

Guidelines for the Accreditation of Opioid Treatment Programs

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Statement of Nonbinding Effect—This guidance document 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 the Substance Abuse and Mental Health Services Administration (SAMHSA) or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations.

1. Introduction

The Center for Substance Abuse Treatment (CSAT) developed the original Guidelines for the Accreditation of Opioid Treatment Programs (OTPs) between 1996 and 1999, using a Treatment Improvement Protocol (TIP) type process, involving two expert panels, field reviews, and clearances from other Federal agencies and the Office of Management and Budget. These guidelines were established to serve as a guide to accreditation organizations in developing accreditation standards, which conform with the Substance Abuse and Mental Health Services Administration's (SAMHSA) Federal Opioid Treatment Standards, found in Title 42 of the Code of Federal Regulations (CFR), Part 8. The guidelines also provide guidance to OTPs, elaborating on and providing examples of ways in which programs can achieve and maintain compliance with Federal 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. Under Title 42 of CFR Part 8 (42 CFR Part 8) which became effective in May 2001, an accreditation organization or State governmental entity that wants to participate in SAMHSA's OTP certification program must apply to become a SAMHSA-approved accreditation body. Among the numerous application requirements, potential accreditation bodies are required to submit a set of accreditation elements and a detailed discussion showing how these ensure that each OTP surveyed is qualified to meet the Federal opioid treatment standards set forth in section 8.12 of the regulations.

The experience gained from the application of the rules and the thousands of accreditation surveys conducted since 2001 have identified issues and areas that would benefit from careful review and update. Because the accreditation guidelines have 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. The panel was 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 selected based on their knowledge and expertise of the following content areas:

- The most recent developments in opioid addiction treatment
- The prevention and treatment of infectious diseases, such as HIV and hepatitis 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
- Office-based treatment

SAMHSA 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. SAMHSA announced the availability of the revised draft guideline in the Federal Register published April 21, 2006. The notice provided information on how to obtain the draft and submit comments during the 60-day comment period. CSAT values the careful thought and attention members of the opioid treatment community gave to the draft guidelines, thus staff carefully considered and reviewed all comments and modified the guidelines as appropriate.

OTPs should be aware of their obligation to protect the confidentiality of patient substance abuse patient records, as set forth in Federal regulations at Title 42 of the Code of Federal Regulations, Part 2. Patient privacy becomes especially important with the national movement toward electronic health records. Additional information about privacy and substance abuse treatment is available at <http://hipaa.samhsa.gov/privacyrule.htm>.

To understand some of the guidelines, the reader may need a more complete explanation of the issue or rationale underlying the standard, as well as some examples to clarify meaning. Superscript letters guide the reader to that information in endnotes, pages 41–47. Additionally, text boxes above each relevant section in the guidelines directly excerpt the text from 42 CFR so that the reader may reference both the guidelines and the regulations concurrently.

Should there be any questions or issues not covered in this guidance document, please contact CSAT's Division of Pharmacologic Therapies (DPT) at 1–240–276–2700.

2. Opioid Treatment Standards

42 CFR § 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) is 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 Federal Government, the Department of Health and Human Services (HHS), the Drug Enforcement Administration (DEA), 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.

It is essential to develop a referral and consultative relationship with a network of agencies and providers capable of providing primary and specialty services for the range of psychiatric comorbid conditions, medical complications, and communicable diseases that may be part of a patient's problem list. Information exchange across this network must both facilitate treatment and protect patient privacy.

(1) Goals

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

(2) Human Resources Management

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

- (b) Programs maintain individualized personnel files as a record of employment. These files contain employment and credentialing data deemed appropriate by the employer. The files also 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. 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 onsite
 - (b) Is clean and well maintained, similar to and consistent with other treatment facilities 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) Provides 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.) If there is a change of sponsor, SAMHSA requires formal notification within 3 weeks of the change.
- (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 including the responsibility to hire and fire employees, and carry out multiple management activities, 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.) If there is a change of medical director, SAMHSA requires formal notification within 3 weeks of the change.

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 medication error is made. Procedures should include a mechanism for reporting untoward incidents to appropriate program staff.
- (ii) Provides a mechanism to address patient emergencies by establishing an emergency contact system to obtain dosage levels and other pertinent patient 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, or utilize 9–1–1 or similar local emergency resources.
- (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 situations in which security guards or police need to be summoned.

(b) Program Emergencies^a

Each treatment program

- (i) Develops, maintains, and updates regularly a disaster plan that addresses maintenance of fire extinguishers, fire drills, emergency evacuation procedures, and that 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. The plan should include a mechanism for informing patients of these emergency arrangements.
- (iv) Ensures that needed supplies are available in the event of an emergency.

(2) Continuous Quality Improvement^b

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 or standard infection control precautions promulgated by the Centers for Disease Control and Prevention (CDC).
- (g) Measures and monitors treatment outcomes and processes on a regular basis—for example, quarterly—to provide feedback on measures of performance. Monitors and measures treatment outcomes such as
 - (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 restoring physical and mental health and functional status
 - (v) Increasing retention in treatment
 - (vi) Increasing numbers of patients who are employed
 - (vii) Increasing abstinence from drugs of abuse

(3) Events That Require Immediate Response and Investigation^c

Each treatment program

- (a) Establishes procedures to guard against critical incidents, which are defined as any events that could have a negative impact on patients and their family members and the program or staff. This includes events that involve the loss of life or function, any serious physical or psychological injury, and medication errors. Critical events are also known as sentinel events, significant adverse events, and untoward events.
- (b) Establishes procedures, in case a critical incident occurs, to ensure
 - (i) Full documentation of the incident
 - (ii) Prompt investigation and review of the situation surrounding the incident
 - (iii) Implementation of timely and appropriate corrective action(s)

- (iv) Ongoing monitoring of any corrective actions until their effectiveness is established
- (c) Reports each critical incident to the accrediting organization in accordance with procedures established by these organizations. Examples of reportable critical incidents involving patient deaths include:
 - (i) Drug-related deaths
 - (ii) Methadone or buprenorphine deaths
 - (iii) Unexpected or suspicious deaths
 - (iv) Treatment-context deaths that raise individual, family, community, or public concern
- (d) As appropriate, reports critical incidents to the Food and Drug Administration (FDA) Adverse Event Reporting Program regarding (MedWatch, <http://www.fda.gov/medwatch/>; at 1-800-332-1088). Examples of reportable critical incidents include
 - (i) Serious adverse events and medications errors
 - (ii) All types of deaths related to any drug

(4) Community Relations and Education^d

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 (e.g., 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, the community and mutual concerns and 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 for a specified period of time in accordance with State and Federal regulations.

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 has a diversion control plan (DCP) that demonstrates accountability to its patients and to the community. The DCP 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.

Guidance: DCPs should contain specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and should assign specific responsibilities 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 DCP 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 DCP 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 OTPs may set up a system of rounds in which security or staff walks 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 treatment 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 OTP's committees, such as the quality assurance committee or the management committee. If the OTP 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 identified diversion problems. Several strategies may be helpful. Always investigate the alleged or actual source of diversion. If necessary, change the frequency of take-home reviews. Drug testing regimens 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^e

Each treatment program ensures the following:

- (1) Doctors, nurses, and other licensed professional care providers maintain current licenses and comply with the credentialing requirements of their own professions. Specific credentialing for work in addictions, by any formal body, is desirable, but not required.
- (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 used in the OTP and tailored to the patient populations served.
- (4) All staff members receive continuing education on opioid addiction treatment and related subjects. Staff may be qualified for their positions through training, education, and/or experience.
- (5) The OTP implements an individual annual training plan for each staff member.
- (6) The OTP develops detailed job descriptions for credentialed and noncredentialed staff. Job descriptions clearly define the qualifications and competencies needed to provide specific services.
- (7) Records of staff training events are kept and include the qualifications of educators, outlines of content, descriptions of methods, and rosters of attendees. OTPs maintain records of staff training events 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.

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 diagnose addiction or dependence, document that diagnosis, and admit each patient to maintenance or detoxification treatment as medically necessary.

Criteria for admission should be based on the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) (American Psychiatric Association [APA] 2000) definition of opioid dependence. Behavior supportive of a diagnosis of opioid dependence includes

- (i) Significant levels of tolerance resulting in 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) (APA 2000)
- (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 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 1-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 1-year history of addiction.
- (5) Finally, there may be individuals in special populations who have a history of opioid use, but 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 1-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) A physician assesses each patient before admission to medication-assisted treatment. The exceptional circumstance is that the physician may review the medical examination performed by another qualified health professional 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.^f

G. Informed Consent

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) Before medicating the patient, obtains voluntary, written, informed consent from each patient to the specific pharmacotherapy ordered by the physician.

