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Sequence Number: 10-23-23
Notice ID(s): 3742
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.

Agency/Board/Commission:	Department of Mental Health and Substance Abuse Services
Division:	Division of Substance Abuse Services
Contact Person:	Krysten Velloff
Address:	500 Deaderick Street, 5th Floor, Andrew Jackson Building, Nashville, TN 37243
Phone:	615-881-5280
Email:	Krysten.Velloff@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:	Austin Nichols
Address:	500 Deaderick Street, 5th Floor, Andrew Jackson Building, Nashville, TN 37243
Phone:	615-426-2689
Email:	Austin.L.Nichols@tn.gov

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:	1:00 PM	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 and are due by close of business (4:30 PM CDT) on Thursday, 12/28/2023.

Revision Type (check all that apply):

X Amendment

X New

X 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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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**
0940-05-42	Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities
Rule Number	**Rule Title**
0940-05-42-.01	Definitions
0940-05-42-.02	Application of Rules
0940-05-42-.03	Licensing Procedures
0940-05-42-.04	Designation of State Opioid Treatment Authority (SOTA) and Powers and Duties of Sota
0940-05-42-.05	Policy and Procedures
0940-05-42-.06	Intake, Admissions, and Discharges
0940-05-42-.07	Service Recipient Record Requirements
0940-05-42-.08	Multiple Enrollments
0940-05-42-.09	Orientation
0940-05-42-.10	Service Recipient Transfers
0940-05-42-.11	Individualized Program Plan
0940-05-42-.12	Special Populations
0940-05-42-.13	Professional Services
0940-05-42-.14	Counseling
0940-05-42-.15	Medication Management
0940-05-42-.16	Pharmacotherapy Guidelines
0940-05-42-.17	Drug Screens
0940-05-42-.18	Detoxification and Medically Supervised Withdrawal
0940-05-42-.19	Diversion Control Plan
0940-05-42-.20	Central Registry
0940-05-42-.21	Reporting Requirements
0940-05-42-.22	Quality of Care
0940-05-42-.23	Infectious Hazardous Waste
0940-05-42-.24	Infection Control
0940-05-42-.25	Managing Disruptive Behavior

0940-05-42-.26	Hours of Operation
0940-05-42-.27	Service Recipients' Rights
0940-05-42-.28	Community Relations
0940-05-42-.29	Personnel and Staffing Requirements
0940-05-42-.30	Mobile Units

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

Rule 0940-05-42-.01 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)"Opioid Treatment Program (OTP)" or "Alcohol & Drug Non-Residential Opioid Treatment Program" (also may be referred to herein as "Facility" or "Program," previously referred to as "Non-Residential Substitution-based Treatment Center for Opiate Addiction") includes, but is not limited to, standalone clinics offering methadone, products containing buprenorphine, or products containing any other formulation approved by the FDA for detoxification and maintenance treatment of opioid use disorder by preventing symptoms of withdrawal, with the goal of the service recipient becoming free from any drug which is not medically indicated.

(b)"Advanced Practice Nurse" means a person qualified by the Tennessee Board of Nursing under Rules Chapter 1000-04 as an advanced practice nurse with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs. 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 partial opioid agonist used as an analgesic and as a medication treatment in the management of opioid use disorder. It has been approved by the FDA for maintenance treatment of opioid use disorder.

(d)"Central Registry" means an electronic system used to register service recipients currently receiving medication assisted treatment at an OTP. The Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS or department) or State Opioid Treatment Authority (SOTA) may require Facilities to initiate a clearance inquiry and service recipient registration into an approved central registry for the purpose of gathering Facility information, evaluating treatment outcomes, collecting demographic information, andpreventing simultaneous enrollment in other Facilities.

(e)“Coordination of Care” means the process of coordinating care, treatment, or services provided by an organization, including referral to appropriate community resources and liaison with others involved in care, treatment, or services (for example, with an individual’s physician, primary care provider, or another healthcare organization or agency) to meet the ongoing identified needs of the individual served, to ensure implementation of the plan of care, treatment, or services, and to avoid unnecessary duplication of services. The aim is to facilitate the appropriate and efficient delivery of healthcare services both within and across systems.

(f)"Counseling Session" means a therapeutic discussion between service recipient(s) and a Facility counselor for a period of no less than 30 minutes designated to address a service recipient's opioid use disorder, coping strategies, and Individualized Treatment Plans. Therapeutic discussions may be delivered across different platforms but must be in compliance with all applicable state and federal regulations.

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

(h)"Detoxification" or "Short-Term Withdrawal Management" means the dispensing of treatment medication in decreasing doses to the service recipient to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the service recipient to a drug-free state within that period.

(i)"Dispense" or "Dispensing" means, for purposes of these rules, to prepare and give out dose(s) of a medication for opioid use disorder to a service recipient at the Facility.

(j)"Diversion Control Plan" means specific measures, including assigning responsibilities to medical and administrative staff, to reduce the possibility of diversion of controlled substances.

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

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

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

(n)"Inspection" means any examination, either onsite or by virtual means, by the department, or its representatives, of a Facility 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 or not a Facility is operating in compliance with 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.

(o)"Maintenance Treatment" means the dispensing of a medication intended to treat opioid use disorder, at relatively stable dosage levels, for a continuous, open-ended period deemed medically necessary by a program provider or medical director. The medication shall be provided in conjunction with efforts to address the serive recipient's needs and goals for treatment, and with the intention to restore normal function in a service recipient's life and improve family and community relationships.. A "maintenance dose" or dose rendered as part of a service recipient's maintenance treatment is the individualized dose of the treatment medication considered to consistently suppress signs or symptoms of withdrawal from opioid drugs and opioid drug cravings for individuals with opioid use disorder.

(p)"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 performed by the Facility, including compliance with all federal, state and local laws and rules regarding medical treatment of opioid use disorder. The medical director shall have the experience and credentials specified in paragraph 0940-05-42-.29(4) of these rules.

(q)"Medical Record" means medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made, or maintained in a Facility that pertains to services rendered to service recipients.

(r)"Medication Assisted Treatment" means the use of FDA approved medications for the purpose of detoxification and maintenance treatment of opioid use disorder in combination with counseling and behavioral therapies.

(s)"Methadone" means a synthetic opioid agonist which has been approved by the FDA for detoxification and maintenance treatment of opioid use disorder.

(t)“Mobile Unit” or a “Mobile Methadone Unit” for the purposes of these rules refers to the operation of a “mobile narcotic treatment program” as described in 21 CFR Part 1301.

(u)"Multidisciplinary Treatment Team" or "Treatment Team" means professionals which may include a licensed physician, licensed advanced practice nurse, licensed physician assistant, licensed nurse, or qualified counseling provider who assess service recipient progress.

(v)"Office of Licensure" means the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Office of Licensure.

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

(x)"Opioid Use Disorder" means a problematic pattern of opioid use leading to problems or distress, with at least two present symptoms listed within the current DSM in a 12-month period. It is a chronic, lifelong disorder, with serious potential consequences including disability, relapses, and death.

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

(z)“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.

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

(bb)"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.

(cc)"Prescription Monitoring Program" or "PMP" means a program established by the Tennessee Department of Health to monitor the prescribing and dispensing of Schedule II, III, IV and V controlled substances.

(dd)"Psychiatrist" means a physician, who specializes in the assessment and treatment of individuals having psychiatric disorders, is certified by the American Board of Psychiatry and Neurology or has the documented equivalent in education and training, and who is fully licensed to practice medicine in the State of Tennessee.

(ee)“Qualified Counseling Provider” means an individual 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 licensure requirements as outlined in 0940-05-42-.29(4)(f) of these rules to provide counseling services to individuals receiving treatment at a Facility.

(ff)"Random Testing" means drug screens conducted by the Facility that lack a definite pattern of who and when service recipients are tested; indiscriminate testing.

(ff)"Relapse" means the failure of a service recipient to maintain abstinence from illicit drug use verified through a drug screen or through a service recipient's self-report.

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

(hh)“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.

(ii)"State Opioid Treatment Authority" or "SOTA" means any individual person designated by the Commissioner of Mental Health and Substance Abuse Services to exercise the responsibility and authority for governing the treatment of opioid use disorder in accordance with all applicable state and federal regulations. The individual also serves as a liaison with the appropriate federal agencies.

