Vermont Department of Health
Medication Assisted Therapy for Opioid Dependence Rules

AUTHORITY, PURPOSE, AND ESSENTIAL REQUIREMENTS

I. Authority

These rules are established under the authority of Title 33, Chapter 7, which authorizes the division of alcohol and drug abuse programs to be responsible for the treatment of alcohol and drug abuse in Vermont, as well as the Department's general rulemaking authority.

II. Basic Definitions

SOTA: State Opioid Treatment Authority, as designated by the Vermont Department of Health, Commissioner.

Office Based Opioid Treatment (OBOT): Office based narcotic replacement treatment as established by DATA 2000

OTP: Opioid Treatment Program as defined by federal statute

Medication Assisted Treatment (MAT): MAT is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders (per CSAT). For purposes of this document it includes both OBOT and OTP programs

Medically Supervised Withdrawal : The voluntary, gradual reduction, or tapering, of the medication dosage over time under the supervision of a physician, to achieve the elimination of tolerance and physical dependence to opioid medications.

Administrative withdrawal: The involuntary process of medically supervised withdrawal

ADAP Preferred Provider: A certified provider organization as defined by the VT Department of
Health, Division of Alcohol and Drug Abuse Programs

III. Purpose

These rules constitute minimum requirements for a regional system of opioid addiction treatment and are based upon the Center for Substance Abuse Treatment (CSAT) Guidelines for the Accreditation of Opioid Treatment Programs, revised in 2007. These rules, in compliance with Vermont Statute, also apply to office based (OBOT) programs or prescribers who have 30 or more patients on narcotic replacement treatment. While only governing physicians with 30 or more patients these rules are recommended for any physician prescribing narcotic replacement treatment.

IV. Requirements

Prior to operating, opioid addiction treatment programs must receive written approval by the Vermont Department of Health. Any program/provider seeking approval to provide opioid addiction treatment must comply with the following essential requirements:

1. **Behavioral Therapy**

   Patients must receive appropriate, comprehensive behavioral therapy from a licensed clinical professional. Examples of these licensed providers include: LADC, LCMHC, LICSW, Licensed Psychologist, and/or a Licensed Psychiatrist, who is providing intervention beyond pharmacological management.

2. **Continuation and Cessation of Pharmacological Treatment**

   Programs/providers will continue medication-assisted treatment as long as the patient derives benefit from treatment, desires continued treatment and the physician is in agreement to continue the treatment. There should be no fixed length of time in treatment. In fact, indefinite medication-assisted treatment may be clinically indicated. The physician should also be prudent in considering other medications during the course of treatment, as clinically indicated.

3. **Dispensing of Pharmacological Treatments**

   Federally approved pharmacological treatments for opioid addiction must be dispensed *only* by authorized treatment programs/providers.

4. **Education and Training Requirements**

   Comprehensive education and training requirements must be established, including relevant aspects of behavioral therapy and pharmacological treatment, for physicians, pharmacists, and certified or licensed alcohol and drug abuse/behavioral health counselors affiliated with an approved treatment program. (For technical assistance identifying specific training options, please contact the Vermont Department of Health, Division of Alcohol and Drug Abuse Programs).

5. **Rules of Conduct**

   Rules of conduct for patients must be established in writing with clear description of violations which may result in the patient's discharge from the treatment program. These rules must include the patient's participation in required urinalysis at such times as the program may direct.

6. **Requirements for Approval:**

   a. The Health Department Commissioner may approve a MAT program/provider, for the term of its accreditation, approved by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), The Commission On Accreditation For Rehabilitation Facilities (CARF), or the Commission on Accreditation (COA).

   b. The Health Department Commissioner may approve a MAT provider which has been reviewed by The Vermont Department of Health; Division of Alcohol and Drug Abuse Programs (ADAP) and found to be in compliance with standards and criteria established by these rules. If a program does not fully meet the standards and criteria, the Commissioner may:

      i. Refuse to award program approval until such time as full compliance is met;
      ii. Award Conditional Approval valid for ninety days. If the program demonstrates full compliance with the standards and criteria during that time, Program Approval will be awarded.

iii. If awarded, program approval will be valid for a period of up to three years from the original date of approval.

c. The Commissioner, at his/her discretion, may upon request, grant a waiver of approval requirements for individual MAT practitioners who meet standards and criteria that are consistent and comparable with the standards specified within this document.

7. Appeals

a. If the Commissioner denies program approval, the applicant shall be afforded an opportunity to have a hearing with the Commissioner of Health pursuant to the provisions of Chapter 25, Title 3, VSA.

b. An appeal of a decision by the Commissioner of Health may be made to the Secretary of the Agency of Human Services, and an opportunity to have a hearing with the Secretary will be given pursuant to the provisions of Chapter 25, Title 3, VSA.

TABLE OF CONTENTS

OPIOID TREATMENT APPROVAL RULES

These rules are based on the Center for Substance Abuse Treatment (CSAT) *Guidelines for the Accreditation of Opioid Treatment Programs, revised 2007 and The Vermont Buprenorphine Treatment Guidelines, revised 2010,* and have been written to comply with Vermont statute. These rules will also apply to office based programs or prescribers who have 30 or more patients on narcotic replacement treatment.

I. Introduction

Treatment Considerations Related to the Natural History of the Disease:

1. The clinical assessment of all patients should take into account the patient's history of opioid addiction as altered by time and treatment. Patients normally proceed from one stage of treatment to the next, or move back and forth among the naturally occurring stages.

