

**CSAT Guidelines for the
Accreditation of Opioid
Treatment Programs**

CSAT GUIDELINES FOR THE ACCREDITATION OF OPIOID TREATMENT PROGRAMS

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Statement of Non Binding Effect—This guidance documents represents the agency’s current thinking on the Federal Opioid Treatment Standards set forth under 42 CFR § 8.12. It does not create or confer any rights for or on any person or program and does not operate to bind CSAT or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statute and regulations.

1. Introduction

The Center for Substance Abuse Treatment developed the original Guidelines for the Accreditation of Opioid Treatment Programs (OTPs) between 1996 and 1999, through a Treatment-Improvement-Protocol-type process, involving two expert panels, field reviews, and clearances from other Federal agencies and by the Office of Management and Budget. These guidelines were written to serve as a guide to accreditation organizations in developing accreditation standards, which conform, with the Federal Opioid Treatment Standards found in Title 42 of the Code of Federal Regulations, Part 8. The guidelines also serve to provide guidance to opioid treatment programs, elaborating on and providing examples of ways that programs can achieve and maintain compliance with Federal regulations.

Under Title 42 of the Code of Federal Regulations Part 8, (42 CFR Part 8) which became effective in May 2001, accreditation organizations or State Governmental entities that choose to participate in SAMHSA's accreditation program are required to apply to become SAMHSA-approved accreditation bodies. Among the numerous application requirements, potential accreditation bodies are required to submit a set of accreditation elements or standards and a detailed discussion showing how these standards ensure that each OTP surveyed is qualified to meet the Federal opioid treatment standards set forth in section 8.12 of the regulations. OTPs must be certified by SAMHSA before they may dispense opioid drugs in the treatment of opioid addiction. To become certified, an OTP must meet the Federal opioid treatment standards in section 8.12 of the regulation, must have current valid accreditation status from a SAMHSA-approved accreditation body, and must comply with any other conditions for certification established by SAMHSA.

The experience gained from the application of the rules and the thousands of accreditation surveys since 2001 has identified issues and areas that would benefit from careful review and update. Because the Accreditation Guidelines had not been updated since 1999, and have not been substantially reviewed and revised by experts since 1998, an Expert Panel was convened in October-November 2005 and charged with revisiting and revising the guidelines in light of new scientific research findings, advancements in the field, and state-of-the-art evidence-based practices. Expert panel members were chosen because they are knowledgeable about the following areas:

- most recent developments in opioid addiction treatment;
- the prevention and treatment of infectious diseases, such as HIV and the hepatitis A, B, C, and D viruses;
- best practices and standards of practice;
- the addition of buprenorphine to the armamentarium of available treatment medications;
- the growing problem of prescription drug abuse;
- issues relating to diversion control;
- medication for unsupervised or take-home use;
- methadone-associated mortality;
- planning and acting in emergencies;
- detoxification from drugs of abuse;
- medically supervised withdrawal from opioids;
- community or State resistance to medication-assisted treatment;
- cardiac complications;
- pain management;

- third-party reimbursement;
- physician and staff education; and
- office-based treatment.

CSAT is committed to Good Guideline Practices, and such practices include periodic review and update of guidelines as evidence and experiences associated with best practices advance. CSAT announced the availability of the revised draft guideline in the Federal Register of April 21, 2006. The notice provided information on how to obtain the draft and submit comments. A 60-day comment period was provided.

NOTE: For some of the guidelines, CSAT believed a fuller explanation of the issue or rationale underlying the standard was needed as well as some examples to clarify meaning. That information is presented in endnotes.

2. Opioid Treatment Standards

42 CFR Sec. 8.12 Federal opioid treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction, which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP complies with all applicable Federal, State, and local laws and regulations.

42 CFR § 8.2 *Medical director* means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

Program sponsor means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

42 CFR § 8.11 (f)(5) OTPs shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

a. Administrative Organization and Responsibilities

Administrative responsibilities, both for organizations and individual practitioners, are adequate to ensure quality patient care and to meet the requirements of the laws and regulations of the Department of Health and Human Services, Drug Enforcement Administration, and the States.

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.

(1) Goals

Each treatment program shall have a statement of its goals for patient care.

(2) Human Resources Management

Each treatment program has a plan to ensure that staffing patterns are appropriate and adequate for the needs of the patients being served.

b. Management of Facility and Clinical Environment

(1) Each treatment facility

(a) has 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 on site.

(b) is clean and well maintained, similar to and in accord with other treatment resources for different medical and behavioral disorders.

- (c) maintains documentation that it meets all local and State safety and environmental codes.
 - (d) ensures protection of confidentiality, including the use of locked files and the availability of private, individual offices for counseling.
 - (e) will provide services during hours that meet the needs of the overwhelming majority of patients, including hours before and/or after the traditional 8:00 a.m. to 5:00 p.m. working day, when possible.
- (2) The program sponsor is the person ultimately responsible for the operation of the program. Importantly, the program sponsor is responsible for assuring that the program complies with all Federal, State, and local laws and regulations. (See 42 CFR § 8.2)
 - (3) The program director or program manager is the person who manages the program operations from day-to-day and whose authority is delegated by the program sponsor (who retains ultimate responsibility for program operations). Program directors have varying levels of program responsibility, frequently hire and fire employees, and carry out multiple management responsibilities depending on the duties assigned to them by the sponsor. (Not all programs have program directors or program managers, and the regulations do not require them. In some OTPs, the program sponsor also acts as the program director.)
 - (4) The medical director is responsible for monitoring and supervising all medical services provided by the OTP. In some cases, the medical director serves as the program sponsor; however, only a licensed physician may serve as the Medical Director of an OTP. (See 42 CFR § 8.2)

42 CFR 8.12(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

c. Risk Management and Continuous Quality Improvement

(1) Life Safety Issues

(a) Each treatment program

- (i) develops procedures to ensure that the correct dose of medication(s) is administered and that appropriate actions are taken if a medical error is made, including a mechanism for reporting untoward incidents to appropriate program staff.
- (ii) provides a mechanism to address patient emergencies by verifying dosage levels and enrollment information on a 24-hour, 7-day a week basis, as appropriate under confidentiality regulations. Facility 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.
- (iii) ensures that there are appropriately trained staff members on duty who are trained and proficient in cardiopulmonary resuscitation (CPR), management of opiate overdose, medical emergencies, and other techniques as appropriate.

- (iv) establishes policies and 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 when security guards or police need to be summoned.

(b) Program Emergencies

Each treatment program

- (i) develops, maintains, and updates regularly a disaster plan that addresses maintenance of fire extinguishers, fire drills, emergency evacuation procedures, and includes links to community agencies.
- (ii) maintains a 24-hour telephone answering capability to respond to facility emergencies. A record of patients and medication dosages is accessible to the staff person on call for verification purposes.
- (iii) maintains an up-to-date plan for emergency administration of medications in case the program must be closed temporarily, including a mechanism for informing patients of these emergency arrangements.
- (iv) ensures that needed supplies are available in the event of an emergency.

(c) Guidance for Treating OTP Patients from Areas Impacted by Emergency Closure of Programs in the Event of a Disaster

On August 31, 2005, the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) Division of Pharmacologic Therapies (DPT) issued guidance to the State Methadone Authorities (SMAs) and Opioid Treatment Programs (OTPs) in those states directly affected by Hurricane Katrina. That guidance can be found on our Web site, <http://dpt.samhsa.gov>. As the evacuation of residents from those states moved beyond the region to become a nationwide phenomenon, a guidance document was developed for OTPs and States to assist in providing short-term and long-term emergency medication-assisted treatment services to populations affected by this or future disasters. This guidance addresses patients in OTPs and persons who are dependent on opioids, but not enrolled in addiction treatment.

Guidance: Every effort should be made to contact the home treatment program of a person who has had to evacuate the area in which they live after an emergency or disaster. Information about the program may be obtained from the CSAT OTP Directory on the Division of Pharmacologic Therapies Web site (referenced above) or at the SAMHSA Substance Abuse Treatment Facility Locator at: <http://dasis3.samhsa.gov/>. If unable to contact the patient's home program, the OTP receiving an evacuated patient should follow procedures listed below, along with existing emergency plans:

- The emergency guest patient should show a valid picture identification that includes an address in close proximity to the area impacted.
- The patient should show some type of proof that indicates the patient was receiving services from a clinic located in one of the affected areas, e.g., a medication bottle, program identification card, receipt for payment of fees, or the like. In cases in which the patient does not have any items of proof including a picture ID, the physician should use his or her best

medical judgment, combined with a stat drug test for the presence of methadone (lab test with quick turn-around, dipstick, or similar procedure).

- An OTP may administer the amount of medication that the patient reports as his or her current dose; however, please remind each patient that the dose that is reported will be verified with the home program as soon as possible. In cases in which the reported dose appears questionable, it is best to use good medical judgment when determining the dose level. In certain cases in which the patient can demonstrate no prior enrollment in treatment or medication dosage amount, it may be advisable to treat the patient as a new admission, and follow initial dosing procedures for a routine admission. (See 42 CFR § 8.12 (h)(3)(ii) and Section 3 u(1) and (2), below.)
- Emergency guest patients should be medicated daily with take-home doses provided only for days that the program is closed (Sundays and holidays). If the patient's current take-home status can be verified, take-home doses may be provided in accordance with State and Federal regulations (42 CFR Part 8). In the case of a patient who is unable to travel to the program daily due to a medical or other hardship, take-home medication for unsupervised use may be considered using the SMA-168, "Request-for-Exception" process.
- Documentation of guest patient services should be a priority for OTPs. Each guest patient should be assigned a clinic identification number and issued a temporary chart. Reasonable efforts should be made to contact the patient's home program periodically to verify patient information prior to dispensing medication. The results should be recorded in the temporary chart. The OTP should record the day, date and amount of medication administered to each patient along with any observations made by the staff. As time passes and affected OTPs reopen, some patients may elect to remain in treatment at the receiving facility and change from guest to permanent status. Upon conclusion of the emergency treatment, the receiving program may be asked to report the number of patients treated and the types of services provided to the State SMA and/or CSAT.

Opioid-Dependent Evacuees Not Currently In Treatment: There are individuals dependent on opioids, including, but not limited to heroin, who may arrive at your treatment program seeking help as a result of the disruption in the supply of street drugs. OTPs may admit, treat, and dose these patients under existing guidelines and regulations. Patients new to medication-assisted treatment may be appropriate for initiation on buprenorphine products. CSAT can facilitate the Drug Enforcement Administration (DEA) registration of the OTP to use buprenorphine. For assistance, contact Mr. Nick Reuter at 240-276-2716.

Evacuees Treated by Pain Clinics: Some OTPs may be contacted by evacuees who were being treated for pain with methadone by a physician, in a clinic or other setting, and are now out of medication. The first response should be to refer the patient to a local physician, particularly a pain management specialist. Additionally, the CSAT guidelines provide the following guidance:

- Patients are generally not admitted to OTPs to receive opioids for pain only.
- Patients with a chronic pain disorder **and** physical dependence are managed by multidisciplinary teams that include pain and addiction medicine specialists. The site of such treatment may be in a medical clinic or in an OTP, depending on patient need and the best utilization of available resources. Similarly, addiction patients maintained on methadone or buprenorphine are not prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics.

- “Tapering”—discontinuation of opioid medications used during an acute pain treatment episode—The Narcotic Addiction Treatment Act and the Drug Addiction Treatment Act were established to allow for maintenance and detoxification treatment with opioid controlled substances. These requirements and limitations in no way affect the ability of a practitioner to utilize opioids for the treatment of pain when acting in the usual course of medical practice. Consequently, when it is necessary to discontinue a patient’s opioid therapy for the treatment of his/her pain by tapering or weaning doses, there are no restrictions with respect to the drugs that may be used. Because this is not considered “detoxification” as it is applied to addiction treatment, no separate DEA registration as an NTP or DATA waiver requirements apply.
- Patients who are diagnosed with physical dependence and a pain disorder are not prohibited from receiving methadone or buprenorphine therapy for either maintenance or withdrawal in an OTP, if such a setting provides expertise or is the only source of treatment.

Should there be any questions or issues not covered in this guidance document, please contact Mr. Nick Reuter or Mr. Todd Rosendale of CSAT’s Division of Pharmacologic Therapies (DPT) at 240–276–2700.

(2) Continuous Quality Improvement Policies

Each treatment program

- (a)** provides regular and continuous staff education.
- (b)** maintains staff development plans.
- (c)** reviews and recertifies program policies and procedures at least annually.
- (d)** elicits ongoing input into program policies and procedures by patients in consideration of community concerns.
- (e)** develops and implements periodic patient satisfaction surveys.
- (f)** adheres to universal infection control precautions promulgated by the CDC.
- (g)** measures and monitors treatment outcomes and processes on a regular basis to provide feedback on measures of performance. Measures of treatment outcomes may include:
 - (i)** reducing the illicit use of illicit opioids, illegal drugs, and the problematic use of alcohol and prescription medicines;
 - (ii)** reducing associated criminal activities and entry into the criminal justice system;
 - (iii)** reducing behaviors contributing to the spread of infectious diseases;
 - (iv)** improving quality of life by restoration of physical and mental health and functional status;
 - (v)** increasing retention in treatment;
 - (vi)** increasing employment;
 - (vii)** increasing abstinence.

(3) Critical Incidents or Sentinel Events¹

Each treatment program

- (a) establishes procedures to guard against untoward incidents or events that could have a negative impact on patients and their family members, the program or staff. This includes events that involve the loss of life or function of an individual served.
- (b) establishes procedures, in case a specified or unanticipated event occurs, to ensure
 - (i) full documentation of the incident;
 - (ii) prompt investigation and review of the situation surrounding the event;
 - (iii) implementation of timely and appropriate corrective action(s);
 - (iv) ongoing monitoring of any corrective actions until their effectiveness is established.

