FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

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FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

INTRODUCTION

The *Federal Guidelines for Opioid Treatment Programs* (Guidelines) describe the Substance Abuse and Mental Health Services Administration's (SAMHSA) expectation of how the federal opioid treatment standards found in Title 42 of the Code of Federal Regulations Part 8 (42 CFR § 8) are to be satisfied by opioid treatment programs (OTPs). Under these federal regulations, OTPs are required to have current valid accreditation status, SAMHSA certification, and Drug Enforcement Administration (DEA) registration before they are able to administer or dispense opioid drugs for the treatment of opioid addiction. As stated in 42 CFR § 8.12(i)(2), these regulations apply to "opioid agonist treatment medications that are approved by the Food and Drug Administration." Currently, these drugs are methadone and pharmaceutical products containing buprenorphine, hereafter referred to as buprenorphine. The regulations apply equally to both of these medications, with the only difference being the time and treatment requirement for unsupervised dosing spelled out in 42 CFR § 8.12(i)(3). Other pharmacotherapies may be provided in a manner consistent with the best medical practices for each drug. For example, the use of naltrexone has a place in OTPs but is not subject to these regulations.

The regulations describe a minimum acceptable standard for the operation of OTPs. They are not intended to provide clinical or medical guidelines but rather to assure, to the greatest extent possible, the safety of both the patient and the public. Given that OTPs provide a medical service, the care delivered should be comparable to the medical care provided in other settings. These guidelines are but one piece of what is necessary to provide comprehensive patient-centered care. They are not intended to take the place the professional judgment of healthcare providers and are not professional standards of care.

SAMHSA- approved best practices for methadone can be found in the Treatment Improvement Protocol 43 (TIP 43): Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf). For SAMHSA's best practices for the use of buprenorphine, refer to TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (http://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/TOC.pdf).

In addition, SAMHSA partnered with the National Institute on Drug Abuse (NIDA) to provide guidance for the use of medication-assisted treatment with extended-release injectable naltrexone for the treatment of an opioid use disorder. The *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide* can be accessed at http://store.samhsa.gov/shin/content/SMA14-4892/SMA14-4892.pdf. This brief guide includes a summary of the key differences between extended-release injectable naltrexone, methadone, and buprenorphine. It covers key information on assessing the patient's need for treatment, initiating medication-assisted treatment, monitoring patient progress and adjusting the treatment plan, and deciding whether and when to end medication-assisted treatment.

Although the federal regulations have not changed since their original adoption in 2001, the real-world issues of opioid use disorders, the delivery of healthcare, and the problems impacting the health of the public change continuously. By updating the Guidelines periodically, SAMHSA is

not reinterpreting the regulations, but rather is expressing how these regulations may be applied in the context of clinical and medical issues confronted by OTPs today.

Compliance with the regulations is assessed by SAMHSA-approved and -monitored accrediting organizations. The determination of compliance is made by these accrediting organizations based on the guidelines put forth in this document and informed by the recognized best-practices of medicine and healthcare delivery. While these guidelines address only 42 CFR § 8.12, all of 42 CFR § 8 contains information of interest to OTPs. In some cases, it is necessary to be aware of regulations from other titles or parts of the Code of Federal Regulations in order to understand the intent of 42 CFR § 8.12. These other regulations are cited in this document where needed.

SAMHSA encourages persons interested in OTP operation to familiarize themselves with all of 42 CFR § 8 by accessing http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr8_main_02.tpl.

GUIDELINE DEVELOPMENT PROCESS

Between 1996 and 1999, SAMHSA followed a Treatment Improvement Protocol-type process and developed federal guidelines to assist accreditation organizations with developing standards in conformance with those set forth in 42 CFR § 8.12. This process included convening two expert panels to provide input into what the Guidelines should cover, conducting field reviews, and obtaining clearances from other federal agencies and the Office of Management and Budget. As a result of this process, SAMHSA published the first edition of the *Federal Guidelines for the Accreditation of Opioid Treatment Programs* in 2001. Then, in 2007, SAMHSA published an updated edition that reflected changes in medication-assisted treatment policies and evidence-based practices that occurred over the years.

As policies, research, and practices in medication-assisted treatment continued to evolve, SAMHSA once again recognized the need to revise the guidelines. In 2012, a stakeholder panel was convened and charged with revisiting what is called the Federal Guidelines for the Accreditation of Opioid Treatment Programs in light of new research findings; advancements in the field; and state-of-the-art, evidence-based practices. This panel was composed of federal and state regulatory authorities, addiction treatment providers and counselors, accreditation organizations, patient advocates, and others with knowledge and expertise in the following content areas:

- Recent developments in opioid addiction treatment.
- New buprenorphine take-home dose regulation.
- The prevention and treatment of infectious diseases, such as the human immunodeficiency virus (HIV) and hepatitis viruses.
- Best practices in addiction treatment.
- Use of all addiction treatment medications.
- New addiction pharmacotherapies (buprenorphine/naloxone and injectable naltrexone)
- 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 (medically supervised withdrawal) from drugs of abuse.
- Medically supervised withdrawal from opioids.
- Community or state resistance to medication-assisted treatment.
- Cardiac complications.
- Management of co-occurring disorders, including chronic pain.
- Third-party reimbursement.
- Physician and staff education.
- Office-based opioid treatment (OBOT).
- Approval of ER injectable naltrexone for opioid dependence.