- (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 discusses present level of functioning, course of treatment, and future goals. These discussions should not place an unfair burden or pressure on the patient to withdraw from medication or to remain on medication maintenance unless medically indicated.
- (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(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.

H. 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, program staff members complete a comprehensive physical examination, laboratory workup as indicated, psychosocial assessment, preliminary treatment plan, and patient orientation during the initial treatment stage.

(1) Screening, Assessment, and Evaluation^g

“Screening” is the process of determining whether large groups of people have certain risk factors associated with a substance abuse disorder, and referring appropriate candidates for further assessment. When conducting an individual screening, if the clinician determines that one or more risk factors are present, then the patient should receive an assessment for admission to treatment or be referred elsewhere for followup. Screening usually involves the use of one or more standardized techniques, such as a questionnaire or a structured interview. Screening may include observation of known presenting complaints and symptoms that are indicators of substance use disorders. Screening involves triage, a clinical determination to decide whether the patient is sufficiently physically and mentally stable to undergo assessment and treatment safely at the screening location (CSAT 2005, p. 293). If professional staff members identify a patient who is medically or mentally

unstable or at risk for imminent harm to himself or herself or others, then staff should arrange appropriate transfer to the required type and level of care.

“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 completing a personal substance abuse history, physical examination, laboratory evaluation, and determination of disease morbidity. Often, professional staff may further assess the severity of disease in terms of physiologic dependence, organ system damage, and psychosocial morbidity. Assessment also may involve determining patient motivation and readiness for change. (CSAT 2005, 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) A patient who is being admitted to treatment should receive intensive evaluations, including a medical and health history and physical examination, to determine initial dosage and to place the patient into the appropriate level of treatment. Collecting a health history and determining the length of drug dependence is helpful for appropriately placing the patient and to identify other chronic or acute medical conditions that need to be addressed. Upon completion of proper patient consent, the program should seek medical records from other health care providers.
- (b) Each program
 - (i) Determines current physical dependence and addiction. Staff members take a history, conduct an examination, and perform screening 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) Assesses the impact of induction onto the treatment drug. Methadone has well documented impacts on several organ systems, including the respiratory, nervous, liver, and cardiac systems. Therefore, the medical exam should consider whether the treatment drug will be methadone, buprenorphine, or another medication, or whether the treatment indicated is induction, detoxification, or maintenance. This assessment should occur upon entry into the program and includes documenting a list of medications the patient is currently taking with the actual (rather than prescribed) doses, any diverted or illicit substances the patient is taking, potential adulterants sometimes contained within illicit substances that are in themselves medically active (e.g., quinine), and medically active over-the-counter (OTC) or natural remedies. The physician should check on and consider interactions between these medications and the medication ordered to treat opioid addiction prior to initiating treatment.

For example, many medications can act to increase the QT interval seen on an electrocardiogram (EKG) and potentially lead to torsades de pointes, a potentially life-threatening cardiac arrhythmia. Physicians should be particularly aware of potential QT-prolonging effects of methadone, especially with high doses. In addition, physicians

should be aware of interactions between methadone and other medications that also have QT-prolonging properties, or with medications that slow the elimination of methadone (CSAT 2005, p. 35). The medical assessment should specifically cover the symptoms and risk factors for torsades de pointes, and any indicated follow-up tests that may include an EKG or a more comprehensive electrophysiological assessment. The treatment plan should also address concerns related to the discovery or risk of torsades de pointes.

- (iii) Documents medical and family history, including sex and age of children, whether children are living with parents, and family medical and drug use histories. A complete medical history is documented, and includes current information to determine chronic or acute medical conditions, such as diabetes; renal diseases; hepatitis A, B, C, and D; 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.
- (iv) Completes a psychiatric history and mental status examination with DSM-IV-TR (APA 2000) categorization.
- (v) Conducts a comprehensive evaluation conducted by one or more disciplines that include the 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 or earlier when necessary. The program completes assessment updates and treatment plan updates quarterly for the first year of continuous treatment. In subsequent years, the OTP updates assessments and treatment plans semiannually.
- (vi) Triage and refers patients who have the need for services not provided by the OTP to other care providers, as appropriate.
- (vii) For patients referred elsewhere, ensures that the exchange of information conforms to confidentiality regulations for patients in drug or alcohol treatment (42 CFR Part 2) and HIPAA regulations (45 CFR Part 160 and Subparts A and E of Part 164).

(2) Medical Laboratory Evaluation/Diagnostic Criteria

Based on an individual's history and physical examination, programs evaluate the possibility of infectious disease, liver or pulmonary conditions, cardiac abnormalities, psychiatric problems, dermatologic sequelae of addiction, and possible concurrent surgical and other problems by conducting testing or referring patients for consultation and testing. Not all assessments, screenings, and diagnostic evaluations need to be done within the program itself. It may be more appropriate to case manage the array of evaluations needed through a network of qualified and cooperating agencies and consultants. The program should have appropriate information-sharing agreements with these other providers, in accordance with Federal regulations. Patients referred for outside services should have access to nearby providers to facilitate better care for patients and to avoid additional travel and inconvenience.

- (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) Complete blood count (CBC) and lipid panel
 - (v) Electrocardiogram (EKG), chest x ray, Pap smear, and screening for sickle cell disease
 - (vi) Liver function tests and viral hepatitis marker tests
 - (vii) HIV testing and counseling
 - (viii) Tests appropriate for the screening or confirmation of illnesses or conditions, as recommended by U.S. Preventive Services Task Force or based on concerns specific to the patient regarding renal function, electrolyte imbalance, metabolic syndromes, pain, and so forth
 - (ix) Pregnancy test when indicated
 - (x) Appropriate neurological or psychological testing and assessment, as indicated
 - (xi) Based on baseline screening tests, appropriate referral for more diagnostic testing, especially when those results have potential to significantly change treatment decisions (such as when a screening EKG suggests a prolonged QT interval in a symptomatic patient)
- (b) 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. Individual patient need and local drug-using conditions and trends determine additional testing.
- (c) 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 on admission. Other tests may be deferred until the patient has stabilized.
 - (ii) Patients may also require other health care. Programs without primary care onsite should refer patients for laboratory tests and follow up on results. The optimal deadline for completing needed health-related procedures is 3 months after admission.

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.

I. Pregnant and Postpartum Patients^h

NOTE: Although promising, the level of evidence supporting buprenorphine maintenance during pregnancy is not as compelling as the evidence supporting methadone maintenance for pregnant women. As of this writing, both methadone and buprenorphine are Pregnancy Category C drugs,

which call for a careful risk/benefit analysis, but for which there is no known harm to the human fetus when medication is taken as directed and relapse is avoided.

- (1) The treatment program gives priority to pregnant women who seek treatment and documents on an intake log or in other accessible program records the reasons for denying admission to any pregnant applicant.
- (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 the treatment program refers the patient elsewhere for prenatal care, there are 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 if the pregnant patient cannot afford care or refuses prenatal care services, the treatment program, at a minimum, offers her basic prenatal instruction on maternal, physical, and dietary care as part of the counseling services 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 the program offered these services but the patient refused them.
- (5) For pregnant women in methadone treatment, the program
 - (a) Maintains patients who become pregnant during treatment on the prepregnancy dosage, if effective, and applies the same dosing principles as used with any other nonpregnant 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 a split dose.
 - (d) In general, detoxification during pregnancy is not recommended or considered the best practice. If a pregnant patient elects to withdraw from methadone and stays in the program, a physician experienced in addiction medicine supervises the withdrawal process with regular fetal assessments, as appropriate, for gestational age, as part of the withdrawal process. The physician should not initiate withdrawal before 14 weeks' or after 32 weeks' gestation.
- (6) The program supports the decision to breast-feed during methadone treatment, unless medically contraindicated, for example, by the presence of HIV or HTLV I or II infection in the mother. The treatment program should document appropriate counseling and informed decisionmaking between provider and patient to ensure that issues mentioned in the latest patient information sheets and product inserts for methadone are covered and understood.
- (7) The treatment program establishes and implements policies and procedures, including informed consent, to ensure appropriate followup and primary care for the new mother and well-baby care for the infant. Informed consent refers to the patient's agreement to receive treatment as well as agreement to release information to and obtain information from pertinent health care providers.