(4) Community Relations and Education²

For existing and/or new programs, to help minimize negative impact on the community, promote peaceful coexistence, and plan for change and program growth, programs develop and implement a general set of practices, policies, and procedures that,

- (a) consider community need and impact in selecting sites for programs.
- (b) elicit input from the community on the program's impact in the neighborhood.
- (c) ensure that the facility's physical appearance is clean and orderly and that the physical setting does not impede pedestrian or traffic flow.
- (d) identify community leaders for the purpose of fostering good community relations, and establish interpersonal contact, and proactive associations with identified leaders—for example, publicly elected representatives; local health, substance abuse, social, and/or human service agency directors; business organization leaders; community and health planning agency directors; grassroots community organization leaders; local police and law enforcement officials; and religious and spiritual leaders.
- (e) develop and support a community relations plan, specific to the configuration and needs of the program within its community that includes the following steps:
 - (i) establishing a liaison with community representatives to share information about the program and community and mutual issues;
 - (ii) identifying program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan;
 - (iii) serving as a community resource on substance abuse and related health and social issues, as well as promoting the benefit of medication-assisted treatment in preserving the public health;
 - (iv) soliciting community input about medication-assisted treatment and the program's presence in the community;

- (v) developing program policies and procedures to effectively address or resolve community problems (including patient loitering and medication diversion), and ensuring that program operations do not affect community life adversely.
 - (f) document community relations efforts and community contacts, evaluate these efforts and contacts over time, and address outstanding problems or deficiencies.
 - (g) devise communication mechanisms so that interested parties and potential patients may obtain general information about the program outside regular operating hours.
- (5) Voluntary and Involuntary Program Closure**
- (a) Programs develop a plan to establish, through State authorities or other governmental entities, 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) Programs develop a plan to ensure that patient records from programs that are closing are secured and maintained in accordance with State and Federal regulations for a specified period of time.

42 CFR 8.12(c)(2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

d. Diversion Control

Each program shall have a diversion control plan that demonstrates accountability to its patients and to the community. The diversion control plan also should demonstrate 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. The plan shall include the following:

Guidance—Diversion control plans should contain specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and should assign specific responsibility to the medical and administrative staff for implementation. The goal of this program responsibility is to reduce the scope and significance of diversion and its impact on communities. The diversion control plan should contain a mechanism for periodic monitoring of clinical and administrative activities to reduce the risk of medication diversion. OTPs should also have a mechanism for problem identification and correction as well as for prevention of related diversion problems.

A part of the diversion control plan should be surveillance and monitoring of potential diversion and community problems, which may be associated with opioid agonist treatment. One of the goals of surveillance and monitoring is to answer the question, "Is there a diversion problem; and, if so, how does the clinic or the community know?" For example, some clinics may set up a system of rounds in which security or clinic staff walk around the perimeter of the clinic on a regular and periodic basis to assess the activities at the entrances and in hallways, alleys, and the parking lot. This simple system of regularly checking the environment will help the program assess whether it has a loitering or diversion problem close to the clinic site. The clinic should examine its dosing and take-home dispensing practices to ensure that there are no potential weaknesses in the dispensing of medication that could lead to diversion problems. Another example of surveillance and monitoring involves consulting periodically with law enforcement in the community and in areas where patients live to discuss surveillance findings and the perceived and actual problems encountered.

It may be helpful to assign diversion problem identification, correction, and prevention functions to one of the clinic's committees, such as the quality assurance committee or the management committee. If the clinic is small, there may be only one committee for all staff and management business. In some OTPs, this is called the committee of the whole.

OTPs should have a plan in place to address a diversion problem once the problem is identified. Several strategies may be helpful. Always investigate the alleged or actual source of diversion. If needed, change the frequency of take-home reviews. Drug testing regimes may have to be reevaluated. Special, intensified groups or individual counseling sessions may be helpful for individuals or groups at risk for diversion problems. Patient committees to advise on policies, procedures, and problem solving may also help by giving patients a voice in keeping the treatment environment therapeutic and safe

42 CFR 8.12(d) *Staff credentials*. Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

e. Professional Staff Credentials and Development

Each treatment program shall ensure the following:

- (1) Doctors, nurses, and other licensed professional care providers maintain their current license and comply with the credentialing requirements of their own professions. Specific credentialing for work in addictions, by any formal body is desirable, but not essential.
- (2) Addictions counselors meet the qualifications outlined by the employing program and the State.
- (3) Before staff members provide care to patients, they receive initial education specific to the medication-assisted treatment to be used and tailored to the patient populations to be served.
- (4) All staff members receive continuing education. Staff may be qualified by training, education, and/or experience.
- (5) An individual annual training plan is implemented for each staff member.
- (6) Detailed job descriptions are developed for credentialed and non-credentialed staff that clearly define the qualifications and competencies needed to provide specific services.
- (7) Records of staff training events are kept that include the qualifications of educators, outline of content, description of methods, and attendees; records of staff training events should be kept in personnel files.
- (8) Resources for problem solving and troubleshooting are accessible.
- (9) There are an adequate number of physicians, nurses, counselors, and other staff for the level of care provided, related to the number of patients enrolled in the program. While there are no set ratios in Federal regulations, four states (Rhode Island, Wisconsin, Georgia, and Texas) have a required client-to-counselor ratio of 50:1. Alabama has a required ratio of 30:1. Arkansas has a required counselor-to-client ratio of 40:1. All of these states allow for an increase in the ratio under certain circumstances.

42 CFR 8.12(e) *Patient admission criteria.*--(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e) (1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

42 CFR § 8.2 *Opiate addiction* is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

f. Patient Admission Criteria

(1) Evidence of Current Physiological Dependence and Opioid Addiction

(a) The program physician must document that treatment is medically necessary.

Criteria for admission should be based on DSM IV definition of opioid dependence. Behavior supportive of a diagnosis of opioid dependence includes:

- (i)** significant levels of tolerance resulting in experiencing withdrawal symptoms on abrupt discontinuation of opioid substances;
- (ii)** signs and symptoms that reflect compulsive, prolonged self-administration of opioid substances that are used for no legitimate medical purpose or, if a general medical condition is present that requires opioid treatment, use of opioid doses that are greatly in excess of the amount needed for pain relief;
- (iii)** such regular patterns of compulsive drug use that daily activities are typically planned around obtaining and administering opioids;
- (iv)** purchase of opioids on the illegal market or obtaining opioids by faking or exaggerating general medical problems or by receiving simultaneous prescriptions from several physicians;
- (v)** engaging in drug-related crimes, such as, fraudulently writing prescriptions for opioids or diverting opioids prescribed for other patients or from pharmacy supplies. (DSM-IV-TR)

(2) Behavior indicative of opioid addiction includes:

- (a)** continuing use of the opiate despite known adverse consequences to self, family, or society;
- (b)** obtaining illicit opiates;

- (c) using prescribed opiates inappropriately;
- (d) previous attempt(s) at tapering using methadone or other drugs.
- (3) Patients often exhibit the physical signs and symptoms of opioid dependence. Onsite (“point of collection”) test devices may be useful in screening a patient’s current physiological dependence.
- (4) A one-year history of addiction is necessary for admission to maintenance treatment. The absence of current physiological dependence should not be an exclusion criterion, and admission is clinically justified. OTPs can accept arrest and medical records, information from significant others and relatives, and other information to document the one-year history of addiction.
- (5) Finally, there may be individuals in special populations who have a history of opioid use, who are not currently physiologically dependent. These populations include persons recently released from a penal institution; pregnant patients; previously treated patients—as listed above in the regulation—or persons recently discharged from a chronic care facility. Federal regulations waive the one-year history of addiction for these special populations because individuals in these populations are susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life-threatening consequences.
- (6) It is expected that physicians will assess every 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 by phone or fax, make the required diagnosis and admit the patient. The physician would then review and countersign the patient record within 72 hours. Standing orders for admitting patients are not acceptable.³

g. Informed Consent⁴

Each treatment program

- (1) obtains voluntary, written, program-specific informed consent to treatment from each patient at admission.
- (2) informs each patient about all treatment procedures, services, and other policies and regulations, throughout the course of treatment.
- (3) obtains voluntary, written, informed consent to the prescribed pharmacotherapy from each patient, before dosing begins.
- (4) informs each patient of the following:
 - (a) that the goal of medication-assisted treatment is stabilization of functioning;
 - (b) that, at periodic intervals, in full consultation with the patient, the provider will discuss 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.
- (5) informs each patient, at admission, about State-specific requirements and program policies regarding the report of suspected child abuse and neglect as well as other forms of abuse (e.g., violence against women).

- (6) 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).
- (7) promulgates and makes available a written description of patients' rights and responsibilities.

42 CFR 8.12(e) (4) Detoxification treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

h. Detoxification, Tapering Off of Opioid Medications or Medically Supervised Withdrawal⁵

Patients may be admitted to OTPs for “detoxification” treatment, hereinafter referred to as “medically supervised withdrawal.” “Medically supervised withdrawal” refers to a medically supervised, gradual reduction or tapering of dose of medication over time, to achieve the elimination of tolerance and physical dependence to opioid medications. “Tapering off” is sometimes used as a synonym for these terms, as well.

- (1) Voluntary supervised medical withdrawal from medication-assisted treatment—as distinct from involuntary tapering and administrative withdrawal and other types of medically supervised withdrawal—is initiated only when desired by the patient, in partnership with the physician.
- (2) If medical tapering is initiated, dosages of medication are reduced at a rate that is well tolerated by the patient and is in accordance with sound clinical judgment. For example, a dose may be decreased by 1.0 to 2.5 mg. per day for inpatients and 2.5 to 10.0 mg. per week for outpatients if medically supervised withdrawal is undertaken.
- (3) For women of childbearing potential, the results of a pregnancy test are reviewed before initiating medically supervised withdrawal of medications.
- (4) The opportunity to resume medication-assisted treatment is present in the event of actual or impending relapse.

42 CFR 8.12(f) *Required services.*--(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

i. Patient Medical and Psychosocial Assessment

The purpose of an assessment is to determine treatment eligibility, develop a treatment plan, and establish a measure for the response to treatment. For all applicants initially deemed eligible for medication-assisted treatment, a comprehensive physical examination, laboratory workup as indicated, psychosocial assessment, preliminary treatment plan, and patient orientation are completed during the initial treatment stage.

(1) Screening, Assessment and Evaluation⁶

“Screening” is the process of determining whether a prospective patient has a substance use disorder before admission to treatment. Screening usually involves use of one or more standardized techniques, most of which includes a questionnaire or a structured interview. It may include observation of known presenting complaints and symptoms that are indicators of substance use disorders (TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, p. 293).

“Assessment” is the process of identifying the precise nature and extent of a patient’s substance use disorder, and other medical, mental health, and social problems, as a basis for treatment planning. Assessment usually begins during program admission and continues throughout treatment. It includes a personal substance abuse history, physical examination, laboratory evaluation, and determination of disease morbidity. Severity of disease often is assessed further in terms of physiologic dependence, organ system damage, and psycho-social morbidity. Assessment also may involve determining patient motivation and readiness for change. (TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, p. 284).

“Evaluation” is the close examination or appraisal of a patient’s health, including the patient’s physical and mental capacity and potential.

- (a)** Patients being admitted to treatment should receive an intensive evaluation, which includes a medical and health history and physical examination, to determine initial dosage and place the patient into the appropriate level of treatment. Upon completion of proper patient consent, the program seeks medical records from other health care providers. The health history is used to determine the length of drug dependence for appropriately placing the patient and to identify other chronic or acute medical conditions that need to be addressed.

- (b)** Each program
 - (i)** determines current physical dependence and addiction. History, examination, and screening are used to determine the patient’s current degree of dependence on narcotics and, to the extent possible, the length of time the patient has been dependent on opioids. This assessment includes a physical examination for the presence of clinical signs of addiction, such as old and fresh needle marks, constricted or dilated pupils, and/or an eroded or perforated nasal septum, and a state of sedation or withdrawal. The examination evaluates the observable and reported presence of withdrawal signs and symptoms, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea.

 - (ii)** documents medical and family history. A complete medical history is documented, including current information to determine chronic or acute medical conditions, such as diabetes, renal diseases, hepatitis A, B, C, and delta, HIV exposure, tuberculosis (TB), sexually transmitted diseases (STDs), other infectious diseases, sickle-cell trait or anemia, pregnancy (including past history of pregnancy and current involvement in prenatal care), and chronic cardiopulmonary diseases. Programs complete a full medical evaluation within 14 days of treatment initiation. Physicians should be aware of potential QT-prolonging effects of methadone, especially with high doses. In addition, physicians should be aware of interactions with other medications that also have QT-prolonging properties, or with medications that slow the elimination of methadone.

- (iii) completes a psychiatric history and mental status examination with DSM- IV categorization (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision).
- (iv) completes information on the patient's family, including sex and age of children, whether children are living with parents, and family medical and drug use histories.
- (v) conducts a comprehensive evaluation by one or more disciplines that must include the following: medical, psychosocial, vocational, educational, behavioral, family, financial, legal, health, and self-care needs of the patient. This evaluation should be conducted within approximately 30 days of admission to treatment. Assessment updates and treatment plan updates should be conducted quarterly, for the first year of continuous treatment, and semiannually, for subsequent years.

(2) Medical Laboratory Evaluation/Diagnostic Criteria

Based on an individual's history and physical examination, programs evaluate the possibility of infectious disease, pulmonary, cardiac abnormalities, dermatologic sequelae of addiction, and possible concurrent surgical and other problems by conducting or referring patients for consultation and testing.