Between 2012 and 2014, SAMHSA sought the input of panel members, other federal and state agency staff, and members of the public for the third edition of the guidelines, entitled *Federal Guidelines for Opioid Treatment Programs* (Guidelines). The revised Guidelines were edited, organized, and formatted in accordance with the Federal Plain Language Guidelines. In 2013, the draft Guidelines were published in the Federal Record for public comment. These comments were then reviewed and addressed.

DIFFERENCES BETWEEN 2007 AND 2015 GUIDELINES

There are several significant differences in content between the 2007 and 2015 Guidelines. First, the 2015 Guidelines reflect the obligation of OTPs to deliver care consistent with the patient-centered, integrated, and recovery oriented standards of addiction treatment and medical care in general.

Also provided herein is guidance regarding the implementation of technological and other changes within healthcare. This information is provided throughout the document in the context of the regulation most impacted by these changes. The subjects included are:

- The electronic health record.
- Prescription drug monitoring programs (PDMPs).
- Nursing scope of practice.
- The role of non-physician authorized prescribers.
- Telemedicine.
- Benzodiazepine misuse in the context of opioid agonist therapy.
- The rule that went into effect January 7, 2013, removing the "time in treatment" requirement for patients receiving buprenorphine for take-home use from OTPs.

FORMAT HIGHLIGHTS

This document is organized so that the corresponding regulation in 42 CFR § 8.12 is cited in a shaded text box that follows a related subject heading. Programs should contact CSAT's Division of Pharmacologic Therapies (DPT) at otp-extranet@opioid.samhsa.gov or via the SAMHSA website at www.samhsa.gov should they have any questions regarding the information in this document or OTP-related issues not covered here.

FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

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.

SAMHSA's federal opioid treatment standards, found in 42 CFR § 8.12 (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=0d945f6e5f6068b536698ccc72159bc8&r=PART&n=42y1.0.1.1.10#se42.1.8_112), became effective in May 2001. As stated in 42 CFR § 8.12(a), OTPs are required to have current valid accreditation status and SAMHSA certification before they are able to dispense opioid drugs for the treatment of opioid addiction.

TELEMEDICINE

Compliance with various aspects of the regulations contained in 42 CFR § 8.12 is impacted in a general way by larger trends in healthcare delivery. One of these is the use of technology. Digital communications, including telemedicine, telehealth, and e-therapy, both enriches and complicates providing treatment that is in compliance with federal regulations. The terms telemedicine, telehealth, and e-therapy often are used interchangeably. The Institute of Medicine defines telemedicine as the "use of medical information exchanged from one site to another via electronic communications to improve patient health status." As a result of telemedicine, individuals unable to avail or who lack access to medication-assisted treatment may receive appropriate services. The Center for Medicare and Medicaid Services (CMS) provides the following guidance with regard to telemedicine.

- Medicaid guidelines require all providers to practice within the scope of their state practice. Some states have enacted legislation that requires providers using telemedicine technology across state lines to have a valid state license in the state where the patient is located. Any such requirements or restrictions placed by the state are binding under current Medicaid rules.

- For the purposes of Medicare and Medicaid, telemedicine services must be conducted via an interactive audio and video telecommunications system that permits real-time communication between the healthcare provider at the distant site and the patient at the originating site. An originating site is the location of the patient at the time the service being furnished via a telecommunications system occurs.

- The full CMS guidance on telemedicine can be accessed at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html.

Meanwhile, a number of states are adopting requirements that those practicing telemedicine comply with standards used for face-to-face services, have formalized policies in place, or

acquire certification. The Joint Commission and other accrediting bodies have established certification for telemedicine providers including providers of mental health and substance abuse treatment services. The National Association of State Alcohol and Drug Abuse Directors supported this concept in its report entitled *Telehealth in State Substance Use Disorder (SUD) Services*. For further information from CMS about telemedicine, access http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcsfctsht.pdf.

OTPs are advised to proceed thoughtfully and with full understanding of requirements established by the state or health professional licensing boards. Exceptional attention needs to be paid to data security and privacy in this evolving field. Telemedicine services should, under no circumstances, expand the scope of practice of a healthcare professional or permit practice in a jurisdiction (the location of the patient) where the provider is not licensed. Also, telemedicine may not substitute for a physical examination when one is needed, although it may be used to support the decision making of a physician when a provider qualified to conduct physical examinations and make diagnoses is physically located with the patient.