2. The stages of pharmacological treatment are listed below. It is important at all stages that psychosocial, as well as medical treatment, be of sufficient intensity and duration to be effective.

   a. Initial treatment/Induction

   b. Stabilization

   c. Long-term treatment/maintenance

   d. Medically supervised withdrawal with continuing care, if and when appropriate

3. The patient's response to treatment determines her/ his progression through the stages of treatment.

II. Administrative Organization and Responsibilities

1. Administrative responsibilities, both for organizations and individual practitioners, must be adequate to ensure quality patient care and to meet the requirements of the laws and regulations of the U.S. Department of Health and Human Services, Drug Enforcement Administration, and the State of Vermont.

2. Physician authority over the medical aspects of treatment is essential. Physicians retain the autonomy to make continuing treatment decisions in accord with clinical course and emergent research findings.

3. Each provider will develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of behavioral difficulties, psychiatric co-morbid conditions, medical complications, and communicable diseases that may be part of a patient's problem list. Information exchange across this network must both facilitate treatment and protect patient privacy, consistent with HIPAA and 42 CFR part 2.

4. Mission Statement and Goals

    a. Each treatment program shall have a written statement of its mission and/or goals for patient care.

5. Human Resources Management

    a. Programs/providers will maintain individualized personnel files as a record of employment. These files contain employment and credentialing data deemed appropriate by the employer. The files will also retain employment application data, date of employment, updated licensing and credentialing data, detailed job descriptions, performance evaluations, and appropriate intramural and extramural training records.

III. Management of Facility and Clinical Environment

1. Each facility:

    a. Must have sufficient space and adequate equipment for the provision of all specified services, including diagnosis, evaluation, and treatment of other medical, psychiatric, and behavioral disorders, if they are to be carried out onsite.

    b. Must be clean and well maintained.

    c. Ensures protection of confidentiality, including the use of locked files and the availability of private, individual offices for counseling.

    d. The program sponsor is the person ultimately responsible for the operation of the program and for ensuring that the program complies with all Federal, State, and local laws and regulations. (See 42 CFR § 8.2.) If there is a change of sponsor, The Vermont Department of Health; State Opioid Treatment Authority (SOTA) requires formal notification within 30 days. For OTP programs, SAMHSA requires formal notification within 3 weeks of the change.

2. The medical director of an **OTP** is responsible for monitoring and supervising all medical services provided by the program. Only a licensed physician may serve as the medical director of an OTP (See 42 CFR § 8.2.) If there is a change of medical director, the Vermont Department of Health; SOTA requires formal notification within 30 days and for OTP programs SAMHSA requires formal notification within 3 weeks of the change.

3. For **OBOT** programs only a licensed physician can currently prescribe buprenorphine and is also responsible for monitoring and supervising the medical services provided by the program. If there is a change in physician, the Vermont Department of Health SOTA additionally requires formal notification within 30 days

IV. Quality Improvement

1. Risk Management and Continuous Quality Improvement

a. Life Safety Issues: each treatment program/provider will:

    i. Establish procedures to guard against critical incidents, which are defined as any events that could have a negative impact on patients and their family members and the program or staff. This includes

events that involve the loss of life or function, any serious physical or psychological injury, and significant medication errors.

ii. Provide a mechanism to address patient emergencies by establishing an emergency contact system, as appropriate under confidentiality regulations. Treatment offices and waiting areas should display the names and telephone number of individuals (e.g., physicians, hospitals, emergency medical technicians) who should be contacted in case of emergency, or utilize 9–1–1 or similar local emergency resources.

iii. Ensure that there are appropriately trained staff members on duty who are trained and proficient in cardiopulmonary resuscitation (CPR), management of opioid overdose, medical emergencies, and other techniques as appropriate.

iv. Establish regularly updated policies and/or procedures that address safety and security issues for patients and staff, including training for staff to handle physical or verbal threats, acts of violence, inappropriate behavior, or other escalating and potentially dangerous situations, with emphasis on situations in which security guards or police need to be summoned.

b. Program Emergencies

i. Each treatment program/provider will maintain a plan for emergency administration of medications in case the program must be closed temporarily. The plan should include a mechanism for informing patients of these emergency arrangements. For all MAT programs the plan should identify emergency procedures for obtaining prescriptions/access to medications in case of temporary program/office closure. OTP programs should develop a cooperative agreement with their local emergency room to utilize the "72 Hour Rule" in case of inclement weather, emergency shut down, etc.

2. Events That Require Immediate Response and Investigation

Each treatment program/provider will:

a. Develop procedures for reporting critical incidents to appropriate program staff and the Vermont Department of Health, State Opioid Treatment Authority (SOTA).

b. Establish procedures, in case a critical incident occurs, to ensure:

i. Full documentation of the incident

ii. Prompt investigation and review of the situation surrounding the incident

iii. Implementation of timely and appropriate corrective action(s)

iv. Monitor corrective actions until their effectiveness is established

c. Report each critical incident to the appropriate accrediting organization, and the Vermont Department of Health, State Opioid Treatment Authority (SOTA), within 24 business hours of the incident. Some examples of reportable critical incidents involving patient deaths include:

   i. Drug-related deaths

   ii. Methadone or buprenorphine deaths

   iii. Suspicious deaths

   iv. Treatment-context deaths that raise individual, family, community, or public concern

d. As appropriate, report critical incidents to the Food and Drug Administration (FDA) Adverse Event Reporting Program regarding (MedWatch, http://www.fda.gov/medwatch/; at 1–800–332–1088). Examples of reportable critical incidents include:

   i. Serious adverse events and medications errors

   ii. All types of deaths related to any drug

3. Voluntary and Involuntary Program Closure

In the event of involuntary or voluntary program closure, each program/provider will:

a. Develop a plan, through State authority, detailing procedures to ensure continuity of care for patients in the event of voluntary or involuntary closure of programs or individual medical practices. The plan includes steps for the orderly transfer of patients, records, and assets to other programs or practitioners.