- (a) Recommended tests and assessments, as medically appropriate, include the following:
 - (i) Vital signs, including blood pressure, pulse, respirations, and temperature;
 - (ii) TB skin test and chest x-ray, if skin test is positive (including consideration for anergy);
 - (iii) Screening test for syphilis;
 - (iv) CBC and Lipid panel;
 - (v) EKG, chest x-ray, Pap smear, and screening for sickle cell disease;
 - (vi) Viral hepatitis markers, e.g., Hepatitis B surface antigen (HbsAG) and hepatitis B surface antibody (anti-HBs) HCV, etc.;
 - (vii) HIV testing and counseling;
- (c) Programs conduct an initial toxicology test as part of the admission process. Programs test admission samples for opiates, methadone, amphetamines, cocaine, marijuana, and benzodiazepines, at the minimum. Additional testing is based on individual patient need and local drug-using conditions and trends, as well as access to funding.
- (d) Other considerations include the following:
 - (i) Financial problems, transportation to referral sites, stress, and poor mental and physical well-being may be barriers to comprehensive laboratory testing upon admission. Other tests may be deferred until the patient has stabilized.
 - (ii) Patients are usually in poor physical health and require other health care. Programs without primary care onsite refer patients for laboratory tests and follow-up on results. Three months after admission is the optimal deadline for completing needed health-related procedures.

42 CFR § 8.12(f) (3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

j. Pregnant and Postpartum Patients⁷

NOTE: Although promising, the level of evidence supporting buprenorphine maintenance during pregnancy is not as high as that supporting methadone maintenance for pregnant women. As of this writing, buprenorphine is a Pregnancy Category C drug, which calls for a careful risk/benefit analysis.

- (1) The treatment program gives priority to pregnant women who seek treatment and documents the reasons for denying admission to any pregnant applicant on an intake log or in other program records that can be retrieved.
- (2) The treatment program ensures that every pregnant patient has the opportunity for prenatal care, provided onsite or by referral to appropriate health care providers. If referred, the treatment program has agreements in place, including informed consent procedures, which ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care.
- (3) If appropriate prenatal care is not available onsite or by referral or 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, and documents the provision of these services in the clinical record.
- (4) 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 these services were offered but refused.
- (5) For pregnant women in methadone treatment, the program
 - (a) maintains patients who become pregnant during treatment on the pre-pregnancy dosage, if effective, and applies the same dosing principles as used with any other non-pregnant patient.
 - (b) ensures 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.
 - (c) monitors 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 may necessitate either an increased or split dose.
 - (d) ensures that if a pregnant patient elects to withdraw from methadone, a physician experienced in addiction medicine supervises the withdrawal process; regular fetal assessments as appropriate for gestational age are part of the withdrawal process; and withdrawal is not initiated before 14 weeks' or after 32 weeks' gestation.
- (6) The program encourages breast-feeding during methadone treatment, unless medically contraindicated, e.g., by the presence of HIV or HTLV I and II infection in the mother.

- (7) 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 patient agreement to receive treatment as well as agreement to release information to and obtain information from pertinent health care providers.
- (8) If a pregnant patient is discharged, the program will identify the physician to whom the person served is being discharged. The name, address, and telephone number of the physician should be recorded in the record of the person served.

k. Concurrent Pregnancy and HIV Infection

- (1) Pregnant women in methadone 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.
- (2) Treatment programs offer pregnant patients with HIV diagnoses the same treatment opportunities and services, directly or by referral, as HIV-diagnosed patients who are not pregnant.
- (3) Treatment programs 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.

l. Neonatal Abstinence Syndrome

Infants prenatally exposed to opioids have a high incidence of neonatal abstinence syndrome, characterized by hyperactivity of the central and autonomic nervous systems that is reflected in changes in the gastrointestinal tract and respiratory system. Withdrawal symptoms may begin at any time from minutes or hours after birth, to 2 weeks later, but most appear within 72 hours. Infants with this syndrome may engage in frantic sucking behaviors, but may have difficulty feeding because their sucking reflex is uncoordinated.

Programs ensure that mothers who have infants who may be susceptible to neonatal abstinence syndrome seek comprehensive evaluation and treatment for the infant. A medical evaluation is important because various other conditions may mimic neonatal abstinence syndrome, such as hypoglycemia, sepsis, and neurological illnesses. Treatment may include pharmacological management. (TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, pp. 218–219.)

42 CFR § 8.12 (f) (4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

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

(1) Treatment Considerations Related to the Natural History of the Disease

The clinical assessment of all patients should take into account the natural 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. **Treatment tasks are determined in relation to the patient's stage in the disease.**

The stages of medication-assisted 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: consisting of intensive assessment and intervention, from 3 to 7 days in duration.
- (b) Early stabilization: from the third to seventh day of treatment through 8 weeks.
- (c) Long-term treatment: from the end of early stabilization for an indefinite period of time in either a program setting or in an office-based setting.
- (d) Medically supervised withdrawal with continuing care, if and when appropriate.
- (e) Immediate emergency treatment: provision of medication-assisted treatment in situations where access to a comprehensive treatment program is not feasible (e.g., emergency room, detention center, Acquired Immune Deficiency Syndrome [AIDS] hospice, inpatient hospital unit) or for conditions such as pregnancy, HIV-spectrum disease, or other illnesses and psychiatric problems.

The patient's response to treatment determines her or his progression through the stages of treatment. Some patients may remain in one stage for a considerable period of time while, in contrast, others may progress very quickly. It is not uncommon for a patient to relapse. There is both an individual and public health advantage to maintaining a patient on medication, even when psycho-social treatment may not be yielding optimum results.

Pharmacotherapy may benefit the individual patient even when he or she does not appear to be benefiting from other clinic services. Additionally, pharmacotherapy may benefit the patient who no longer needs ancillary services.

(2) Intensity and Duration of Treatment

- (a) In general, a greater intensity of services is desirable at the beginning of treatment.
- (b) Psychosocial services are often needed by many patients for an extended period of time because of the multiplicity of their problems.
- (c) For long-term opiate addiction treatment, many patients need continuing medication, with or without psychosocial services, as outlined in TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*.
- (d) There are no limits on the duration or the dosage level of medication, unless clinically indicated. Likewise, there are no limitations on psychosocial services offered even when patients are receiving "0" dose levels.

(3) Retention in Treatment⁸

- (a) Programs and individual practitioners make every effort to retain patients in treatment as long as clinically appropriate, medically necessary, and acceptable to the patient.
- (b) Appropriate therapeutic measures are taken to address the other problems identified in the treatment plan.

(4) Voluntary Patient Relocations and Program Transfers⁹

When a patient relocates and/or transfers to another treatment program, the original treatment program ensures that the patient makes a smooth transition and attempts to avoid breaks in treatment that could lead to relapse.

(5) Relapse Prevention

- (a) Psycho-social treatment continues for patients electing to discontinue pharmacotherapy.
- (b) If possible, clinics and individual practitioners track patients and reinstitute pharmacotherapy at the first sign of relapse or impending relapse (see “Support of Medical Withdrawal,” below).
- (c) Some patients progress into long-term pharmacotherapy and no longer need psycho-social services. If the need for psycho-social services reemerges, however, programs provide the opportunity to return to full services.

n. Administrative Withdrawal and Discharge

A major goal for programs is to retain patients for as long as they can benefit from treatment and express a desire to continue it. Since this is not always possible, programs provide two types of procedures for medically supervised withdrawal from medication—voluntary medically supervised withdrawal and administrative withdrawal. Voluntary medically supervised withdrawal is conducted at the patient’s request, in consultation with the physician. In contrast, administrative withdrawal is usually involuntary. However, when a patient must be administratively discharged from pharmacotherapy, the program offers a humane schedule of medically supervised withdrawal using sound clinical judgment. A suggested medically supervised withdrawal schedule for administrative withdrawal is generally a minimum of 30 days, but may be adjusted depending on clinical factors. The person’s condition during medically supervised withdrawal is periodically recorded in the patient’s record. Upon discharge, appropriate alternative referrals are made. Given the short time frame and poor prognosis for the withdrawal procedure, patient referral or transfer to a suitable alternative treatment program is the preferred approach.

- (1) Administrative withdrawal may result from
 - (a) nonpayment of fees. Remedies may include referral to a more affordable treatment program. As a last resort, programs provide a humane schedule of medically supervised withdrawal.
 - (b) disruptive conduct or behavior. Such behaviors are considered to 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 violence, credible threat of violence, dealing drugs, repeated loitering, and flagrant noncompliance resulting in an observable, negative impact on the program, staff, and other patients. Programs should consider a mental health explanation for the disruptive behavior and make an appropriate referral prior to administrative withdrawal.
 - (c) incarceration or other confinement.
- (2) The opioid treatment program follows due process procedures for any involuntary terminations of patients.
- (3) Efforts should be documented regarding referral or transfer of the patient to a suitable alternative treatment program.

o. Medically Supervised Withdrawal from Medication¹⁰

- (1) Medically supervised withdrawal is conducted
 - (a) as a voluntary and therapeutic process, agreed upon by staff and patient, or
 - (b) in response to the request of the patient, against the advice of the physician, counselor, and other staff; that is, against medical advice (AMA).
- (2) Voluntary medically supervised withdrawal—as distinct from involuntary withdrawal and administrative withdrawal and other types of withdrawal—is initiated only when desired by the rehabilitated patient, in partnership with the physician.
 - (a) If medically supervised withdrawal is initiated, dosages of medication are reduced at a rate that is well tolerated by the patient and in accordance with sound medical practices.
 - (b) For women of childbearing potential, the results of a pregnancy test are reviewed before initiating medically supervised withdrawal.
 - (c) Medication-assisted treatment is resumed in the event of impending relapse.

(3) Support of Medically Supervised Withdrawal

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

- (a) Dose reduction occurs at a rate consistent with good clinical judgment.
 - (b) A variety of supportive options is available to improve chances of a successful episode of medically supervised withdrawal.
 - (c) Increased counseling is available prior to discharge.
 - (d) Participants are encouraged to attend a self-help program that is sensitive to the needs of patients receiving medication-assisted treatment.
- (4) Additional Considerations for Medically Supervised Withdrawal Against Medical Advice (AMA)**
- (a) The patient has the right to leave treatment when he or she chooses to do so. The program explains the risks of leaving treatment and offers information about or referral to alternative treatment options.
 - (b) The physician, in consultation with the patient, determines the schedule for medically supervised withdrawal from medication-assisted treatment.
 - (c) In the case of a patient who leaves a program abruptly, the program may readmit the patient within 30 days without a formal reassessment procedure.
 - (d) The program documents the issue that caused the patient to seek discharge and provides a full documentation of steps taken to avoid discharge.
 - (e) If medically supervised withdrawal fails, consideration should be given to maintenance treatment.

p. Continuing Care

- (1) Continuing care is considered an essential part of treatment and includes discharge planning and relapse prevention.
- (2) Continuing care also includes procedures that address patients' physical and mental health problems following medically supervised withdrawal from medication-assisted treatment, including the need for counseling and appropriate medication to help with sleep disorders, depression, and other problems.
- (3) Provisions are made for continuing care following the last dose of medication, including making a referral for continuing outpatient care and planning for re-entry to maintenance treatment if relapse occurs.

q. Additional Treatment Planning Considerations**(1) Management of Co-occurring Disorders**

When possible, co-occurring disorders are concurrently managed onsite. This includes management of multiple drug use problems as well as psychiatric and medical disorders. Coexisting conditions, especially in patients from disenfranchised populations, are most effectively treated at a single site.

(2) Alcohol and other Drug Abuse

- (a) Concurrent abuse of other drugs is managed within the context of the medication-assisted treatment effort following principles described in TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*.
- (b) Program staff members are knowledgeable about current effective strategies for treating alcohol, cocaine, and other drug abuse.
- (c) Ongoing multi-drug use is not necessarily a reason for discharge. Patients engaging in such multi-drug use must be carefully evaluated to determine the most therapeutic course of treatment, in light of the fact that many patients (and communities) continue to benefit from medication-assisted treatment even when the patients are not fully abstinent from all drugs of abuse. In addition, the patient's condition and the best clinical judgment of the treatment team also must be taken into account. Efforts should be made to coordinate care with providers outside the opioid treatment program who may prescribe medication with abuse potential.

(3) Care of Patients with Mental Health Needs

- (a) Programs ensure that patients with mental health needs are identified through the assessment process and referred to appropriate treatment.
- (b) Program discharge procedures ensure that patients are monitored during withdrawal for emergence of symptoms of mental illness.
- (c) Programs establish and use linkages with mental health providers in the community.
- (d) Programs establish a mechanism to evaluate mental health medication jointly with the mental health provider. If possible and if indicated, programs may even dispense such medications in conjunction with the daily dose of opioid medication.

(4) HIV Testing and Care of HIV-Positive Patients

- (a) Programs develop and implement a plan for educating patients about HIV/AIDS, testing procedures, confidentiality, reporting, follow-up care, counseling, safer sex, social responsibilities, and sharing of intravenous equipment.
- (b) Programs offer HIV-positive patients options to balance medication-assisted treatment and HIV/AIDS care and treatment. Programs pay special attention to drug/drug interactions.
- (c) Programs establish and use linkages with HIV/AIDS treatment programs in the community and any harm reduction strategies available in the community. These linkages should facilitate systems that continue opioid medication for debilitated patients and may include collaboration or transfer of care to primary physicians when AIDS becomes the primary health concern.

(5) Treatment Considerations for Viral Hepatitis

- (a) Patients who test positive for viral Hepatitis should be referred for further evaluation and treatment, if necessary.
- (b) Staff should demonstrate knowledge about viral Hepatitis and its' effect on the health of the patient. It is especially important that staff members receive education about hepatitis C because it is the most common blood-borne virus among intravenous drug users.

(6) Treatment Considerations for Smoking Cessation

Treatment programs address smoking cessation with patients as an integral part of their treatment.

(7) Patients Who Experience Pain¹¹

(a) Pain Management in Maintenance Patients

- (i) For the patient in medication-assisted treatment, management of chronic pain may include referral for consultation with a specialist in pain medicine, when possible and appropriate.
- (ii) For the patient in medication-assisted treatment, management of acute pain entails
 - continuation of the regularly scheduled dose of medication.
 - additionally prescribing adequate doses of appropriate medications, including short-acting opioid medications.