An additional consideration regarding telemedicine in the context of OTPs is the possible provision of buprenorphine under DATA 2000. When buprenorphine is administered or dispensed for a patient enrolled in the OTP, the provision of care via telemedicine is not impacted by the Controlled Substances Act (CSA) (28 USC § 802) (http://www.deadiversion.usdoj.gov/21cfr/21usc/802.htm), which defines the limits on the use of telemedicine in the context of providing a valid prescription for a controlled substance. When patients are receiving buprenorphine for an opioid use disorder from a physician who has a waiver under the DATA 2000, policies must be in place to assure compliance with the CSA. The restrictions may be reviewed by accessing 21 USC § 802. There are no restrictions or limitations on the use or administration of extended release injectable naltrexone (ERIN). For more information, please refer to *An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People With Opioid Dependence* at https://store.samhsa.gov/shin/content/SMA12-4682/SMA12-4682.pdf.

E-therapy means using electronic media and information technologies to provide services for patients in different locations. It is used by skilled and knowledgeable professionals (e.g., counselors, therapists) to address a variety of individual, familial, and social issues. E-therapy can (1) include a range of services, including screening, assessment, primary treatment, and after care; (2) provide greater access to treatment services for populations who rely extensively on electronic devices (i.e., adolescents and young adults); (3) help people access treatment services who traditionally would not seek services because of barriers related to geography, shame and guilt, stigma, or other issues; and 4) be provided as a sole treatment modality or in combination with other treatment modalities, like traditional or existing treatments.

To guide programs in the development and implementation of substance abuse treatment services via technology, SAMHSA published *Consideration for the Provision of E-Therapy*, which can be found at http://store.samhsa.gov/shin/content/SMA09-4450/SMA09-4450.pdf.

ADMINISTRATIVE ORGANIZATION AND RESPONSIBILITIES OF INDIVIDUAL PRACTITIONERS

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.

An OTP's administrative organization serves to support the safe and effective delivery of medication-assisted treatment and assures compliance with the requirements, laws, and regulations of the Department of Health and Human Services (HHS), the Drug Enforcement Administration (DEA), and the states. Typically, an OTP's administrative organization comprises, at a minimum, a program sponsor, program director or manager, and a medical director. Within the organizational structure, it is essential for physicians to have authority over the medical and nursing aspects of medication-assisted treatment and to retain autonomy so as to ensure ongoing decisions are individualized according to the needs of each patient, the clinical course of treatment, and the standards of medical practice.

PROGRAM SPONSOR AND MEDICAL DIRECTOR

42 CFR § 8.2 defines the roles and responsibilities of the medical director and the program sponsor as follows:

- "*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 42 CFR § 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."

The program sponsor is the person ultimately responsible for the operation of the program, and most importantly, ensuring the program is in continuous compliance with all federal, state, and local laws and regulations. If there is a change of program sponsor, SAMHSA requires formal notification within 3 weeks of the change.

While the program sponsor retains the ultimate responsibility for an OTP's operations, the day-to-day management of the program often is assigned to the program director or manager who assumes the duties assigned by the program sponsor. It is important to note that the regulations do not require OTPs to have program directors or managers on staff nor define the role of a program director; therefore, the program sponsor in some OTPs also serves as the program director.

The medical director is responsible for monitoring and supervising all medical and nursing services provided by the OTP. The medical director should have completed an accredited residency training program and have at least 1 year of experience in addiction medicine or addiction psychiatry. Board certification in his or her primary medical specialty and in addiction psychiatry or addiction medicine is preferred. All OTP physicians are urged to complete the training in the use of buprenorphine required by the Drug Addiction Treatment Act 2000 (DATA 2000), even if they do not plan to provide buprenorphine under office-based opioid treatment (OBOT) rules. In some cases, the one individual may be both medical director and program sponsor but only a 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.

The medical director is responsible for assuring all medical, psychiatric, nursing, pharmacy, toxicology, and other services offered at the OTP are conducted in compliance with federal regulations at all times. The medical director should be present at the program a sufficient number of hours to assure regulatory compliance and carry out those duties specifically assigned to the medical director by regulation. The medical director may directly provide the required services to the OTP's patients or assure that the needed services are provided by appropriately trained and licensed providers in compliance with federal and state regulation.

Some aspects of medication-assisted treatment services may be provided by an authorized healthcare professional other than a physician such as an advanced practice nurse, physician assistant, or advanced-practice pharmacist. It is the responsibility of the OTP to review the individual licensing, scope of practice, and supervision requirements of each state with regard to the duties of such an authorized healthcare professional within the OTP beyond the federal roles and limits spelled out in these Guidelines.