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

J. 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.

K. Neonatal Abstinence Syndrome

Infants prenatally exposed to opioids may experience neonatal abstinence syndrome, characterized by hyperactivity of the central and autonomic nervous systems 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 they 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 in accordance with current clinical practice guidelines and best medical practice (CSAT 2005, 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.

L. 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 recovery.

The stages of medication-assisted treatment are listed below. It is important at all stages that psychosocial treatment, 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 3rd to 7th day of treatment through 8 weeks.
- (c) Long-term treatment: from the end of early stabilization for an indefinite period, either in 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 in which access to a comprehensive treatment program is not feasible (e.g., emergency room, detention center, inpatient hospital unit, or other health care settings outside of certified OTPs) or for conditions such as pregnancy, HIV-spectrum disease, or other illnesses and psychiatric problems.
- (f) Findings from the initial medical assessment should be reassessed should there be any noted changes in the patient's physical condition or should the patient develop symptoms consistent with adverse events related to specific opioid medication treatment (e.g., developing symptoms consistent with torsades de pointes). Additionally, if there is any change in medication or other drug use documented in the initial and subsequent medical exams, then the clinical staff should pay specific attention to potential medication interactions.

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, while, in contrast, others may progress very quickly. It is not uncommon for a patient to relapse. There is both an individual and a public health advantage to maintaining a patient on medication, even when psychosocial 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 and when staff members identify a patient's relapse or when relapse "trigger" conditions exist.
- (b) Many patients often need psychosocial services for an extended period 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" (CSAT 2005).
- (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 Treatmentⁱ

- (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) The treatment program takes appropriate therapeutic measures to address the other problems identified in the treatment plan.

(4) Voluntary Patient Relocations, Program Transfers, and “Guest Dosing”

When a patient relocates, transfers to another treatment program, or needs temporary care at another program (“guest dosing”), the original treatment program ensures that the patient makes a smooth transition, and the program attempts to avoid breaks in treatment that could lead to relapse.

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

(5) Relapse Prevention

- (a) Psychosocial 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 N. (3), “Support of Medically Supervised Withdrawal.”)
- (c) Some patients progress into long-term pharmacotherapy and no longer need psychosocial services. If the need for psychosocial services reemerges, however, programs provide the opportunity to return to full services.

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 1 year.

M. Detoxification, Tapering, or Medically Supervised Withdrawal^j

As clinically appropriate, a physician may admit a patient to an OTP for “detoxification” treatment, hereinafter referred to as “medically supervised withdrawal.” “Medically supervised withdrawal” refers to a gradual reduction, or tapering, of the medication dosage over time under the supervision of a physician, to achieve the elimination of tolerance and physical dependence to opioid medications. “Tapering” is also a synonym for these terms. “Detoxification” is a legal and regulatory term that has fallen into disfavor with the medical community; some experts view “detoxification” as a misnomer because drugs used to treat addiction are not toxic when administered in proper dosages.

N. Medically Supervised Withdrawal From Medication^k

- (1) Medically supervised withdrawal is conducted
 - (a) As a voluntary and therapeutic process, agreed on by physician 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) The physician initiates voluntary supervised withdrawal from medication-assisted treatment in collaboration with and at the request of the rehabilitated patient. Voluntary supervised withdrawal is completely different and distinct from involuntary tapering or administrative withdrawal or other types of medically supervised withdrawal.
- (a) In initiating medically supervised withdrawal, the physician reduces dosages of medication at a rate well tolerated by the patient and in accordance with sound clinical judgment. For example, the physician decreases a dose by 1 to 2.5 mg per day for inpatients and 2.5 to 10 mg per week for outpatients.
 - (b) For women of childbearing potential, the physician conducts an assessment for pregnancy and reviews the results of a pregnancy test before initiating medically supervised withdrawal. (See 2. I. (5) (d)—The physician should not initiate withdrawal before 14 weeks’ or after 32 weeks’ gestation.)
 - (c) The OTP resumes medication-assisted treatment if the patient experiences impending or actual 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) A variety of supportive options is available to improve chances of a successful episode of medically supervised withdrawal.
- (b) Increased counseling is available prior to discharge.
- (c) Participants are encouraged to attend a 12-step or other mutual-help program that is sensitive to the needs of patients receiving medication-assisted treatment.

(4) Additional Considerations for Medically Supervised Withdrawal Against Medical Advice

- (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) In the case of a patient who leaves a program abruptly, the program may readmit the patient within 30 days without repeating the initial assessment procedure required by regulation 42 CFR § 8.
- (c) The program documents the issue that caused the patient to seek discharge and provides full documentation of steps taken to avoid discharge.
- (d) If medically supervised withdrawal fails, the physician considers initiating maintenance treatment.
- (e) In the case of a pregnant patient, the program keeps the physician or agency following the patient for prenatal care informed, consistent with privacy standards of 42 CFR 2.

O. 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. Because retaining the patient is not always possible, programs provide procedures for administrative withdrawal that employ the principles involved in medically supervised withdrawal from medication. Administrative withdrawal is usually involuntary. When a program makes the decision administratively to discharge a patient 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 the physician may adjust this timeframe depending on clinical factors. The program documents the person's condition during medically supervised withdrawal in the patient's record. On discharge, the program makes appropriate alternative referrals. Given the short timeframe 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 may have an adverse effect on the program, staff, or patient population of such gravity as to justify the involuntary medically supervised withdrawal and discharge of a patient, despite an extremely poor prognosis. Disruptive behaviors include violence, direct threat of violence, dealing drugs, repeated loitering, and flagrant noncompliance, resulting in an observable, negative impact on the program, staff, and other patients. Patients who exhibit disruptive behaviors should receive a mental health evaluation and referral, as appropriate, prior to administrative withdrawal.
 - (c) Incarceration or other confinement.
- (2) The OTP takes into consideration all factors affecting the patient on a case-by-case basis, and documents procedures for any involuntary terminations of patients.
- (3) Efforts made regarding referral or transfer of the patient to a suitable alternative treatment program should be documented.
- (4) The program makes specific efforts to ensure referrals are followed through to completion for the pregnant patient in the rare event the patient is administratively withdrawn and discharged. Provider(s) should carefully follow up with both patient's pregnancy and opioid dependency. It may be helpful for the program to establish prearranged agreements for treatment for this very purpose.

P. Continuing Care

- (1) An essential part of treatment is continuing care that includes discharge planning and relapse prevention.
- (2) Continuing care also includes procedures that address patients' physical and mental health problems following medically supervised withdrawal. For example, the program addresses the need for counseling and appropriate medication to help with sleep disorders, depression, and other problems.

- (3) The treatment program provides for continuing care following the last dose of medication, including making a referral for continuing outpatient care and planning for reentry to maintenance treatment if relapse occurs.

Q. Additional Treatment Planning Considerations

(1) Management of Co-Occurring Disorders

When possible and appropriate, 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. It is most critical that the treatment provider has an understanding of both the substance use and co-occurring disorder. If the appropriate level of expertise is not available within the program, then staff members arrange for the patient to receive appropriate care elsewhere. Consideration should be given to limit barriers to treatment, e.g., financial and transportation burdens and time to and from care.

(2) Alcohol and Other Drug Abuse

- (a) Programs manage concurrent abuse of other drugs within the context of the medication-assisted treatment, following principles described in TIP 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs” (CSAT 2005).
- (b) Program staff members are knowledgeable about current effective strategies for treating alcohol, cocaine, and other drug abuse.
- (c) Ongoing multidrug abuse is not necessarily a reason for discharge. Patients engaging in such multidrug use receive careful evaluations 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. The treatment decision for poly-drug-abusing patients should take into account the patient’s condition and the treatment team’s best clinical judgment. Treatment programs coordinate care with providers outside the OTP who prescribe medication with abuse potential.