(b) Other Principles of Pain Management

- (i) Programs should make careful diagnostic distinctions between the physical dependence associated with chronic administration of opioids for relief of pain and the disease of opioid addiction. Apparent drug-seeking behaviors, typically associated with the disease of chronic opioid addiction, may occur as a response to inadequately treated or prolonged pain (“pseudo-addiction”).
- (ii) Generally, patients are not admitted to medication-assisted treatment to receive opioids only for pain.

- (iii) Patients with a **chronic pain disorder and addiction** should be managed by multidisciplinary teams that include pain and addiction medicine specialists. The site of such treatment may be either in a medical clinic or in an opioid treatment program, depending on patient need and the best utilization of available resources.
- (iv) Patients who are diagnosed with physical dependence and a pain disorder are not prohibited from receiving medication-assisted treatment for either maintenance or medically supervised withdrawal in a program setting. Similarly, addiction patients in medication-assisted treatment are not prohibited from receiving medication-assisted treatment as well as adequate doses of opioid analgesics.

(8) Cultural Competency

- (a) Programs 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.
- (b) Programs are sensitive to the culture and values of the persons being treated.
- (c) Programs ensure that persons in positions of authority are professionally and culturally competent. (For example, these persons should be able to work effectively with the local community and/or receive input from advisors or committee members in the local community in terms of gender, ethnicity, and language or are representative of it.)
- (d) Unbiased language is used in print materials, electronic media, and course offerings.
- (e) As appropriate, treatment is offered in groups organized by special needs (e.g., gender, sexual minority, seniors, and Spanish language).

(9) Care of Adolescents in Treatment

- (a) Programs tailor assessments to the developmental stage of the patient.
- (b) Programs develop and implement policies to ensure that adolescents are not harassed or exploited by older patients or staff.

(10) Criminal Justice Issues

- (a) Programs develop procedures to coordinate with agents of the criminal justice system on behalf of patients.
- (b) Programs communicate and cooperate with the criminal justice system in a way that advocates for continuous treatment of incarcerated patients as well as those on probation or parole.

(11) General Principles Regarding Care of Women in Treatment

- (a) The policies and procedures of each treatment program reflect the specific needs of female patients.
- (b) Treatment programs make provisions to provide respectful and safe treatment of women.
- (c) The use of physical space, including restrooms, reflects the special needs of female patients.

- (d) All staff members receive intensive training in the specific characteristics and needs of women participating in their particular treatment program.
- (e) Program policies ensure appropriate clinical flexibility in assigning female patients to counselors who are sensitive to and trained to address their individual needs (e.g., domestic violence, sexual abuse).
- (f) Program policies and procedures ensure that the option of single sex groups is available to all patients, as needed.

(12) Family Needs

- (a) Treatment programs provide opportunities for involvement of family and significant others in therapy.¹²
- (b) The treatment program offers onsite education and training for all male and female parenting patients, or refers patients to appropriate parenting skills services, and makes appropriate child care services available.
- (c) Program services include reproductive health education for all patients and appropriate referrals, as needed, for contraceptive 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 offer referrals to appropriate resources and/or parenting support groups (TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*).

(13) Alternative Therapies

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

42 CFR § 8.12(f) (5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients either who request such services or who have been determined by the program staff to be in need of such services.

r. Concurrent Services

(1) Orientation to Treatment¹³

Patients receive orientation to treatment initially, and receive ongoing education about:

- (a) signs and symptoms of overdose and when to seek emergency assistance;

- (b) the medication they are taking, including side effects and common myths about the medication or modality of treatment;
- (c) the nature of addictive disorders;
- (d) the benefits of treatment and nature of the recovery process, including phases of treatment;
- (e) clinic guidelines, rules, and regulations, including the requirement to sign a formal agreement of informed consent and fees and billing procedures;
- (f) noncompliance and discharge procedures, including administrative medication withdrawal;
- (g) patient's rights;
- (h) confidentiality;
- (i) toxicology testing procedures;
- (j) dispensing of medication;
- (k) HIV-spectrum and other infectious diseases;
- (l) potential drug interactions.

(2) Substance Abuse Counseling

Appropriately trained, experienced, and qualified substance abuse counselors provide services of the intensity and duration required to meet the individual needs of the patient population. Staffing patterns are determined by the characteristics and needs of a particular patient population. Likewise, patient-to-staff ratios are sufficient to ensure reasonable and prompt access to counselors by patients, and to provide the frequency and intensity of counseling services required.

(3) Self-Help Groups

The use of self-help groups is encouraged but not required in pharmacotherapy. Traditional self-help groups are sometimes unfamiliar with maintenance patients. Programs can establish their own self-help programs or identify those groups that are accepting of maintenance pharmacotherapy.

(4) Counseling on HIV Disease¹⁴

- (a) Programs provide counseling on HIV disease, other prevalent infectious diseases, and their prevention for every at-risk patient.
- (b) Programs provide risk reduction education to patients.

(5) Medical Services

Providing basic primary care, onsite in clinics or in the individual practitioner's office, is highly recommended but not required. Referrals for medical and psychiatric treatment shall be made when indicated. Coordination of care also should be provided, and those staff responsible for making linkages should be knowledgeable about pharmacotherapy treatment (e.g., drug interactions, acute withdrawal, and overdose). Medications that have their effectiveness enhanced by directly observed therapy (DOT)—such as tuberculosis medications and psychiatric medications—can be effectively

dispensed with the daily opioid dose. Likewise, psychotropic medications, which are indicated but subject to abuse, may be given through DOT.

42 CFR § 8.12(f)(6) 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, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

s. Testing for Drug Use

- (1) Drug and alcohol screening and testing are used as aids in monitoring and evaluating a patient's progress in treatment, within a context that assesses a variety of outcomes.
- (2) All treatment personnel in a medication-assisted treatment program understand the benefits and the limitations of toxicological testing procedures.
- (3) Programs collect all urine or other toxicological specimens in a therapeutic context that suggests trust and respect and minimizes falsification. Reliance on direct observation, although necessary for some patients, is neither necessary nor appropriate for all patients.
- (4) Drug testing should be determined by community drug use patterns and individual medical indications. This may include, but is not limited to: opiates, benzodiazepines, barbiturates, cocaine, marijuana, methadone (and its metabolites), amphetamines, and alcohol.
- (5) It is also strongly recommended that barbiturates and alcohol be included in drug screening and testing panels. Alcohol is the most widely used mood-altering substance in the United States and barbiturates are often prescribed for detoxification and chronic seizure disorders. Detection of barbiturates or alcohol is important in ongoing assessment, treatment planning, and medication management.
- (6) Workplace standards for drug testing are not appropriate in the treatment context.
- (7) Program staff addresses results of toxicology testing with patients promptly. Programs document in the patient record both the results of toxicology tests and follow-up therapeutic actions.
- (8) After admission drug testing, the frequency of toxicological testing is determined by the clinical appropriateness for each individual patient and related to the stage of treatment.
- (9) The results of toxicological tests assist clinical staff in making treatment decisions regarding take-home medication privileges; however, clinical decisions about take-homes or discharge are not based on toxicology test reports solely.
- (10) Rapid intervention should be used to address the disclosure of illicit drug use or possible diversion of opioid medication, as evidenced by lack of opioids or such metabolites in drug toxicology tests.
- (11) Consideration should be given to confirming the results of drug screening tests with additional testing. Treatment programs 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*, Chapter 9.

42 CFR § 8.12 (g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

t. Record Keeping and Documentation¹⁵

All records required by the CSAT “Guidelines for the Accreditation of Opioid Treatment Programs” should be retained for a minimum of 3 years.

(1) Patient Records

Patient records are confidential and updated in a timely manner. They contain legible entries, and are organized in a manner that facilitates access to specific elements of the record, as well as measurement of individual patient treatment outcomes. Programs should have record retention policies and safeguards for the destruction of old containers, labels, printouts, and clinic records. Programs' procedures should ensure security of electronic transfers and protection of confidential data stored in computers.

Individual records maintained for each patient contain the following:

- (a) Identifying and basic demographic data and results of the screening process. In lieu of identification data, each file may bear a unique code or identification reference designation that gives ready and sure access to such required identification information. All information should be accessible and understandable to appropriate authorities.
- (b) Documentation of compliance with the approved central registry system (if applicable) or an alternative mechanism to avoid dual registration.
- (c) The initial assessment report.
- (d) Narrative bio-psychosocial history, prepared within approximately 30 days of the patient's admission or as required by State regulation.
- (e) Medical reports, including results of physical examination; past and family medical history; review of systems; nursing notes; laboratory reports, including results of regular toxicology screens; and progress notes, including documentation of current dose and other dosage data. Information in the medical record is entered by physicians and other licensed health professionals.
- (f) Dated case entries of all significant contacts with patients, including a record of each counseling session in chronological order.
- (g) Dates and results of case conferences for patients.

- (h) The treatment plan, and any amendments to it; quarterly reviews and updates of the assessment and treatment plan for the first year of continuous treatment; semiannual assessment and treatment plan updates for subsequent years; and, in subsequent years, a semiannual summary by the counselor that includes an evaluation of the existing treatment plan and the patient's response to treatment.
 - (i) Documentation that all services listed in the treatment plan are available, and actually have been provided.
 - (j) A written report of the process and factors considered in decisions impacting patient treatment (e.g., take-home medication privileges, changes in counseling sessions, changes in frequency of urine tests) or any other significant change in treatment, both positive and negative.
 - (k) A record of correspondence with patient, family members, and other individuals, and a record of each referral for service and its results.
 - (l) Documentation that the patient was provided with a copy of the program's rules and regulations and a statement of patients' rights and responsibilities, and that these items were discussed with her or him.
 - (m) Consent forms, release(s) of information, prescription documentation, travel, employment, and "take-home" documentation, etc.
 - (n) A closing summary, including reasons for discharge and any referral. In the case of death, the cause of death is documented.
- (2) Records of Storage, Dispensing, and Administering Opioid Medication**
- (a) Each program has policies and procedures consistent with DEA statutes and regulations.
 - (b) Each medication order and dosage change is written on an acceptable order sheet signed by the physician.
 - (i) Each dosage dispensed, prepared, or received is recorded and accounted for by signed notation, in a manner that creates a perpetual and accurate inventory of all medications, 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 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 appears at the end of each page of the medication sheet.
 - (v) The substance is totaled in milligrams daily.
 - (c) Programs have a procedure for calibrating medication dispensing instruments, consistent with manufacturers' recommendations, to ensure accurate patient dosing and substance tracking.

(3) Other Records

- (a) Programs maintain individualized personnel files as a record of employment. These files contain employment and credentialing data deemed appropriate by the employer. It is recommended that they contain employment application data, date of employment, updated licensing and credentialing data, detailed job descriptions, performance evaluations, and appropriate intramural and extramural training records.
- (b) Programs develop and implement procedures to avoid duplication of information gathering without compromising objectives of multiple agencies.

(c) Avoiding Multiple Program Enrollments

- (i) Reasonable measures are taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. These measures are commensurate with the severity of the problem and its documented consequences. In some cases, an OTP may, after obtaining patient consent, contact other OTPs within a reasonable geographic distance (100 miles) to verify that a patient is not enrolled in another OTP.
- (ii) Programs should be encouraged to participate, when applicable, in central registries designed and implemented by some States. The program should participate in registries in a manner consistent with confidentiality regulations.

42 CFR §8.12(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

(i) Methadone; and

(ii) Levomethadyl acetate (LAAM);

(iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid addiction.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

NOTE: The provision of medication-assisted treatment with Subutex[®] and Suboxone[®] in OTPs does not require a DATA 2000 waiver. Additionally, such treatment is not subject to the 30-patient limit that applies to individual physicians providing medication-assisted treatment outside the OTP system, under the authority of a DATA 2000 waiver. The provision of medication-assisted treatment with Subutex[®] or Suboxone[®] in treatment settings other than OTPs, even by physicians who are licensed to practice in OTPs, does require a DATA 2000 waiver and is subject to the 30-patient limit for individual physicians.

A physician with a DEA X-waiver who also works in an OTP may issue a prescription for Subutex[®] and Suboxone[®] in accordance with the 30-patient limit.

u. Guidelines for Therapeutic Dosage¹⁶

(1) General Dosage Principles

- (a) The physician employs clinical judgment to determine the individual dose of opioid medication. The physician should have been granted program treatment privileges and be knowledgeable about, and experienced in, addiction medicine, including medication-assisted treatment.¹⁷
- (b) Maintenance medication doses are sufficient to produce the desired response in the patient for the desired duration of time, with allowance for a margin of effectiveness and safety.
- (c) When necessary to withdraw the patient from opioid treatment, the tapering protocol will be of sufficient duration for patient safety.
- (d) Program-wide dose caps or ceilings run contrary to the principle of individualized treatment, and programs should not establish them. Program procedures or policies that hinder making patient dosage adjustments whenever indicated should be minimized.
- (e) Effective therapy involving medication-assisted treatment has the following desired outcomes:
 - (i) preventing the onset of subjective and/or objective signs 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 any illicitly acquired, self-administered opioids, without inducing undesirable effects that are experienced by the patient or noticed by other observers.

