Special Populations
0940-05-35-.12	Counseling
0940-05-35-.13	Medication Management
0940-05-35-.14	Drug Screens
0940-05-35-.15	Detoxification and Medically Supervised Withdrawal
0940-05-35-.16	Diversion Control Plan
0940-05-35-.17	Reporting Requirements
0940-05-35-.18	Patient Rights
0940-05-35-.19	Community Relations
0940-05-35-.20	Personnel and Staffing Requirements

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

Rule 0940-05-35-.01 Purpose is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

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.

Rule 0940-05-35-.02 Definitions is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(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 opioid use disorder by preventing symptoms of withdrawal to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients.

1. "Nonresidential office-based opiate treatment facility" does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction, otherwise referred to as a nonresidential opioid treatment program as licensed under Rule 0940-05-42.

(b) "Advanced Practice Nurse" means a person qualified by the Tennessee Board of Nursing under Rules Chapter 1000-04 as an advanced practice nurse with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs. Advanced practice nurses may perform any and all functions allowed by current federal and state laws and regulations within this practice setting and within their scope of allowed professional licensure.

(c) "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, as well as any FDA-approved pharmaceutical product that contains buprenorphine.

(d) "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.

(e) "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.

(f) "Counseling" or "Counseling Session" means any face-to-face individual therapeutic counseling session lasting not less than twenty (20) minutes with a qualified counseling 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 counseling provider. Counseling shall be focused on issues related to the patient's identified needs in their treatment plan 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. Counseling is separate and apart from any other medical and/or clinical activities of the Facility. The Facility shall document each counseling session's topic of focus and the duration of minutes of the counseling in the patient's medical chart.

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

(h)"Detoxification" or "Detoxification Treatment" means the use 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 Facility's overall compliance with federal, state, and local laws and regulations regarding the operation of a nonresidential office-based opiate treatment facility, and for all Facility employees including practitioners, agents, or other persons providing services at the Facility. Non-physician facility directors shall not supervise medical staff.

(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 an OBOT 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 an OBOT 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 who meets the qualifications set out in 0940-05-35-.20(3)(b) and who has been designated by the governing body of the Facility to be responsible for the supervision of all medical staff at the Facility and 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 FDA, in combination with counseling and behavioral therapies, for the treatment of an opioid 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, evaluate, or treat a patient.

(r)"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 staff with documented training on procedures of observing drug screens or contracted medical or lab staff so as to ensure against the tampering with or falsification of the results.

- (s)"Office of Licensure" means the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Office of Licensure.
- (t)"Opiate/Opioid" means a drug that contains opium, derivatives of opium, or any of several semi-synthetic or synthetic drugs with agonist activity at the opioid receptor.
- (u)"Patient" or "Service Recipient" shall refer to an individual receiving treatment for opioid 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 opioid use disorder by preventing symptoms of withdrawal.
- (w)"Phases of Treatment" means the induction, stabilization, and maintenance phases of treatment a patient is in at a particular point-in-time and referenced in 0940-05-35-.10..
- (x)"Physician Assistant" means a person qualified by the Tennessee Board of Medical Examiners and Committee on Physician Assistants under Rules 0880-03, with authorization from their supervising physician, to write and sign prescriptions and/or issue legend drugs. Physician assistants may perform any and all functions allowed by the current federal and state regulations within this practice setting and within their scope of allowed professional licensure.
- (y)"Program Physician" means any physician, including the medical director, who provides medical services to patients at the Facility.
- (z)"Program Provider" means any physician, physician's assistant, pharmacist, or advanced practice nurse, including the medical director, who is employed by the Facility to provide medical services to service recipients. Any Facility program provider who is not a medical director shall work under the supervision of the Facility's medical director.
- (aa)"Qualified Counseling Provider" means any individual meeting one of the following conditions:
  - (i)Licensed by the State of Tennessee as one (1) of the following (with experience or supervision as described, where specified); or
    - (A)Alcohol and Drug Abuse Counselor I or II (commonly referred to as LADAC I or LADAC II);
    - (B)Psychologist;
    - (C)Psychological examiner under the supervision of a licensed psychologist;
    - (D)Physician with experience or training in counseling;
    - (E)Registered nurse with experience or training in counseling;
    - (F)Social worker, meeting one of the following:
      - 1.If licensed as a baccalaureate social worker (LBSW) with training in counseling and direct supervision by a master's level social worker (LCSW or LMSW);

2. Professional Counselor; or

3. Marriage and Family Therapist

(ii) Actively engaged in a recognized course of study or another formal process for pursuing licensure of a discipline described in (i) above. Supervision shall be in accordance with the respective laws, rules, and regulations governing the professional licensure pursued; and

(iii) Be qualified by education and/or experience for the specific duties of their position and only perform those duties within the scope of their applicable professional practice acts and Tennessee license.