(3) Care of Patients With Mental Health Needs

Treatment programs

- (a) Ensure that patients with mental health needs are identified through the assessment process and referred to appropriate treatment.
- (b) Ensure that patients are monitored during withdrawal and/or discharge for emergence of symptoms of mental illness.
- (c) Establish and use linkages with mental health providers in the community.
- (d) 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, followup care, counseling, safer sex, social responsibilities, universal precautions, and sharing of intravenous equipment.
- (b) Programs offer people living with HIV/AIDS options to promote maximum benefits of medication-assisted treatment during the course of HIV/AIDS treatment, including addressing medication side effects and toxicity.
- (c) Programs establish and utilize linkages with community HIV/AIDS treatment programs, social support services, and other HIV/AIDS prevention programs. 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. Programs arrange confidential information exchange—consistent with 42 CFR 2—to ensure that appropriate information reaches the providers caring for the patient.
- (d) The treatment program and the provider responsible for HIV/AIDS medication management work together to monitor and case manage medication adherence and adverse events.

(5) Treatment Considerations for Viral Hepatitis

- (a) Patients who test positive for viral hepatitis receive a referral for further evaluation and treatment, if necessary. Patients who test negative are immunized against hepatitis A and B, as appropriate, and against other viral hepatitis strains as those vaccines become available.
- (b) Staff should receive education about all forms of viral hepatitis and their effects on the health of the patient and engage in patient teaching on these subjects. Staff and patient education about hepatitis C is especially important, because it is the most common blood borne virus among intravenous drug users. Staff and patients should also be educated regarding the prevention of all forms of viral hepatitis, and the treatments for hepatitis, especially as they may affect the mental health of the patient and dosage levels of opioid medications.
- (c) Many patients identified as positive for hepatitis C virus (HCV) may benefit from antiviral therapy. The treatment program and the agency responsible for HCV and any other viral hepatitis medications should work together to monitor and case manage medication adherence and adverse events. Information exchanges, with patient agreement consistent with 42 CFR 2, ensure that appropriate information reaches the providers caring for the patient.

(6) Treatment Considerations for Smoking Cessation

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

(7) Co-Occurring Pain Patients¹**(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) Management of acute pain entails
 - Continuing the regularly scheduled dose of medication and
 - Additionally prescribing adequate doses of appropriate pain medications, including short-acting opioid medications.

(b) Other Principles of Pain Management

- (i) Treatment programs 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. This phenomenon is often referred to as “pseudo-addiction.”
- (ii) Generally, patients are not admitted to medication-assisted treatment to receive opioids only for pain, but there are exceptions to this principle especially if no pain treatment settings are available in the community.
- (iii) Patients with both chronic pain disorder and addiction should receive treatment from pain and addiction medicine specialists employing a multidisciplinary-team approach. The site of such treatment may be either a medical clinic or an OTP, depending on the patient’s 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 an OTP setting. Similarly, addiction patients in medication-assisted treatment may receive both medication-assisted treatment and adequate doses of opioid analgesics for pain; the regulations and treatment guidelines permit administering both when medically necessary.

(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 patients in treatment.
- (c) Programs ensure that persons in positions of authority are professionally and culturally competent. For example, program leadership should be able to work effectively with the local community and/or receive input from members of minorities or from advisers knowledgeable of gender, ethnicity, and language issues.
- (d) Print materials, electronic media, and course offerings employ unbiased and nonstigmatizing language.
- (e) As appropriate, programs offer treatment for groups organized with special needs in mind (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.^m
- (b) Treatment programs offer onsite education and training for all male and female parenting patients, or refer patients to appropriate parenting skills services, and make referrals for appropriate childcare services.
- (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 (CSAT 2005).

(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 nonharmful

alternative therapies as indicated (e.g., providing a space for sweat lodge ceremonies in a rural clinic serving Native Americans, or offering acupuncture).

(14) Treatment of Other Diseases and Conditions of Public Health Interest

- (a) Programs should treat patients diagnosed with disorders that require reporting to public health departments or refer those patients for further evaluation and treatment elsewhere. Examples of these types of diseases include TB and STDs. Programs should ensure that each patient has access to low-cost or free immunizations recommended by the CDC.
- (b) Staff members should become knowledgeable about existing and emerging diseases of a public health interest and educate patients about these conditions. Treatment programs are continually prepared to review and modify clinical approaches—and to address related mental health issues for patients and staff—as the public health environment changes.
- (c) Programs exchange information appropriately with the providers and health departments caring for the patients with reportable diseases or conditions, taking into account informed patient consent consistent with 42 CFR 2.

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 Treatment^a

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 withdrawal from medication

- (g) Patient's rights
- (h) Confidentiality and how release of information is permitted in accordance with 42 CFR Part 2
- (i) Toxicology testing procedures
- (j) Dispensing medication
- (k) HIV-spectrum and other infectious diseases
- (l) Potential drug interactions
- (m) Agreements needed to exchange appropriate information within the network of consultants and referral agencies in accordance with HIPAA Regulations and 42 CFR Part 2.

(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. Programs determine staffing patterns by taking into account the characteristics and needs of particular patient populations. Likewise, patient-to-staff ratios are sufficient to ensure that patients have reasonable and prompt access to counselors, and to provide the required frequency and intensity of counseling services.

(3) Twelve-Step or Other Mutual-Help Groups

The use of 12-step or other mutual-help groups should be encouraged. Sometimes these groups are unfamiliar with opioid addiction treatment. OTPs can establish their own 12-step or other mutual-help programs and should identify those groups that are accepting of maintenance pharmacotherapy.

(4) Counseling on HIV Infection and Other Conditions or Diseases of Public Health Importance^o

- (a) Programs provide counseling on HIV infection and other prevalent infectious diseases, such as hepatitis, sexually transmitted infections, and TB. Counseling also includes infectious disease prevention for at-risk patients, and the need for patients to adhere to treatment and to communicate honestly with the provider when treatment has begun.
- (b) Programs provide risk reduction education to patients.

(5) Medical Services

Providing basic primary care onsite is highly recommended but not required. Programs make referrals for medical and psychiatric treatment when indicated. Staff members provide coordination of care also, 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 TB 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) Programs use drug and alcohol screening and testing as aids in monitoring and evaluating a patient's progress in treatment.
- (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) Clinicians should determine the drug-testing regime by analyzing community drug-use patterns and individual medical indications. Testing may include opiates, benzodiazepines, barbiturates, cocaine, marijuana, methadone (and its metabolites), amphetamines, and alcohol, but testing is not limited to these substances.
- (5) It is 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 established by the Center for Substance Abuse Prevention are not appropriate for patients in the treatment context. The procedures and methodology for Workplace Standards employ a forensic approach that is entirely different from the therapeutic approach to treatment used in the clinical setting.
- (7) Program staff addresses results of toxicology testing with patients promptly. Programs document in the patient record both the results of toxicology tests and followup therapeutic interventions.
- (8) After the patient's initial admission drug testing, clinicians determine the frequency of toxicological testing by evaluating the clinical appropriateness for each patient in relation to the patient's stage in treatment.
- (9) The results of toxicological tests assist clinical staff in making treatment decisions regarding take-home medication privileges; however, clinicians do not base decisions about take-home medications or discharge solely on toxicology test reports.
- (10) Clinicians rapidly intervene to address the disclosure of illicit drug use, a positive drug test, or possible diversion of opioid medication, as evidenced by lack of opioids or related metabolites in drug toxicology tests.
- (11) Clinicians consider 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” (CSAT 2005, 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 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 Documentation^P

All records required by 42 CFR § 8.12 (g) 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 program records. Program procedures should ensure security of electronic data transfers and protection of confidential data stored in computers. Clear guidelines should exist for access, transfer, and disposal of records, to include procedures under disaster conditions or in the event of program closure, in accordance with 42 CFR 2.

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

Individual records maintained for each patient contain the following:

- (a)** Identification and basic demographic data and results of the screening process. In lieu of patient identification data, each file may bear a unique identifying code that gives reliable 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-psycho-social 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 all medications and dosages. 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 drug 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 received 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; and travel, employment, "take-home" documentation, and so forth.
 - (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 medications signs his or her name or initials at each notation.
 - (iv) If initials are used, the full signature of the qualified person administering or dispensing appears at the end of each page of the medication sheet.
 - (v) The medication dose 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) Avoiding Multiple Program Enrollments

- (a) 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.

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: Subutex and Suboxone Treatment for Patients Admitted to OTPs. SAMHSA-certified OTPs are authorized to dispense or administer (but not to prescribe) approved opioid treatment medications to patients admitted for opioid treatment. At this time, methadone and the buprenorphine products, Subutex and Suboxone, are approved for use in OTPs. Such treatment is not subject to the "30-patient limit" placed on physicians certified under the Drug Addiction Treatment Act (DATA) of 2000 or to the 100-patient limit placed on physicians under The Office of National Drug Control Policy Reauthorization Act of 2006. In addition, the special credentialing and 8-hour training requirements under that law do not apply to methadone and buprenorphine treatment for patients admitted to an OTP.

