

**RULES
OF
DEPARTMENT OF MENTAL HEALTH AND SUBSTANCE ABUSE SERVICES**

**CHAPTER 0940-05-36
MINIMUM PROGRAM REQUIREMENTS FOR NONRESIDENTIAL OFFICE-BASED OPIATE
TREATMENT FACILITIES WITH DISPENSING AUTHORIZATION**

TABLE OF CONTENTS

| | | | |
|----------------|--------------------------|----------------|--|
| 0940-05-36-.01 | Purpose | 0940-05-36-.08 | Labeling and Packaging of Buprenorphine Products |
| 0940-05-36-.02 | Definitions | 0940-05-36-.09 | Inventory |
| 0940-05-36-.03 | Application of the Rules | 0940-05-36-.10 | Prerequisites to Issuing Prescriptions or Dispensing Medications |
| 0940-05-36-.04 | Licensing Criteria | 0940-05-36-.11 | Central Registry |
| 0940-05-36-.05 | Medication Storage | | |
| 0940-05-36-.06 | Recordkeeping | | |
| 0940-05-36-.07 | Reporting | | |

0940-05-36-.01 PURPOSE.

The rules in this chapter implement the law relative to licensure and regulation of “Nonresidential office-based opiate treatment facility with dispensing authorization” or “OBOT Plus” pursuant to Chapter 978 of the Public Acts of 2018.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 4-5-202, 4-5-204, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, 53-11-311, and Chapter 978 of the Public Acts of 2018.

Administrative History: Original rule filed August 29, 2003; effective December 29, 2003. Repeal filed July 21, 2004; effective November 26, 2004. New rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.02 DEFINITIONS.

- (1) Definitions of general terms used in these rules can be found in Rule 0940-05-01.
- (2) Definitions specific to this chapter are as follows:
 - (a) “Nonresidential office-based opiate treatment facility with dispensing authorization” or “Facility” or “OBOT Plus” is a service entity that includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing and dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opioid use disorder by preventing symptoms of withdrawal to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients. An association by contract, fee for service, business arrangement, or two or more unaffiliated authorized providers with a DATA 2000 waiver operating at the same physical location and who dispense products containing buprenorphine shall be considered an OBOT Plus. An OBOT Plus does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction.
 - (b) “Authorized provider” means a healthcare provider authorized by the state or federal government who has authority to issue and dispense prescriptions for buprenorphine.
 - (c) “Authorized caregiver” means any person who is given written authorization by the patient to act on the patient’s behalf.

(Rule 0940-05-36-.02, continued)

- (d) “Buprenorphine” means a semi-synthetic opioid partial agonist that activates the opioid receptors but not to the same degree as full agonists such as morphine and heroin, as well as any FDA-approved pharmaceutical product that contains buprenorphine.
- (e) “Care Team” means the group of healthcare professionals, social workers, and counselors who help manage the patient’s detoxification and maintenance of abstinence from the patient’s drug of choice.
- (f) “Central Registry” means an electronic system approved by the Department to register patients currently receiving treatment at an Opiate Treatment Program (“OTP”) or OBOT Plus.
- (g) “Controlled substance(s)” means a drug, substance, or immediate precursor in Schedules I through VI as defined or listed in the Tennessee Drug Control Act, compiled in T.C.A., Title 39, Chapter 17, part 4.
- (h) “DATA 2000 waiver” means the registered authority given to a qualified health care professional by the U.S. Drug Enforcement Administration to prescribe FDA-approved narcotic medication for opioid detoxification or maintenance treatment pursuant to 21 U.S.C. §823(g).
- (i) “DEA” means the United States Drug Enforcement Agency.
- (j) “Dispense” means preparing, packaging, compounding or labeling for delivery and actual delivery of a prescription drug, nonprescription drug or device in the course of professional practice to a patient or the patient’s agent, to include a licensed health care practitioner or a health care facility providing services or treatment to the patient or patients, by or pursuant to the lawful order of a prescriber. This definition does not include administration, or supervised self-administration, as otherwise permitted by law.
- (k) “Dispenser” means an authorized provider who dispenses buprenorphine to an ultimate user.
- (l) “Dispensing area” refers to the actual physical location where dispensing occurs. It does not include any waiting or common areas.
- (m) “Drug” means a substance recognized by the official United States pharmacopeia or formulary intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or, a substance intended to alter the structure or function of the human body.
- (n) “Facility director” means the person designated by the Facility’s governing body who is responsible for the operation of the Facility, for the Facility’s overall compliance with federal, state and local laws and regulations regarding the operation of a non-residential office-based opiate treatment facility with dispensing authorization, and for all Facility employees including practitioners, agents, or other persons providing services at the Facility. Non-physician facility directors shall not supervise medical staff.
- (o) “FDA” means the United States Food and Drug Administration.
- (p) “Licensee” means a proprietorship, partnership, association, governmental agency, or corporation, that operates a facility or a service and has obtained a license under this part.