(bb) "Referral" means a proactive effort by facility personnel to guide a patient towards a healthcare provider or facility for additional evaluation, treatment, or support. The facility is responsible for documenting the referral attempt in the patient's medical chart. To facilitate the referral, the facility must complete a release of information to the patient with the referring facility and the location appropriate for the referral completed on the document. If the patient declines, the facility must keep a record of the completed release of information indicating the patient declined to share records for continuity of care. The clinic personnel must document the referral outcome, including if the patient obtained an appointment time, and whether the patient attended or not.

(cc) "Relapse" means a process in which an individual who has established abstinence or sobriety experiences a recurrence of signs and symptoms of active addiction, often including resumption of the pathological pursuit of reward and/or relief through the use of substances and other behaviors.

(dd) "S.M.A.R.T. goals" means objective goals created using the S.M.A.R.T. goal framework that aids in creating personal and professional goals for service recipients. These goals are intended to be utilized in a service recipient's treatment plan or individual counseling sessions to track achievement of short and long-term goals and progress at the Facility. S.M.A.R.T. goals shall be specific, measurable, achievable, relevant, and time-sensitive.

(ee) "Taper", "Tapering", and "Medically Supervised Withdrawal" are interchangeable terms for the purposes of these rules.

(ff) "TDMHSAS" or "Department" means the Tennessee Department of Mental Health and Substance Abuse Services.

(gg) "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 may 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 use as a contributing factor to physical, psychological, and social dysfunction and to arrest or reverse the progress of any associated problems.

(hh) "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, Chapter 912 of the Public Acts of 2016, and Chapter 978 of the Public Acts of 2018.

Rule 0940-05-35-.03 Application of the Rules is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(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.

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.

Rule 0940-05-35-.04 Licensing Procedures is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(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 holds an unrestricted license from the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination. "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 a physician who holds an unrestricted license from the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination 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)In the case of a for-profit corporate entity, 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 all prescribers 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 or the Health Related Boards for any non-physician prescribers;

(d)Comprehensive listing of all members of the organization's ownership structure;

(e)Evidence of the Facility Director's experience in managing individuals showing at least one (1) year of supervisory type responsibilities; 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 develop written policies and procedures that substantially comply with the provisions of this Chapter, as well as with Administrative Chapter 0940-05-06.

(7)The Department may release to and/or gather information from the Tennessee Department of Health 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 access electronic information of the Facility and/or 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 access electronic information of and/or enter upon the premises of an unlicensed facility prescribing buprenorphine-type products to better determine that unlicensed 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. Non-physician facility directors shall not supervise medical staff.

(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.

Rule 0940-05-35-.05 Policy and Procedures is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(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 (0940-05-35-.09);

(e)Phases of Treatment (0940-05-35-.10);

(f)Special Populations (0940-05-35-.11);

(g)Counseling (0940-05-35-.12);

(h)Medication Management (0940-05-35-.13);

(i)Drug Screens (0940-05-35-.14);

(j)Detoxification and Medically Supervised Withdrawal (0940-05-35-.15);

(k)Diversion Control Plan (0940-05-35-.16);

(l)Reporting Requirements (0940-05-35-.17);

(m)Patient Rights (0940-05-35-.18);

(n)Community Relations (0940-05-35-.19); and

(o)Personnel and Staffing Requirements (0940-05-35-.20).

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.

Rule 0940-05-35-.06 Admissions and Discharges and Best Practices Utilized is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1)Initial Screening. Prior to admission to the Facility, each prospective patient shall be evaluated by the medical director or program provider or staff who have been determined to be qualified by education, training, and experience to perform or coordinate the provision of such screening. The purpose of such screening 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 patient. No prospective patient shall be processed for admission until it has been verified that the patient meets all applicable criteria.