Subutex and Suboxone Treatment for Patients Treated by "Waivered Physicians." Physicians may seek and obtain a "waiver" under the DATA of 2000. If qualified, the physician is authorized to prescribe or dispense Subutex or Suboxone for up to 100 patients at any given time. The DATA does not limit the treatment settings for physicians with a waiver. Accordingly, the physician may treat patients in an office-based setting, a residential or inpatient facility that is not an OTP, or in an OTP (including as an OTP physician), as long as the total number of patients treated at any one time does not exceed 100.

U. Guidelines for Therapeutic Dosage⁴

(1) General Dosage Principles

- (a) The physician employs clinical judgment to determine the individual dose of opioid medication. The physician should have obtained program treatment privileges and should be knowledgeable about, and experienced in, addiction medicine including medication-assisted treatment.^r
- (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 medically supervised withdrawal protocol will be of sufficient duration for patient safety.
- (d) Program-wide dose caps or ceilings are contrary to the principle of individualized treatment, and programs should not establish them. Programs avoid establishing procedures or policies that hinder making patient dosage adjustments whenever indicated.
- (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 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. The physician should also take into account local conditions, such as the relative purity of available drugs and the source of the drugs, whether the patient illicitly purchased or obtained them from friends or family members. Medication dosage is also based on the physician's assessment and evaluation of other medications that the patient reports taking, including OTC drugs, prescription medications, and prescription medications containing controlled substances.⁹
- (c) The first dose of any opioid treatment medication should be low 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 mg. The physician considers carefully the reasons for exceeding an initial dose of 30 mg and documents these reasons in the clinical record. The total amount of medication administered should not exceed 40 mg per day, unless the physician documents that 40 mg did not suppress opiate abstinence symptoms after a 3-hour period of observation. Patients abusing diverted, prescribed opioids alone may also require a low initial dose of methadone. The physician should calculate the dosage based on standard dose conversion tables and the patient's recent amount of opioid intake. During the induction phase, caution should be exercised regarding an overly rapid increase in dosage because of the long half-life of methadone. As a suggestion, once the patient reaches a dose of 60 mg per day, it may be medically indicated to maintain a stable dosage amount for 3 to 5 days before further increasing the dosage, depending on the patient's clinical status and symptoms.
- (d) Initial doses of buprenorphine or LAAM (if reintroduced for dispensing) and other approved medications should be based on the package insert. The physician documents the justification for any deviations from this principle.
- (e) The total dose of medication and the interval between doses may require adjustments for the patient who has concurrent health conditions or atypical metabolic patterns, or if the patient takes other prescribed medications that alter rates of opioid medication metabolism.
- (f) Programs do not adjust medication doses 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) Programs continue medication-assisted treatment as long as the patient derives benefit from treatment and desires treatment. There should be no fixed length of time in treatment. In fact, indefinite medication-assisted treatment may be clinically indicated. The physician should also be prudent in considering other medications during the course of treatment, as clinically indicated.

- (h) If a program switches from one generic formulation to another and differences in effective dose cause clinically relevant complaints, the physician may decide to adjust the medication dosage. Additionally, physicians should exercise caution when a patient has missed several doses, because patient tolerance may have changed over time.
- (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 1-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)^t

(1) Approving Take-Home Medication

- (a) In determining patient eligibility for *any* take-home medication, including a single take-home dose for a day that the clinic is closed for business, such as Sunday or a State or Federal holiday, the program physician considers the eight-point criteria and employs good clinical judgment.

Take-home medication is a valuable therapeutic tool and is part of an individualized treatment plan. 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. Program policies that do not permit take-homes for any patients are unacceptable, because these policies preclude individualized patient care. Take-home medication often becomes a critical issue for 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. Physicians and staff members should consider public health issues 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 to patients' continuing in treatment. Program policies foster decisions about entering and remaining in medication-assisted treatment 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. Physicians and staff members review decisions periodically, as clinically appropriate, and document them in the patient record. The review should consider the eight-point criteria and other relevant clinical factors. The physician should note conclusions reached in this review in the patient's record.

- (b) Programs should exercise caution when dispensing Subutex; Suboxone is the preferred medication for take-home dispensing (or prescriptions) unless otherwise clinically indicated. Treatment with Suboxone may follow guidelines described in CSAT's Treatment Improvement Protocol 40 (TIP 40) and other related CSAT publications. In following these guidelines, take-home medication decisions may differ if the patient is receiving Suboxone instead of methadone. Programs should use the CSAT patient exception process to justify take-home medications for Suboxone.¹
- (c) Temporary take-home medication may be dispensed for documented family or medical emergencies or other exceptional circumstances.¹ In such emergencies, take-home medication

usually should not exceed 3 days. This does not obviate the need for a CSAT patient exception, only the need for preapproval.

(2) Monitoring Unsupervised Use of Medications^u

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

(3) Medication Security^v

- (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 establish a mechanism for monitoring medications to prevent diversion.

W. 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 inform patients, both verbally and in writing, of clinic rules and regulations and patients' rights and responsibilities.
- (d)** Programs establish procedures to provide medication to traveling patients and consider providing take-home medication. At times, when patients must transfer to a different level of care or location, it may be appropriate for the program to provide sufficient medication for the patient until arrival at the new location. Under these circumstances, a record of chain of custody for transporting methadone to the new program may be required. Please see Standard and Example Forms, p. 64 for an example of the Chain-of-Custody form.
- (e)** Programs establish reimbursement expectations with the patient, and work with the patient to receive, through agreed procedures, reimbursement for services rendered. Programs establish processes to resolve patient's financial difficulties that might occur over the course of treatment. Programs also establish policies in the event of nonpayment.

(2) Patients' Rights and Responsibilities^w

(a) Informed Consent and Information Disclosure

- (i)** Patients have the right to receive accurate, easily understood information. Some require assistance in making informed health care decisions about choosing 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 interventions are documented. The patient receives a written copy of these rights, including the following information:
 - Programs provide treatment that is fair and impartial, regardless of race, sex, age, and source of payment, and that conveys a sense of dignity and trust to the patient.
 - Programs provide treatment 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 patients are offered a written acknowledgment 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 acknowledgment 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 are 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 OTC pharmacological agents, other medical procedures, and food.
- (vi) Programs inform patients about 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 choose health care providers that are sufficient, and that ensure access to appropriate high-quality health care.
- (ii) Each patient receives an assessment, and then staff members notify the patient of acceptance into the program, as appropriate. In the case of denial of admission, the OTP provides a full explanation and a referral to another program based on the results of the initial assessment.
- (iii) Patients 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 the most accommodating and least intrusive and disruptive schedule for the majority of patients.

- (iv) Patients 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 the treatment plan jointly.
- (v) The program provides an adequate number of competent, qualified, and experienced professional clinical staff to implement and supervise the treatment plan, consistent with patient needs.
- (vi) Patients are 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 representation 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 can be made to an alternative method of care.

Treatment and other services may not be denied for patients who refuse to participate in research activities.

(f) Confidentiality of Health Information and Patient Privacy^x

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 a 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 are encouraged and assisted throughout treatment to understand and exercise their rights, 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
- Telephone number of the State regulatory agency responsible for the program and name of a specific individual or title of the person within that agency who receives complaints
- Please see Standard and Example forms, p. 63, for the Consent-to-Treatment form.

(iii) Preventing, Investigating, and Resolving Patient Complaints

Programs develop and 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 is 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 program acts responsibly in that it does not change the patient's dose of opioids or other medications 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 quality improvement in a cost-conscious environment.

- (i)** Patients should be involved in their treatment plans so that they become more likely to agree with them.
- (ii)** Once the treatment plan is formulated, the patient should make every effort to follow it and discuss with the primary counselor any difficulties adhering to it. If possible, the patient may also recommend modifications in the treatment plan that make adherence to it easier.
- (iii)** Patients should be encouraged to be honest with their primary counselor and discuss relapse concerns and possible barriers to following the treatment plan.
- (iv)** If relapse occurs, the patient works with the counselor and is involved in contingency plans and in formulating a modified treatment plan.