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

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

(ll)“Telehealth” means the distribution of health-related services and information via electronic information and telecommunication technologies. Telehealth services are intended to remotely support and facilitate the delivery of both clinical and non-clinical services to its recipients. Telehealth technologies include, but are not limited to, live video conferencing, mobile health applications, and phone calls

(mm)"Treatment" means a broad range of services including outreach, identification, assessment, diagnosis, detoxification, therapy, medical services, lectures/seminars, group process social services, and follow-up or aftercare for individuals with opioid use disorder. The overall goal is to eliminate the opioid use disorder as a contributing factor to physical, psychological and social dysfunction and to decrease or reverse the progress of any associated problems.

(nn)“Treatment Plan” or “Individualized Treatment Plan” means a comprehensive, progressive, personalized plan that includes all prescribed treatment services. It is person-centered, recovery oriented, culturally competent and addresses personalized goals and objectives.

(oo)"Volunteer" means a person who is not paid by the licensee and whose varied skills are used by the licensee to support and supplement the efforts of the paid Facility staff.

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

Rule 0940-05-42-.02 Application of 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)In addition to this chapter, the licensee of a Facility shall comply with the following rules:

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

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

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

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

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

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

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

Rule 0940-05-42-.03 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)When making an application for a new license, the applicant shall submit an application on a form provided by the department along with a copy of the Certificate of Need (CON) issued by the Tennessee Health Facilities Commission or any other applicable state agency. If the CON is not required, documentation must be submitted to the Office of Licensure and the SOTA office as to why it was not required. Any condition placed on the CON will also be placed on the license.

(2)The written application for operation of a Facility shall be filed simultaneously with the Federal Substance Abuse and Mental Health Service Administration (SAMHSA) and the DEA, and/or any other applicable federal agencies.

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

(4)Service recipients shall not be admitted to the Facility until the Facility is registered and active in the Central Registry.

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

Rule 0940-05-42-.04 Designation of State Opioid Treatment Authority (SOTA) and Powers and Duties of Sota 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 Commissioner of the Department of Mental Health and Substance Abuse Services shall designate an individual within the department to serve as the SOTA to facilitate oversight and technical assistance to licensed Facilities under this part. The individual designated shall have demonstrated education and background evidencing comprehensive knowledge of opioid drugs and their effects.

(2)The powers and duties of the SOTA, and SOTA designees, include, but are not limited to, the following:

(a)Facilitating the development and implementation of rules, regulations, standards and best practice guidelines to assure the quality of services delivered by Facilities;

(b)Acting as a liaison between relevant State and federal agencies;

(c)Reviewing opioid treatment guidelines and regulations developed by the federal government;

(d)Assuring delivery of technical assistance and informational materials to Facilities as needed;

(e)Performing unannounced inspections to Facilities;

(f)Consulting with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate;

(g)Reviewing and approving exceptions to federal and state dosage policies and procedures;

(h)Receiving and addressing service recipient appeals and grievances;

(i)Monitoring of performance outcomes. The following performance indicators may be used to evaluate the impact of the Facility on service recipients and the community:

1.Service recipient satisfaction.

2.Service recipient employment status.

3.Improvement in medical conditions.

4.Drop-out rate.

5.Recidivism rates.

6.Alcohol use.

7.Criminal arrests.

8.Illicit drug use, as indicated by drug screens.

9.Improvement in social and living standards; and

(j)Working cooperatively with other relevant state agencies to determine the service need in the location of a

proposed 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, and 33-2-404.

Rule 0940-05-42-.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 it is administered and operated in accordance with written policies and procedures in the below-listed subject areas and in accordance with these rules. Each Facility shall clearly identify the governing body, as defined in Rule 0940-05-01-.01(18), in its policies and procedures manual including the name and contact information of the governing body.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(y)Mobile Units (0940-05-42-.30)

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

Rule 0940-05-42-.06 Intake, Admissions, and Discharges is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1)Prior to admission to the Facility, each potential service recipient shall be evaluated by the medical director or program provider and clinical staff who have been determined to be qualified by education, training, and experience to perform or coordinate the provision of such assessments. The purpose of such assessments shall be to determine whether medication assisted treatment will be the most appropriate treatment modality for the service recipient. No prospective service recipient shall be processed for admission until it has been verified that the service recipient meets all applicable criteria.

(2)Except as otherwise authorized by law, no person shall be admitted for treatment without written authorization from the service recipient and, if applicable, parent, guardian or responsible party. The following information shall be explained by a trained staff person to the service recipient and other consenters and documented in the service recipient's file:

(a)The Facility's services and treatment;

(b)The specific conditions that will be treated;

(c)Explanation of treatment options, including maintenance treatment and short-term withdrawal management, if available, and clinic charges, including the fee agreement, signed by the prospective service recipient or the service recipient's legal representative; and

(d)The Facility's rules regarding service recipient conduct and responsibilities.

(3)A program provider shall document that treatment is medically necessary. The admissions and initial dosing decision ultimately rests with the medical director or a program provider, as applicable and allowed by federal and state laws, rules, and regulations.

(4)A Facility shall only admit and retain service recipients whose known needs can be met by the Facility in accordance with its licensed Facility purpose and applicable federal and state laws, rules, and regulations.

(5)Pregnant females with an opioid use disorder shall be given priority for admission and services when a Facility has a waiting list for admissions and it is determined that the health of the mother and/or unborn child is more endangered than is the health of other service recipients waiting for services.

(6)No Facility shall provide incentives for referral of potential service recipients to the clinic.

(7)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;

(j)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 themself, 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.

(8)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:

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

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

(II)Frequency of use; and

(III)Duration of use;

(Bii)Symptoms of physical dependence or withdrawal;

(Ciii)History of treatment for addictive behaviors;

(Div)Adverse consequences of use; and

(Ev)Inappropriate use of prescribed substances;

8.Previous behavioral health services, including:

(Ai)Diagnostic information;

(Bii)Treatment information; and

(Ciii)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.

(9)At the time of admission, the Facility shall conduct an inquiry with the Central Registry in accordance with Rule 0940-05-42-.20.

(10)Non-Admissions. The Facility shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs shall identify the reasons why the persons were not admitted and what referrals were made for them by the Facility.

(11)Discharge and Aftercare Plans. A Facility shall complete an individualized discharge and aftercare plan for service recipients who complete their course of treatment.

(a)Upon admission a Facility shall begin development of a service recipient's discharge plan.

(b)All discharge and aftercare plans shall include documentation that the Facility's treatment team has discussed with the service recipient an individualized treatment plan appropriate to the service recipient's discharge

and aftercare plans.

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

(d)The discharge plan shall be completed within seven days of discharge by the person who has primary responsibility for coordinating or providing for the care of the service recipient. It shall include a final assessment of the service recipient's status at the time of discharge and aftercare planning. If applicable, parents or guardian, or responsible persons may participate in discharge and aftercare planning. The reason for any service recipient not participating in discharge and aftercare planning shall be documented in the service recipient's record.

(e)Service recipients that have lost contact with the Facility for greater than 30 days shall be discharged from the Facility and will require a new admission upon return.

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

Rule 0940-05-42-.07 Service Recipient 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)Facilities shall organize and coordinate service recipient records in a manner which demonstrates that all pertinent service recipient information is accessible to all appropriate staff and to the SOTA and TDMHSAS.

(2)All documentation will be clearly dated and initialed, or signed, by the staff member involved

(3)Records shall be preserved for not less than 10 years even if the Facility discontinues operations. The records may be generated, maintained, or transferred in whole or in part to any recording medium that assures accurate preservation of the record.

(4)The Facility shall discuss final storage or disposition of the Facility's records with TDMHSAS 90 days in advance of the closing of a Facility.