(2)Initial Assessment. Within seven days of admission, the Facility shall complete an initial assessment. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for the

service recipient's disease severity and the need for any appropriate referrals. Whenever possible and with service recipient consent, the initial assessment shall include a family member or significant other to assist in the provision of accurate information and a full understanding and retention of instructions given to the service recipient. The initial assessment shall include, but not be limited to, the following:

- (a) A physical examination, unless otherwise exempt under federal controlled substance prescribing allowances, that includes a review of systems, vital signs, a pain assessment, and laboratory testing;
  - (b) A past medical history
  - (c) A substance use history that includes type, frequency, and amount of substances used, including illicit substances, tobacco, and alcohol;
  - (d) A list of currently prescribed or over-the-counter medications;
  - (e) A personal and family history of substance use;
  - (f) A confirmation of the opioid use disorder diagnosis;
  - (g) A full drug screen to identify the current use of drugs including, but not limited to, opioids (including fentanyl, buprenorphine, and methadone), amphetamines, cocaine, barbiturates, and benzodiazepines;
  - (h) A screening test for all applicable sexually transmitted infections (STIs), tuberculosis, or any other communicable disease based on the Tennessee Department of Health guidance for the population served by the Facility;
  - (i) Other tests as necessary or appropriate (e.g., CBC, EKG, chest x-ray, hepatitis B, hepatitis C, HIV testing). Tests not directly conducted by the Facility at admission shall be conducted within seven days after admission. The Facility is responsible for obtaining and maintaining documentation of required laboratory tests performed by an alternative provider.
  - (j) A determination if the prospective service recipient needs special services, such as treatment for alcohol use disorder or psychiatric services, and determination that the Facility is capable of addressing these needs either directly or through referral. If referral to an outside provider is deemed necessary, efforts of the Facility in making the referral shall be documented in the service recipient's chart.
  - (k) If a prospective service recipient is under 18 years of age, verification of two documented unsuccessful attempts at short-term withdrawal management within a twelve-month period unless a parent, legal guardian and/or representative, or in the case of an emancipated minor the minor themselves, consents in writing to such treatment. Such consent shall be documented in the patient chart.
  - (l) The Facility may utilize components of the initial assessment performed by an outside provider if conducted within 14 days preceding the admission and obtained by the Facility within 7 days of admission.
- (3) 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.

(4)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.

(5)Drug dependent pregnant females shall be given priority for admission and services.

(6)No Facility shall provide a bounty or other reward to a third party for referral of potential patients to the clinic.

(7)Comprehensive Assessment. Within 30 days of admission, the Facility shall have completed a comprehensive assessment. The comprehensive assessment shall include information obtained by the patient, family members, friends, peers, and other collateral sources, where appropriate and with the service recipient's consent. The comprehensive assessment shall include, but not be limited to, the following:

(a)A review of the information collected in the initial assessment;

(b)A review of any outside medical records obtained by the facility with the service recipient's consent;

(c)A social and family history;

(d)A criminal justice history, including any current criminal justice involvement; and

(e)A psychosocial assessment that shall include information about the service recipient's:

1.Motivation for treatment;

2.Personal treatment goals;

3.Personal strengths;

4.Individualized needs;

5.Urgent needs, including suicide risk;

6.Abilities and/or interests;

7.Presenting problems including a thorough analysis of the service recipient's high-risk behaviors such as:

(A)Licit and illicit drugs used, including alcohol;

(I)Amount(s) and method(s) used;

(II)Frequency of use; and

(III)Duration of use;

(B)Symptoms of physical dependence or withdrawal;

(C)History of treatment for addictive behaviors;

(D)Adverse consequences of use; and

(E)Inappropriate use of prescribed substances;

8.Previous behavioral health services, including:

(A)Diagnostic information;

(B)Treatment information; and

(C)Efficacy of current or previously used medication;

9.Mental status;

10.Current level of functioning;

11.Need for, and availability of, social supports;

13.Adverse childhood experiences ;

14.Adjustment to disabilities/disorders; and

15.Level of education.

(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 qualified counseling providers and/or program providers have 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 at the time of the patient's 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.

(9)The Facility shall document when a patient discontinues services at an OBOT. Determination of the events that constitute a patient's discontinuation of services at an OBOT shall be at the OBOT's discretion.