FACILITY MANAGEMENT

Each OTP must have sufficient space and adequate equipment to provide all required services, including diagnosis; evaluation; and treatment of other medical, psychiatric, and behavioral disorders, if performed onsite. Policies forbidding children in the facility are not acceptable. While programs may not be able to provide services for children, every effort should be made to provide a safe and supportive environment for parents and their children.

The facility must:

- Be clean and well maintained, similar to and consistent with facilities for other medical or behavioral healthcare.
- Be maintained in full compliance with all relevant safety and environmental codes and be able to provide documentation of continuous compliance.
- Assure patient privacy. Internal controls on privacy are often overlooked in facility design and staff-to-patient and patient-to-patient communication. Windowed or open workspaces; a cashier located in a public area; untrained security guards; common medication dispensing areas; and hallway conversations about treatment plans, failed urinalysis, or psychiatric medications are all examples of how patient privacy may be violated. OTPs should take measures to prevent or correct such problems, when possible. Attention must also be paid to the privacy of electronic patient information. This may include keeping computer screens out of view, assigning individual login names for staff, and requiring regular password changes. For further discussion of protecting patient privacy in the electronic environment, access: http://www.healthit.gov/sites/default/files/smallpracticesecurityguide-1.pdf.
- Provide services during hours that meet the needs of the overwhelming majority of patients, which includes hours outside of the traditional 8:00 a.m. to 5:00 p.m. Monday through Friday work schedule.
- Comply with Occupational Safety and Health Administration (OSHA) workplace health and safety standards.

MEDICATION UNIT

According to 42 CFR § 8.11(i)(1), a certified OTP may establish a medication unit or units to administer or dispense medication therapy. Such a medication unit must have a separate and unique DEA registration. SAMHSA only requires notification via submission of an updated on-line SMA-162 (http://dpt2.samhsa.gov/sma162/); no additional certification is needed. Such a unit is intended to facilitate access to medication-assisted treatment for patients who would otherwise have to travel great distances. Other required services must still be provided at the certified OTP. Please see the FAQs section in the Guidelines for further instruction.

The full regulatory language describing medication units can be found in 42 CFR § 8.12 (http://www.ecfr.gov/cgi-bin/text-idx?SID=b7de4cc92bf0a4d977929a4978c64e30&node=42:1.0.1.1.10.2.1.1&rgn=div8).

Medication units are not required to be free-standing entities. For example, a medication unit can be located at a hospital or community pharmacy.

To open a medication unit, a program must submit the online SMA-162, available on SAMHSA's Extranet at http://otp-extranet.samhsa.gov, with all requested attachments and signed documents to SAMHSA. In Item 14, "Purpose of Application," "Medication Unit" must be checked off. SAMHSA will process the form and forward it for approval to the DEA, which will arrange an inspection. The program also should submit all required materials to the State Opioid Treatment Authority (SOTA) to seek state approval, as appropriate. Once approved by the DEA, the medication unit will be assigned a new DEA registration number. For further information please refer to the FAQs section of the Guidelines.

HUMAN RESOURCES MANAGEMENT

Each OTP must have an adequate number of physicians; nurses; counselors; recovery coaches; and other staff appropriately licensed, trained, and available for the level of care provided as well as the acuity and number of patients enrolled. Individual personnel files must be maintained for each staff person and are to contain employment application data, date of employment, updated licensing and credentialing information, detailed job descriptions, performance evaluations, appropriate intramural and extramural training records, and other employment and credentialing data deemed appropriate. Great care should be taken in the development of nursing job descriptions. For example, registered nurses (RNs) and licensed practical or vocational nurses (LPNs) have distinctly different scopes of practice. Of note, LPNs are generally considered "dependent practitioners." (See Professional Staff Credentials and Development section of the Guidelines.)

RISK MANAGEMENT

Each OTP must provide for patient and staff safety, program emergencies, and adverse events that require immediate response and investigation by developing and maintaining effective policies and procedures.

Patient and Staff Emergencies

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 911 or similar local emergency resources. A mechanism to address patient medical or psychiatric emergencies occurring outside of program hours of operation must be provided. Typically, this includes the establishment of an emergency contact system to obtain dosage levels and other pertinent patient information on a 24-hour, 7-days-a-week basis, as appropriate under confidentiality regulations. Every patient should be given an identification

card that identifies the opioid use disorder pharmacotherapy being administered through the OTP. The card also should include the emergency contact information so that appropriate clinical information and dosing information can be obtained in an emergency. For additional information on emergencies, access 42 CFR § 2.51 (http://www.ecfr.gov/cgi-bin/text-idx?SID=07521f1d15ff4661f403ec736facfdb7&node=42:1.0.1.1.2.4.1.1&rgn=div8).