(5)A voluntary, written, Facility-specific informed consent to treatment from each service recipient at admission to include:

(a)Information about all treatment procedures, services, and other policies and regulations throughout the course of treatment, including clinic charges in the form of a fee agreement signed, either in-person, electronically, or by documented verbal acknowledgment by the service recipient;

(b)Acknowledgment of the individualized, prescribed therapy before dosing begins, including information about potential interactions with and adverse reactions to other substances, including interactions and adverse reactions to alcohol, other prescribed medications, over-the-counter medications, other medical procedures and food;

(c)Information that the goal of opioid treatment is stabilization of functioning;

(d)Information that short-term withdrawal management from opioids over 30 to 180 days is a treatment alternative to long-term maintenance;

(e)Acknowledgement that the service recipient has been informed of the Facility's rules regarding service recipient conduct and responsibilities and continuing documentation of the service recipient's compliance with the Facility's policies;

(f)Acknowledgement that the service recipient has been informed of their rights (0940-05-42-.27);

(g)Information that at regular intervals, in full consultation with the service recipient, the Facility shall discuss the service recipient's present level of functioning, course of treatment and future goals; and

(h)Information that the service recipient may choose to withdraw from, or be maintained on the medication as they desire unless medically contraindicated;

(6)Documentation of the initial and comprehensive assessments as required by 0940-05-42-.06(8) and (9);

(7)Medical reports including results of the physical examination; past and family medical history; review of systems; laboratory reports, including results of required toxicology screens; and progress notes, including documentation of current dose and other dosage data. Information in the medical record shall be entered by a program provider;

(8)Dated and signed case entries of all significant contacts with service recipients, including a record of each counseling session in chronological order;

(9)Dates and results of treatment team meeting for service recipients;

(10)The initial treatment plan, any amendments to the plan, reviews of the plan, and the long-term, individualized treatment plan, including any amendments to that document and reviews of the plan;

(11)Documentation that services listed in the plan are available and have been provided or offered;

(12)Documentation that the service recipient was informed about the process and factors considered in decisions impacting the service recipient's treatment or any other significant change in treatment;

(13)A record of correspondence with the service recipient, family members and other individuals and a record of each referral for services and its results;

(14)Documentation that the service recipient was provided a copy of the Facility's rules and regulations and a copy of the service recipient's rights and responsibilities and that these items were discussed with them;

(15)A closing summary, including reasons for discharge and any referral. In the case of death, the reported cause of death shall be documented;

(16)A written fee agreement as detailed in Rules Chapter 0940-05-42-.06 dated and signed by the service recipient, or the service recipient's legal representative, prior to provision of any services. This fee agreement shall include an explanation of the financial aspects of treatment and the consequences of nonpayment of required fees, including the procedures for medically supervised withdrawal in the event that a service recipient becomes unable to pay for treatment. If the cost of services changes while the service recipient is receiving treatment at the Facility, a new fee agreement shall be signed, either in person, electronically, or by documented verbal acknowledgment. If a service recipient is a utilizing a third-party payor or other benefit to cover the cost of services, the payor and the service recipient's payor identification number must be documented on the fee agreement;

(17)Documentation of Central Registry clearance as required under these rules; and

(18)All other information and documents as required by the SOTA and these rules.

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

Rule 0940-05-42-.08 Multiple Enrollments 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 a procedure which shall ensure that no service recipient is enrolled in more than one Facility.

(2)The procedure shall take into account requirements for service recipient confidentiality.

(3)The Facility shall obtain a release of information from the service recipient in order to check the records of every Facility within Tennessee and those Facilities within a minimum of 75 miles of the Facility, or those Facilities that participate with the Central Registry. The release of information shall state that its purpose is to obtain information and records developed during prior admission(s) not contacts with admission. Results of this check shall be maintained in the service recipient's medical record. This check shall be duplicated if the service recipient is discharged and readmitted at any time.

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

Rule 0940-05-42-.09 Orientation 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 provide, and document, an orientation to service recipients within 24 hours of admission for treatment and again within 30 days following the admission date. The orientation shall be designed to educate the service recipient and ensure that the service recipient understands the Facility's program.

(2)Orientation shall be done by a designated staff person who has been determined to be qualified by education, training and experience to perform the task.

(3)Facilities shall ensure that each service recipient signs, either in person, electronically, or by documented verbal acknowledgment, a statement confirming that the following information has been explained to the service recipient:

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

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

(c)An explanation of individualized treatment planning.

(4)Facilities shall ensure that each service recipient signs, either in person, electronically, or by documented verbal acknowledgment, a statement confirming that they have been offered short-term withdrawal management services as an admission alternative and that the following has been discussed with the service recipient:

(a)An explanation of the types of detoxification services offered by the Facility, including administrative detoxification; and

(b)An individualized assessment of the medical risks and benefits of detoxification for the service recipient.

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

Rule 0940-05-42-.10 Service Recipient 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 service recipient has previously been discharged from treatment at another methadone clinic or facility, the admitting facility shall initiate an investigation into the prospective service recipient's prior treatment history, inquiring of the last program attended and the reasons for discharge from treatment.

(2)Service recipients who were terminated from a prior Facility due to noncompliance shall be admitted as a new service recipient.

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

Rule 0940-05-42-.11 Individualized Program 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 TreatmentPlan (ITP) for each service recipient within 30 days of admission. Each service recipient shall be involved in the development and review of their ITP. The initial ITP and all reviews shall be signed, either in person, electronically, or by documented verbal acknowledgement, by the service recipient, qualified counseling provider, and program provider. ITPs shall document the following:

(a)A consistent pattern of substance use treatment services and medical care appropriate to the individual service recipient's needs;

(b)A documented discussion regarding the service recipient’s readiness and willingness to taper down or off of the medication used in treatment.; and

(c)S.M.A.R.T. treatment goals discussed and agreed upon by the qualified counseling provider, program provider and the service recipient.

(2)The admission requirements of 0940-05-42-.06 shall be completed prior to the development of an ITP.

(3)Medical care, including referral for necessary medical service, and evaluation and follow-up of service recipient complaints shall be compatible with current and accepted standards of medical practice. All service recipients shall receive a physical 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 provider shall record the results of the annual medical examination and review of service recipient medical records in each service recipient's record.

(4)In recognition of the varied medical needs of service recipients, any case histories, ITPs, short-term withdrawal management plans, and discharge plans shall be reviewed at least every 90 days for service recipients in treatment less than one year and at least every six months for service recipients in treatment more than one year. This review will be conducted by the medical director or program provider along with the primary qualified counseling provider and other appropriate members of the treatment team involved in the service recipient's treatment. This review shall also include an assessment of the current dosage, schedule, and the rehabilitative progress of the individual, as part of a determination that additional medical services are indicated. If this review results in a determination that additional or different medical or behavioral health services are indicated the Facility shall ensure that such services are made available to the service recipient, either at the Facility or by referral to the appropriate medical professional. Any referrals shall be documented and followed up on as appropriate.

(5)When the program provider prescribes other controlled substances to service recipients in the Facility, the Facility shall ensure that such prescription is in compliance with all applicable statutes and regulations and with current and accepted standards of medical practice. Such prescriptions shall not be issued to any service recipient unless the program provider first sees the service recipient and assesses the service recipient's potential for abuse of such medications.

(6)As part of the rehabilitative services provided by the Facility, each service recipient shall be provided with individual and group counseling appropriate to their needs. The frequency and duration of counseling provided to service recipients shall be in conformity with 0940-05-42-.14 and be consistent with the ITP. ITPs shall indicate a specific level of counseling services needed by the service recipient as part of the rehabilitative process.

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

(8)When appropriate, the Facility shall provide each service recipient information regarding enrollment in a vocational education program, be engaged in a vocational activity (vocational evaluation, education or skill training) or assisting in efforts to seek gainful employment. Deviations from compliance with these requirements shall be explained in the service recipient's record. Each Facility shall take steps to ensure that a comprehensive range of rehabilitative services, including vocational, educational, legal, mental health, treatment for other drugs of abuse and alcohol use disorder, and social services, are made available to the service recipients who demonstrate a need for such services. The Facility can fulfill this responsibility by providing support services directly or by

appropriate referral. Support service(s) recommended and utilized shall be documented in the service recipient's record. Each Facility shall have policies for matching the service recipient's needs to treatment.

(9)All Facilities will develop and implement policies for matching service recipient's needs to treatment. These policies may include treatment phasing in which the intensity of medical, counseling, and rehabilitative services provided to a service recipient is individualized for each service recipient depending upon the service recipient's phase of treatment.

(10)If the service recipient experiences a relapse, their ITP shall document evidence of intensified services. Such evidence shall include, but is not limited to, an increase in individual or group counseling session(s) and a reduction in the service recipient's take-home privileges.

(11)Discussion shall be held with the service recipient regarding their continued desire to remain in the program for maintenance treatment. Alternatives such as medically-supervised withdrawal shall be presented to the service recipient at the time of the discussion and documented in the service recipient's record. The service recipient shall sign and date, either in person, electronically, or by documented verbal acknowledgement, a statement indicating that they wish to continue maintenance treatment. If the service recipient 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, and 33-2-404.

Rule 0940-05-42-.12 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)The Facility shall ensure that program providers are knowledgeable in the management of opioid use disorder in the context of chronic pain and pain management. The Facility may not prohibit a service recipient diagnosed with chronic pain from receiving medication-assisted treatment for either maintenance treatment or short-term withdrawal management.