(2) Maintenance Therapy

- (a) A medical evaluation, including documented history and physical examination, support the judgment by the physician and/or appropriately licensed practitioner that the patient is a suitable candidate for opioid therapy.
- (b) The initial full-day dose of medication is based on the physician's evaluation of the history and present condition of the patient, with added knowledge of local conditions such as the relative

purity of available street drugs. Medication dosage is also based on the physician's assessment and evaluation of other medications that the patient reports taking, including over-the-counter drugs, prescription medications, and prescription medications containing controlled substances.¹⁸

- (c) The first dose of any opioid treatment medication should be lower if a patient's opioid tolerance is believed to be low, the history of opioid use is uncertain, or no signs of opioid withdrawal are evident. Regulations stipulate that the initial dose of methadone should not exceed 30 milligrams. Reasons for exceeding an initial dose of 30 mg need to be considered carefully. These reasons should be documented in the clinical chart and the dose should not exceed 40 mg/per day, unless the physician documents in the patient's record that 40 mg did not suppress opiate abstinence symptoms after a 3-hour period of observation. Patients abusing diverted medical opioids alone may require a lower initial dose of methadone, and should have the initial dose of methadone based on standard dose conversion tables and their recent amount of opioid intake. During the induction phase, caution should be exercised regarding overly rapid increase in dosage due to the long half-life of methadone. As a suggestion, based on clinical symptoms, once the patient reaches a dose of 60 mg, it may be medically indicated to maintain a stable dosage amount for three to five days before further increasing the dosage.
- (d) Initial dosing of buprenorphine or LAAM and other approved medications should be based on the package insert. Deviations from this must be documented by the physician.
- (e) The total dose of medication and the interval between doses may require adjustments for patients who have concurrent health conditions, atypical metabolism patterns, or are prescribed other concurrent medications that alter rates of opioid medication metabolism.
- (f) Medication doses should not be adjusted to reinforce positive behavior or to punish negative behavior. For example, a patient's noncompliance with a treatment plan, including a positive toxicology screen, should not necessarily result in a decreased dosage. In fact, in certain circumstances this may indicate the need for an increased dosage.
- (g) Medication-assisted treatment is continued as long as benefit is derived from treatment and the treatment is desired by the patient. There should be no fixed length of time in treatment; in fact, indefinite medication-assisted treatment may be clinically indicated. It may be prudent during the course of treatment that other medications be considered, as clinically indicated.
- (h) Doses of medication are adjusted as needed if a program switches from one generic formulation to another, and differences in effective dose cause clinically relevant complaints. Additionally, physicians should exercise caution when a patient has missed several doses because patient tolerance might have changed.
- (i) The program should have the capability to obtain medication blood levels when clinically indicated.

42 CFR §8.12 (h) (4) (i) Unsupervised or "take-home" use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

- (i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;
 - (ii) Regularity of clinic attendance;
 - (iii) Absence of serious behavioral problems at the clinic;
 - (iv) Absence of known recent criminal activity, e.g., drug dealing;
 - (v) Stability of the patient's home environment and social relationships;
 - (vi) Length of time in comprehensive maintenance treatment;
 - (vii) Assurance that take-home medication can be safely stored within the patient's home; and
 - (viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.
- (3) Such determinations and the basis for such determinations, consistent with the criteria outlined in paragraph (i) (2) of this section, shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:
- (i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.
 - (ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i) (1) of this section) is two doses per week.
 - (iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i) (1) of this section) is three doses per week.
 - (iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.
 - (v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.
 - (vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.
- (4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.
- (5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 et seq.)).

v. Unsupervised Approved Use (Take-Home Medication)

(1) Approving Take-Home Medication

- (a)** In determining patient eligibility for take-home medication, programs consider the eight-point criteria using good clinical judgment.

Providing medication for unsupervised use is a reflection of the physician's judgment and staff's assessment of a patient's behavior while in treatment. Time in treatment is also an important factor. Take-home medication is a valuable therapeutic tool and is part of an individualized treatment plan. Program policies that do not permit take-homes for any patients are unacceptable as these policies would preclude individualized patient care. Take-home medication often becomes a critical issue with patients who are deciding whether to enter and remain in treatment. Program staff members use discretion in customizing medication schedules for each patient, according to that patient's best interests. Public health issues should be considered in approving take-home medication (e.g., preventing diversion, ensuring safe storage and security of medication, preventing overdoses). Staff should ensure that policies for approval of take-home medication do not create barriers for patients continuing in treatment. Program policies foster

decisions about entering and remaining in medication-assisted treatment that are based on medical factors.

A multidisciplinary team, typically led by the primary clinician, provides recommendations and essential input for review, while a physician makes the final decision about approving take-home medication. Decisions should be reviewed periodically, as clinically appropriate and documented in the patient record. The review should consider the eight-point criteria and other relevant clinical factors. The physician's conclusions on this review should be noted in the record.

- (b) Programs should exercise caution when dispensing Subutex; Suboxone is the preferred medication for take-home prescriptions unless otherwise clinically indicated.
- (c) Temporary (usually not to exceed three days) take-home medication may be approved for documented family or medical emergencies or other exceptional circumstances.

(2) Monitoring Unsupervised Use of Medications¹⁹

- (a) Treatment programs monitor patients' dispensed take-home medications in a manner that complies with Federal regulations.
- (b) Program policies enable a physician to evaluate a patient's stability and response to take-home medication and to adjust dosages at regular intervals.

(3) Medication Security²⁰

- (a) Program policies ensure responsible handling and secure storage of take-home medication in childproof containers.
- (b) Programs inform patients of their rights and responsibilities in ensuring the security of opioid medications.
- (c) Programs shall establish a mechanism for monitoring medications to prevent diversion.

z. Patients' Rights

(1) Program Responsibilities

- (a) Program administration obtains and is responsive to patients' feedback concerning their care.
- (b) Programs develop and implement policies and procedures to promote and protect patients' rights as well as their health and well-being.
- (c) Programs must inform patients, both verbally and in writing, of clinic rules and regulations and patients' rights and responsibilities.
- (d) Programs establish procedures to cooperate in the medicating of traveling patients.

(2) Patients' Rights and Responsibilities²¹

- (a) Informed Consent and Information Disclosure**

- (i) Patients have the right to receive accurate, easily understood information, and some require assistance in making informed health care decisions about their health plans, professionals, and facilities.
- (ii) At the time of admission, each patient is informed of patients' rights and responsibilities and of the program's rules and regulations regarding patient conduct, in a language that the patient understands. Patients who are unable to read have the rules and regulations explained verbally, and such actions documented. The patient receives a written copy of these rights, including the following information:
 - Treatment provided will be fair and impartial regardless of race, sex, age, source of payment, etc., and will convey a sense of dignity and trust between program and patient.
 - Treatment will be provided according to accepted clinical practice and community standards of care.
- (iii) Patients' rights and responsibilities are posted at the treatment site and are reviewed with the patient following admission, at the end of the stabilization period, and when any changes have been made to the list of rights and responsibilities.

The patient will be offered a written acknowledgement to sign, indicating that patients' rights and responsibilities and the program's rules and regulations have been explained. In the event the patient declines to sign this acknowledgement or expresses concerns, staff members should document the interaction.

- (iv) Patients have the right to full disclosure of information about treatment and medication, including accommodations for those who do not speak English, or who are otherwise unable to read an informed consent form.
- (v) Patients will be informed about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures, and food.
- (vi) Patients will be informed regarding the financial aspects of treatment, including the consequences of nonpayment of required fees.
- (vii) 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) Choice of Treatment, Providers, and Plans

- (i) Patients have the right to a choice of health care providers that is sufficient to ensure access to appropriate high-quality health care.
- (ii) Patients will be given an assessment, acceptance into the program or, in the case of denial of admission, a full explanation and a referral to another program, based upon the results of the initial assessment.

- (iii) Patients will receive services within the least restrictive and most accommodating environment possible. Procedures are in place to ensure that patients are provided a medication schedule (dosing times/program hours) that is most accommodating and least intrusive and disruptive for **the majority of** patients.
- (iv) Patients will receive an individualized treatment plan, participate in the development of that plan, and receive treatment based on the plan. Periodically, the patient and staff will review of the treatment plan jointly.
- (v) The program will provide an adequate number of competent, qualified, and experienced professional clinical staff to implement and supervise the treatment plan, consistent with patient needs.
- (vi) Patients will be informed about alternative medications, treatment alternatives, alternative modalities, and scientific advances affecting treatment.

(c) Access to Emergency Services

Patients have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a patient presents to an emergency department with acute symptoms of sufficient severity—including severe pain—such that a “prudent layperson” could reasonably expect the absence of medical attention to result in placing that patient’s health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any body organ or part.

(d) Participation in Treatment Decisions

Patients have the right and responsibility to participate fully in all decisions related to their health care. Patients who are unable to participate fully in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators.

(e) Respect and Nondiscrimination

Patients have the right to considerate, respectful, humane, and adequate care from all members of the health care system, at all times, and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.

Patients must not be discriminated against in the delivery of health care services, consistent with the benefits covered in their policy or as required by law, based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Programs have the responsibility to protect other patients, staff, and the public from a patient who acts out. However, programs also have a responsibility to determine the cause of that behavior so an appropriate referral to an alternative method of care can be made.

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

(f) Confidentiality of Health Information and Patient Privacy²²

Patients have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Patients also

have the right to review and copy their own medical records and request amendments to their records.

Patients have a right to privacy, both inside and outside the program setting.

Patients have the right to confidentiality in accordance with Federal rules on confidentiality of medical records (42 CFR Part 2) and HIPAA (45 CFR Part 160 and Subparts A and E of part 164).

Patients have the right to be informed of the extent and limits of confidentiality, including the conditions under which information can be released without patient consent, the use of identifying information for purposes of central registry, program evaluation, billing, and statutory requirements for reporting abuse.

(g) Complaints and Appeals

- (i)** All patients have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.
- (ii)** Patients will be encouraged and assisted throughout treatment to understand and exercise their rights as a patient, including,
 - reporting, without fear of retribution, any instances of suspected abuse, neglect, or exploitation of patients being served in the program;
 - a grievance and appeal process, in accordance with State laws and regulations;
 - input into program policies and services through patient satisfaction surveys.

(iii) Preventing, Investigating, and Resolving Patient Complaints

Programs develop and in the patient care area, display policies and patient grievance procedures that specify minimum elements of due process applicable to the program setting and resources, including the following:

- The right of patients to express verbally or in writing their dissatisfaction with or complaints about treatment received.
- The right to initiate grievance procedures.
- The right to be informed of the grievance procedures in a manner that can be understood, and a right to a copy of the procedures upon request. Such procedures should be clearly articulated, well publicized, posted in conspicuous places within the program, and easily available to patients. They include program rules, consequences of noncompliance, and procedures for filing a complaint and/or grievance.
- The right to receive a decision in writing, with the reasoning articulated.
- The right to appeal the decision to a final, unbiased source.

- The responsibility of the program to make every attempt, before a patient is discharged, to accommodate the patient's desire to remain in opioid-therapy at an alternative treatment program.
- The use of involuntary withdrawal, only as a sanction of last resort that is accomplished in the most humane manner and consistent with the safety and well-being of staff, other patients, and the program.
- The patient's dose of opioids or other medications shall not be changed without the patient's knowledge unless the patient signs a document waiving such consent.

(h) Patient Responsibilities

In a health care system that protects patients' rights, it is reasonable to expect and encourage patients to assume reasonable responsibilities. Greater individual involvement by patients in their care increases the likelihood of achieving the best outcomes and helps support a quality improvement, cost-conscious environment.

3. References

1. **Critical Incidents or Sentinel Events:** The specific events or incidents requiring preventive action, documentation, investigation, and corrective action will vary by program and patient characteristics. Such significant incidents or adverse events might include accidental injury on the premises, medication errors, patient deaths, harm to family members or others from ingesting a patient's medication, selling drugs on the premises, medication diversion, harassment or abuse of patients by staff, and violence. An accreditation organization should consider making an unannounced visit to a treatment program if it determines that an adverse event involves immediate threat to the care or safety of an individual, the adverse event is believed to indicate the possibility of serious operational or personnel problems in the treatment program, there has been more than one serious adverse event in 6 months, or the adverse event has the potential to undermine public confidence in the treatment program.
2. **Community Relations:** Before a new program moves in and opens its doors, there is a strong need to educate all entities impacted by the program, including the medical community, neighbors, and those who will be asked to provide support services.
3. **“Standing Orders”:** In some disciplines of medicine, *standing orders* traditionally referred to a practice in which dosing or admission decisions were based upon an algorithm that included objective findings, time in treatment, and other factors—usually delegated to a nurse or other ancillary health professional. Sometimes, program physicians issued standing orders that stated that dose levels be adjusted on a PRN (“as needed”) basis. These types of standing orders do not reflect individualized care and are unacceptable.
4. **Risk Management and Continuous Quality Improvement:** Many States already require written consent for all types of medical care. This is essential in a climate of increasing patient litigation and questions from insurers. Requests from managed care groups for treatment records, which are needed to recertify patients for payment, require strict attention to Federal confidentiality regulations. Ethical conduct by staff and the program also requires attention and use of specific expectations and standards. Carefully specified grievance procedures are imperative and must be followed in all involuntary termination procedures. The currency of staff credentials may become a legal issue if someone is not properly licensed at the time of an incident or other adverse action.
5. **Tapering Medication Dosage or Medically Supervised Withdrawal:** Methadone should not be considered to be a “toxic” substance, and, from a medical perspective, *detoxification* is not an accurate term to use. These guidelines focus on patients who have been participating in medication maintenance treatment, instead of on issues of medical withdrawal (short- and long-term detoxification as defined in Federal regulation) of opioid-addicted persons who are not eligible for maintenance treatment, or who do not elect this type of treatment. Involuntary “administrative withdrawal” requires that due process be defined and followed. No schedule for dose reductions will fit all patients; some individuals tolerate more rapid withdrawal than others do. The underlying goal is to have voluntary medically supervised withdrawal reflect a humane partnership between the patient and the physician.
6. **Screening, Assessment, and Evaluation:** The initial assessments focus on the patient's admission to treatment and determine dosage level. A comprehensive examination is performed within approximately 30 days when the patient is stable and better able to participate fully. Other evaluations that may prove necessary include formal psychiatric and vocational assessments and ancillary medical workups. The program is responsible for arranging such evaluations and for follow-up. A patient reentering treatment may need a repeat examination depending on the timing of the original exam. All patients also undergo periodic health assessments, including regular screenings based on clinical guidelines as appropriate for age and gender.