Policies and procedures must also address safety and security issues for patients and staff. Procedures should include a mechanism for reporting untoward incidents to program staff or outside agencies including accrediting bodies and the SOTA as appropriate. Staff should be trained to recognize and respond preemptively to patients who demonstrate behaviors with the potential to escalate to threats or violence or are suggestive of a mental health crisis. Staff should be trained and supported to deescalate physical or verbal threats, access mental health crisis services on behalf of patients, and secure their own safety and that of other patients in the event that a violent or threatening situation cannot be deescalated. Staff should be authorized to notify security guards or police when needed.

Program Emergencies

Each OTP should maintain an up-to-date disaster plan that addresses fire suppression, including maintenance of fire extinguishers, fire drills, and emergency evacuation procedures; ensures that needed supplies are available in the event of an emergency requiring staff or patients to shelter in place, and includes links to community agencies.

In the event of an emergency leading to temporary closure of a program, an up-to-date plan for emergency administration of medications should be maintained. An alternative dosing location should be secured in advance because DEA registration of the new location may be required if it is not already an OTP. Facilities should have the capability to respond to emergencies on a 24-hour basis. Designated staff persons should have access to a record of active patients, their medication dose, schedule, and last dose administered in order to provide accurate dosing at an alternative location. In addition, the plan should include a mechanism for informing patients of emergency arrangements, alternative dosing locations; and a procedure for notifying SAMHSA, DEA, and state authorities of the situation. To review specific disaster guidance provided by SAMHSA, access http://www.dpt.samhsa.gov/pdf/dearColleague/GuidanceKatrina_090905.pdf.

Events that Require Immediate Response and Investigation

Each OTP should establish procedures to guard against critical incidents, defined as events that could have a negative impact on patients and their family members, the program or staff, or the health of the public. This includes events that involve the loss of life or function, any serious physical or psychological injury, and medication errors. Critical incidents are also known as sentinel events, significant adverse events, and untoward events. Critical incidents should be reported to the appropriate federal and state agencies and others according to the program's procedures and any applicable regulatory and accrediting organization requirements.

Significant incidents or adverse events that may require advance preparation, reporting, investigation, or corrective action will vary by program. These events may include accidental injury or violence on the premises; medication errors; 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; unexpected or suspicious deaths; deaths related to overdose or medication interactions; or any other injury or death that raises individual, family, community, or public concern.

In case a critical incident occurs, an OTP's established procedures provide for:

- Full documentation of the incident.
- Prompt investigation and review of the situation surrounding the incident.
- Timely and appropriate implementation of corrective action(s).
- Ongoing monitoring of any corrective actions until their effectiveness is established.

CONTINUOUS QUALITY IMPROVEMENT

> 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.

The continuous monitoring of an OTP's policies, procedures, practices, and patient outcomes serves to improve operations, customer service, patient satisfaction, and, ultimately, treatment outcomes. A continuous quality improvement plan should include, at a minimum:

- A statement of the program's patient outcome goals.
- A description of steps to be implemented to achieve patient outcome goals.
- Provisions for regular and continuous staff education.
- Up-to-date, individualized staff development plans.
- Review and recertification of program policies and procedures at least annually.
- Evaluation and modification, if needed, of the program diversion control plan.
- Patient input into program policies and procedures regarding patient and community concerns.
- Development, implementation and corrective response to patient satisfaction surveys.
- Adherence to universal or standard infection control precautions as promulgated by the Centers for Disease Control and Prevention (CDC). These standards may be found at: http://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html.

- Measurement and monitoring of patient treatment outcomes and processes on a regular basis—for example, quarterly—to inform quality improvement. Treatment outcomes may include patients':

  - Use of illicit opioids, illegal drugs, marijuana, and the problematic use of alcohol and prescription medicines.
  - Criminal activities and involvement with the criminal justice system.
  - Behaviors contributing to the spread of infectious diseases.
  - Quality of life such as physical and mental health and functional status.
  - Retention in treatment.
  - Employment.
  - Engagement in recovery support services.

- Consideration of monitoring an OTP's progress in adopting a "recovery-oriented systems of care" (ROSC) model with an atmosphere of acceptance. For guidance, access *Guiding Principles and Elements of Recovery-Oriented Systems of Care: What do we know from the research?* (http://beta.samhsa.gov/sites/default/files/partnersforrecovery/docs/Guiding_Principles_Whitepaper.pdf.)

COMMUNITY RELATIONS AND EDUCATION

Before a new OTP moves into a community or neighborhood and opens its doors to patients, there is a strong need to educate all entities affected by the program's presence, including the medical community, neighbors, and those who provide support services. States may have specific community relations plan requirements for opening or moving an OTP into a community or neighborhood.