(a)With the service recipient's consent, the Facility shall ensure continuity of care and communication between the Facility's program providers and any outside provides regarding the service recipients receiving opioid use disorder and pain treatment.

(b)If the service recipient refuses consent for the two entities to communicate and coordinate care, the Facility shall document refusal and may make clinically appropriate decisions regarding treatment, such as, take-home medication privileges, medication dosing, or an increase in counseling.

(2)The Facility shall ensure that service recipients with mental health needs are identified and referred to appropriate treatment with appropriate follow up. Any referrals or attempts at referrals shall be documented in the service recipient's record.

(a)The Facility shall closely monitor service recipients during medically supervised withdrawal, or dose tapering, to identify of symptoms of mental illness.

(b)The Facility shall establish and document established referral relationships with mental health providers in the community.

(3)The Facility shall have a policy regarding the treatment of co-morbid disorders such as psychiatric and medical disorders. The goal of treatment shall be to facilitate treatment for these disorders as seamlessly as possible, while, maximizing service recipient convenience and compliance with appointments and recommendations. The Facility shall attempt to ensure a smooth referral process and exchange of information. The Facility shall organize and facilitate communication between two or more participants involved in a service recipient’s care (such as the Facility and primary care provider, specialty services, and/or mental health services) to achieve safer and more effective care. This shall be documented in the service recipient’s record.

(4)The Facility shall address use of alcohol and other non-opioid substances to provide treatment or referral to appropriate

outside providers, as appropriate.

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

(b)Ongoing multi-drug use is not necessarily a reason for discharge . The treatment team shall consider the service recipient's condition and address the situation from an individualized clinical perspective. The program provider shall consider the risks and benefits of the patient's current level of care being provided, medication dosage, and other services being provided when treating service recipients with ongoing multi-drug use. The program provider shall refer and document the service recipient to a higher level of care when indicated.

(c)Social barriers to higher levels of care, such as inability to pay, or concerns regarding loss of employment, shall be documented. In cases where a higher level of care is recommended yet declined by the client or unattainable due to external factors, the clinician will document the rationale for continuing to treat the service recipient 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, and 33-2-404.

Rule 0940-05-42-.13 Professional Services is repealed.

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

Rule 0940-05-42-.14 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 essential to promote and guide the service recipient to a more productive life style of abstinence from illicit medications or drugs . The assigned qualified counseling provider is responsible for developing and implementing the service recipient's ITP, in coordination with the treatment team. The ITP shall include S.M.A.R.T. goals developed between the qualified counseling provider, the service recipient, and the treatment team. The qualified counseling provider is responsible for assisting the service recipient to alter lifestyles and patterns of behavior to improve the service recipient's quality of life.

(2)The qualified counseling provider caseload shall:

(a)Be no larger than one (1) qualified counseling provider to fifty (50) service recipients;

1.The Facility can petition the SOTA office, in writing, for a consideration to exceed the ratio for a period no longer than six (6) months. The Facility shall include justification and documentation for requiring the adjustment; and

2.An extension can be submitted, for a period not to exceed an additional six (6) months, to the SOTA office with sufficient documentation outlining why an extension is necessary;

(b)Allow the Facility to provide adequate:

1.Psychosocial assessment;

2.Treatment planning; and

3.Individualized counseling;

(c)Allow for regularly scheduled counseling sessions; and

(d)Allow service recipients access to their primary counselor if more frequent contact is merited by need or is requested by the service recipient.

1.Telehealth is available as an option for more frequent contact with the counselor if desired or needed by the service recipient. Telehealth visits should not exceed fifty (50) percent of the service recipient’s total visits.

(3)The qualified counseling provider supervisor caseload shall:

(a)Be no larger than one (1) qualified counseling prover supervisor to twenty five (25) service recipients;

1.The Facility can petition the SOTA office, in writing, for consideration to exceed the ratio for a period no longer than six (6) months. The Facility shall include justification and documentation for requiring the adjustment;

(4)The Facility shall take service recipient preferences into account when assigning their qualified counseling provider, as appropriate.

(5)For all service recipients, the following counseling schedule shall be followed:

(a)During the first 30 days of treatment, counseling session(s) shall take place in-person at least two times per week;

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

(c)During the following 90 days of treatment (day 121 to day 210) and the service recipient demonstrates treatment stability, as defined in 0940-05-42-(1)(c)6., counseling session(s) shall take place either via telehealth or in-person at least two times per month;

(d)For subsequent 90 day periods of treatment (day 211 forward) and the service recipient demonstrates treatment stability, as defined in 0940-05-42-(1)(c)6., counseling session(s) shall take place either via telehealth or in-person as needed or indicated in the service recipient's ITP, but not less frequently than monthly.

(e)Counseling sessions occurring on day 31 and forward can utilize telehealth visits for up to fifty (50) percent of the service recipient’s sessions. Session type shall be based on counselor evaluation and service recipient needs and be clearly documented in the service recipient’s record.

(6)Exceptions to the frequency of counseling sessions shall be clearly justified and documentation.

(7)The program provider evaluating the service recipient's eligibility for take-home doses shall carefully consider the service recipient's participation in the counseling sessions as a factor in their decision.

(8)The qualified counseling provider or program provider is responsible for documentation of their significant contact with each service recipient, which shall be filed in the service recipient's medical record.Significant contact can include, but not be limited to, in-person counseling, telephone calls, telehealth calls, or web-based calls.

(9)The counseling session documentation shall include a thorough and detailed description of:

(a)The reason for or nature of the contact;

(b)The service recipient's current condition;

(c)Significant events occurring since prior contact;

(d)The assessment of the service recipient's status;

(e)A description of the therapeutic technique used during the session; and

(f)A plan for action or further treatment that addresses the goals of the treatment plan.

(7)Each entry shall be completed within 24 hours of the contact and shall be clearly dated and initialed or signed by the staff person involved.

(8)Opportunities for family involvement in counseling shall be provided and documented.

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

Rule 0940-05-42-.15 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 prescribing, dispensing, and administration of medications and their security. No standardized routines or schedules of increases or decreases of medications may be established or used. These policies and procedures shall include the following:

(a)Administration.

1.A program provider shall perform a medical assessment to determine the service recipient's initial dose and schedule. The provider shall communicate the initial dose and schedule to the person supervising medication and document the dose in the service recipient's record.

2.The initial dose shall be based on the clinical judgment of the program provider who has examined the service recipient and who has considered all available relevant information, including, but not limited to, drug screens, service recipient interview, and specific circumstances pertaining to the individual service recipient.

3.A program provider may assign such dose and schedule by verbal order only on an emergency basis. If a verbal order is given, the physician shall examine the service recipient within 72 hours. Both the verbal order and the results of the physical examination shall be documented in the service recipient's record.

4.The initial dose of methadone may not exceed 30 milligrams. Only in extraordinary circumstances may the total dose for the first day exceed 40 milligrams. A transferring service recipient may receive an initial dosage of no more than the last daily dosage authorized at the former Facility unless in the clinical judgment of the medical director, there are extenuating circumstances documented in the records which justify an initial dosage that is greater than the last daily dosage authorized at the former Facility.

5.Subsequent doses shall be authorized by a program provider. Additional dosage may be dispensed in the first day where the program provider documents that the initial dose does not suppress withdrawal symptoms. Service recipients are stabilized on methadone when they are receiving a therapeutic dose that is sufficient to stop opioid cravings and misuse and sufficient to keep the service recipient comfortable for at least 24 hours.

6.No dosage increases shall occur on the days that the Facility is closed.

7.No methadone may be administered unless the prospective service recipient has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the service recipient's medical record. In that case, intake procedures shall be completed on the next working day. No take-home medication may be given in such an emergency.

8.No dose of methadone in excess of 120 milligrams may be ordered or administered without the prior

approval of the SOTA. If a service recipient has transferred to a new Facility and has a prior ordered or administered dose in excess of 120 milligrams, the new Facility shall submit a request for approval by the SOTA.

9.Service recipients that are guest-dosing at the Facility and receiving a dose of greater than 120 milligrams must be approved by the program provider and will not require SOTA approval.