b. No less than 30 days prior, the program/provider will notify the Vermont Department of Health; SOTA of the anticipated closure, discuss the rationale for closure and efforts to establish continuity of care for the patients. It is expected that providers/programs experiencing difficulties will demonstrate all due diligence to ensure patients have access to reasonable care, dependent upon state and local resources.

c. Develop a plan to ensure that patient records are secured and maintained for a specified period of time in accordance with State and Federal regulations.

4. Diversion Control Program

Each treatment provider must develop:

a. A diversion control plan (DCP) that demonstrates accountability to its patients and to the community. The DCP should reflect the efficient use of personnel and other resources to achieve the highest quality of patient care, while reducing possibilities for diversion of controlled substances from legitimate treatment to illicit use.

b. *Diversion* of both the mono and combination buprenorphine preparations present additional challenges, due to the office based nature of OBOT. While not a mandatory reportable offense, programs/providers must inform patients that diversion is a reportable criminal offense, and indicate how suspicions or evidence of diversion will be clinically handled. Physicians/programs should have clinical procedures in place for minimizing diversion risk to ensure appropriate addiction treatment, such as the following:

- Routine toxicology screens
- Pill call backs (for counting)
- Bubble packing of prescriptions
- Making copies of the ID numbers listed on the "strip" packaging to be available for call backs

c. MAT prescribers/programs shall register with the *Vermont Prescription Drug Monitoring System (VPMS),* established by the Vermont Department of Health to provide health care professionals an electronic database and reporting system for electronic monitoring of prescriptions for controlled substances. The *VPMS* may be accessed online by registered prescribers and pharmacists at http://healthvermont.gov/adap/VPMS.aspx. Additional information is available through the Alcohol and Drug Abuse Programs (ADAP) office at 802-652-4147.

5. Continuous Quality Improvement Policies

a. Each treatment program/provider:

i. Provides regular and continuous staff education.

ii. Reviews program policies and procedures at least annually.

iii. Adheres to universal or standard infection control precautions promulgated by the Centers for Disease Control and Prevention (CDC) and the Vermont Occupational Safety and Health Administration (VOSHA) requirements.

V. General Program Medical and Behavioral Health Standards

1. Medical Standards/Patient Admission Criteria

a. Evidence of Current Physiological Dependence and Opioid Addiction

i. The program physician must either diagnose or certify opioid addiction or dependence, as defined in either the current edition of the Diagnostic and Statistical Manual of Mental Disorders, or the current edition of the International Classification of Diseases. In either situation, the physician will document or co-sign that diagnosis, and admit each patient to maintenance or detoxification treatment as medically necessary. If pharmacological treatment is medically appropriate, there is an assessment conducted to determine the appropriateness of treatment with buprenorphine, prior to prescribing Methadone.

ii. A 1-year history of addiction is necessary for admission to a MAT **maintenance** treatment program. Individuals with less than a 1 year history of dependence may require pharmacological intervention, however **medically supervised withdrawal** would be the rationale for admission

rather than the expectation of long-term maintenance. The absence of current physiological dependence should not be an exclusion criterion, and admission is acceptable when clinically justified. MAT providers can accept arrest and medical records, information from significant others and relatives, and other information to document the 1-year history of addiction.

iii. For populations of individuals who have a prior history of narcotic dependence however who may not have any current or active use, such as those being released from penal institutions or previously treated patients, Federal OTP regulations waive the 1-year history of active addiction for these special populations. However in OBOT situations it is **strongly** recommended that programs/providers seek consultation with an addiction specialist.

iv. A physician assesses/reviews assessment results with each patient **before** admission to medication-assisted treatment. The exceptional circumstance is that the physician may review the medical examination performed by another qualified health professional and make/certify the required diagnosis, and admit the patient in an emergent situation. The physician would then review and countersign the patient record within 72 hours. The patient/physician would then have either a face-to-face meeting or contact through an approved form of communicative technology to review the assessment and discuss the medical services.

v. Consistent with Federal regulations, **OTP's** must consider drug injecting patients (IV drug users) as a priority population and prioritize those patients for admission.

vi. OBOT programs that are ADAP Preferred Providers must prioritize drug injecting patients for admission, provided the patient is determined clinically appropriate for an OBOT level of care. Otherwise OBOT providers will refer patients to an appropriate treatment program.

2. Medical Evaluation

At a minimum it is expected that patients receive:

a. Comprehensive physical examination inclusive of the patient, reviewing: health history, identification of other chronic or acute health conditions, current objective measures of health, pregnancy status of female patients, and selected lab work as deemed medically appropriate by the physician and as available given the existing community resources.

b. Based on an individual's history and physical examination, programs/providers will evaluate the possibility of infectious disease, liver or pulmonary conditions, cardiac abnormalities, psychiatric problems, dermatologic sequelae of addiction, and/or possible concurrent surgical and other problems by conducting testing or referring patients for consultation and testing, as deemed appropriate by the physician.