OTPs must have policies and procedures to measure and minimize the negative impact an existing or new program may have on a community, promote peaceful coexistence, and plan for change and program growth. Such policies and procedures should address:

- Community need and impact when selecting sites for programs.

- Community input on the potential impact a program may have on a neighborhood.

- Maintenance of a clean and orderly facility that does not impede pedestrian or traffic flow.

- Identification and maintenance of communication with community leaders for the purpose of fostering good community relations. Examples of community leaders are: publicly elected representatives; community business associations; local health, substance abuse, and 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.

- Development and implementation of a community relations plan that is specific to the configuration and needs of the program within its community and includes but is not limited to the following actions:
  - Establish a liaison with community representatives to share information about the program, the community, and mutual concerns and issues.
  - Identify program personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan.
  - Serve as a community resource on substance use and related health and social issues as well as promote the benefit of medication-assisted treatment in preserving the public health.
  - Solicit community input about medication-assisted treatment and the program's presence in the community.
  - Develop program policies and procedures to effectively address or resolve community problems (including patient loitering and medication diversion) and ensure that program operations do not affect community life adversely.
- Document community contacts and community relations efforts and evaluate the effectiveness of activities over time in addressing outstanding problems or deficiencies.
- Develop communication mechanisms that provide interested parties and potential patients with general information about the program outside of regular operating hours.

VOLUNTARY AND INVOLUNTARY PROGRAM CLOSURE

OTPs, through state authorities and other relevant governmental entities, must establish procedures that ensure continuity of care for patients in the event of either a voluntary or involuntary closure of programs. The plan should include steps for the notification and orderly transfer of patients, records, and assets to other programs or practitioners and the procedure for securing and maintaining patient records for a specified period of time in accordance with state and federal regulations.

DIVERSION CONTROL

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.

An OTP must develop and maintain a diversion control plan (DCP). The goal of a DCP is to reduce the scope and significance of diversion and its impact on communities. Each program's DCP should make every effort to balance diversion control against the therapeutic needs of the individual patient.

DCPs should address at least four general areas of concern: program environment, dosing and take-home medication (take-homes), prevention of multiple program enrollment, and prescription medication misuse.

- *Program Environment*: Diversion in the program environment can be deterred and detected by regular surveillance and the monitoring of areas in and around the program, where opportunities for diversion may exist. Some OTPs use video surveillance; however, few rely solely on this method. A system of rounds, where security personnel or other staff walk around the interior and exterior of the clinic on a regular and periodic basis to observe activities at the entrances and in the hallways, adjacent alleys, and parking areas, provides an opportunity to assess and intervene in suspicious behaviors such as loitering. A visible human presence at a program's location gives community members the opportunity to approach staff with concerns and communicates the program's commitment to assuring a safe environment and a positive impact on the surrounding community. It also is recommended that OTP staff consult periodically with law enforcement in the surrounding community and where patients live to discuss surveillance findings (assuming it will not impair any criminal investigation) and the perceived and actual problems encountered.

  Patient involvement in assuring a therapeutic and safe treatment environment is an essential part of a DCP. Patient committees can advise on program policies and procedures and how they are implemented. Patients can make important contributions to problem solving and help balance diversion control strategies with the needs of patients.

- *Dosing and Take-homes:* In the area of dosing and take-homes, diversion control encompasses careful control of inventory, attentive patient dosing, and close supervision of take-homes. Although observing a patient take his or her dose and having each of them drink and speak after dosing are fundamental components of diversion control, it is easy to lose sight of the importance of these repetitive nursing tasks.

  Take-home dosing should be provided with careful attention to regulatory compliance and the therapeutic benefit and safety these regulations are meant to promote. Random call backs to inventory a patient's take-home doses are an important element of any DCP. Patients must be clearly informed of the responsibility they have to keep take-home opioid medications in a child-proof medication container and store them in a secure location. It also is important to perform toxicology testing on patients with take-home doses without falling into a predictable routine and to have clear policies and procedures to prevent the falsification of toxicology specimens. A program's response to toxicology specimens that are negative for methadone or otherwise indicative of falsification needs to address the possibility of diversion of methadone. Simple strategies, such as requiring the return of all take-home dose bottles, can reduce the opportunity for passing off diverted methadone as legitimate. Always

investigate the alleged or actual source of diversion, and, if necessary, change the frequency of take-home reviews.

Drug testing regimens also may have to be reevaluated. Special, intensified group or individual counseling sessions may be helpful for individuals or groups at risk for diversion problems. Programs currently closing for Sundays or holidays should have clearly spelled out policies and procedures for determining who may have a take-home dose for these days. Universally granting take-homes for days when the program is closed increases the program's risk for diversion and adverse outcomes. Consideration should be given to opening on these days for a short period to administer medications to those patients not yet able to dose safely without supervision.