10.Benzodiazepine Use. If a service recipient has a positive benzodiazepine screen:

(i)The treatment team shall meet with the service recipient, either in person or via video conferencing platform, within 14 days of receiving the results of the screen, to develop a benzodiazepine action plan in the service recipient's record. The plan shall be reviewed and signed by the medical director or designated program provider;

(ii)If the plan requires the service recipient to remain abstinent from benzodiazepines, a time period for supervised withdrawal shall be established. Coordination, or the attempt to coordinate with the benzodiazepine prescriber must be documented in the service recipient’s record;

(iii)The Facility shall provide benzodiazepine gradual dose reductions or tapering services either directly or through referral to another provider. Any referrals must be documented in the service recipient’s record;;

(iv)If the plan calls for the continued use of benzodiazepines, the Facility shall coordinate the care with a qualified provider and document this coordination in the service recipient's record;

(v)The Facility shall document any follow-up action to any deviation from the benzodiazepine action plan; and

(vi)The benzodiazepine action plan and subsequent progress notes about plan implementation shall be documented in the service recipient's medical record.

(b)Any opioid drug ordered and administered shall be documented on an individual medication administration record. The record shall include:

1.Name of medication;

2.Date prescribed;

3.Dosage;

4.Frequency of administration;

5.Route of administration;

6.Date and time administered; and

7.Documentation of staff administering medication or supervising self-administration.

(c)Take-home doses of methadone or buprenorphine shall comply with the following requirements.

1.Take-home schedule:

(i)Days 1 – 30: Daily dosing

(ii)Days 31- 365:

I.Service recipient demonstrating treatment stability: Clinic attendance once every two weeks

II.Service recipient demonstrating treatment instability: Clinic attendance three nonconsecutive days per week

(iii)Days 366 onward:

I.Service recipient demonstrating treatment stability: Clinic attendance once a month

II.Service recipient demonstrating treatment instability: Clinic attendance three nonconsecutive days per week for a minimum of 2 weeks, then once every two weeks for a minimum of one month, then return to monthly clinic attendance.

(iv)When determining treatment stability for this section, please refer to 0940-05-42-.15(1)(c)3. below.

2.All requests for take-home exceptions shall be reviewed and approved by the SOTA and any other applicable federal agency.

(i). The Facility shall check the PMP database prior to requesting any take-home or dosing exceptions and include this information with the exception request.

(ii). The Facility shall provide counseling prior to providing take-home doses to any service recipient. Progress notes in the service recipient's record shall document the counseling provided.

(iii). The Facility shall include the service recipient’s Central Registry ID number, details regarding the service recipient’s treatment stability, details regarding the need for the exception request and why alternatives would not be appropriate.

3.The Facility shall document in the service recipient's record the basis for determining treatment stability approving "take-home" medication for the service recipient. The following criteria shall be considered in determining the service recipient's treatment stability and determining eligibility for "take-home" medications.

(i)Cessation of illicit drug use;

(ii)Regularity of program attendance;

(iii)Length of time and level of treatment in medication therapy (ability to responsibly self-medicate);

(iv)Absence of known recent criminal activity;

(v)Absence of serious behavioral problems;

(vi)Absence of misuse of drugs, including excessive use of alcohol;

(vii)Other special needs of the service recipient, such as split dosing, physical health needs, pain treatment, etc.;

(viii)Capacity to safely store "take-home" medication within the service recipient's home;

(ix)Stability of the home environment and social relationships;

(x)Service recipient's work, school, or other daily-life activity schedule; and

(xi)Hardship experienced by the service recipient in traveling to and from the Facility.

(d)Adverse drug reactions and errors shall be reported to a program provider immediately and corrective action shall be initiated. The adverse reaction or error shall be recorded in the service recipient's medical record, the medication administration record, the nurse progress notes, and the ITP, and all persons who are authorized to administer medication or supervise self-medication shall be alerted.

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

(f)Medication orders and dosage changes shall be written, printed, provided electronically, on a form which clearly displays the program provider's signature. The Facility shall maintain an accurate, perpetual inventory at all times. Every dose shall be recorded in the service recipient's individual medication record at the time the dose is dispensed or administered. If initials were used, the full signature and credentials of the qualified person administering or dispensing shall appear at the end of each page on the medication sheet. The perpetual inventory shall be totaled and recorded in milligrams daily. Any inventory variances shall be documented, including the reason for the variance and any follow-up actions, and reported to the SOTA office.

(g)No standardized routines or schedules of increases or decreases of medications may be established or used

(h)Computer-based Recording.

1.Any such computerized system shall have the capability of producing a hardcopy printout of any medical or dosing order data which the Facility is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. Any computerized system shall, upon the request of the SOTA, send or provide such a printout within 48 hours excluding weekends.

2.In the event a Facility experiences system down-time, the Facility must have a written or readily retrievable auxiliary policy and procedure for documentation of all medical and dosing orders. The auxiliary procedure shall ensure that each medical or dosing order is authorized, and that all appropriate data are retained for on-line data entry as soon as the computer system is available for use again.

(i)Guest Dosing.

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

2.Service recipients shall have been enrolled at the home clinic for a minimum of 30 days before being eligible for a guest dose. Service recipients enrolled less than 30 days at the home clinic shall be eligible for guest dosing only if approved by the SOTA.

3.Service recipients shall have two consecutive favorable drug screens before being eligible for a guest dose unless the medical director determines that the benefits of guest dosing outweigh the risks and documents the justification for granting guest dosing privileges in the service recipient's record.

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

Rule 0940-05-42-.16 Pharmacotherapy Guidelines 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 develop pharmacotherapy guidelines for service recipients covering the Facility's own prescribing and the review of prescriptions from other providers. These shall minimally include:

(a)Procedures to ensure that service recipients' 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 including, but not limited to, the loss of take-home privileges, to ensure compliance with this rule; and

(c)If a Facility is unable to acquire information about a service recipient's prescriptions, the Facility shall document efforts made to obtain information about prescriptions from outside providers or pharmacies in the service recipient's record.

(2)The Facility shall queuery the PMP:

(a) Upon admission of a service recipient;

(b) After any unfavorable drug screen which results may be attributable to a prescription medication; and

(c) Every three (3) months for the first one year of treatment, or if the service recipient demonstrates treatment instability, and every six (6) months thereafter. The service recipient’s record shall include documentation of the check of the PMP database, the date upon which it occurred, the results of the PMP check, and any follow-up actions from the results. If the PMP report yields a result that the service recipient is receiving other controlled prescription medication(s), appropriate documentation of the prescription(s) must be in the service recipient’s record;

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

Rule 0940-05-42-.17 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 urine drug screening or other adequately tested toxicological procedures shall be used for the purposes of assessing the service recipient's progress in treatment.

(2)Drug screening procedures shall be individualized and shall include at least weekly observed random drug screens for newly admitted service recipients during the first 30 days of treatment and then at least eight times annually thereafter. For service recipient’s demonstrating treatment stability, as referred to in 0940-05-42-.15(1)(c)3., shall receive a randomized observed drug screen at least 4 times annually.

(3)Service recipients whose drug screen results are unfavorable, or otherwise indicate treatment instability, shall receive a randomized observed drug screen weekly for at least two weeks, or longer, if clinically indicated.

(4)Each sample collected shall be screened to include, but not be limited to:

(a)Opioids including fentanyl and other synthetics;

(b)Methadone, buprenorphine, or any other treatment medication used by the Facility's program;

(c)Benzodiazepines;

(d)Cocaine;

(e)Methamphetamine/amphetamines; and

(f)Other drugs as indicated by individual service recipient use patterns, community standards, regional variation, or clinical indication (e.g., THC, carisoprodol, barbiturates) or as directed by the SOTA.

(7)Collection and testing shall be done in a manner that assures that specimins collected from service recipients are

unadulterated. In the case of urine collection, such collection and testing shall include random direct observation conducted professionally, ethically, and in a manner which respects the service recipients' privacy.

(8)Any refusal to participate in a random drug screen shall be considered an unfavorable screen. A drug screen is considered an unfavorable screen whenthe results indicate the presence of any drug or substances listed in section (4) of this rule that is illegal or for which the service recipient cannot provide a valid prescription or any drug or substance prohibited by the Facility or SOTA; the presence of medication which is documented as part of the service recipient's treatment plan shall not be considered an unfavorable screen.