(Rule 0940-05-36-.02, continued)

- (q) "Medication order" or "prescription order" means a prescription order for any prescription drug or device or related material issued by an authorized prescriber to authorized healthcare personnel in a practice site or facility.
- (r) "Office of Licensure" means the Tennessee Department of Mental Health and Substance Abuse Services Office of Licensure.
- (s) "Opiate" or "opioid" means a drug that contains opium, derivatives of opium, or any of several semi-synthetic or synthetic drugs with agonist activity at the opioid receptor(s).
- (t) "Patient" or "service recipient" means an individual receiving treatment for opiate use disorder at an OBOT Plus.
- (u) "Patient counseling" means communication, by an authorized provider, of information to the patient or authorized caregiver in order to improve therapeutic outcomes and ensure optimal care.
- (v) "Consultant Pharmacist" means a pharmacist with an active license in good standing from the Tennessee Board of Pharmacy that is employed or contracted by the OBOT Plus.
- (w) "Physical location" means real property on which is located a physical structure, whether or not that structure is attached to real property, containing one (1) or more units and includes an individual apartment, office, condominium, cooperative unit, mobile or manufactured home, or trailer, if used as a site for prescribing and/or dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate use disorder by preventing symptoms of withdrawal.
- (x) "Professional samples" means small quantities (less than a typical 30, 60, or 90-day supply) of medication provided to prescribers or authorized healthcare personnel to be administered to patients.
- (y) "State Opioid Treatment Authority" or "SOTA" means any individual person designated by the commissioner to exercise the responsibility and authority for governing the treatment of opioid addiction in accordance with all applicable state and federal regulations, and serves as a liaison with the appropriate federal agencies.
- (z) "TDMHSAS" or "Department" means the Tennessee Department of Mental Health and Substance Abuse Services.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 4-5-202, 4-5-204, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

Administrative History: Original rule filed August 29, 2003; effective December 29, 2003. Repeal filed July 21, 2004; effective November 26, 2004. New rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.03 APPLICATION OF THE RULES.

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

(Rule 0940-05-36-.03, continued)

- (c) Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities; and
 - (d) Chapter 0940-05-36 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization (“OBOT Plus”).
- (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, 4-5-202, 4-5-204, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.
Administrative History: Original rule filed August 29, 2003; effective December 29, 2003. Repeal filed July 21, 2004; effective November 26, 2004. New rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.04 LICENSING CRITERIA.

- (1) Eligibility
 - (a) In order to be authorized to dispense buprenorphine containing products, the interested entity must be a current Full licensed Office-Based Opiate Treatment Facility in good standing with the Department that has been in licensed operation for at least one (1) calendar year.
 - (b) The Facility seeking dispensing authorization shall comply with Rule 0940-05-35-.04.
- (2) Procedures
 - (a) The current Full licensed Office-Based Opiate Treatment Facility shall make a request for dispensing authorization in written form and shall pay a \$50 fee - as established in Rule 0940-05-02-.23 - via invoice provided by the Office of Licensure.
 - (b) The Facility seeking dispensing authorization shall be subject to an on-site inspection to ensure compliance with Rule 0940-05-36-.05 Medication Storage.
 - (c) Each Facility seeking a license must submit to the Office of Licensure proof that every authorized provider at the facility has submitted to their respective professional licensing board notice of his or her intent to dispense buprenorphine products.
 - (d) Each Facility seeking a license must submit to the Office of Licensure proof that the Facility is participating in the Central Registry.
- (3) Prior to renewal of the license, the OBOT Plus shall be required to develop written policies and procedures that are specific to the dispensing of buprenorphine products, and substantially comply with the provisions of this Rule, as well as with Administrative Chapters 0940-05-06 and 0940-05-35.
- (4) With or without notice, the Department, or its representatives, shall have the right to enter upon or into the premises of an OBOT Plus in order to make inspections and/or investigations deemed necessary to determine compliance with applicable law. The OBOT Plus shall comply with all reasonable requests of the Department and allow it to obtain information from third parties if necessary.