3. Informed Consent

Each treatment program will:

a. Obtain voluntary, written, program-specific informed consent to treatment from each patient at admission. Releases of information for all ancillary

individuals/providers should also be obtained from each patient receiving a copy and 1 copy of each form for the record.

b. Inform each patient about all relevant treatment procedures, services, and other policies and regulations throughout the course of treatment.

c. Before medicating the patient, each program/provider obtains voluntary, written, informed consent from each patient to the specific pharmacotherapy ordered by the physician. In cases of OBOT a copy of the Buprenorphine Treatment Agreement should also be forwarded to the identified pharmacy.

d. Informs each patient of the following:

i. That the goal of medication-assisted treatment is stabilization of functioning.

ii. That, at periodic intervals, in full consultation with the patient, the provider discusses present level of functioning, course of treatment, and future goals. These discussions should not place an unfair burden or pressure on the patient to withdraw from medication or to remain on medication maintenance unless medically indicated.

e. As a mandated reporter, informs each patient, at admission, about State-specific requirements and program policies regarding the report of suspected child abuse and neglect, danger of harm to self and/or others, abuse or neglect of a disabled individual, and other behaviors having negative impact on the client or others.

f. Adheres to all requirements of the Federal confidentiality regulations (42 CFR Part 2) and HIPAA (45 CFR Part 160 and Subparts A and E of Part 164).

4. Treatment Considerations

a. Medical Services:

Providing basic primary care or integrated psychiatric care onsite is highly recommended but not required. Programs make referrals for medical and/or psychiatric treatment when indicated.

b. Retention in Treatment

i. Programs/providers will make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.

ii. The treatment program/provider takes appropriate therapeutic measures to address the other problems identified in the treatment plan, either directly or through referral.

iii. All MAT programs informed consent should consist of discussion of treatment expectations, "clinical appropriateness", anticipated responses to use of licit/illicit substance, physician tolerance for behavior, and potential MAT alternatives, or non-MAT alternatives.

c. Voluntary Patient Relocations, Program Transfers, and "Guest Dosing"

i. When a patient relocates, transfers to another treatment program, or needs temporary care at another program ("guest dosing"), the original MAT program ensures that the patient makes as smooth a transition as is feasible, and the program attempts to avoid interruptions in treatment that could lead to relapse.

ii. The original treatment program should forward relevant medical records to the receiving treatment program, with patient consent in accordance with the privacy standards of 42 CFR 2.

d. Relapse Prevention:

Psychosocial treatment continues for patients electing to discontinue pharmacotherapy in OTP programs while either continued treatment, or referrals for continued psychosocial supports, should be offered to OBOT patients as needed

5. Record Keeping and Documentation

All records required by 42 CFR § 8.12 (g) should be retained for a minimum of 3 years.

a. Patient Records:

MAT programs/providers are required under 42 CFR §8.11(f) (3) to comply with the Federal confidentiality regulations set forth under 42 CFR Part 2. As such, records of the identity, diagnosis, prognosis, or treatment of any patient that are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the program shall, except as provided in subsection (e) of 42 CFR Part 2, be confidential and be disclosed only for the purposes or circumstances expressly authorized under subsection 42 CFR section 2(b).

b. Records of Storage (Only for Programs that Dispense and Administer Opioid Medication):

Each program/provider must maintain policies and procedures consistent with Drug Enforcement Administration (DEA) statutes and regulations.

c. Each medication order and/or dosage change must be written on an acceptable order sheet signed by the physician (Note: only for programs that dispense and administer opioid medication).

i. Each dosage dispensed, prepared, or received will be recorded and accounted for by signed notation, in a manner that creates a perpetual and accurate inventory of all medications and/or prescriptions, including controlled substances in stock at all times.

ii. Every dose is recorded on an administration sheet, at the time that the dose is administered or dispensed, and recorded on the patient's individual medication dose history.

iii. The qualified person administering or dispensing medications signs his or her name or initials at each notation.

iv. If initials are used, the full signature of the qualified person administering or dispensing will be placed at the end of each page of the medication sheet.

d. Programs/providers will have a procedure for calibrating medication-dispensing instruments, consistent with manufacturers' recommendations, to ensure accurate patient dosing and substance tracking (Note: only for programs that dispense and administer opioid medication).

6. Guidelines for Therapeutic Dosage

a. General Dosage Principles:

The physician will employ clinical judgment to determine the individual dose of opioid medication and should have training in medication assisted treatment.

b. Effective therapy involving medication-assisted treatment has the following desired outcomes:

i. Preventing the onset of opioid abstinence syndrome for at least 24 hours;

ii. Reducing or eliminating the drug craving routinely experienced by the patient;

iii. Blocking the euphoric effects of opioids, without inducing undesirable effects experienced by the patient.