7. **Pregnancy:** Pregnant women are still denied methadone treatment because program staff members are reluctant to initiate medication on an outpatient basis, believing that hospitalization is necessary for induction or withdrawal to ensure that the fetus is not subjected to unnecessary stress. Another barrier is the case-management burden to program staff of the multiple legal ramifications that exist. Because it is crucial that pregnant women who are addicted engage in treatment for their addiction, priority needs to be given to their admission at any point during pregnancy and to providing them with all necessary care, including adequate dosing strategies as well as prenatal and follow-up postpartum services.
8. **Retention in Treatment:** Studies suggest that the duration of retention in treatment is directly related to success in outcome (Gerstein et al., 1994; French et al., 1993; French & Zarkin, 1992; Institute of Medicine, 1990; Hubbard et al., 1989; Simpson et al., 1986). For patients who drop out of treatment, the outcome is usually negative, whereas patients who remain in treatment, despite continued excessive use of alcohol or illicit drugs, tend to benefit from the treatment experience.
9. **Voluntary Patient Relocations and Program Transfers:** Often, patients may voluntarily relocate from one area or State to another because of family, employment or other issues. In such instances, it is the responsibility of the patient's current treatment program to facilitate transfer to another treatment facility. To prevent the possibility of a patient having a break in treatment and risking relapse, transfers should be as seamless as possible. Therefore, when the patient begins to discuss relocating, the counselor should compile a list of the OTPs in the proposed relocation area and discuss them with the patient as soon as possible. The counselor should contact the State Methadone Authority (SMA) in the relocation area and inquire as to whether the new program has waiting lists and if immediate transfers are possible. When the patient confirms the plans to move and has chosen an OTP to which to transfer, and signed the proper release of information forms, the counselor will make contact with the program and initiate the transfer. The original treatment program should retain responsibility for the patient until the patient completes the new program's admission process and is accepted. This helps prevent the patient from relocating and then finding that, because something in the process was incomplete, he or she cannot be medicated or admitted when expected. Whenever this occurs, resolving the situation may require assistance from the transferring program and, if necessary, arranging for the receiving program to guest medicate the patient until the transfer process is successfully completed.
10. **Medically Supervised Withdrawal:** Medically supervised withdrawal does not usually have the same time constraints that are associated with administrative withdrawal. As a result, programs can schedule a longer and more flexible dose reduction. In the case of patient-initiated, medically supervised withdrawal, however, the patient may impose a timeframe that may or may not affect the prognosis.

Methadone should not be considered a "toxic" substance, and, from a medical perspective, *detoxification* is not an accurate term to use. The term "medical withdrawal" was chosen because it more accurately reflects the physician's role in withdrawal. These guidelines focus on patients who have been maintained on methadone or LAAM pharmacotherapy, rather than focus on issues of medical withdrawal of opioid-addicted persons who are not eligible for medication-assisted treatment, or who do not elect this type of treatment. Involuntary withdrawal or "administrative withdrawal" requires that due process be defined and followed. No schedule for dose reductions will fit all patients; some individuals tolerate more rapid withdrawal than others do. The underlying goal is to have voluntary medical withdrawal reflect a humane partnership between the patient and the physician.

11. **Patients Experiencing Pain:** Patients who are diagnosed with physical dependence and a pain disorder are not prohibited from receiving medication-assisted treatment for either maintenance or withdrawal in a program setting if such setting provides expertise or is the only source of treatment. When methadone is used for pain treatment, it usually requires multiple daily doses. Similarly, addiction patients maintained on medication-assisted treatment are not prohibited from receiving needed pain treatment including, when appropriate, adequate doses of opioid analgesics.
12. Family involvement contributes to positive outcome in treatment while providing benefit to the family members. However, engaging family members who have become “burned out” or disengaged from the patient may be difficult. It may be useful to expand the concept of family to include the patient’s social network, significant others, persons in recovery (such as a sponsor), resources from the community (including the outpatient provider), and others, at the patient’s request. Some OTPs use short-term groups to educate the family on medication-assisted treatment, substance use disorders, the effects on the family, and other family issues. Family counseling allows more participants to address their concerns with the patient. When appropriate, referrals for family treatment should be made, and confirmation that follow-up has occurred should be obtained. If needed, identification of the ongoing need for collaboration should occur with informed patient consent.
13. **Orientation to Treatment:** Take into account that the patient may be in withdrawal or intoxicated on first day of treatment. Ongoing informed consent is necessary.
14. **HIV Counseling:** There is some research available on describing effectiveness of HIV counseling. CDC provides training and training materials. As mentioned in TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, these materials might enhance services at OTPs.
15. **Record Keeping:** Standard intake forms or identical data elements are used when possible. The objective is to encourage agencies and programs to be efficient and avoid duplication of record keeping while gathering sufficient data for outcome, cross-site, or other evaluations or studies or to support managed care data requirements.
16. **Dosage:** The thrust of these guidelines was to keep the dosage guidelines for maintenance therapy as simple as possible, with broad latitude for exercising clinical judgment and minimal mention of dosage amounts or schedules. CSAT decided not to elaborate on the advisable waiting time before administering additional incremental doses of methadone after the initial dose, or to specify the amounts of any additional doses, although they did offer fairly specific guidelines for initial dosing. Subsequent dosing during the induction and stabilization periods is discussed in detail in the referenced TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*.
17. **Dosing and administration decisions shall be made by the program physician and documented completely in the patient record.** Nurse practitioners and physician’s assistants who possess a valid DEA registration permitting them to prescribe scheduled drugs are recognized by CSAT to provide medical services in OTPs in States that, in turn, accept and recognize such credentials. Following the admission of patients by the program physician, nurse practitioners and physician’s assistants in these States are empowered to provide medication services such as methadone adjustments (increases/decreases), detoxification regimens, medically assisted withdrawal, and the like.

18. **Patients' Outside Prescriptions:** OTPs should establish policies that relate to the various medication categories that patients may receive while in treatment. These include over-the-counter medications (OTCM) and medications that physicians outside the treatment program prescribe for acute and chronic illnesses—some of which may contain controlled substances. The policies should follow two basic principles: (1) The patient should show all medications, including OTCs and prescribed medications, to the program's medical staff. The patient should explain the purpose of the medication as the patient understands it. (2) If the patient presents a medication containing a controlled substance or other medication, which may be considered dangerous in combination with opioids, the program physician should meet with the patient and discuss the reason for the prescription. It is strongly recommended that the program physician only should conduct this meeting in order to facilitate patient trust and to obtain the patient's consent to contact the outside prescribing physician. Because the use of multiple controlled substances may have the potential for producing respiratory depression or other life-threatening effects, the physician should request that the patient agree to permit the physician to review all outside prescriptions, especially for the benzodiazepine class of drugs. The physician may decide to contact the outside prescribing physician and make a recommendation to the patient about whether a prescribed drug is appropriate or not while the patient is in opioid treatment. The coordination of the patient's care is paramount, and the physicians should consult with one another to determine the appropriate medications. The program physician should also discuss with the patient dependency and withdrawal issues resulting from continued use or abrupt discontinuance of controlled substances and modify the treatment plan if necessary.
19. **Discussion of Monitoring Patients' Unsupervised Use of Medications:** To monitor patients receiving medication for unsupervised use, physicians need a thorough understanding of physiological issues, differences among laboratories, and factors that affect absorption, metabolism, and elimination of opiates. This knowledge is necessary to interpret a negative methadone and/or methadone metabolite toxicology test, for example.

Exception Request and Record of Justification

Form SMA-168

42 CFR § 8.11(h)

In cases in which the patient's treatment needs require an exception to the regulations found in 42 CFR Part 8, the OTP physician may complete an **Exception Request and Record of Justification, Form SMA-168**. Requests for exceptions may include clinic hours conflicting with employment hours, out-of-town work assignments, funerals, and family emergencies. Frequently, these exceptions are granted in spite of clinic infractions because without such an exception, the patient would have to choose between employment and treatment.

For a patient who does not satisfy the Federal time-in-treatment criterion to receive take-home medication, the OTP physician must complete, approve, and submit an SMA-168 Exception Request and Record of Justification to the CSAT Division of Pharmacologic Therapies (DPT). Without Federal approval, the take-home supply of medication may not be dispensed to the patient for unsupervised use. The most important aspect of the exception request is that the purpose, justification, and a clear explanation of hardship (i.e., distance in miles, hours of employment conflict with employment, medical issue, etc.) must be spelled out so that the DPT reviewer clearly understands the situation and can make a decision.

The mechanisms for submitting SMA-168 follow:

1. The preferred method of submission is through the Internet. The program director may apply for the account by calling 800–687–2728. Once an account has been set up, the staff and physicians receive access to the Web site and a specific, individual signature password for signing and submitting the electronic form SMA-168. The turnaround time is the same day, usually within hours; OR
2. In case of emergency, program staff can submit an SMA-168 through *facsimile* (fax) to 240–276–1630. The form may be downloaded from the SAMHSA/CSAT or DPT Web sites, or e-mailed or faxed if you make a verbal request by calling 240–276–2717. The turnaround time for a fax transmission may exceed 24 hours.

Guest Dosing

Guest dosing involves providing medication to a patient at a program—different from the patient’s usual “home” program—in an area where the patient will be visiting. OTPs use this method to medicate patients who have not yet gained the amount of take-home medication necessary to go on a vacation or temporary job placement. Guest dosing is recommended for patients who do not meet the criteria outlined in 42 CFR § 8.12 (i) (2) (1–viii). Whenever a patient has to travel and is stable, providing the take-home medication normalizes travel for the patient, reduces the stress resulting from emergency issues and employment matters, and conveys trust.

Guest dosing may prove helpful when a patient will be remaining in an area for a protracted period of time (beyond the supply of take-home medication provided the patient) for employment purposes, and it is impractical to return to the patient’s home program routinely to pick up the medication. The patient, home program and guest program should arrive at an agreement to provide the patient with clinical services, such as counseling, if the period for guest dosing exceeds 30 days.

20. **Opioid Treatment Patients and Temporary Residential Treatment:** Unused Medications—Periodically, opioid treatment patients may require temporary residential treatment, long-term care, incarceration, etc. Other portions of this guideline address chain of custody for take-home supplies, and other issues that permit patients to continue maintenance during these periods. Occasionally, due to unforeseen circumstances, there are issues that need to be resolved concerning unused medication supply.

An individual patient may not return his or her unused controlled substance prescription medication to the OTP. Federal laws and regulations make no provisions for an individual to return their controlled substance prescription medication to an OTP for further dispensing or for disposal. There are no provisions in the Controlled Substances Act or Code of Federal Regulations (CFR) for a DEA registrant (i.e., an OTP) to acquire controlled substances from a nonregistrant (i.e., individual patient).

The CFR does have a provision for an individual to return unused medication to the OTP in the event of a recall of the controlled substance or if a dispensing error has occurred.

Individuals may dispose of their own controlled substance medication without approval from CSAT or the DEA. Medications should be disposed of in a manner that does not allow the controlled substances to be easily retrieved. In situations in which an individual has expired, a caregiver or hospice staff member may assist the family with the proper disposal of any unused controlled substance medications. OTPs are encouraged to obtain documentation of this disposal, if practical.

Guidelines for Security of Take-Home Medication

Treatment Programs should require patients receiving unsupervised (take-home) medication to use locking containers to store their medication at home. The original requirement for patients to store their medication in locked containers dates back to when take-home medication was first permitted, and there was a concern for the safety of children and others in the patient's home. The concern remains unchanged today. It is strongly recommended that patients should continue to transport the medication to their home and then lock it in the container, placing the container in a safe place in the home. The current regulation remains unchanged (42.8.12(i)(5)) requiring childproof caps and storage in a safe place in the home.

The locking container provides a reasonably safe place for the medication at home but provides little in the way of security from the clinic to the patient's home. Take-home medication can be safely and inconspicuously transported by the patient from the program to the home without mandating a specific type of locking container. In fact, the locked container challenges two regulatory issues: (1) the visibility of the container provides a means of identifying patients in treatment, which presents issues of confidentiality; and (2) the visibility of the container identifies patients possessing take-home medication, which may place the patient at risk for robbery or assault.

Medication Security: Providing Medication to Patients Who Are Incarcerated, in Residential Treatment, Medically Compromised or Homebound

During the course of medication-assisted treatment, there may be occasions when a patient is prevented from reporting to the program site for routine observed ingestion of medication. This may occur because of illness, pregnancy, incarceration, participation in residential treatment, lack of transportation, etc. When these situations occur, the medical and clinical staff is faced with a challenge in safely continuing the patient's treatment while ensuring appropriate handling of the medication from the OTP to the patient's location.

This is usually accomplished through the development of a *Chain of Custody Record*, which is a document containing the signatures of all whose hands have come in contact with the medication. The form should also contain space for the patient to initial each day that the medication is administered, as well as the initials of the one who administered the medication. If possible, without causing the patient unwanted scrutiny, the patient should contact the program immediately if the medication seems altered in any way.

When the patient is ambulatory and can be brought to the program weekly or several days per week, the *Chain of Custody Record* is also used to encourage a responsible person to take charge of the medication and place it under lock and key at the non-program location. The same holds true for incarceration facilities and nursing homes that do not have methadone in stock.

For patients who are homebound, a family member who does not have a history of alcohol or drug abuse and whom the OTP has met and screened may receive permission to pick up the medication. The OTP should request this through the SMA-168 and forward the exception request to the relevant State and Federal Government authorities.

When the *Chain of Custody Record* has been completed, it is to be returned to the program. The original of the record should be placed in the patient's medical record, and a copy may be placed in the Quality Assurance file, as needed.