(Rule 0940-05-36-.04, continued)

- (5) The Department shall be given the authority to enter upon the premises of an unlicensed facility dispensing buprenorphine products to better determine that unlicensed facility's need for TDMHSAS oversight. The Department shall attempt to conduct inspections and investigations in the least intrusive manner needed in order to obtain necessary information. The facility shall be required to provide reasonable amounts of information to the Department for this determination.
 - (a) "Reasonable amounts of information," in this context, may be considered aggregate, non-patient identifying information to include, but not be limited to:
 1. Patient de-identified identifiers;
 2. Lists of medications prescribed to that de-identified patient;
 3. Lists of medications dispensed to that de-identified patient;
 4. The total number of medications dispensed at the physical location in question; and
 5. The total number of patients seen at the physical location in question.
- (6) No provider shall dispense buprenorphine to a patient until an OBOT Plus license has been issued by the Office of Licensure.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 4-5-202, 4-5-204, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.
Administrative History: Original rule filed August 29, 2003; effective December 29, 2003. Repeal filed July 21, 2004; effective November 26, 2004. New rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.05 MEDICATION STORAGE.

- (1) Buprenorphine products shall be stored in a secure storage area in compliance with 21 C.F.R. Part 1301.72.
- (2) All prescription drugs and controlled substances, and related materials, shall be stored in an area not accessible to the public.
- (3) The patient waiting area shall be physically separated from the buprenorphine storage and dispensing area.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 4-5-202, 4-5-204, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.
Administrative History: Original rule filed August 29, 2003; effective December 29, 2003. Repeal filed July 21, 2004; effective November 26, 2004. New rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.06 RECORDKEEPING.

- (1) Each OBOT Plus shall maintain records with the following information for each buprenorphine product dispensed:
 - (a) Name of product;
 - (b) Medication strength;

(Rule 0940-05-36-.06, continued)

- (c) Dosage form;
 - (d) Date dispensed;
 - (e) Adequate identification of patient;
 - (f) Amount dispensed; and
 - (g) Dispenser's initials or other identifier.
- (2) OBOT Plus facilities must maintain documentation of participation in the Central Registry, pursuant to Rule 0940-05-36-.11, in order to prevent dual enrollment, diversion and to ensure patient safety.
 - (3) OBOT Plus facilities must report all medications dispensed to the controlled substances monitoring database, as defined in Rule 0940-05-35-.02(2)(d), to the extent permitted by 42 C.F.R. Part 2.
 - (4) A patient record system shall be maintained by all OBOT Plus facilities for patients for whom prescription or medical orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary to identify previously dispensed prescription or medical orders at the time a prescription or medical order is presented.
 - (a) In the event of a patient record system shut down, dispensing records must be maintained manually and entered into the patient records system as soon as the issue causing the shutdown is resolved.
 - (5) A record of compliance with Rule 0940-05-36-.09 shall be signed by the Facility Director and maintained at the OBOT Plus facility with other controlled substance records for at least two (2) years.
 - (6) Authorized providers shall notify their appropriate licensing board of their intent to dispense buprenorphine at an OBOT Plus facility. OBOT Plus facilities shall be required to maintain records indicating this notification for each authorized provider it employs for as long as he/she is employed and at least one (1) year thereafter.
 - (7) The required recordkeeping of this section will be maintained in a dispensing log at the physical location of the OBOT Plus facility.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018. **Administrative History:** Original rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.07 REPORTING.