7. Maintenance Therapy

a. The total dose of medication and the interval between doses may require adjustments for the patient who has concurrent health conditions or atypical metabolic patterns, or if the patient takes other prescribed medications that alter the rates of opioid medication metabolism

b. Programs/providers utilize available evaluations, including documented history, physical and/or psychiatric examinations, to support the judgment by the physician that the patient is a suitable candidate for opioid therapy.

c. Medication induction should be guided by clinical presentation, patient ability to tolerate the medication and avoidance of negative effects.

d. Federal regulations stipulate that the initial dose of **Methadone,** within the OTP, should not exceed 30 mg. with medical discretion to consider a Maximum 40 mg total first day administration.

e. **Buprenorphine** induction guidelines are also designed with flexibility to adjust based upon clinical presentation, presenting illness, and physician discretion.

f. Programs/providers do not adjust medication doses to reinforce positive behavior or to punish negative behavior, unless the patient is non-compliant with programmatic expectations and the taper constitutes the start of medically

supervised withdrawal or the dosage increase is to address patient symptomology.

g. Programs/providers continue medication-assisted treatment as long as the patient derives benefit from treatment, desires treatment, that the treatment is medically necessary and that the patient is considered to be adherent with the established rules of the program.

h. The program/providers should have the capability to obtain serum methadone levels when clinically indicated and/or urine based buprenorphine/nor-buprenorphine levels.

8. Avoiding Multiple Program Enrollments

Reasonable measures will be taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. Use of the Vermont Prescription Monitoring System (VPMS) is required.

9. Detoxification, Tapering, or Medically Supervised Withdrawal

a. As clinically appropriate, a physician may admit a patient to MAT for "detoxification" treatment, hereinafter referred to as "medically supervised withdrawal."

b. Medically supervised withdrawal is conducted under the following conditions:

i. As a voluntary and therapeutic process, agreed on by physician and patient, or;

ii. In response to the request of the patient—against the advice of the physician, counselor, and other staff, or in other words, against medical advice (AMA).

c. The physician will initiate voluntary supervised withdrawal from medication-assisted treatment in collaboration with and at the request of the patient. NOTE: Voluntary supervised withdrawal is completely different and distinct from involuntary tapering or administrative withdrawal or other types of medically supervised withdrawal.

i. In initiating medically supervised withdrawal, the physician reduces dosages of medication at a rate well tolerated by the patient and in accordance with sound clinical judgment.

ii. For women of childbearing potential, the program/provider will conduct, or refer for, an assessment for pregnancy and review the results of a pregnancy test before initiating medically supervised withdrawal *(See 2. I. (5) (d)—The physician should not initiate withdrawal before 14 weeks' or after 32 weeks' gestation, per OTP guidelines for Methadone).*

d. The program/provider resumes medication-assisted treatment if the patient experiences impending or actual relapse, as applicable and based upon the availability of resources

10. Support of Medically Supervised Withdrawal

a. The following program policies and procedures promote successful medically supervised withdrawal, whether conducted with or against medical advice:

i. Increased counseling will be made available prior to discharge

ii. Patients are encouraged to attend a 12-step or other mutual-help program that is sensitive to the needs of patients receiving medication-assisted treatment.

b. Consideration/discussion with patients of utilizing alternative pharmacology following medically supervised withdrawal. Potential examples of medications to support on-going recovery might include opioid antagonists (eg. Naltrexone and/or Vivitrol).

c. Additional Considerations for Medically Supervised Withdrawal Against Medical Advice

i. The patient has the right to leave treatment when he or she chooses to do so. The program/provider will explain the risks of leaving treatment and offer information about, or referral to, alternative treatment options.

ii. In the case of a patient who leaves an **OTP** program abruptly, the program may readmit the patient within 30 days without repeating the initial assessment procedure required by regulation 42 CFR § 8. **OBOT** providers/programs utilize their discretion to re-admit without repeating an assessment although consideration for pregnancy testing for women of child bearing age should be considered.

iii. If medically supervised withdrawal fails, the program/provider will consider initiating maintenance treatment in conjunction with the patient and ancillary treatment providers.

iv. In the case of a pregnant patient, the program/provider keeps the OBGYN informed, consistent with privacy standards of 42 CFR 2.

11. Administrative Withdrawal and Discharge

a. A major goal for programs/providers is to retain patients for as long as they can benefit from treatment, express a desire to continue and are clinically appropriate. However it is not always possible to retain the patient due to various circumstances. When a program makes the decision to administratively discharge a patient from pharmacotherapy, the program/provider will offer a humane schedule of medically supervised withdrawal, when clinically appropriate and as long as it does not compromise the safety of providers or program staff.

b. Administrative withdrawal may result from:

i. Nonpayment of fees. Remedies may include referral to a more affordable treatment program.

ii. Disruptive conduct or behavior. Such behaviors may have an adverse effect on the program, staff, or patient population of such gravity as to justify the involuntary medically supervised withdrawal and discharge of a patient,

despite an extremely poor prognosis. Disruptive behaviors include but are not limited to: violence/aggression, direct threat of violence, dealing drugs, repeated loitering, and flagrant noncompliance, resulting in an observable, negative impact on the program, staff, and other patients. Per **OTP** guidelines, patients who exhibit disruptive behaviors should receive a mental health evaluation and referral, as appropriate, prior to administrative withdrawal while OBOT providers should clinically monitor patients for potential mental health symptoms.

c. Incarceration or other confinement

d. Providers determine during the process of on-going assessment that the patient is not appropriate for OBOT treatment and may be better served by other treatment modalities. Indicators of this may include: continued use of substances, medication diversion, and/or lack of response to the treatment plan.

e. Clinical Determination of the provider/program

f. Violation of contract with the provider/program:

i. The provider/program will take into consideration all factors affecting the patient on a case-by-case basis, and document procedures for any involuntary terminations of patients.