(10)Multiple relapses are not necessarily a reason for discharge; however, the facility shall facilitate a referral of the patient to more intensive levels of care, to include but not be limited to, intensive outpatient (e.g. methadone treatment) or residential alcohol and drug abuse treatment. The Facility's referral shall be documented in the patient's chart. Considerations for subsequent referrals should be discussed and documented in line with ITP review frequency, as outlined in 0940-05-35-.09(6).

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.

Rule 0940-05-35-.07 Patient Record Requirements is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

- (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 ten (10) business days of the last scheduled visit of the patient.
- (3) The Facility 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 shall 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 client rights as found in 0940-05-35-.18, as well as 0940-05-06-.06.;
  - (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 the client 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 medical record prior to the development of the patient's 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 and aftercare plan pursuant to 0940-05-35-.06(7), including reasons for discharge and any referral. In the case of death, the reported cause of death shall be documented; and

(f)Documentation of coordination of care should be present in those clinical situations which require consultations or coordination of 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.

Rule 0940-05-35-.08 Patient Transfers is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1)If a prospective patient has previously been discharged, inside of the previous twelve (12) months, at a minimum, from treatment at another Facility or other type of treatment program, the admitting Facility, after having the patient sign a release of information, shall initiate an inquiry into the prospective patient's prior treatment history, inquiring of the last Facility or other type of treatment program attended and the reasons for discharge from treatment.

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.

Rule 0940-05-35-.09 Individualized Treatment Plan is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1)A Facility shall develop an individualized treatment plan (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 the Tennessee Non-Residential Buprenorphine Treatment Guidelines, SAMHSA and the American Society of Addiction Medicine. The initial and comprehensive assessments listed in 0940-05-35-.06 shall be completed prior to the finalization of an initial ITP. Any significant findings from the initial or comprehensive assessments that impact the service recipient's success in treatment and recovery shall be documented and addressed in the ITP. The ITP, at minimum, shall contain Specific Measurable Achievable Relevant Time-sensitive (S.M.A.R.T.) goals for identified service needs of the patient, listing of the services provided in-house (including but not limited to: office visit, counseling, case management, drug screen), external services and the frequency of those in-house and external services. The initial ITP and all reviews shall be signed, either in person, electronically, or by documented verbal acknowledgment, by the service recipient, qualified counseling provider, and program provider.

(2)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, or the Tennessee Non-Residential Buprenorphine Treatment Guidelines. The ITP, at minimum, shall contain Specific Measurable Achievable Relevant Time-sensitive (S.M.A.R.T.) goals for identified service needs of the patient, listing of the services provided in-house (including but not limited to: office visit, counseling, case management, drug screening), external services and the frequency of those in-house and external services. The initial ITP and all reviews shall be signed, either in person, electronically, or by documented verbal acknowledgment, by the service recipient, qualified counseling provider, and program provider.

(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 physical exam at least annually and other testing shall be considered clinically determined to be appropriate. The program



provider shall record the results of the examination and tests in the patient's medical record. Any significant findings of the physical exam or other testing that may complicate a patient's treatment at the Facility shall be included in the patient's medical record.

- (4) 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 a patient's needs to treatment.
- (5) 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, a "move back" to more intensive phases of treatment (0940-05-35-.10), an increase in individual or group counseling session(s), or more frequent drug screens.
- (6) A patient's ITP shall be reviewed at least every six (6) months and a 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 on the ITP 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 ITP 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.

Rule 0940-05-35-.10 Phases of Treatment is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1) Requirements for services according to phases of treatment:

- (a) The patient's most current phase of treatment, according to the patient's specific documented history (e.g. patient coming to Facility following transfer from other provider and who may be already under a different phase of treatment), along with rationale for the assigned phase, shall be clearly documented in the patient's medical record.
- (b) For the purposes of this section, the following definitions apply:
  - 1. "Induction or stabilization" means the phase of treatment when the patient is new to treatment or exhibits active symptoms of substance use disorder and receives more frequent treatment services. The facility staff should more closely evaluate the patient for signs of reduced symptoms of their substance use disorder, including but not limited to: reduced or eliminated illicit drug use, reduced cravings for illicit substances, suppression of withdrawal symptoms, evaluation of medication side effects, or patient reports of treatment needs.
  - 2. "Maintenance" means the phase of treatment when the patient demonstrates treatment stability and their substance use disorder is considered to be in remission. Treatment stability is determined by evaluating, but not limited to, the following: stable dosing of the treatment medication, favorable drug screens, reduced or eliminated cravings for illicit substances, regular clinic attendance, participation in counseling, and absence of illegal activity related to illicit substance use.