21. (1)Adapted and expanded, in part, from the “Consumer Bill of Rights” drawn up by the Advisory Commission on Consumer Protection and Quality in the Health Care Industry—appointed by President Clinton on March 26, 1997, to “advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system.”

(2) Patients’ Rights and Responsibilities: Patients undergo sufficient stress during admission that additional opportunities to review their rights and responsibilities are warranted once they are better able to understand them. Patients need this information in multiple formats, appropriate to culture, language, and literacy level. Examples include signs in the waiting room, pamphlets, electronic media (video, tapes), and “talk through” with staff.

22. **Privacy:** Internal controls on privacy are often overlooked in facility design and in staff-to-patient and patient-to-patient communications. Examples include windowed/open work space; cashier in public area; untrained security guards; common medication dispensing areas; and hallway conversations about HIV/AIDS, failed urinalysis, or psychiatric medications.

4. Guideline Panel

On October 31 and November 1, 2005 CSAT convened a panel of experts in Washington, DC to review and begin to revise the current *CSAT Guidelines for the Accreditation of Opioid Treatment Programs*. The Expert Panel members were asked to consider, in reviewing the current Guidelines, issues such as the length of the processes, the consensus development process, the quality of the advice (as opposed to quantity), and whether or not supporting data exist.

The panel participants separated into four groups to review and suggest revisions to the Guidelines. Participants were asked to consider the perspectives of regulation, science, and burden of the Guidelines and to consider issues such as settings, timelines for delivering care, and the extent to which the Guidelines should be prescriptive. The four groups focused on the following overall themes:

1. *Organizational Structure and Administrative Responsibilities*
2. *Individualized Patient Care*
3. *Medication Management*
4. *Medical Issues and Co-occurring Disorders*

The representatives of accreditation organizations sat in as observers within the breakout groups to provide information and clarification, however, they did not take part in the group decision-making for final suggestions to CSAT for editing and updating the current Guidelines.

Accreditation Guidelines Expert Panel October 31–November 1, 2005

Chair

Lawrence Brown, M.D., M.P.H.
Senior Vice President
Addiction Research and Treatment Corporation
Brooklyn, NY

Panelists

Morton Albert, M.D.
President and Medical Director
United Behavioral Health of the Mid-Atlantic
Rockville, MD

**Theodora Binion-Taylor, M.S., M.D.V.,
C.A.D.C.**
Director, Division of Alcoholism and
Substance Abuse
Department of Human Services, Chicago
Chicago, IL

Thomas Brady, M.D., M.B.A.
Vice President and Chief Financial Officer
CRC Health Group, Inc.
Cupertino, CA

Ron Jackson, M.S.W.
Program Sponsor
Evergreen Treatment Services
Seattle, WA

Patti Juliana, M.S.W.
Administrative Director, MMTP Department
Beth Israel Medical Center
New York, NY

Jason Kletter, Ph.D.
President, Bay Area Addiction Research and
Treatment (BAART)
San Francisco, CA

Joseph Liberto, M.D.

Acting Lead Psychiatrist
Medical Director
Baltimore Veterans Hospital
Baltimore, MD

Chilo (Cirilio) Madrid, Ph.D.

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Karla Mione, M.P.H.A., C.A.D.C.

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Jo L. Sotheran, Ph.D., C.M.A.

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Philadelphia, PA

Lisa Mojer Torres, Esq.

Faces and Voices of Recovery
Lawrenceville, NJ

Terry Willis, M.S.

C.E.O.
Georgia Therapy Associates, Inc.
Griffin, GA

Accrediting Body Meeting Observers

Karen Callender, M.S.W.

Council on Accreditation (COA)
New York, NY

Mary Cesare-Murphy, Ph.D.

Executive Director
Behavioral Health Care Services
Joint Commission on Accreditation of
Healthcare Organizations (JCAHO)
Oakbrook Terrace, IL

R. Scott Chavez, Ph.D., M.P.H.

Vice President
National Commission on Correctional
Health Care
Chicago, IL

Bettye Harrison, M.S.W.

Commission on Accreditation on
Rehabilitation Facilities
Tucson, AZ

Megan Marx, M.P.A.

Associate Director
Joint Commission on Accreditation of
Healthcare Organizations (JCAHO)
Littleton, CO

Terry Morris, M.S.

Director of Clinical Services
Missouri Department of Mental Health
Jefferson City, MO

5. Frequently Asked Questions

I. SMA-162 Application Process

1. Q—How does an OTP inform SAMHSA of program changes?

A—Submit a SMA-162 form. In Item 8 of the form, check the box that indicates why you are submitting the application. Choices that appear on the form are:

Provisional Certification, New Sponsor, New Medical Director, Relocation Medication, Unit Renewal

You may access this form at www.dpt.samhsa.gov.

2. Q—What do you check on the form for a generic program update? For example, if a new Program Director comes on board in my program, how do I inform SAMHSA of the change? How do I notify SAMHSA of other relevant changes to my organization?

A—You do not need to check a box on the form to submit a generic program update. However, SAMHSA prefers that you fill out an SMA-162 and attach an explanation of the change. You may also inform SAMHSA of the organizational change with a letter. Please fax the form (or letter) to 240-276-1630.

Substance Abuse and Mental Health Services Administration
Office of Pharmacologic and Alternative Therapies
Attention: OTP Certification Program
Room 2-1075
1 Choke Cherry Road
Rockville, MD 20857

3. Q—What do you do if you start a new program and do not have an FDA number?

A—Submit a completed SMA-162 and in Item 8 on the form, check the “Provisional Certification” box. SAMHSA will review your application for completeness using the checklist included in your application packet, and we will notify you of the need for additional information. After your State and the DEA have completed their OTP approval process and have notified SAMHSA, SAMHSA will complete the approval review. Once your program is approved, SAMHSA will assign a number to you.

4. Q—What do you do if you are an existing program and do not know your SAMHSA number?

A—To find out your SAMHSA number, please email otp@samhsa.hhs.gov or call 240-276-2700.

5. Q—Does an existing medication unit have to submit an SMA-162 separately from the original OTP?

A—No, we require only a single submission. Medication units are defined under Federal regulations as facilities, including community pharmacies that dispense treatment medications. The SAMHSA-certified OTP assumes all responsibilities for medication units. If the OTP already has an existing medication unit and the OTP is filing an SMA-162 with a program update, then the program needs to submit only one SMA-162 and the appropriate attachments. One of the attachments always will be a description of the medication unit along with the DEA Registration number assigned to that medication unit. The medication unit’s DEA number will be different from the DEA number for the original OTP. For instructions on how to open a new medication unit, see the next question.

6. Q—How does an OTP apply to open a new medication unit?

A—Please submit an SMA-162 with all requested attachments and signed documents to SAMHSA. In Item 8 of the application, “Purpose of Application,” check off “Medication Unit.” After SAMHSA processes the form, it will forward its approval to the DEA, which will arrange an inspection. The program should also submit any required materials to the State Methadone Authority to seek State approval, as appropriate. Once the DEA approves the medication unit, it will assign a new registration number for that medication unit. The SAMHSA-assigned number usually will stay the same for both the original site and the medication unit.

7. Q—Does “Program Sponsor” on the SMA-162 refer to a program or a person?

A—A Program Sponsor should always be a person’s name, not the name of a program. The sponsor is the person who is legally responsible for the OTP and serves as the formal contact between SAMHSA and the OTP.

8. Q—How much notice does an OTP have to give when informing SAMHSA of a program change?

A—OTPs should notify SAMHSA within 3 weeks of any change indicated in Item 8 of the SMA-162 (e.g., medical director or program sponsor).

9. Q—What is the difference provisional certification, certification, and accreditation?

The following are definitions of the terms.

- **Certification** is the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards. To become certified by SAMHSA, OTPs must successfully complete the accreditation process and meet other requirements enumerated in regulation, 42 CFR Part 8. Once certified, programs must renew certification at least every 3 years.
- **Provisional Certification** is a temporary certification granted for up to 1 year for a new OTP until it becomes accredited. SAMHSA may grant provisional certification to an OTP that has applied for accreditation. Provisional certification is granted to OTPs that have submitted form SMA-162, along with a statement identifying the accreditation body to which the OTP has applied, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification may be granted for 1 year unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification.
- **Accreditation:** 42 CFR § 8.2 defines accreditation as the process of review and acceptance by an accreditation body. An accreditation body is an independent, not-for-profit organization or State governmental entity that has been approved by SAMHSA under § 8.3 to accredit OTPs using opioid agonist treatment medications. An OTP must receive accreditation before it may be certified.

10. Q—When a new OTP is just getting started, how much time does it have to get accreditation?

A—Up to 1 year. New OTPs must apply for accreditation with a SAMHSA-approved accreditation body and then apply to SAMHSA requesting Provisional Certification. With the application (SMA-162), the OTP should include a statement identifying the accreditation body to which the OTP has applied, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. A provisional certification

will be granted for up to 1 year, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification. The program must achieve accreditation within that same year.

III. Detoxification Programs

1. Q—Is a detoxification program considered to be an OTP?

A—Yes The Federal Regulations define an Opioid Treatment Program (OTP) as a “program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication,” and the new rule [42 CFR § 8.11(a) (1)] states that an OTP must have a current, valid certification from SAMHSA to be considered qualified by the Secretary of DHHS to dispense methadone and levo-alpha-acetyl-methadol (LAAM) for the treatment of addiction. A unit of a hospital that intends to offer new detoxification services using methadone should apply to SAMHSA for provisional certification (see QI-1).

2. Q—Will SAMHSA require inpatient detoxification programs that use methadone to be accredited and certified? As a freestanding detoxification/rehabilitation facility dispensing methadone for detoxification only, will we be held to these accreditation/certification standards?

A—Yes. The new Federal regulations address all forms of opioid treatment, including maintenance and detoxification treatment.

3. Q—If so, will the process differ in any way from what is being required of maintenance programs?

A—No. Detoxification programs are subject to the same standards as maintenance programs. Standards are detailed in the Final Rule (42 CFR § 8). OTPs providing inpatient detoxification services must be accredited and certified. Accreditation bodies may develop specific detoxification treatment accreditation standards and processes for surveying OTPs providing such services.

4. Q—Please comment on the guidelines for physicians and clinics who administer detoxification without SAMHSA accreditation.

A—Under the Narcotic Addiction Treatment Act of 1974, all practitioners who use narcotic drugs for treating opiate addiction must obtain a separate registration. However, according to the DEA, an exception to the registration requirement, known as the “3-day emergency exception” (Title 21, Code of Federal Regulations, Part 1306.07(b)), allows a practitioner who is not separately registered as a narcotic treatment program to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient’s referral for treatment, under the following conditions: (1) not more than 1 day’s medication may be administered or given to a patient at one time; (2) this treatment may not be carried out for more than 72 hours; (3) this 72-hour period cannot be renewed or extended.

The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he or she may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid-dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent, the separate registration requirement. This information may be found at <http://www.deadiversion.usdoj.gov/drugreg/faq.htm>.

In addition, there are other situations in which registration and certification may not be required. The Final Rule, 42 CFR §8.11 (1) (2), contains the following language:

“Certification as an OTP will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility.”

5. Q—Are there restrictions on how many times a patient can be detoxified this way?

A—The 3-day emergency exception cannot be renewed or extended. Because this is a DEA rule, for further details consult DEA.

6. Q—The regulations state that in order to have take-home medications, a person has to be in a comprehensive maintenance program, but long-term detoxification is not addressed. Old regulations did not allow take-homes for those on long-term detoxification. Is it the same with the new regulations?

A—No. Both maintenance patients and long-term detoxification patients are eligible for take-home medications, while short-term detoxification patients are not.

IV. Take-Home Privileges

1. Q—The regulations regarding take-home privileges indicate that a patient may have an extra take-home dose for the day that the clinic is closed. Can you make weekly take-homes adjacent to one-another, so that patients may receive take-homes for a longer period around the weekend?

A—Sometimes. You may not give this privilege to all patients in a clinic. This practice may be justified for an individual patient on occasion. By granting take-home privileges, you are acknowledging that the patient meets the eight criteria in the regulations for take-home medications. The take-home schedule must be tailored to each patient. It also would not be appropriate to give a relatively new patient take-homes in such a manner as to place the patient at risk of diversion or relapse.

2. Q—Our program is considering dispensing tablets for take-home patients. Is this a diversion risk?

A—All opioid treatment medications pose a risk of diversion. The physician must determine that a patient is responsible enough to receive solid take-home medication. Diskettes formulated to reduce the potential for intravenous administration are less of a diversion risk than tablets.

3. Q—The regulations state that a person on short-term detoxification cannot have take-home medications. How does this apply to the programs that want to close on a holiday or on a Sunday?

A—The previous regulation prohibited take homes for both short- and long-term detoxification patients. Under the previous regulation, FDA approved program-wide exemptions to permit holiday take homes. SAMHSA will review annual program-wide exemption requests to permit take-home dosages for patients in short-term detoxification treatment for holidays.

4. Q—The regulations state that in order to have take-home medications, a person has to be in a comprehensive maintenance program. Old regulations did not allow take-homes for those on long-term detoxification. Is it the same with the new regulations?

A—No. Both maintenance patients and long-term detoxification patients are eligible for take-home medications, while short-term detoxification patients are not.

5. Q—Assume that a patient is in a comprehensive maintenance program, is on take-home status, and requests a medically supervised withdrawal. Can she or he remain on take-homes during the withdrawal period?

A—Yes. The patient was admitted to maintenance treatment. Take-homes would be permitted.

V. Treatment

1. Q—The regulation regarding Medical Examination Services, § 8.12 (f) (2), Initial Medical Examination Services, states that the initial exam should take place before admission or within the first 14 days. Can the patient begin treatment immediately upon admission and see the physician any time within that 14-day period or must she or he see the physician before treatment commences?