ii. Efforts made regarding referral or transfer of the patient to a suitable alternative treatment program should be documented, inclusive of psycho-social support referrals.

iii. The program/provider makes specific efforts to ensure referrals are followed through to completion for the pregnant patient, in the event the patient is administratively withdrawn and discharged. Provider/program(s) should carefully follow up with both patient's pregnancy and opioid dependency. It may be helpful for the program to establish prearranged agreements for treatment for this very purpose.

g. Continuing Care:

i. An essential part of treatment is continuing care that includes discharge planning and relapse prevention.

ii. Each program/provider will ensure the discharge planning process includes procedures that address patients' physical and mental health problems following medically supervised withdrawal, as clinically appropriate.

iii. The treatment program/provider will provide for continuing care following the last dose of medication, including making a referral for continuing outpatient care, as needed, and planning for reentry to maintenance treatment if relapse occurs and resumption of care continues to be appropriate and as resources are available.

12. Psychosocial Assessment/Behavioral Health Services:

Each program/provider will ensure that for each patient receives:

a. Comprehensive Psychosocial Assessment:

A comprehensive psychosocial evaluation will be completed on all patients receiving medication assisted treatment. In MAT programs with on-site licensed, Behavioral Health clinicians, it is expected that this assessment be completed by the 3rd visit. For those OBOT providers without co-located Behavioral Health Clinicians, it is anticipated that these individuals are referred for an evaluation of behavioral therapy supports and that releases are signed such that the prescriber obtains a copy of this assessment from the referred clinician.

b. The assessment must include an evidenced based tool and should, minimally, include the following domains: Mental Health history and mental status examination with current DSM categorization, interpretive summary, diagnosis, and ASAM patient placement criteria.

c. Refers patients who have the need for services not provided by the program/provider to other care providers, as appropriate.

d. For patients referred elsewhere, ensures that the exchange of information conforms to confidentiality regulations for patients in drug or alcohol treatment (42 CFR Part 2) and HIPAA regulations (45 CFR Part 160 and Subparts A and E of Part 164).

e. Clinicians must possess a substance abuse apprentice certification, certification and/or licensure in addiction treatment. Clinicians with other behavioral health licensures with sufficient experience in addictions would also be considered qualified.

f. For patients determined by assessment to benefit from behavioral interventions, services provided are of the intensity and duration to meet the needs of the individual patient. Cessation of behavioral treatment should be done in consultation with the patient, clinician and physician.

13. Treatment Planning, Evaluation of Patient Progress in Treatment, and Continuous Clinical Assessment

a. The behavioral health clinician/treatment team will complete assessment reviews and treatment plan updates **quarterly for the first year** of continuous treatment. In subsequent years, the program/provider **updates** assessments and treatment plans **semiannually.**

14. Concurrent Services

a. Orientation to Treatment and ongoing education on:

i. Signs and symptoms of overdose and when to seek emergency assistance

ii. The medication they are taking, including side effects and common myths about the medication or modality of treatment

iii. The nature of addictive disorders

iv. The benefits of treatment and nature of the recovery process, including phases of treatment

v. Clinic guidelines, rules, and regulations, including the requirement to sign a formal agreement of informed consent, and fees and billing procedures

vi. Noncompliance and discharge procedures, including administrative withdrawal from medication

vii. Patient's rights

viii. Confidentiality and how release of information is permitted in accordance with 42 CFR Part 2

ix. Toxicology testing procedures

x. Dispensing medication or prescriptions

xi. HIV-spectrum and other infectious diseases

xii. Potential drug interactions

b. Counseling on HIV Infection and Other Conditions or Diseases of Public Health Importance

i. Programs/providers will provide basic counseling/information on HIV infection and other prevalent infectious diseases, such as hepatitis, sexually transmitted infections, and TB. Counseling also includes infectious disease prevention for at-risk patients, and the need for patients to adhere to treatment and to communicate honestly with the provider when treatment has begun.

ii. Programs will provide risk reduction education to patients, as appropriate.

15. Drug Testing

a. Each program/provider will:

i. Use drug and alcohol screening and testing as aids in monitoring and evaluating a patient's progress in treatment.

ii. Ensure that treatment personnel in a medication-assisted treatment program understand the benefits and the limitations of toxicological testing procedures.

iii. Collect all urine or other toxicological specimens in a therapeutic context

iv. Determine the drug-testing regime by analyzing community drug-use patterns and individual medical indications.

v. Address results of toxicology testing with patients promptly. Programs document in the patient record both the results of toxicology tests and follow-up therapeutic interventions.

vi. Ensure that following the patient's admission toxicology screening, clinicians determine the frequency of toxicological testing by evaluating the clinical appropriateness for each patient in relation to the patient's stage in treatment. For patients receiving services from multiple providers, attention to coordinating/sharing toxicology results is expected.

vii. Ensure that clinicians consider confirming the results of drug screening tests with additional testing. Treatment programs will establish procedures for addressing potentially false positive and false negative urine or other toxicology test results following principles outlined in TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005, chapter 9).

viii. Ensure compliance with all federal regulations related to urine toxicology results, 42 CFR § 8.12(f) *Drug abuse testing services.* **OTPs** must provide adequate testing or analysis for drugs of abuse, including at least **eight random drug abuse tests per year**, per patient, in maintenance treatment (defined as on a stable dosage for a period in excess of 21 days per 42 CFR 8.2), in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment (less than 30 days per 42 CFR 8.2), the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment (30-180 day duration per 42 CFR 8.2), the program shall perform initial and monthly random tests on each patient.