(9)Unfavorable drug screen results after the first six months in a Facility shall result in the following:

(a)Upon the first unfavorable drug screen result, the Facility shall:

1.Contact the service recipient the day of receiving the drug screen result, provide mandatory and documented weekly counseling, which shall include weekly meetings with a qualified counseling provider, either in person or via telehealth platforms; and

2.Require the service recipient to attend the clinic a minimum of three days per week;

(b)Upon a second unfavorable drug screen result within six months of the first unfavorable drug screen result, the Facility shall:

1.Contact the service recipient the day of receiving the drug screen result, provide mandatory and documented weekly counseling which shall include weekly meetings with a qualified counseling provider, either in person or via telehealth platforms;

2.Require the service recipient to attend the clinic a minimum of three days per week; and

3.Provide mandatory, in-person, documented treatment team meetings with the service recipient and review the service recipient’s ITP to ensure it is addressing the service recipient’s needs;

(c)Upon a third unfavorable drug screen result within six months of the second unfavorable drug screen result, the Facility shall:

1.Contact the service recipient the day of receiving the drug screen result, provide mandatory and documented weekly counseling, which shall include weekly meetings with a qualified counseling provider, in-person;

2.Require the service recipient to attend the clinic a minimum of three days per week; and

3.Provide mandatory, in-person, and documented treatment team meetings with the service recipient which shall include, at a minimum: a review of the ITP, a discussion related to the need for continuing treatment; a discussion of other treatment alternatives; and documentation on whether a referral to a higher level of care is appropriate.

(10)The Facility shall document both the results of drug screens and the follow-up therapeutic action taken in the service recipient record.

(11)The Facility shall work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens.

(12)The Facility shall ensure that program providers demonstrate competence in recognizing factors that may contribute to "false negative" and "false positive" laboratory results.

(13)Absence of methadone or other medications ordered by the Facility for the service recipient shall be considered evidence of possible medication diversion and evaluated by the program provider accordingly.

(18)Nothing contained in this rule shall preclude any Facility from administering any additional drug screens it determines

necessary.

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

Rule 0940-05-42-.18 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)In the event the service recipient becomes unable to pay for treatment, the Facility shall develop procedures for administrative withdrawal or medically supervised withdrawal, including an appropriate time frame over which the procedure would take place. The schedule of withdrawal may be brief, less than 30 days if necessary. Such procedures shall include documentation of referral of the service recipient to alternative treatment resources.

(a)The Facility shall develop policies and procedures clearly describing under what circumstances a service recipient may be subject to administrative withdrawal. Administrative withdrawal may result from:

1.Non-payment of fees. The Facility shall make every effort to consider all clinical data including service recipient participation and compliance with treatment prior to initiating administrative withdrawal for non-payment. If the service recipient has a history of compliance and cooperation with treatment, the Facility shall document every effort to explore alternatives to administrative withdrawal with the service recipient prior to initiation of administrative withdrawal;

2.Disruptive conduct or behavior considered to have an adverse effect on the Facility, staff, or service recipient population to justify the involuntary withdrawal and discharge of a service recipient. ; or

3.Other reasons as determined by the Facility and approved by the SOTA.

(b)Medically supervised withdrawal occurs as a voluntary and therapeutic withdrawal agreed upon by staff and service recipient. In some cases, the withdrawal may be against the advice of clinical staff (against medical advice).

1.The Facility shall supply an individualized schedule of dose reduction well tolerated by the service recipient.

2.The Facility shall offer supportive treatment including increased counseling sessions and referral to a self-help group or another counseling provider as appropriate.

3.If the service recipient leaves the Facility's program abruptly against medical advice, the Facility may readmit the service recipient within 30 days without having to complete a new Initial or Comprehensive Assessment referred to in 0940-05-42-.06(7) and (8). The Facility shall document attempting to assist the service recipient in any issues which may have precipitatedtheir abrupt departure.

4.The Facility shall make provisions for continuing care for each service recipient following the last dose of medication and for re-entry to maintenance treatment if relapse occurs or if the service recipient should reconsider medically supervised withdrawal.

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

Rule 0940-05-42-.19 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 clinic shall develop policies and procedures for a Diversion Control Plan that contains specific measures to reduce the possibility of diversion of controlled substances 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. The Diversion Control Plan shall contain, at a minimum, a random call-back program with

mandatory compliance.

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

(b)Each service recipient receiving three or more consecutive take-home medications per week shall be called back randomly within the three-month period immediately following the previous call-back.

(c)Upon call back a service recipient shall report to the clinic within 24 hours of notification, with all take-home medications. If a service recipient call-back displays treatment instability, such as: absence for the scheduled call-back, not having the appropriate quantity of take-homes, or the packaging shows signs of tampering, the service recipient shall be required to attend the clinic at least three nonconsecutive days per week and demonstrate treatment stability for a minimum of four weeks prior to returning to regular clinic attendance schedule

(d)Service recipients shall be informed of the above requirements and the Facility's policies and procedures regarding call-backs and receiving take-homes, including follow-up actions for any call-back results that demonstrate treatment instability.

(e)The Facility shall document individual call-back results in the service recipient record.

(2)The Facility's policies and procedures for the iversion control plans shall include the method for which the Facility will prevent the diversion of controlled substances from within the Facility. The plan shall include, at a minimum: maintaining a perpetual inventory, procedures for ordering and receiving controlled substances, and conducting investigations if theft or diversion is suspected: and

(3)The Facility shall submit a report to the SOTA within 48 hours of any theft or diversion of controlled substances from within 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, and 33-2-404.

Rule 0940-05-42-.20 Central Registry is amended by deleting the rule in its entirety and substituting instead the following language so that, as amended, the rule shall read:

(1)All facilities shall participate in the department's Central Registry.

(2)Service recipients shall be informed of the Facility's participation in the Central Registry; and, prior to initiating a central registry inquiry, the Facility shall obtain the service recipient's written consent.

(3)To prevent multiple enrollment of a service recipient in more than one Facility the Facility shall initiate a clearance inquiry by submitting to the approved Central Registry the name, date of birth, anticipated date of admission or discharge and any other relevant information required for the clearance procedure or as required by the SOTA. If a multiple enrollment verification indicates that a service recipient may be enrolled at more than one Facility, the Facility shall immediately attempt to contact the other Facility to coordinate care. This coordination of care shall be documented in the service recipient's record.

(4)Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed Facility or its designated legal representative or as approved by the SOTA, or as required by law. Information made available by the Central Registry to facilities or their designated legal representatives or as approved by the SOTA shall also be treated as confidential.

(5)If a Facility operates within a minimum of 75 miles of another Facility in an adjoining state, the Facility shall share service recipient information, with the service recipient's written consent, with the Facility in the other state, or with the other state's central registry, if applicable, to prevent multiple enrollment of persons in more than one Facility.

(6)The Facility shall submit information to the Central Registry, as directed by the SOTA, for the purposes of outcome tracking and emergency preparedness. Information can include, but not be limited to: service recipient photo and

contact information, service recipient dosing, and periodic assessments.

(7)The Facility shall verify that the information contained in the Central Registry is current and accurate at least monthly. This verification shall be documented by 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, and 33-2-404.

Rule 0940-05-42-.21 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)The Facility shall submit to the SOTA all reports resulting from a survey, inspection, or complaint investigation from the DEA, SAMHSA, the Facility's accrediting organization, and any other applicable agency or organization, either electronically by mail, within five business days of receiving such documents:

(2)The Facility shall report each case of communicable disease to the local county health officer in the manner provided by T.C.A. § 68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health.

(3)The Facility shall report within 24 hours to the Office of Licensure and the SOTA the abuse of a service recipient, an unexpected occurrence or accident that results in death or serious injury to a service recipient, or any action taken against the Facility by the DEA, accrediting body or other state, local or federal agency. Additionally, the following are examples of events that should be reported:

(a)Medication errors that caused or had the potential to cause harm to the service recipient;

(b)Criminal acts;

(c)Suicide or attempted suicide;

(d)Rape;

(e)Neglect of a service recipient;

(f)Service recipient altercations;

(g)Service recipient abuse;

(h)Misappropriation of service recipient funds, including any grant funding, if applicable;

(i)Restraint-related incidents;

(j)Overdose occurring within the Facility; or

(k)Improper disclosure of a service recipient’s protected health information.

(4)Specific incidents that might result in a disruption of the delivery of health care services at the Facility shall be reported to the Office of Licensure and the SOTA within 24 hours after the Facility learns of the incident. These specific incidents include the following:

(a)Strike by the staff at the Facility;

(b)External disaster impacting the Facility;

(c)Disruption of any service vital to the continuous, safe operation of the Facility or to the health and safety of its service recipients and personnel; and

(d)Fires at the Facility which disrupt the provision of service recipient care services, cause harm to service

recipients or staff, or which are reported by the Facility to any entity, including, but not limited to, a fire department or other local emergency services.