A—The statement preceding the question does not reflect the meaning of the language in the regulation. 42 CFR § 8.12 (f) (2) addresses this question as follows: “OTPs shall require each patient to undergo a complete, fully documented physical examination by a program physician or a primary care physician or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.”

2. Q—When a person in treatment for opiate addiction tests negative for opiates, but tests positive for another drug, can we keep him or her in treatment?

A—Yes. SAMHSA encourages OTPs to ensure that the abuse of drugs other than opiates is addressed in treatment. The OTP should provide appropriate counseling and other treatment if abuse of other drugs or alcohol is identified as a problem. When necessary, the OTP may refer the patient to another program for additional treatment services. For further information, please refer to the Treatment Improvement Protocols online at <http://www.treatment.org/Externals/tips.html>

3. Q—The new SAMHSA regulations do not state the drugs for which patients should be tested. How do we determine the drugs for which to test?

A—Regulations require that OTPs perform adequate testing services at minimum intervals. CSAT Guidelines recommend that drug screening tests should include tests for opiates, methadone, amphetamines, cocaine, and barbiturates. Testing for other drug use should be determined by community drug use patterns or individual medical indications. Accreditation bodies may adopt a more flexible standard, which would allow the OTP not to test for drugs that were not commonly used in that particular community or population. The accreditation bodies may offer additional guidance on this subject.

4. Q—What happens when drug testing reveals use of specific drugs, such as amphetamines and barbiturates?

A—The OTP should provide appropriate counseling and other treatment if abuse of other drugs is identified as a problem. When necessary, the OTP may refer patients to other programs for additional treatment services.

5. Q—Until May 2001 (when the regulations changed) the FDA required that all clinics use an FDA Consent to Methadone Treatment form. In that form, it stated that breastfeeding was not recommended for female patients. As clinics, we were required by law to have patients sign this form. How should we advise pregnant or lactating patients?

A—Regulations require that OTPs obtain every patient’s informed consent to treatment, however, there is no longer a standard, required form. OTPs should develop their own form for consent to treatment. The CSAT Accreditation Guidelines state, “The program encourages breastfeeding during methadone/LAAM therapy unless medically contraindicated, e.g., by the presence of HIV/AIDS infection in the mother.” However, this decision is a medical decision and should be left up to the mother and the physician.

6. Q—Is an FDA consent form still required?

A—No. Informed consent is still required, but SAMHSA does not plan to create a standardized consent form. OTPs must develop their own.

7. Q—Although the new regulations require clinics to obtain informed consent to treatment, it seems that many clinics are still using the old FDA form, and just giving it a new name. Is this acceptable?

A—No, SAMHSA recommends that the old “Consent to Methadone Treatment” form no longer be used. It would be better to develop a new informed consent to treatment to comport with the new regulations, scientific advances in treatment, and OTP needs.

8. Q—Scenario: Within a few days of a discharge, a client feels as though she wants to use again. She calls the OTP she was discharged from to request continued treatment. What needs to be in place before she can be readmitted? Does she have to have used again?

A—No. The patient may be readmitted after an examination by the physician and an admission order. The patient does not have to use drugs again to be admitted.

VI. Medication

1. Q—Is there a health problem associated with LAAM?

A—There has been some evidence of a rare condition involving cardiotoxicity associated with levo-alpha-acetyl-methadol (LAAM).

2. Q—Some pain management clinics are dispensing methadone. How can an OTP tell whether a person is legally medicated or using illicit drugs?

A—We are unaware of a foolproof way to determine this. However, a patient may sign consent for release of information and allow a pain management clinic to verify to an OTP that she or he is receiving opioid treatment.

3. Q—What can we do about the dose cap restriction?

A—The new regulation does not refer to dosage caps. The “CSAT Guidelines for the Accreditation of OTPs” discourage dosage caps. OTP and physician education appear to be the best approach for encouraging individualized treatment, with no dosage caps.

4. Q—What is your interpretation of this statement: “Methadone should be dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse” [42 CFR § 8.12 (h) (3) (i)]?

A—Methadone should be dispensed orally only. Parenteral and nonoral forms are prohibited. Previous regulations restricted methadone dispensing for addiction treatment to liquid only; however, the new regulations removed the liquid-only restriction. Diskettes and tablets are formulated to comport with standards; approved solid medications are now acceptable forms of administration of opioid medication. Diskettes formulated so as to reduce the potential for intravenous administration are less of a diversion risk than tablets.

5. Q—What is the new regulation regarding the initial opioid medication dose?

A—The very first dose administered may not exceed 30 mg. However, the total dose for the first day may go up to 40 mg, but shall not exceed 40 mg unless the program physician determines and documents in the patient’s record that 40 mg did not suppress opiate abstinence symptoms [CFR § 8.12 (h) (3) (ii)].

VII. State-Specific Questions

1. Q—A few States and OTPs have recognized that the new medication “take-home” schedule outlined under 42 CFR §8.12(i) is different from the schedule outlined in the previous regulations. These parties contend that the previous regulations permit one or two additional take-home medication doses after the first 90 days of treatment when compared to the new regulation. The States and OTPs question whether Statewide exemptions can be approved to permit application of the previous regulatory schedule between 90 and 270 days. Please clarify.

A—The take-home schedule in the final rule was modified from the schedule in the proposal for clarity and reflects a considerable number of comments. In addition, the new language incorporates the new provision, which allows ORLAAM take-home medications. Finally, the new take-home schedule resembles the schedule in the “CSAT Accreditation Guidelines,” which were part of the accreditation evaluation project.

The new schedule, which includes more intervals in the initial year of treatment, reflects a balance, with patients in treatment beyond 1 year eligible for a 2-week supply. While the previous regulation may have permitted an additional take-home dose of methadone after the first quarter of treatment, those regulations permitted only a maximum of six take-home doses after 3 years of treatment. The new regulations, on the other hand, permit eligible patients to have a 6-day supply of take-home medication after 270 days of treatment, 2 weeks of take-homes after 1 year, and a 1-month supply after 2 years of treatment.

While the Center has reviewed and will continue to accept single-patient exception requests, CSAT has not approved Statewide or program-wide exemptions to permit OTPs to dispense take-homes in accordance with the previous regulatory schedule.

2. Q—In Minnesota, we have always required a lock box for take-homes from methadone clinics, primarily to prevent accidental ingestion by children and the like. This has not been a Minnesota Rule/Statute; rather we have used FDA ruling and interpretation for this purpose. Page 4098 of the Federal regulation of January 17, 2001 under take-home criteria states:

“(vii) Assurance that take-home medication can be safely stored within the patient’s home . . .”

Is it safe to interpret this as continuing to require a lock box for take-homes?

A—No. The new regulations—42 CFR 8.12(i) (5)—require the use of childproof containers and do not specify that a lock box is a requirement. We were unable to locate an explicit requirement in FDA rules addressing the use of lock boxes for take-home supplies. In the past, there has been an implicit understanding that lock boxes should be used, based on the need to prevent accidental ingestion by children. However, the “CSAT Accreditation Guidelines” state “program policies ensure responsible handling and storage of ‘take home’ medication in childproof containers.”

3. Q—Will the new regulations override a State’s authority to prohibit opioid agonist treatment (methadone/LAAM) programs?

A—No. The oversight of methadone and levo-alpha-acetyl-methadol (LAAM) will still be a tripartite system involving the State, the U.S. Department of Health and Human Services (DHHS), and the Drug Enforcement Administration (DEA). States regulate the practice of medicine and, therefore, may regulate methadone and LAAM treatment. There are other State and local regulatory activities such as certificates of need, zoning, and licensure; these may affect the number, size, and locations of methadone programs. State and local regulations are not affected by the change in DHHS regulations.

On the other hand, since the new Federal regulations were proposed, it is encouraging to note that three States, which formerly did not have methadone treatment, now have methadone treatment available. These States are West Virginia, Vermont, and New Hampshire.

Drug Testing

1. Q—Our opioid treatment program (OTP) is exploring the use of oral solution testing. Can an OTP use alternatives to urine specimen testing to fulfill the drug testing requirements under the Federal opioid treatment regulations?

A—Neither the previous FDA regulations nor the new CSAT rules specify urine as the only type of biological sample that can be tested. They do, however, “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, in accordance with generally accepted clinical practices.”

Drug testing is considered a medical service and is an important component in treatment. Test results are used in determining whether dosing adjustments or other treatment interventions are needed. In addition, drug test results are important in determining whether a patient is stable enough to receive medications for unsupervised use. Accordingly, the OTP medical director assumes responsibility for the adequacy of drug abuse testing services and all other medical services provided by the program.

Recognizing the importance of drug abuse testing, CSAT has recently begun a process to establish and publish consensus guidelines for drug testing in clinical addiction treatment. Dr. Louis Baxter, of the New Jersey Medical Society and CSAT’s National Advisory Council, is chairing the consensus panel for these guidelines. CSAT expects this material to provide clinically oriented guidance on test medium, process, frequency, and interpretation. The Center is also revising and combining several preexisting Treatment Improvement Protocols (TIPs) for OTPs, with another panel chaired by Dr. Steven Batki. That TIP will also address the issue of drug testing, specifically in OTPs. It is expected that these initiatives will contribute to the treatment improvement protocol and the best practice guidelines for the treatment of opiate addiction called for under the Drug Addiction Treatment Act of 2000 ((DATA)(Pub. L. 106-310; 21 U.S.C. 823(g)(2)(H)(ii)).

It is important to realize, however, that guidelines are not binding regulations. Instead, guidelines set forth examples of practices that can satisfy a regulatory requirement—in this case, adequate drug abuse testing.

CSAT expects that accreditation bodies will review these guidelines and adopt all or part for inclusion in the accreditation standards they apply to OTPs.

In addition, OTPs should consider that with or without these new guidelines, it remains the Medical Director's responsibility for compliance in this area and to document the adequacy of any testing approach. Whatever drug abuse test the OTP uses, the OTP must (as part of the accreditation survey) be able to support the use of the test with documented evidence showing that the test is adequate. *At this time, CSAT is not aware of data and information that would document that a drug- testing technique other than urine testing is adequate for use in opioid agonist treatment.*

VIII. Miscellaneous

1. Q—What are non-physician healthcare professionals authorized to do under the new regulations?

A—Non-physician healthcare professionals are permitted to conduct various activities under the regulations. For example, under 42 CFR 8.12 (f), an authorized healthcare professional under the supervision of the program physician may conduct the required initial physical examination. On the other hand, only a Medical Director or program physician shall determine a patient's eligibility for take-home medications under 42 CFR 8.12(i)(2).

Under the regulations, the Medical Director and program physicians are responsible for program-wide medication dosing and administration policies. In addition, significant deviations from approved product labeling must be documented by a program physician and Medical Director (see 42 CFR 8.12 (h)(4)). However, under 42 CFR (h)(4)(1), practitioners, or agents of practitioners (under the supervision of a practitioner), who are licensed under State Law and registered under Federal law may administer or dispense opioid agonist treatment medications. In some States, medical assistants and licensed practical nurses, under the supervision of a physician, are authorized to modify patient medication levels. It is incumbent upon the OTP to review and determine State requirements and limitations in this area.

2. Q—Will these regulatory changes increase treatment capacity?

A—SAMHSA expects that adoption of an accreditation model will increase treatment capacity by making it easier for facilities such as hospitals and HMOs that are accustomed to meeting accreditation requirements to enter the marketplace. Accreditation and other reforms will make it easier for existing programs to establish relationships with private practitioners. SAMHSA also plans to encourage private physicians to become more active in the treatment of methadone patients.

3. Q—Will it be cost-effective for individual doctors to treat patients?

A—Yes. Stabilized patients who have been in opioid maintenance treatment for two or more years may be eligible for transfer to medical maintenance. Medical maintenance allows these patients increased amounts of take-home medication for unsupervised use and fewer visits to an office-based physician who, in some circumstances, may be away from the clinic site. The office-based physician maintains a formal arrangement with an established OTP that can provide medication, urine-testing services, and any backup social services the patient may need. SAMHSA/CSAT has issued a letter to the field encouraging programs to pursue this option, which has the potential to expand treatment capacity.

6. Appendix—Standard and Example Forms

Example of Standard Consent to Opioid Maintenance Treatment

CONSENT TO PARTICIPATION IN OPIOID PHARMACOTHERAPY TREATMENT

Patient's Name: _____ **Date:** _____

I hereby authorize and give voluntary consent to the Division and its medical personnel to dispense and administer opioid pharmacotherapy (including methadone or buprenorphine) as part of the treatment of my addiction to opioid drugs. Treatment procedures have been explained to me, and I understand that this will involve my taking the prescribed opioid drug at the schedule determined by the program physician, or his/her designee, in accordance with Federal and State regulations.

It has been explained that, like all other prescription medications, opioid treatment medications can be harmful if not taken as prescribed. I further understand that opioid treatment medications produce dependence and, like most other medications, may produce side effects. Possible side effects, as well as alternative treatments and their risks and benefits, have been explained to me.

I understand that it is important for me to inform any medical provider who may treat me for any medical problem that I am enrolled in an opioid treatment program so that the provider is aware of all the medications I am taking, can provide the best possible care, and can avoid prescribing medications that might affect my opioid pharmacotherapy or my chances of successful recovery from addiction.

I understand that I may withdraw voluntarily from this treatment program and discontinue the use of the medications prescribed at any time. Should I choose this option, I understand I will be offered medically supervised tapering.

For Female Patients of Childbearing Age: There is no evidence that methadone pharmacotherapy is harmful during pregnancy. If I am or become pregnant, I understand that I should tell my medical provider right away so that I can receive appropriate care and referrals. I understand that there are ways to maximize the healthy course of my pregnancy while I am in opioid pharmacotherapy.

Signature of Patient

Date of Birth

Date

Witness: _____

Adapted with permission from Department of Psychiatry and Behavioral Sciences, Albert Einstein College of Medicine, Division of Substance Abuse, Bronx, NY.