VI. Special Populations/Circumstances of Care

1. Additional Treatment Planning Considerations

a. Management of Co-Occurring Disorders

i. When possible and clinically appropriate, co-occurring disorders (poly-drug, medical and/or mental health) will be concurrently managed onsite.

b. Alcohol and Other Drug Abuse

i. When clinically appropriate, programs/providers will manage concurrent abuse of other drugs within the context of the medication-assisted treatment, following principles described in TIP 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs" (CSAT 2005).

ii. Program staff members/providers will remain knowledgeable about current effective strategies for treating other drugs of abuse.

iii. Ongoing multidrug abuse is not necessarily a reason for discharge. Many patients (and communities) continue to benefit from medication-assisted treatment even when the patients are not fully abstinent from all drugs of abuse. Therefore patients engaging in such multidrug use should receive careful evaluations to determine the most therapeutic course of treatment. The treatment decision for poly-drug-abusing patients should take into account the patient's condition, the program/provider(s) best clinical

judgment and a review of the appropriate level of care. Treatment programs/providers should coordinate care with providers outside the MAT program.

2. **Care for Patients with Mental Health Needs**

   Treatment programs/providers will:

   a. Ensure that patients with mental health needs are identified through the assessment process and either offered or referred to appropriate treatment as clinically indicated and as resources are available.

   b. Ensure that patients are monitored during withdrawal and/or discharge for emergence of symptoms of mental illness, as clinically appropriate.

   c. Establish and use linkages with mental health providers in the community, as needed.

3. **HIV Testing and Care of HIV-Positive Patients**

   a. Programs/providers will educate patients about HIV/AIDS, testing procedures, confidentiality, reporting, follow-up care, counseling, safer sex, social responsibilities, universal precautions, and sharing of intravenous equipment, as clinically appropriate.

   b. Programs/providers will offer people living with HIV/AIDS options to promote maximum. benefits of medication-assisted treatment during the course of HIV/AIDS treatment, including addressing medication side effects and toxicity, establishing linkages and referrals with HIV/AIDS treatment programs and social support services.

   c. The program/provider and the provider responsible for HIV/AIDS medication management will work together to case manage and monitor medication adherence and adverse events, as needed.

4. **Treatment Considerations for Viral Hepatitis**

   a. Patients who test positive for viral hepatitis will receive a referral for further evaluation and treatment, if necessary. Patients who test negative are immunized (referred for immunization) against hepatitis A and B, as appropriate, and against other viral hepatitis strains as those vaccines become available. For patients identified positive for HCV and who require antiviral therapies, coordination of care should occur. Counseling/training around blood-borne pathogens should be available to staff and patients.

5. **Treatment Considerations for Smoking Cessation**

   a. Treatment programs/providers address smoking and tobacco cessation with patients as a part of their treatment.

6. **Cultural Competency**

   a. Programs/providers develop and implement written nondiscrimination policies to ensure equal access to treatment for all persons in need, regardless of race, ethnicity, gender, disability, age (with specific reference to policies for minors), or sexual orientation. Programs/providers will be sensitive to the culture and values of patients in treatment.

7. **Criminal Justice Issues**

   a. Programs/providers develop procedures to coordinate with agents of the criminal justice system on behalf of patients.

8. **General Principles Regarding Care of Women in Treatment**

   a. The policies and procedures of each treatment program/provider reflect the specific needs of female patients.

   b. Programs/providers receive training in the specific characteristics and needs of women participating in their particular treatment program, assuring sensitivity to trauma and/or violence related issues. Programs/providers, either internally or through referral, have the ability to coordinate gender specific psycho-social supports.

9. **Family Needs**

   a. Treatment programs/providers provide opportunities for involvement of family and significant others in therapy, as clinically appropriate and consistent with confidentiality laws.

   b. Treatment programs/providers offer onsite education and training for male and female parenting patients, or have the ability to refer patients to appropriate parenting skills services and /or childcare services.

   c. If an **ADAP Preferred Provider**, families are to be offered childcare options during scheduled appointment times to ensure that parents are able to receive appropriate treatment services.

   d. Children of patients in medication-assisted treatment may have special mental health and cognitive needs, especially if there has been physical or sexual abuse or neglect. Treatment programs/providers will offer referrals to resources and/or parenting support groups, as needed (CSAT 2005).

10. **Alternative Therapies**

    a. Programs/providers support patient choice in seeking alternative therapies while providing appropriate guidance in the process. Programs may provide culturally appropriate or popular and nonharmful alternative therapies as indicated (e.g., providing a space for sweat lodge ceremonies in a rural clinic serving Native Americans, or offering acupuncture).