Endnotes

a. Program Emergencies:

Guidance for Treating OTP Patients From Areas Affected by Emergency Closure of Programs in the Event of a Disaster

On August 31, 2005, SAMHSA issued guidance to the State Methadone Authorities (SMAs) and OTPs in those States directly affected by Hurricane Katrina. That guidance can be found at <http://dpt.samhsa.gov> and addresses patients in OTPs, as well as persons dependent on opioids who are not enrolled in addiction treatment.

Guidance: Programs receiving displaced patients should make every effort to contact the home treatment program of people who have had to evacuate the area in which they live after an emergency or disaster. Information about the program may be obtained from the OTP Directory on the DPT Web site (referenced above) or at the SAMHSA Substance Abuse Treatment Facility Locator at: <http://dasis3.samhsa.gov/>. In an emergency, program personnel may disclose information to the program medical director, program physician, registered nurse, or dosing nurse without a patient’s signed consent. If unable to contact the patient’s home program, the OTP receiving a displaced 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 affected.
- 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, for example, a medication bottle, program identification card, or a receipt for payment of fees, etc. In cases in which the patient does not have any items of proof including picture identification, 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 turnaround, dipstick, or similar procedure).
- OTP staff 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. It may be prudent to closely observe an unknown patient for several hours postadministration to ensure that the dosage decision was correct, or take appropriate medical action in the event the dose was too high. 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).)
- Emergency guest patients should be medicated daily with take-home doses provided only for days that the program is closed (Sundays and holidays). The clinic should have a plan to administer methadone appropriately and safely on days or at times when the program is closed. If the patient’s current take-home status is 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 receive daily treatment at the program location due to medical hardship, travel restrictions, or other hardship, take-home medication for unsupervised use may be considered using the SMA-168, “Request-for-Exception” process.
- Documentation of services provided to displaced patients should be a priority for OTPs. The OTP should assign a clinic identification number and maintain a temporary medical record for each guest patient. 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. OTP staff 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. On 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 SMA and/or SAMHSA.

Opioid-Dependent Displaced Patients Not Currently in Treatment: There are individuals dependent on opioids—including heroin or prescription drugs—who may arrive at the guest 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. Initiation on buprenorphine products may be appropriate for patients new to medication-assisted treatment.

Displaced Patients Treated by Pain Clinics: Patients who were being treated for pain with methadone by a physician may contact an OTP when they run out of medication and have no access to the former treatment setting. The first response should be to refer the patient to a local physician, particularly a pain management specialist. Additionally, the SAMHSA guidelines provide the following guidance:

- Patients, in general, are not admitted to OTPs to receive opioids only for pain, but there are exceptions to this principle.
 - 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 each patient’s 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 (DATA) were established to allow for maintenance and detoxification treatment, using certain opioid controlled substances like methadone and buprenorphine. 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 pain by tapering or weaning doses, there are no restrictions, under Federal opioid treatment regulations, 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 OTP 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.
- b. **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 re-certify patients for payment, require strict attention to Federal confidentiality regulations. Ethical conduct by program staff 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 a staff member is not properly licensed at the time of an incident or other adverse action.
- c. **Events That Require Immediate Response and Investigation:** The specific event or incidents requiring preventive action, documentation, investigation, and corrective action will vary by program and patient’s characteristics. Such significant incidents or adverse events might include accidental injury on the premises, medication errors, unexpected 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.

- d. **Community Relations:** Before a new program moves in and opens its doors, there is a strong need to educate all entities affected by the program, including the medical community, neighbors, and those who provide support services.
- e. **Professional Staff Credentials and Development:** 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 client-to-counselor ratio of 40:1. All of these States allow for an increase in the ratio under certain circumstances.
- f. **“Standing Orders”:** In some disciplines of medicine, “standing orders” refer to a practice where dosing (and, in some cases, admission) decisions are based on an algorithm that includes objective findings, time in treatment, and other factors—without the input of an authorized health professional (see above). Sometimes, program physicians issue standing orders that merely state that dose levels be adjusted on a PRN (“as needed”) basis. These types of standing orders do not reflect individualized care and are unacceptable.

There is always the exception or emergency situation when a verbal order may be issued by the physician, but these situations are rare. It is recommended that if standing orders are issued, that they be individualized, reasonable, time limited, and reviewed and signed within a 72-hour period. In addition, the physician should pay special attention to risk and liability concerns in such situations.

- g. **Screening, Assessment, and Evaluation:** The initial assessment’s focus is usually on the patient’s admission to treatment and determining dosage level. A comprehensive examination is performed within approximately 30 days, usually after the patient is stable and 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 making a serious attempt to refer and encourage the patient to obtain appropriate evaluations. The program is responsible for following up on the results. 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.
- h. **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 on program staff because of the multiple legal ramifications that exist. Because it is crucial that pregnant women engage in treatment for their addiction, OTPs should give priority to admitting pregnant patients at any point during pregnancy and to providing them with all necessary care, including adequate dosing strategies as well as referrals for prenatal and followup postpartum services.
- i. **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 often negative, whereas patients who remain in treatment, despite continued excessive use of alcohol or illicit drugs, tend to benefit from the treatment experience.
- j. **Tapering Medication Dosage or Medically Supervised Withdrawal:** These guidelines focus on patients who have been participating in medication maintenance treatment, because research has shown maintenance treatment to be more successful than a regime of medical withdrawal (“detoxification”) for the majority of patients (Institute of Medicine 1995). Patients who are medically withdrawn without an adequate period of stabilization tend to have a high probability of relapse. Thus, the guidelines place less emphasis on issues of medical withdrawal of opioid-addicted persons, even though this modality has a role in the treatment armamentarium. Medical withdrawal from opioids is appropriate for persons who are not eligible for maintenance treatment or who do not elect this type of treatment, such as those on short- and long-term detoxification as defined in Federal regulation. Involuntary “administrative withdrawal” requires

that OTPs define and follow due process. 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.

- k. **Medically Supervised Withdrawal:** Medically supervised withdrawal usually does not have the same time constraints associated with administrative withdrawal. As a result, programs may 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.
- l. **Patients With Co-Occurring :** Patients who are diagnosed with physical dependence and a pain disorder may receive 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.
- m. **Family involvement contributes to positive outcomes in treatment while providing benefits 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, their 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 followup has occurred should be obtained. If needed, identification of the ongoing need for collaboration should occur with informed patient consent.
- n. **Orientation to Treatment:** Take into account that the patient may be in withdrawal or intoxicated in the first days of treatment. Ongoing informed consent is necessary.
- o. **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” (CSAT 2005), these materials may enhance services at OTPs.
- p. **Record Keeping:** Programs use standard intake forms or identical data elements when possible. Programs should be efficient and avoid duplication in record keeping. At the same time, the program gathers sufficient data for outcome, cross-site, or other evaluations or studies, or to support managed care data requirements.
- q. **Dosage:** The thrust of these guidelines is 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 specific guidelines for initial dosing. TIP 43, “Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs” (CSAT 2005) discusses subsequent dosing during the induction and stabilization periods in detail.
- r. **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 to provide medical services in OTPs in States that, in turn, accept and recognize their credentials to prescribe scheduled medications. Following the admission of patients by the program physician, the nurse practitioner or physician’s assistant in the OTP is empowered to provide medication services such as methadone and buprenorphine adjustments (increases/decreases), detoxification regimens, and medically supervised withdrawal.

- s. **Patients' Outside Prescriptions:** OTPs should establish policies that relate to the various medications that patients may receive while in treatment. These include OTC medications and medications—some of which may contain controlled substances that physicians outside the treatment program prescribe for acute and chronic illnesses. The policies should follow two basic principles: (1) The patient should show all medications, including OTC medications 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 that 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 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 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 also should 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.
- t. **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, SAMHSA Form SMA-168**. Frequently, these exceptions may be granted even if the patient has not followed all clinic rules, 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, sign, and submit an SMA-168 Exception Request and Record of Justification. Without Federal approval of an Exception Request, the OTP may not dispense the take-home supply of medication to the patient for unsupervised use. The most important aspect of the exception request is to explain in detail the purpose and justification and to give a clear explanation of hardship—i.e., distance in miles, hours of employment, conflict with employment, and/or medical issue—so that the DPT reviewer is able to understand clearly the patient's 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 1-866-687-2728. 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 processing time for a response is the same day, usually within hours.
2. In case of emergency, program staff may submit an SMA-168 through facsimile (fax) to 1-240-276-1630. The form may be downloaded from the DPT Web site at www.dpt.samhsa.gov, or e-mailed or faxed if a verbal request is made, by calling 1-240-276-2700. The processing time for a response for a fax transmission may exceed 24 hours.