(5)Within seven days of any event described in (3), the Facility shall file a report with the Office of Licensure and the SOTA on the incident consisting of the following:

(a)The actions implemented to prevent the reoccurrence of the event;

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

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

(d)The strategies for the measurements of effectiveness to be established.

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

Rule 0940-05-42-.22 Quality of Care 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 develop and implement a plan for continuous quality improvement. At a minimum, the plan shall include:

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

(b)A service delivery assessment which, at a minimum, shall evaluate the appropriateness of the ITP development and clinical services delivered, completeness of documentation in service recipients' medical records, and the quality and participation in staff training programs, linkage to other community healthcare services, and availability of services and medications for other conditions (e.g. prenatal, tuberculosis, HIV).

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

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

(e)Such process shall serve to continuously monitor the Facility's compliance with the requirements set forth in these rules. Responsibility for administering and coordinating the quality improvement process shall be delegated to a staff person who has been determined by the Facility to be qualified by education, training, and experience to perform such tasks. The Facility's medical director shall be actively involved in the process.

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

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

Rule 0940-05-42-.23 Infectious Hazardous Waste 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 develop, maintain and implement written policies and procedures for the definition and handling of its infectious wastes. These policies and procedures shall comply with the standards of this section and all other applicable state and federal regulations.

(2)Waste shall be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging shall provide for containment of the waste from the

point of generation up to the point of proper treatment of disposal. Packaging shall be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.

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

Rule 0940-05-42-.24 Infection Control 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 to be followed for infection control, including:

(a)Reporting all suspected or diagnosed cases of infectious disease including tuberculosis, AIDS, and sexually transmitted infections (STI) promptly to the regional health department in accordance with applicable local, state, and federal laws, rules, and regulations;

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

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

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

(e)Infectious disease skin or blood testing will be made on a voluntary basis for any service recipient who requests it and be documented in appropriate records. If a clinic does not have the capacity to conduct pelvic exams, the clinic shall establish and document a relationship with a community health care provider so that referrals can be made and care can be coordinated;

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

(g)Documentation on establishing contact between the health department and the Facility to communicate appropriate information to assure that the service recipient receives appropriate care;

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

(i)Conducting case management activities to ensure that individuals receive appropriate treatment services for HIV/AIDS, Hepatitis B or C Virus, and other STI;

(j)Procedures to ensure that the Facility, either directly or through arrangements with other public or private non-profit entities, will make available tuberculosis (TB) services in accordance with current Tennessee TB Guidelines for Alcohol and Drug Treatment Facilities (TB Guidelines), established by the Department of Health TB Elimination Program and the department; and

(k)Testing, treating, and reporting for any public health crisis, pursuant to public health emergencies or otherwise directed by the SOTA (e.g., COVID-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, and 33-2-404.

Rule 0940-05-42-.25 Managing Disruptive Behavior 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 develop policies and procedures which address the methods for managing disruptive behavior. If restrictive procedures are used to manage disruptive behaviors, written policies and procedures shall govern their

use. At a minimum, any restrictive procedure shall be used by the Facility only after all less restrictive alternatives for dealing with the problem behavior have been tried or considered and have been determined to be inappropriate or ineffective.

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

Rule 0940-05-42-.26 Hours of Operation 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's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work.

(2)The Facility shall provide comprehensive services, including dosing and counseling at least six hours per day from Monday through Saturday.

(3)Additionally, the Facility may close for four nonconsecutive days for holidays. Facilities shall notify the SOTA and service recipients of the date of any holiday when the Facility will be closed at least 14 days in advance of the holiday.

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

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

(6)A Facility that intends to voluntarily close shall notify TDMHSAS no later than 90 days prior to closure. In order to assure continuity of care, any Facility which closes, either voluntarily or involuntarily, shall comply with all directions received from the TDMHSAS regarding the orderly transfer of service recipients and their records.

(7)Any temporary Facility closures related to extreme weather or other unexpected emergencies that affect the Facility’s ability to provide services shall be approved by the SOTA prior to Facility closure and notification to service recipients.

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

Rule 0940-05-42-.27 Service Recipients' 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)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 service recipient shall be kept confidential and shall not be disclosed by any person except the individual identified.

(2)Nothing in this rule shall prohibit disclosure, upon proper inquiry, of information as to the current medical condition of a service recipient to any member of the Facility or to the service recipient's relatives or friends in accordance with T.C.A. § 33-3-103; Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 Code of Regulations (CFR) Parts 160 and 164, Subparts A and E; and Confidentiality of Alcohol and Drug Abuse Service Recipient Records regulations at 42 CFR Part 2.

(3)Service recipients shall not be abused or neglected.

(4)Facilities shall develop and implement written policies and procedures regarding the rights and responsibilities of service recipients under Rules 0940-05-06-.07 and 0940-05-06-.08 and the handling and resolution of complaints.

(5)Other service recipient rights include:

(a)Right to a humane treatment environment that affords reasonable protection from harm, exploitation, and coercion;

(b)Right to be informed about the IPP and to participate in the planning, as able;

(c)Right to be promptly and fully informed of any changes in the plan of treatment;

(d)Right to accept or refuse treatment;

(e)Right to receive a written notice of the address and telephone number of the state licensing authority, the Department; and

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

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

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

Rule 0940-05-42-.28 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:

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

(1)A Facility shall be responsible for ensuring that its service recipients do not cause unnecessary disruption to the community or act in a manner that would constitute disorderly conduct or harassment by loitering on the Facility's property.

(2)Each Facility shall provide TDMHSAS, when requested, with a specific plan describing the efforts it will make to avoid disruption of the community by its service recipients and the actions it will take to assure responsiveness to community needs. This plan shall, at a minimum:

(a)Identify Facility personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan.

(b)Include policies and procedures or resolve community problems, including service recipient loitering and medication diversion, to ensure that Facility operations do not affect community life adversely.

(c)Include procedures for soliciting service recipient and community ideas about medication assisted treatment, and addressing community concerns and the Facility's presence in the community.

(3)Each Facility shall document community relations efforts and community contacts, including the resolution of issues identified by community members or service recipients.

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

Rule 0940-05-42-.29 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. A licensee shall maintain written records for each employee and each individual file shall include:

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

(b)A 10-year employment history or a complete employment history if the person has not worked in 10 years.

(c)Records of educational qualifications, if applicable.

(d)Date of employment.

(e)Documentation of training and orientation of the person's duties and responsibilities.

(f)Any records relevant to the employee's performance.

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

(h)Annual verification of basic skills and annual evaluation of personnel performance. Included shall be written verification that the employee has reviewed the evaluation and has had an opportunity to comment on it.

(i)Training and development activities designed to educate the staff in meeting the needs of the service recipients being served, including STD/HIV education.

(2)Tuberculosis.

(a)All new employees, including volunteers who have routine contact with service recipients, shall be tested within three business days of employment for latent tuberculosis infection utilizing the two-step Mantoux method or a single interferon-gama release blood assay (IGRA).

(b)Employees shall have a test for tuberculosis annually and at the time of exposure to active tuberculosis and three months after exposure. Annual tuberculosis testing of previously TST-negative employees and volunteers shall be performed by the one-step Mantoux method.

(c)Employee records shall include the date and type of annual tuberculin tests given to the employee, date of tuberculin test results, and, if applicable, date and results of chest x-ray and any drug treatment for tuberculosis.

(3)Staffing.

(a)Program Director. The governing body of each Facility shall designate in writing a program director who is responsible for the operation of the Facility and overall compliance with federal, state and local laws and regulations regarding the operation of opioid treatment programs, and for all employees including practitioners, agents, or other persons providing services at the Facility. Facilities shall notify the SOTA in writing within 10 calendar days whenever there is a change in program director.

(b)Medical Director. The governing body of each Facility shall designate in writing a medical director to be responsible for the administration of all medical services, including compliance with all federal, state and local laws and regulations regarding the medical treatment of opioid use disorder. No physician may serve as medical director of more than two Facilities without the prior written approval of the SOTA. The medical director shall be physically present, or available for telehealth services and consultation, at the Facility the equivalent of twenty-five (25) percent of the time the Facility is open to the public each week. Facilities shall notify the SOTA in writing within 10 calendar days whenever there is a change in medical director.

(c)Program Physician. Facilities are required to provide sufficient physician services to provide the medical treatment and oversight necessary to serve service recipient needs.