- (1) OBOT Plus facilities must adhere to all reporting requirements of Rule 0940-05-02-.20.
- (2) The Facility Director shall immediately report to the Department and appropriate licensing board(s) any robbery, embezzlement, theft, burglary, fire, or disaster resulting in a loss of prescription drugs, controlled substances, medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs, controlled substances, medical devices, or related materials lost or damaged and, shall include all other requirements under Rule 1140-03-09;

(Rule 0940-05-36-.07, continued)

- (3) Controlled substance bulk inventory lost through breakage, damage, or spillage, other than an individual patient dose, should be considered an accountable loss. Disposal of such controlled substances must be performed in accordance with DEA requirements and must be reported on DEA Form 106 Registrants Inventory of Drugs Surrendered in accordance with 21 C.F.R. 1301.76.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018. **Administrative History:** Original rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.08 LABELING AND PACKAGING OF BUPRENORPHINE PRODUCTS.

- (1) The authorized provider shall affix to the buprenorphine package a label showing at least the following information:
 - (a) Name, address and telephone number of the OBOT Plus;
 - (b) Prescription or medication order serial number;
 - (c) Date of initial dispensing and/or refill date;
 - (d) Name of the patient;
 - (e) Name of the prescriber;
 - (f) Name of the practitioner dispensing the medication;
 - (g) Directions for use and cautionary statements, if any;
 - (h) Name and expiration date of the product, if applicable;
 - (i) The following controlled substance warning: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for who it was prescribed."; and
 - (j) Any other appropriate advisory labels.
- (2) OBOT Plus facilities must ensure that buprenorphine products are packaged in a manner that is designed to reduce the risk of accidental ingestion, including the use of child-proof containers.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018. **Administrative History:** Original rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.09 INVENTORY.

- (1) Each OBOT Plus shall be required to procure all buprenorphine containing products from a wholesaler/distributor licensed by the Tennessee Board of Pharmacy pursuant to Rule 1140-09.
- (2) Each OBOT Plus shall maintain an inventory of buprenorphine products. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the

(Rule 0940-05-36-.09, continued)

date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the physical location.

- (a) Each licensee shall be required to take an initial inventory of all buprenorphine products, in accordance with Rule 0940-05-36-.09(3), prior to dispensing any of these products to patients.
 - (b) After the initial inventory is taken, the OBOT Plus facility shall be required to maintain a perpetual inventory of buprenorphine products.
- (3) Each person authorized to dispense buprenorphine products shall include the following information in the inventory documentation pursuant to 21 C.F.R. Part 1304.11(1)(e)(iii) and (iv):
- (a) The name and address of the OBOT Plus facility;
 - (b) The following information for each buprenorphine product in finished form:
 - 1. The name of the substance;
 - 2. Each finished form of the substance (e.g., 8/2 mg films);
 - 3. The number of commercial containers of each finished form (e.g. four 30-film boxes); and
 - 4. The exact quantity of the finished form on hand.
 - (c) The date of inventory; and
 - (d) The time the inventory was taken.
- (4) The Facility Director or a designated clinical staff member shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials; except that the destruction of controlled substances listed in any schedule shall be witnessed by a second healthcare professional and documented.
- (5) For each damaged or defective controlled substance awaiting disposal, the inventories shall include:
- (a) The name of the substance;
 - (b) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
 - (c) The reason for the substance being maintained by the OBOT Plus facility.
- (6) If an OBOT Plus destroys buprenorphine products they must be destroyed onsite or via a reverse distributor.
- (a) For each buprenorphine product destroyed onsite, the facility shall keep a record of the following:
 - 1. The name of the substance;

(Rule 0940-05-36-.09, continued)

2. The strength of the substance;
 3. The dosage form of the substance;
 4. The total quantity destroyed;
 5. Method of destruction;
 6. Date and time of the destruction;
 7. The signature of the person destroying the substance; and
 8. The signature of at least one person, other than the person destroying the substance, who witnessed the destruction of the substance.
- (7) Each OBOT Plus shall maintain documentation of a current employment or contractual relationship with a consultant pharmacist.
- (a) If an OBOT Plus dispenses buprenorphine to less than 100 unique patients a month, the pharmacist-in-charge shall perform a quarterly inventory review of the OBOT Plus's invoices, perpetual inventory, and documentation of dispensed medications.
 - (b) If an OBOT Plus dispenses buprenorphine to 100 or more unique patients a month, the pharmacist-in-charge shall perform a monthly review of the OBOT Plus's invoices, perpetual inventory, and documentation of dispensed medications and review the inventory for discrepancies.
 1. If a discrepancy is found, an OBOT Plus shall report the discrepancy to the Department immediately upon discovery. The OBOT Plus shall also report to the DEA any discrepancies as appropriate.
 2. Within 14 calendar days of discovery of a discrepancy, the OBOT Plus shall submit to the Department a root cause analysis examining the cause of the discrepancy and a plan to prevent such discrepancies in the future.
 3. Part of the plan may include an increase in inventory review by the pharmacist-in-charge.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018. **Administrative History:** Original rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.10 PREREQUISITES TO ISSUING PRESCRIPTIONS OR DISPENSING MEDICATIONS.