Guest Dosing

Guest dosing involves providing medication to a "guest patient" in a program in which the patient is not enrolled, such as when a patient travels to another city for a period of temporary employment and needs to receive medication. Guest dosing is recommended for patients who do not meet the criteria outlined in

42 CFR § 8.12 (i) (2) (i–viii). Guest dosing may prove helpful when a patient will be remaining in an area for a protracted period, and it is impractical to return to the patient’s home program routinely to pick up a supply of take-home 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.

- u. **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 a toxicology test for methadone metabolites, for example.
- v. **Opioid Treatment Patients and Temporary Residential Treatment:** 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 unused medication supply issues that need to be resolved.

Because an individual patient may not return unused controlled substance prescription medication to the OTP, the program should have a procedure to ensure medications are disposed of in a manner that does not allow the controlled substances to be easily diverted for illegal use.

Guidelines for Security of Take-Home Medication

Patients receiving unsupervised (take-home) medication should use locking containers to store their medication at home. The locking container provides a reasonably safe place for the medication at home but provides little in the way of security from the program to the patient’s home. Patients inconspicuously and safely transport take-home medication from the program to the home without the program mandating a specific type of locking container. In fact, the locked container challenges two regulatory issues: (1) if the locked container is publicly visible, it may offer a means to identify someone in treatment and violate patient confidentiality; and (2) the container’s visibility may identify the patient possessing take-home medication, and place the patient at risk for robbery or assault.

For patients reporting to the clinic once or twice per month, receiving 15- to 30-day supplies of medication, the OTP should dispense dry medication diskettes in one single bottle for ease of discrete transport home. Programs should also consider medication diskettes for patients using air transportation. Dispensing dry medications will mitigate any potential for bacterial growth in liquid media.

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 unable to report to the program for routine observed ingestion of medication. This absence may occur because of illness, pregnancy, incarceration, participation in residential treatment, lack of transportation, and the like. When these situations occur, continuing the patient’s treatment safely while ensuring appropriate handling and delivery to the patient is a challenge for clinical staff.

This is usually accomplished by using a “Chain-of-Custody Record,” which is a document containing the signatures of all people who have handled the medication (see page 64). This record should also contain space for the patient to initial each day that the medication is administered, as well as space for the initials of the person who administered the medication. The patient and the person administering the medication should contact the program immediately if the medication seems altered in any way.

When the patient is unable to report to the program as required, a Chain-of-Custody Record is used to encourage a responsible person to take charge of the medication and place it under lock and key at the

offsite 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 staff members have 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.

- w. (1) **Consumer Bill of Rights:** 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 may undergo significant stress during admission, and programs should offer additional opportunities for them to review their rights and responsibilities 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.
- x. **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 workspace; a cashier located in public area; untrained security guards; common medication dispensing areas; and hallway conversations about HIV/AIDS, failed urinalysis, or psychiatric medications. OTPs should take measures to correct such problems, when possible.

Appendix A. References

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Appendix B. 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 “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 considered the perspectives of regulation, science, and the burden of conformance to the guidelines. They also considered issues such as treatment 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. They did not take part in the final group decisionmaking process, which resulted in the editing and updating of the current guidelines.

Accreditation Guidelines Expert Panel October 31–November 1, 2005

Chair

Lawrence Brown, M.D., M.P.H.

Senior Vice President
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Panelists

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Appendix C. Frequently Asked Questions

I. SMA-162 Application Process

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

A—Submit an SMA-162 form. In Item 14 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, and Renewal.

You may access this form on the Internet 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 1-240-276-1630. You may also mail the form to the address listed below.

Substance Abuse and Mental Health Services Administration
Office of Pharmacologic and Alternative Therapies
Attention: OTP Certification Program
Room 2-1086
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—Now that SAMHSA provides oversight for opioid addiction treatment under 42 CFR Part 8, the “FDA number” is now called a “SAMHSA number.” To request a SAMHSA number, please submit a completed SMA-162, and in Item 14 on the form, check the “Provisional Certification” box. SAMHSA will review your application for completeness using the checklist, included in your application packet, and 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 e-mail otp@samhsa.hhs.gov or call 1-240-276-2700.

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 14 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 (SMA) 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 (Item 6) 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 who 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 Items 6 and 10 (14?) of the SMA-162 (e.g., medical director or program sponsor).

9. Q—What are the differences between provisional certification, certification, and accreditation?

- **Certification** is the process by which SAMHSA determines that an OTP 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 the patient’s health would be adversely affected by the granting of provisional certification.
- **Accreditation** is defined by 42 CFR § 8.2 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 that use opioid agonist treatment medications. An OTP must receive accreditation before it may be certified by SAMHSA.

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.

II. Detoxification Programs

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

A—Yes. CFR defines an OTP as a “program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.” The regulations—42 CFR § 8.11 (a) (1)—state that an OTP must have a current, valid certification from SAMHSA to be considered qualified by the Secretary of DHHS to dispense methadone, LAAM, or buprenorphine 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.

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. Title 42 of the CFR Part 8 addresses 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”—21 CFR 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 emergencies in which a patient undergoing withdrawal needs treatment. 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 is available 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, please consult with DEA for further details.

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.

III. 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-home medications in such a manner because it may place the patient at risk for relapse or tempt the patient to divert medication for illegal use.

2. Q—Our program is considering dispensing tablets for patients who have take-home privileges. 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 pose less 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-home medication for both short- and long-term detoxification patients. Under the previous regulation, FDA approved program-wide exemptions to permit holiday take-home medications. SAMHSA will review annual program-wide exemption requests to permit take-home dosages for holidays for patients in short-term detoxification treatment.

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.

IV. 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 on 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 health care 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 it identifies abuse of other drugs or alcohol 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 at <http://www.treatment.org/Externals/tips.html> online.

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

A—The regulations require that OTPs perform adequate testing services at minimum intervals. SAMHSA 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 are 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. On 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 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 that the physician and the mother should make.

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 OTPs no longer use the old “Consent to Methadone Treatment” form. 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 from which she was discharged 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 the physician examines the patient and writes an admission order. The patient does not have to use drugs again to be admitted.

V. 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 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 “Guidelines for the Accreditation of OTPs” discourage dosage caps. OTP and physician education appears 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 in opioid addiction treatment. 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 to reduce the potential for intravenous administration pose less risk of a diversion 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)).

VI. 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 LAAM take-home medications. Finally, the new take-home schedule resembles the schedule in the “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 deemed eligible for a 2-week supply. While the previous regulation may have permitted an additional take-home dose of methadone after the 1st 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 SAMHSA has reviewed and will continue to accept single-patient exception requests, SAMHSA 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 (vii), states, “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 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 “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 LAAM will still be a tripartite system involving the State, HHS, and 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 four States, which formerly did not have methadone treatment, now have methadone treatment available. These States are West Virginia, Vermont, New Hampshire, and Mississippi.

VII. Drug Testing

1. Q—Our 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 SAMHSA rules specify urine as the only type of biological sample that can be tested; however, they do say: “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 to determine 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.

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 to comply in this area and to document the adequacy of any testing approach. Whatever drug abuse test the OTP uses as a part of the accreditation survey, the OTP must be able to support the use of the test with documented evidence showing that the test is adequate.

Oral Fluid Testing—A CSAT letter to the field dated July 18, 2003, provides that offsite drug testing using oral fluids may be adequate, at least in some populations, for the purposes of 42 CFR 5 8.12 (f) (6). It is CSAT’s view that sufficient information is now available for medical directors to make a determination of the adequacy of oral fluid testing in the OTP setting.

VIII. Miscellaneous

1. Q—What are nonphysician health care professionals authorized to do under the regulations?

A—Nonphysician health care professionals are permitted to conduct various activities under the regulations. For example, under 42 CFR 8.12 (f), an authorized health care 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, physician assistants and nurse practitioners, under the supervision of a physician, are authorized to modify patient medication levels. It is incumbent on 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 health maintenance organizations (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 2 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 has issued a letter to the field encouraging programs to pursue this option, which has the potential to expand treatment capacity.

Appendix D. 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 withdrawal.

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.