(c) A patient in the induction or stabilization phases of treatment shall:

- 1. Have weekly program provider-interactive visits scheduled with the ability for 1-on-1 therapeutic discussions between the patient and program provider;



2. Receive appropriate counseling sessions with a qualified counseling provider at least twice a month;
3. Be administered one (1) observed drug screen at least weekly, for a minimum of three (3) weeks; and
4. Receive case management services weekly.

(d) A patient in the maintenance phase of treatment for less than one (1) year shall:

1. Have a scheduled program provider-interactive visit at least every two (2) to four (4) weeks with the ability for 1-on-1 therapeutic discussions between the patient and program provider;
2. Receive counseling sessions with a qualified counseling provider at least monthly;
3. Be administered a random observed drug screen at least twelve (12) times annually; and
4. Receive case management services at least monthly.

(e) A patient in the maintenance phase of treatment for one (1) year or more shall:

1. Have a scheduled program provider-interactive visit at least every two (2) months with the ability for 1-on-1 therapeutic discussions between the patient and program provider;
2. Receive counseling sessions with a qualified counseling provider at least monthly;
3. Be administered a random observed drug screen at least eight (8) times annually; and
4. Be offered case management services at least every two (2) months. In addition to case management services provided, any offers for case management shall also be documented in the patient's medical record.

(f) A patient in a continued maintenance phase of treatment for two (2) years or more:

1. Have a scheduled program provider-interactive visit at least every (6) months with ability for 1-on-1 patient and program provider-based discussions;
2. Counseling services shall be offered and documented at least monthly and shall actually hold counseling sessions with a qualified counseling provider at least every six (6) months;
3. Be administered a random observed drug screen at least four (4) times annually; and
4. Be offered case management services at least every six (6) months. In addition to case management services provided, any offers for case management shall also be documented in the patient's medical 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, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

Rule 0940-05-35-.11 Special Populations is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

- (1) Pregnant Women/Women of Child Bearing Age and Potential. Upon the initial screening, the Facility shall screen all women of child bearing age and potential for pregnancy. For this purpose, a woman of child-bearing age and potential is aligned with Tennessee Code Annotated 53-11-308(h). The Facility will ensure that pregnant women and women of child bearing age and potential 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 prenatal care to pregnant patients, the Facility shall ensure that there is coordination of care between the Facility and the pregnant patient's prenatal care provider.

(a)The Facility shall document, in the patient's medical record, that the Facility has informed all pregnant women and women of child bearing age and potential, initially and at regular intervals, of the risks and benefits of the utilization of voluntary, reversible, long-acting contraception, of the risks and benefits of medication assisted treatment and detoxification treatment with buprenorphine containing products, and of the risks associated with the continued use of opioids, including neonatal abstinence syndrome. The information provided to pregnant women and women of child bearing age and potential shall be based on current best practices and research.

(2)Pain Management. The Facility shall ensure that program providers are knowledgeable in the management of opioid use disorder in a context of chronic pain and pain management. The Facility shall ensure continuity of care and communication between treatment programs or physicians regarding patients receiving treatment in both a non-residential office-based opiate treatment facility and a licensed pain management clinic or a pain management specialist'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, or provided, appropriate treatment.

(a)The Facility shall monitor, assess, and document in the patient's record, during treatment the emergence of symptoms of mental illness.

(b)The Facility shall establish relationships with mental health providers in the community for referral/additional treatment services as indicated. See 0940-05-35-.09(4).

(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 Facility shall facilitate a referral of the patient, with documentation of referral in the patient record, 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 recovery (drug) courts, to act as a resource for individuals in the criminal justice system to receive the necessary treatment services including medications and counseling. The Facility shall document in this policy the extent of its work with this community.

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.

Rule 0940-05-35-.12 Counseling is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1)Counseling is a mandatory component of treatment 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 receive documentation 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 its 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 offering to make appointments on the patient's behalf and by coordinating care after initiation of services at the outside provider.

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.