11. Treatment of Other Diseases and Conditions of Public Health Interest

a. Programs/providers should treat patients diagnosed with disorders that require reporting to public health departments or refer those patients for further evaluation and treatment elsewhere. Examples of these types of diseases include TB and STDs.

b. Programs/providers exchange information appropriately with the providers and health departments caring for the patients with reportable diseases or conditions, taking into account informed consent

12. Pregnant and Postpartum Patients

NOTE: As of this writing, both Methadone and Subutex are Pregnancy Category C drugs, which call for a careful risk/benefit analysis before administering. Currently, there is no known harm to the human fetus when medication is taken as directed and relapse is avoided.

a. OTP providers will ensure:

i. The treatment program gives priority to pregnant women who seek treatment within 48 hours of initial patient contact. If treatment is denied, notification to the Vermont Dept. of Health, Office of Alcohol and Drug Abuse programs is expected within 48 hours.

ii. The treatment program will ensure that every pregnant patient has the opportunity for prenatal care provided onsite, or by referral, to appropriate health care providers, with the appropriate releases signed by the patient for shared information.

iii. In the event that prenatal care is not available onsite or by referral, or if the pregnant patient cannot afford care or refuses prenatal care services, the treatment program, at a minimum, offers her basic prenatal instruction on maternal, physical, and dietary care as part of the counseling services. The provider will document the provision of these services in the clinical record.

iv. If a pregnant patient refuses direct prenatal services or appropriate referral for such care, the treating physician in the treatment program may use informed consent procedures to have the patient formally acknowledge, in writing, that the program offered these services but that the patient refused them.

b. For pregnant women on methadone treatment, the program will:

i. Maintain patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and apply the same dosing principles as used with any other non-pregnant patient.

ii. Ensure that the initial methadone dose for a newly admitted pregnant patient and the subsequent induction and maintenance dosing strategy reflect the same effective dosing protocols used for all other patients.

iii. Monitor the methadone dose carefully, especially during the third trimester when pregnancy-induced changes in the rate at which methadone is

metabolized or eliminated from the system and which may necessitate either an increased or a split dose.

iv. In general, detoxification during pregnancy is not recommended or considered the best practice. If a pregnant patient elects to withdraw from methadone and stays in the program, a physician experienced in addiction medicine will supervise the withdrawal process with regular fetal assessments, as appropriate, for gestational age, as part of the withdrawal process. The physician should not initiate withdrawal before 14 weeks' or after 32 weeks' gestation.

v. The program supports the decision to breast-feed during methadone treatment, unless medically contraindicated, for example, by the presence of HIV or HTLV I or II infection in the mother. The treatment program should document appropriate counseling and informed decision making between provider and patient to ensure that issues mentioned in the latest patient information sheets and product inserts for methadone are covered and understood.

vi. The treatment program establishes and implements policies and procedures, including informed consent, to ensure appropriate follow-up and primary care for the new mother and well-baby care for the infant. Informed consent refers to the patient's agreement to receive treatment as well as agreement to release information to and obtain information from pertinent health care providers.

vii. If a pregnant patient is discharged, the program should identify the physician/program to whom the patient served is being discharged. The program staff records the name, address, and telephone number of the physician who will be caring for the patient after discharge.

13. OBOT/MAT Providers with Buprenorphine:

a. Should questions arise regarding the treatment of pregnant women with buprenorphine, please contact the Vermont Department of Health, Office of Alcohol and Drug Abuse Programs at (802)651-1550 who can assist providers with resources and support.

i. A risk/benefit discussion providing informed consent to each patient is expected upon confirmation of pregnancy. For existing patients on OBOT/MAT, transition the patient to Subutex if, after offering informed consent related to pregnancy, the patient desires to continue on MAT/OBOT. Otherwise a referral for Methadone should be made. It is HIGHLY recommended that opioid dependent women be referred to high risk obstetrics providers given the heightened risk of pregnancy and obstetrical complications. Additionally, OBOT and MAT providers should coordinate this care with adherence to pre-natal care being a strong factor in the consideration of continued office based care.

b. Concurrent Pregnancy and HIV Infection

i. Pregnant patients in treatment with concurrent HIV infection are subject to the same policies and procedures established for all HIV-infected patients in treatment and receive the same services.

ii. Treatment programs/providers offer pregnant patients with HIV diagnoses the same treatment opportunities and services, directly or by referral, as HIV-diagnosed patients who are not pregnant.

iii. Treatment programs/providers ensure that all pregnant patients with concurrent HIV infection are (1) informed that HIV medication treatment is currently recommended to reduce perinatal transmission and (2) provided with appropriate referrals and case management for this treatment.

14. Care of Adolescents in Treatment

a. For OTP consideration, "A person under 18 is required to have had two documented attempts at short-term medically supervised withdrawal (detoxification) or drug free treatment to be eligible for maintenance treatment. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age, except an "emancipated minor", may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult completes and signs consent form, Form FDA 2635 "Consent to Methadone Treatment."

b. Programs will tailor assessments to the developmental stage of the patient.

c. Buprenorphine within the office based setting may be prescribed to individuals age 16 and older based upon the clinical judgment of the physician. It is **strongly** suggested that if buprenorphine maintenance is being considered (rather than medically supervised withdrawal) that physicians consult with an addiction specialist.

15. Participation in Opioid (pharmacological) Therapy Research Activities

a. Patients have the right to give informed consent prior to being involved in research projects, and the right to retain a copy of the informed consent form.

b. Patients have the right to full disclosure of information about treatment and medication, including accommodation for those who do not speak English, or who are otherwise unable to read an informed consent form.

c. Programs are encouraged to participate in research activities as long as they do not compromise the integrity of the treatment process.

d. Research conducted in the treatment program does not compromise the integrity of the treatment process.

e. The director of the treatment program has the authority to consider participation in proposed research or study that is based on sound scientific principles.

f. All research involving human subjects is conducted in accordance with accepted Federal human subject protection standards.

g. Treatment and other services are not jeopardized for any patient who refuses to participate in research activities.