Monitoring patients receiving medication for unsupervised use requires the physician to have knowledge of physiological issues; a thorough understanding of the differences among laboratories; and the factors that affect absorption, metabolism, and elimination of opioids. Knowledge and understanding in these areas are essential, for example, to interpret a toxicology test that is negative for methadone or methadone metabolites. All staff members may contribute to the safety and therapeutic benefits of unsupervised medication use. Any observations or information relevant to the use of unsupervised medication use acquired in the course of interacting with patients is to be conveyed to the medical director for his or her consideration in making dosing and management decisions.

- *Prevention of Multiple Program Enrollment:* Reasonable measures should be taken to prevent patients from enrolling in treatment provided by more than one clinic or individual practitioner. These measures should be commensurate with the severity of the problem and the documented consequences. An OTP, after obtaining patient consent, may contact other OTPs within a reasonable geographic distance (100 miles) to verify that a patient is not enrolled in another OTP. Refer to CFR 42 § 2.1 Statutory authority for confidentiality of drug abuse patient records (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=601aa488f5b738f0e5b9befaf27d2637&n=42y1.0.1.1.2&r=PART&ty=HTML%20-%2042:1.0.1.1.2.1.1.1) for further clarification.

- *Misuse of Prescription Medication:* The misuse of prescription medication has become an area of great concern nationally and impacts diversion control planning at OTPs. Nearly all states have a prescription drug monitoring program (PDMP) of some sort. Up-to-date information about each state's PDMP can be found at Brandeis University's PDMP Training and Technical Assistance Center. In addition, the National Alliance of Model State Drug Laws is another source of information.

  While state programs may vary from one another, all OTP physicians and other healthcare providers, as permitted, should register to use their respective state's PDMP and query it for each newly admitted patient prior to initiating dosing. The PDMP should be checked periodically (for example, quarterly) through the course of each individual's treatment and, in particular, before ordering take-home doses as well as at other important clinical decision points. Querying the PDMP will result in a range of possible results. In some cases, no use of scheduled prescription medications will be identified. In others, the history of prescription

use reported by the patient will be confirmed. If the patient has ongoing relationships with prescribers from whom they may still acquire prescriptions for controlled substances or other psychotropics, strategies to prevent or limit this activity should be established. Ideally, releases of information should be obtained from each prescriber in order to coordinate needed medical care while avoiding the use of medications that may interact with the pharmacotherapy for a substance use disorder. Lastly, the PDMP may reveal ongoing receipt of prescriptions not reported to the program for substances known to be misused by the patient. An assertive strategy of care coordination combined with additional treatment strategies, such as medically supervised withdrawal from the misused prescription medications and intensive behavioral interventions, may need to be implemented. In some situations, the presence of active diversion may lead to discharge for reasons of patient safety or the safety of the community. Of particular concern is when a patient refuses to sign a release of information to allow care coordination with other prescribers.

The program should develop detailed policies and procedures to govern the use of and response to PDMP information for diversion control. Every effort, including full psychiatric assessment, higher levels of substance use disorder treatment, detoxification services, and intensive counseling, should be made to address the addictive behaviors underlying the individual's polysubstance use.

The responsibility to implement and monitor each aspect of the DCP should be clearly assigned to specific clinical, administrative, or medical staff members as appropriate. These staff members should have the opportunity to meet regularly to update one another on issues and communicate concerns. This may be accomplished during regular meetings of a specific diversion control committee. In smaller programs, the DCP may be a regular business item during meetings of all staff. Specific procedures for monitoring possible diversion in each of these areas and how to address it should be spelled out.

PROFESSIONAL STAFF CREDENTIALS AND DEVELOPMENT

> 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.

Each staff position in an OTP should have a specific and detailed position description that outlines the duties assigned to the position, the qualifications required to enter into the position, and the training and performance standards required to remain in the position. Before providing care to patients, staff members should receive initial education that is specific to the medication-assisted treatment(s) used in the OTP and tailored to the patient populations served. In addition, continuing education in opioid addiction treatment and related subjects, along with resources for problem solving and troubleshooting, should be accessible. The position descriptions and assigned duties for both licensed clinical and medical professionals should respect the scope of

practice assigned to each licensed profession by the respective staff licensing authority. All licensed individuals employed in OTPs must comply at all times with the licensing and credentialing requirements of their respective professions. Physicians should have completed an accredited residency training program and have at least 1 year of experience in addiction medicine or psychiatry. Board certification in their primary medical specialty and in addiction psychiatry or addiction medicine is preferred. All OTP physicians are urged to complete training on the use of all FDA approved medications for the treatment of opioid use disorders. Other healthcare professionals employed in OTPs should be similarly qualified.