Rule 0940-05-35-.13 Medication Management is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1)Opioid Drugs. Facilities shall develop and implement written policies and procedures for the prescription of opioid drugs. 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 provider 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 patient dose greater than sixteen milligrams (16mg), or its equivalent, per day, for more than thirty (30) consecutive days, shall be considered a high dose and shall clearly document in the patient's medical record why the patient needs the high dosage amounts.

4.A patient dose greater than twenty milligrams (20mg), or its equivalent, per day, for more than thirty (30) consecutive days, shall be transferred care to, or shall be required to consult with, a physician that meets the credentialing requirements as specified in Tennessee Code Annotated 53-11-311(d)(1)-(2). If the program provider cannot make the required consultation or referral, the reasons shall be set out in the medical record.

5.A patient dose of twenty-four milligrams (24mg), or its equivalent, per day shall be considered a maximum dose. Doses greater than the maximum dose may only be used with prior written approval from the State Opioid Treatment Authority. Documentation of this approval shall be kept in the patient's medical chart or otherwise be readily retrievable upon request or facility

inspection.

6.A copy of all prescriptions for a patient at the Facility shall be documented in the patient's medical chart.

7.The program provider shall demonstrate to the patient appropriate techniques for administering the particular prescribed treatment medication.

(b)Dispensing. An office-based opiate treatment facility without dispensing authorization is prohibited from dispensing buprenorphine-containing products.

(c)Protocols for initiating or switching a patient to a high dose of the treatment medication used at the facility.

1.The patient's medical chart shall include documentation of rationale that it is clinically appropriate for the patient to receive a high dose of the treatment medication.

2.The program provider shall have a discussion with the patient and the patient shall provide written consent acknowledging that the patient will receive a high dose of the treatment medication and associated risks.

(i)The program provider shall document that this discussion included an assessment of the patient's administration technique and that the patient is using the appropriate technique for the prescribed medication.

3.The program provider shall not establish or use standardized routines or schedules of increases or decreases of treatment medication doses for the patient. Decisions about dosing should be individualized with documentation of reasons for choice of dosing.

(d)Program Provider-Initiated-and-Led Tapering Discussions

1.Program provider shall initiate and lead a discussion with the patient regarding patient readiness to taper down or taper off treatment medications employed in the patient's treatment with each patient at any time upon the patient's request but no later than one (1) year after initiating treatment and then every six (6) months thereafter.

(i)Documentation of this discussion shall be placed in the patient's medical chart.

(2)CSMD Check. The Facility shall check the CSMD upon every visit of the patient with a program provider. The patient's medical record shall include documentation of the check of the CSMD and the date upon which it occurred.

(3)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 shall not be initiated with a patient with opioid use disorder or the disease of addiction who has never been prescribed these products or has a history of misusing or abusing these products. Notwithstanding, in rare circumstances:

1.Patients who present with a longstanding prescription for benzodiazepines for a legitimate medical condition from another prescriber may be prescribed buprenorphine products by a program provider. Contact should be initiated with the prescriber of the benzodiazepine to coordinate care and clear documentation should be recorded in the patient's medical record.

2.A program provider 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.

3.If a patient presents at an OBOT with a dual diagnosis of opioid 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 program provider at an OBOT may prescribe a long-acting benzodiazepine, such as clonazepam or its equivalent, under the following conditions:

(i) 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 daily is considered "high dose therapy".

(II) Patients receiving high dose therapy should have justification for the dosing clearly documented in the patient's record.

(III) Patients receiving high dose therapy should be tapered as rapidly as tolerable to two (2) milligrams or less of clonazepam, or its equivalent, daily. 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 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.

(4) The Facility shall have a policy and procedure developed for reviewing of prescriptions from other providers, including:

(a) Procedures to ensure that a patient's prescriptions from outside providers will be reported to the medical staff and reviewed by the program provider at admission and annually thereafter;

(b) Procedures describing the Facility's response when information about prescriptions from outside providers is not reported to ensure compliance with this rule; and,

(c) Documentation of the Facility's efforts to obtain information about prescriptions from outside providers 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, Chapter 912 of the Public Acts of 2016, and Chapter 978 of the Public Acts of 2018.

Rule 0940-05-35-.14 Drug Screens is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1) Random observed urine drug screening shall be conducted for every patient at least once yearly. This shall be done for the purposes of assessing the patient's misuse of substances and evaluating a patient's progress in treatment. Outside of this once-a-year urine-based drug screening, drug screening frequency, using adequately tested toxicological procedures, shall follow individual patient's corresponding phase of treatment as described in 0940-05-35-.10.