Methadone Chain-of-Custody Record

Date: _____

Name of Treatment Program: _____

Name of Treatment Program Dispensing Nurse: _____

Medication To Be Delivered (Methadone/Suboxone/Subutex): _____

Number of Doses To Be Delivered: _____

Medication Provided From _____ to _____
(Date) (Date)

Name of Person Transporting Medication: _____

License Number of Person Transporting Medication: _____

Date Medication Received: _____ Number of doses received: _____

Medication Received Covering _____ to _____
(Date) (Date)

COMMENTS: _____

Signature of person receiving medication

Signature of person transporting medication

Date of Administration and Initials of Patient Receiving Medication

DATE	Pt. Initials	DATE	Pt. Initials
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

SMA-162 and SMA-168

<p>D. Attached are the names, addresses, and a description of each hospital, institution, clinical laboratory, or other facility used by this program to provide the necessary medical and rehabilitative services.</p> <p>E. A medical director will be designated to assume responsibility for administering all medical services performed by the program. If a medical director is responsible for more than one program, the feasibility of such an arrangement will be documented and submitted to SAMHSA. Within three weeks of any replacement of the medical director, I shall notify SAMHSA.</p> <p>F. Attached is the address of each medication unit or other facility under control of the OTP. Any new dispensing site for this program, including medication units shall be approved by SAMHSA and the State authority prior to its use. SAMHSA and the State authority shall be notified within three weeks of the deletion of any facility used to dispense opioid treatment drugs.</p> <p>G. A patient records system will be established and maintained to document and monitor patient care in this program. It shall be maintained so as to comply with the Federal and State reporting requirements relevant to narcotic treatment. A drug dispensing record will be maintained to show dates, quantity, and batch or code marks of the drug administered or dispensed, traceable to specific patients. This drug dispensing record must be retained for a period of three years from the date of dispensing.</p> <p>H. I have a copy of or access to 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. I have read and understand the requirements to maintain the confidentiality of alcohol and drug abuse treatment patient records. I agree to protect the identity of all patients in accordance with the regulations.</p>	<p>I. I shall comply with the security standards for the distribution of controlled substances, as required by 21 CFR § 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances.</p> <p>J. I agree to comply with the conditions of certification set forth under 42 CFR § 8.11(f). In addition, I shall allow, in accordance with Federal controlled substance laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, the DEA, and by authorized employees of any relevant State or Federal governmental authority. I agree that OTPs must operate in accordance with Federal opioid treatment standards and accreditation elements.</p> <p>K. I agree to adhere to all rules, directives, and procedures set forth in 42 CFR Part 8, and any regulation regarding the use of an opioid drug for the treatment of narcotic addiction which may be promulgated in the future. I shall inform other individuals who work in this treatment program of the provisions of this regulation, and monitor their activities to assure compliance with the provisions.</p> <p>L. I understand that failure to abide by the rules, directives, and procedures described above may cause a suspension or revocation of approval of my registration by the Drug Enforcement Administration.</p> <p>M. I, as program sponsor, certify that the information submitted in this application is truthful and accurate.</p>
PROGRAM SPONSOR (<i>Signature</i>)	DATE
<p><i>Please send three copies of this form and all attachments to:</i></p> <p>Center for Substance Abuse Treatment Division of Pharmacologic Therapies Substance Abuse and Mental Health Services Administration Attention: OTP Certification Program 1 Choke Cherry Road, Suite 2-1086 Rockville, MD 20857</p> <p>Overnight: 1 Choke Cherry Road, Suite 2-1086 Rockville, MD 20850</p> <p><i>and two copies to the appropriate State authority.</i></p> <p><i>If submitting this form electronically, please submit electronic copies of all attachments by e-mail to otp@samhsa.hhs.gov or submit three copies of all attachments to the mailing address above.</i></p>	
<p>Paperwork Reduction Act Statement</p> <p>Public reporting burden for this collection of information is estimated to average between 6 minutes and 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to SAMHSA Reports Clearance Officer, Paperwork Reduction Project (0930-0206); Suite 7-1043, 1 Choke Cherry Road, Rockville, MD 20857. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0206.</p>	

FORM SMA-162 (revised January 2007) (BACK)

DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION CENTER FOR SUBSTANCE ABUSE TREATMENT		Form Approved: OMB Number 0930-0206 Expiration Date: 01/31/2010 See OMB Statement on Reverse	
Exception Request and Record of Justification Under 42 CFR § 8.11(h)		DATE OF SUBMISSION: _____	
Note: This form was created to assist in the interagency review of patient exceptions in opioid treatment programs (OTPs) under 42 CFR § 8.11(h).			
Detailed INSTRUCTIONS are on the cover page of this form. PLEASE complete ALL applicable items on this form. Your cooperation will result in a speedy reply. Thank you.			
Program OTP No: <input type="text"/> - <input type="text"/> , <input type="text"/> - <input type="text"/> (Same as FDA ID)		Patient ID No: <input type="text"/>	
BACKGROUND INFORMATION	Program Name: _____		
	Telephone: _____ Fax: _____ E-mail: _____		
	Name & Title of Requestor: _____		
	Patient's Admission Date: _____ Patient's current dosage level: _____ mg <input type="checkbox"/> Methadone <input type="checkbox"/> LAAM <input type="checkbox"/> Buprenorphine <input type="checkbox"/> Other: _____		
	Patient's program attendance schedule per week (Place an "X" next to all days that the patient attends*): <input type="checkbox"/> S <input type="checkbox"/> M <input type="checkbox"/> T <input type="checkbox"/> W <input type="checkbox"/> T <input type="checkbox"/> F <input type="checkbox"/> S *If current attendance is less than once per week, please enter the schedule: _____		
	Patient status: <input type="checkbox"/> Employed <input type="checkbox"/> Homemaker <input type="checkbox"/> Student <input type="checkbox"/> Disabled <input type="checkbox"/> Other: _____		
	Nature of Request: <input type="checkbox"/> Temporary take-home medication <input type="checkbox"/> Temporary change in protocol <input type="checkbox"/> Detoxification exception <input type="checkbox"/> Other: _____		
	Decrease regular attendance to (Place an "X" next to appropriate days*): <input type="checkbox"/> S <input type="checkbox"/> M <input type="checkbox"/> T <input type="checkbox"/> W <input type="checkbox"/> T <input type="checkbox"/> F <input type="checkbox"/> S Beginning date: _____ *If new attendance is less than once per week, please enter the schedule: _____		
	Dates of Exception: From _____ to _____ # of doses needed: _____		
	Justification: <input type="checkbox"/> Family Emergency <input type="checkbox"/> Incarceration <input type="checkbox"/> Funeral <input type="checkbox"/> Vacation <input type="checkbox"/> Transportation Hardship <input type="checkbox"/> Step/Level Change <input type="checkbox"/> Employment <input type="checkbox"/> Medical <input type="checkbox"/> Long-Term Care Facility <input type="checkbox"/> Other Residential Treatment <input type="checkbox"/> Homebound <input type="checkbox"/> Split Dose <input type="checkbox"/> Other: _____		
REQUEST FOR CHANGE	Regulation Requirements:		
	1. For take-home medication: Has the patient been informed of the dangers of children ingesting methadone or LAAM? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
	2. For take-home medication: Has the program physician determined that the patient meets the 8-point evaluation criteria to determine whether the patient is responsible enough to handle methadone as outlined in 42 CFR § 8.12(i)(2)(i)-(viii)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
	3. For multiple detoxification admissions: Did the physician justify more than 2 detoxification episodes per year and assess the patient for other forms of treatment (include dates of detoxification episodes) as required by 42 CFR § 8.12(e)(4)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A		
REQUIREMENTS	Submitted by: _____ Printed Name of Physician Signature of Physician Date		
	State response to request: <input type="checkbox"/> Approved <input type="checkbox"/> Denied _____ State Methadone Authority Date		
	Explanation: _____		
	Federal response to request: <input type="checkbox"/> Approved <input type="checkbox"/> Denied _____ Public Health Advisor, Center for Substance Abuse Treatment Date		
	Explanation: _____		
APPROVAL	Please fax to CSAT/DPT at (240) 276-1630 or e-mail: otp@samhsa.hhs.gov		
	This exception is contingent upon approval by your State Methadone Authority (as applicable) and may not be implemented until you receive such approval.		

FORM SMA-168 (revised January 2007) (FRONT)

Purpose of Form: This form was created to facilitate the submission and review of patient exceptions under 42 CFR § 8.11(h). This does not preclude other forms of notification.

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FORM SMA-168 (revised January 2007) (BACK)

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