1.Physician services include, but are not limited to, performing medical history and physical exams, determining a diagnosis under current DSM criteria, determination of opioid use disorder, ordering take-home privileges, discussing cases with the treatment team and issuing any emergency orders.

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

nurses with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs may perform any functions under Tennessee law or regulations.

(e)Program Providers. The Facility shall provide on-site program provider services at least one hour per week for every 35 service recipients.

(f)Nurses. Facilities shall ensure that adequate nursing care is provided at all times the Facility is in operation and that a nurse is present at all times when medication is administered at the Facility. Facilities that do not employ a registered nurse to supervise the nursing staff shall ensure that licensed practical nurses adhere to written protocols and are properly supervised consistent with Rules Chapter 1000-02 Rules and Regulations of Licensed Practical Nurses.

(g)Qualified Counseling Providers. There shall be sufficient group and individual counseling available to meet the requirements pursuant to 0940-05-42-.14.

(h)Pharmacist. The Facility must have a pharmacist, as defined in TCA § 63-10-204(34) present whenever take-home doses are prepared or dispensed to patients. The Facility's pharmacist shall be involved in the development of the Facility's policies and procedures regarding the use of medications and be available for consultation for Facility staff and patients.

(4)Staff Qualifications.

(a)Medical Director. All medical directors shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain their licenses in good standing and shall have the following experience and/or credentials:

1.Three years of documented experience in the provision of services to persons with a substance use disorder, including the treatment of opioid use disorder; or

2.Board eligibility in psychiatry and two years of documented experience in the treatment of persons with a substance use disorder, including the treatment of opioid use disorder; or

3.Certification or actively engaged in a recognized course of study or another formal process for pursuing certification as an addiction medicine specialist and two years of documented experience in the treatment of persons with a substance use disorder, including the treatment of opioid use disorder.

(b)Waiver from Medical Director Qualifications. Facilities that are unable to secure the services of a medical director who meets the requirements of subparagraph (a) above may apply to the TDMHSAS Office of Licensure for a waiver. The TDMHSAS Office of Licensure, in consultation with the SOTA, may grant such a waiver when there is showing that:

1.The Facility has made good faith efforts to secure a qualified medical director;

2.The Facility can secure the services of a licensed physician who is willing to serve as medical director and participate in the training plan;

3.A training plan has been developed which is acceptable to the SOTA and which consists of a combination of continuing education in addiction medicine and in-service training by a medical consultant who meets the qualifications specified in subparagraph (a) above; and

4.A medical consultant who meets the requirements of subparagraph (a) above shall be available, consistent with a training plan approved by the SOTA, to oversee the training of the medical director and the delivery of medical services at the Facility requesting the waiver.

(c)Program Provider. All program proviers shall be licensed to practice in Tennessee, shall maintain their licenses in good standing and shall have at least one year of documented experience in the treatment of persons with a substance use disorder.

(d)Waiver from Program Provider Qualifications. Facilities seeking to employ a program provider, in addition to the medical director, but are unable to secure the services of a program provider who meets the requirements of subparagraph (c) above may apply to the TDMHSAS Office of Licensure for a waiver. The TDMHSAS Office of Licensure, in consultation with the SOTA, may grant such a waiver when there is a showing that:

1.The Facility has made good faith efforts to secure a qualified program physician;

2.The Facility can secure the services of a licensed physician who is willing to serve as program physician and participate in the training plan;

3.A training plan has been developed which is acceptable to the SOTA and which consists of a combination of continuing education in addiction medicine and in-service training by the Facility's medical director; and

4.The Facility employs a qualified medical director who has the experience and credentials specified in subparagraph (a) above, has completed the training program specified in subparagraph (b) above or has completed the continuing education specified in subparagraph (e) below.

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

(f)Qualified Counseling Providers. All qualified counseling providers shall: .

1.currently meet one (1) of the following conditions:

(a)Licensed by the State of Tennessee as one (1) of the following (with experience or supervision as described, where specified):

(i)Alcohol and Drug Abuse Counselor I or II (commonly referred to as LADAC I or LADAC II);

(ii)Psychologist;

(iii)Psychological examiner under the supervision of a licensed psychologist;

(iv)Physician with experience or training in counseling;

(v)Registered nurse with experience or training in counseling;

(vi)Social worker;

I. If licensed as a bachelorette social worker (LBSW) with training in counseling and direct supervision by a master’s level social worker (LCSW or LMSW)

(vii)Professional Counselor;

(viii)Marriage and Family Therapist; or

(b)Actively engaged in a recognized course of study or another formal process for pursuing licensure of a discipline described in part 1, subparts (i)-(viii), above. Supervision shall be in accordance with the respective laws, rules, and regulations governing the professional licensure pursued.

2.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.

(g)Pharmacist. All pharmacists shall be licensed to practice in Tennessee and shall maintain their license in good standing.

(h)Program Directors. All Facility program directors shall have at least one year of supervisory or administrative experience in the field of mental health or substance use disorder treatment, or a minimum of 6 months of experience with approval from the SOTA.

(i)Professional Practice. All professional staff including, but not limited to, physicians, physician assistants, nurses, pharmacists, and counselors may perform only those duties that are within the scope of their applicable professional practice acts and Tennessee licenses.

(5)Staff Training and Orientation. Prior to working with service recipients, all staff providing treatment or services shall be oriented in accordance with these rules and shall thereafter receive additional training with these rules.

(a)Orientation shall include instruction in:

1.The Facility's written policies and procedures regarding its purposes and description; service recipient rights, responsibilities, and complaints; confidentiality; and other policies and procedures that are relevant to the employee's range of duties and responsibilities;

2.The employee's assigned duties and responsibilities; and

3.Reporting service recipient progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services.

(b)Additional training consisting of a minimum of eight hours of training or instruction shall be provided annually for each staff member who provides treatment or services to service recipients. Such training shall be in subjects that relate to the employee's assigned duties and responsibilities, and in subjects about current clinical practice guidelines for medication assisted treatment. In-house training for staff may be substituted for external training with the approval of the SOTA. The following areas shall receive emphasis during training:

1.Dosage level as determined through a providers's clinical decision-making and the individual service recipient's needs;

2.Counseling;

3.Drug screens;

4.Treatment stability;

5.Treating multiple substance use disorders;

6.Opioid treatment during pregnancy and chronic diseases;

7.HIV and other infectious diseases;

8.Co-morbid psychiatric conditions;

9.FDA-approved drugs for the treatment of opioid use disorder;

10.Take-home medication practices;

11.Chronic pain and pain management; and

12.Referring service recipients for primary care or other specialized services.

(c)The SOTA may require facilities to attend mandatory training in addition to any other training required by these rules.

(d)Facilities shall maintain records documenting that each staff member has received the required annual training.

(6)Employee Drug Screening. Facilities shall establish and implement written policies and procedures for pre-employment and ongoing random drug screening of all Facility employees. Each sample collected shall be screened for opioids, fentanyl, methadone, amphetamines, cocaine, benzodiazepines, and other drugs as indicated by the SOTA.

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

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

New

Rule 0940-05-42-.30 Mobile Units is a new rule. All subsequent rules, and references thereto, are renumbered accordingly.

(1)Facilities that plan to operate a mobile unit must also comply with Title 21 of the Code of Federal Regulations (C.F.R.) Parts 1300, 1301, and 1304.

(2)Procedure for Initiation of Mobile Unit Services.

(a)The Facility shall provide written notification of intent to provide mobile unit services to the SOTA and the Office of Licensure along with a Certificate of Need (CON), if required by the Tennessee Health Facilities Commission or any other applicable state agency. The OTP must receive written approval from the SOTA and Office of Licensure prior to providing services via the mobile unit.

(b)At a minimum of 30 days prior to operating the mobile unit a schedule of locations where the unit will provide services shall be submitted to the SOTA.

(c)The SOTA shall be notified of changes to the declared scheduled 14 days in advance of operating at the alternative locations. Should it be required by the Tennessee Health Facilities Commission (or any other applicable state agency), the appropriate CON for the alternative location shall be provided with the notification of change.

(3)Policy and Procedures.

(a)Registration. All required DEA and vehicle registrations shall be maintained at the Facility and available for inspection, upon request.

(b)Operations. The Facility shall develop and implement policies and procedures for the operation of the mobile unit, including but not limited to:

1.The transfer and use of medications

2.Security of the mobile unit and staff

3.Staffing

4.Downtime procedures and emergencies

5.Regulatory Compliance

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

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

Date: 10/20/2023

Signature: Leandra Mitchell

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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