- (1) Prior to writing a prescription or medication order, an OBOT Plus provider shall comply with Rule 0940-05-35 and Rule 0880-02-.14(2).
- (2) Buprenorphine dispensed by an OBOT Plus may only be filled and labeled by:
 - (a) An authorized provider; or
 - (b) By a designated agent of the authorized provider, if:

(Rule 0940-05-36-.10, continued)

1. The filling and labeling is done in the physical presence of the authorized provider at the OBOT plus;
 2. The authorized provider acts as the final check in the dispensing process, and is responsible for the dispensing process in its entirety; and
 3. The authorized provider documents that he or she has completed a final verification of the dispensing.
- (3) Authorized providers may dispense an initial prescription only after checking the CSMD and central registry.
- (4) Authorized providers must check the CSMD for every prescription dispensed.
- (5) When a patient is first seen at a Facility and the patient has previously been dispensed buprenorphine, the authorized provider shall make a reasonable effort to contact the patient's previous dispenser and obtain dosing information.
- (6) Authorized providers dispensing buprenorphine pursuant to Rule 0940-05-36-.10(2) above, must comply with medication counseling requirements pursuant to Rule 1140-03-.01 and Rule 0940-05-35.
- (a) Upon the initial receipt of a prescription or medication order and following a review of the patient's record, the authorized provider shall personally counsel the patient or authorized caregiver "face-to-face" if the patient or authorized caregiver is present. If the patient or authorized caregiver is not present, an authorized provider shall make a reasonable effort to counsel through alternative means.
 - (b) The authorized provider must document the counseling or document the reasonable efforts taken to provide counseling. If the patient or authorized caregiver refuses counseling, the authorized provider must document this refusal.
 - (c) Patient counseling shall cover matters as defined in Rule 1140-03-.01, which in the exercise of the authorized provider's professional judgement, the authorized provider deems significant. This shall include, but is not limited to, the following:
 1. The name and description of the medication;
 2. The dosage form, dose, route of administration, and duration of drug therapy;
 3. Special directions and precautions for preparation, administration, and use by the patient;
 4. Common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 5. Techniques for self-monitoring drug therapy;
 6. Proper storage; and
 7. Action to be taken in the event of a missed dose.

(Rule 0940-05-36-.10, continued)

- (d) Upon a subsequent dispensing of a buprenorphine product, the authorized provider, or a person designated by the authorized provider, shall offer for the authorized provider to personally counsel the patient or caregiver about the medication.
- (7) An OBOT Plus shall not require that a patient's buprenorphine be dispensed from that OBOT Plus. An OBOT Plus shall provide patients with a list of alternative locations where buprenorphine is dispensed should the patient choose to fill his or her prescription at another location.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018. **Administrative History:** Original rules filed March 29, 2019; effective June 27, 2019.

0940-05-36-.11 CENTRAL REGISTRY.

- (1) All OBOT Plus facilities shall participate in the Central Registry.
- (2) Patients shall be informed of the Facility's participation in the Central Registry. Prior to initiating a central registry inquiry, the Facility shall obtain the service recipient's written consent.
- (3) To prevent simultaneous enrollment of a service recipient in more than one OBOT Plus, the Facility shall initiate a clearance inquiry by submitting to the Central Registry the name, date of birth, or any other relevant information required for the clearance procedure or as required by the SOTA prior to dispensing buprenorphine products. No person who is reported by the Central Registry to be enrolled at another such Facility shall be admitted to an OBOT Plus, or in the event a multiple enrollment is found, the patient shall not continue to be dispensed buprenorphine until the patient enrollment status is active solely at a single OBOT Plus where the patient is currently receiving buprenorphine products.
- (4) Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed OBOT Plus 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.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018. **Administrative History:** Original rules filed March 29, 2019; effective June 27, 2019.