(2) More frequent collection and analysis of drug samples during episodes of relapse or medically-supervised or other types of withdrawal may occur.

(3) Collection and testing shall be done in a manner that assures that samples 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.

- (4) 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.
- (5) The Facility shall document all results of toxicological tests in the patient record.
- (6) Absence of medications prescribed by the Facility for the service recipient shall be considered evidence of possible medication diversion and evaluated by the program provider accordingly.
- (7) 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.

Rule 0940-05-35-.15 Detoxification and Medically Supervised Withdrawal is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

- (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 (e.g., referral to other community resources for counseling) 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.

Rule 0940-05-35-.16 Diversion Control Plan is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

- (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.

Rule 0940-05-35-.17 Reporting Requirements is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(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 (5) 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 address current citation and 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.

Rule 0940-05-35-.18 Patient Rights is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

- (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.
- (4) In addition to the above Patient Rights, Facility shall follow the Patient Rights requirements that apply to non-residential



settings as detailed in 0940-05-06.

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

Rule 0940-05-35-.19 Community Relations is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(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, while on the Facility's premises, do not cause unnecessary disruption to the community or act in a manner that would constitute disorderly conduct or harassment by loitering.

(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.

Rule 0940-05-35-.20 Personnel and Staffing Requirements is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(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 by the Facility. A licensee shall maintain written records for each employee and volunteer utilized by the Facility.

(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 at the Facility. However, non-physician facility directors shall not supervise medical staff. Facilities shall notify the TDMHSAS Office of Licensure in writing within ten (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 medical director to be responsible for the supervision of all medical staff at the Facility and 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 twenty-five (25) percent of the time the Facility is open to the public each week. On a monthly basis, the medical director shall review ten (10) percent of the medical charts for patients currently admitted at the Facility and document each chart review. No physician may serve as medical director of more than three (3) 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 qualification requirements for a medical director are still met.
- (d)Physician Assistants and Nurse Practitioners. Licensed physician assistants and nurse practitioners 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 laws or regulations. Any physician assistants and/or nurse Practitioners issuing prescriptions at the Facility shall have their supervising or collaborating physician clearly documented in their personnel file, if applicable. Physician assistants and nurse practitioners shall maintain an unrestricted license with their applicable Health Related Board.
- (e)Case management/care coordination. Each Facility shall provide case management/care coordination services by a person with at least a Bachelor's level completed education.

### (3)Staff Qualifications.

- (a)Staff Training. Prior to working with patients, all staff with direct patient interaction/responsibility shall be oriented in accordance with all applicable administrative rules (as listed in 0940-05-35-.03), 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 an unrestricted license to practice medicine or osteopathy, be designated by the OBOT's governing body, 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 addiction psychiatry; and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or
  - 2.Certification as an addiction medicine specialist by the American Board of Addiction Medicine (ABAM) or the American Board of Preventive Medicine (ABPM) or exam eligible for certification as an addiction medicine specialist and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or
  - 3.Meet the Tennessee Department of Health definition of addiction specialist as outlined in Rule 0880-02-.14; or
  - 4.For an OBOT that is accredited by a national accrediting healthcare organization listed in Rule 0940-05-02-.12(1)(a) or (b) in a behavioral health or opioid treatment service category, or equivalent, the medical director may be exempted from the requirements of (1)-(3) above.
- (c)Program Physician. A program physician shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain an unrestricted license to practice medicine or osteopathy, and hold an active DATA 2000 waiver from the DEA.
- (d)Facility Directors. All Facility directors shall have at least one (1) year of supervisory or administrative experience in the field of opioid use disorder treatment.
- (e)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.

- (4)Direct Care Drug Screening. Facilities shall implement pre-employment/pre-contracting and ongoing random drug screening, at least once per calendar year, of all persons in the Facility, or provided services on behalf of the Facility, whose position descriptions include direct patient interaction for OBOT services

(5) In addition to the above Personnel and Staffing Requirements, the Facility shall follow the Personnel and Staffing Requirements as detailed in 0940-05-06.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 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: 10/20/2023

Signature: 

Name of Officer: Leandra Mitchell

Title of Officer: Deputy General Counsel, TDMHSAS

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Tre Hargett  
Secretary of State

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