Detailed job descriptions that clearly define the qualifications and competencies needed to provide specific services should be developed for credentialed and non-credentialed staff. Non-licensed staff may be qualified for their positions through training, education, and/or experience. In states that permit non-licensed addictions counselors, programs should develop the position description in accordance with standards put forward by a formal body such as those published by the National Certification Commission for Addiction Professionals.

A personnel file should be maintained for each staff person. The file should contain an individualized annual training plan; documentation of training, which includes a record of attendance; the qualifications of the educators; outlines of the content; description of the teaching methods employed; and performance evaluations as well as employment application data, date of employment, updated licensing and credentialing information, detailed job descriptions, and other employment and credentialing data deemed appropriate.

PATIENT ADMISSION CRITERIA

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 medical withdrawal (detoxification) or drug-free treatment within a 12-month period to be eligible for methadone 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 with a documented history of opioid use disorder (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

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

Admission to an OTP for maintenance or medical withdrawal with pharmacotherapy requires fulfillment of specific criteria. The OTP should have up-to-date policies and procedures in place to assure that all admission criteria are met or exceptions obtained, as appropriate. These policies and procedures should include a requirement for programs to demonstrate how the treatment needs of those persons for whom admission is not appropriate will be met, regardless of whether they are through other services offered by the program or a formal referral. All persons to be admitted for maintenance therapy must be determined to be "currently addicted to an opioid drug."

The regulations specify that accepted medical criteria such as those described in the most current version of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) be used. New criteria in DSM-V, the current version, use language that is consistent with the current understanding of substance use disorders, departing somewhat from the familiar terms of "abuse" and "dependence." The diagnostic criteria described in the DSM-V, however, are substantially the same as those used in earlier versions of the DSM. Based on the number of criteria identified for an individual patient, the substance use disorder is now classified as mild, moderate, or severe. Because there is no basis for concluding that medication-assisted treatment is only for those persons with severe disease, careful consideration and patient-center decision

making must be used when considering the most appropriate pharmacotherapy for patients at all stages of opioid use disorder. For more information, refer to *Decision in Recovery: Medication for Opioid Addiction*, a multimedia interactive decision support tool available soon on samhsa.gov. If a patient has a mild or moderate opioid use disorder without meeting criteria for tolerance/withdrawal, opioid agonist medications that will themselves produce physical dependence must be carefully considered due to the difficulty experienced by many of the discontinuation of opioids on which an individual has become physically dependent. Other options such as psychotherapy or antagonist pharmacotherapy such as oral/injectable naltrexone treatment should be considered. The new criteria require a more comprehensive approach to patient assessment and more sophisticated treatment matching. More information can be found on http://www.fda.gov/downloads/Drugs/DrugSafety/UCM206669.pdf. Additionally, the SAMHSA advisory on the use of extendable release of injectable naltrexone for the treatment of people with opioid dependence can be accessed at http://store.samhsa.gov/product/An-Introduction-to-Extended-Release-Injectable-Naltrexone-for-the-Treatment-of-People-with-Opioid-Dependence/SMA12-4682.

The scope of the problem of opioid misuse and consequent overdoses requires a more highly individualized approach to treatment decision making and access to the full range of pharmacotherapies including antagonists. OTPs should endeavor to provide a full range of pharmaceuticals for medication-assisted therapy in order to best meet the needs of the patient. A decision to admit a patient for opioid agonist or antagonist maintenance treatment should be based on an assessment by appropriately "qualified personnel." (42 CFR § 8.12(e)). Since the admission criteria require a diagnostic and treatment decision, the OTP staff person who performs this function should be permitted by license and credential to conduct interviews and physical examinations, review records of other providers, and diagnose and treat patients. Reference should be made to state licensing authorities to determine whether advanced practice nurses, physician assistants, or others can be permitted to determine whether admission criteria are fulfilled. The DEA maintains a table of prescribing authority by state for health professionals that can be found at http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf. While "qualified personnel" may perform admission assessments for maintenance treatment, only physicians may perform the following functions under 42 CFR § 8.12(e).

- "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." (42 CFR § 8.12(e)(1)).

- "the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1)." (42 CFR § 8.12(e)(3))."

- "for pregnant patients (program physician must certify pregnancy)" (42 CFR § 8.12(e)(3).

Informed Consent

An acceptable informed consent policy should:

- Inform each patient about all treatment procedures, services, and other policies and regulations throughout the course of treatment. It should also 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.

- Ensure that before medicating the patient the physician receives voluntary, written, program-specific informed consent to treatment with the specific pharmacotherapy ordered by the physician. Within 30 days post-admission, an appropriate program staff member should review informed consent with the patient.

- Inform each patient at admission and upon a 30-day review that the goal of medication-assisted treatment is stabilization of functioning.

- Inform each patient at admission of 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).

- Include a written description of patients' rights and responsibilities that is reviewed with the patient. An example can be found at http://www.nlm.nih.gov/medlineplus/ency/article/001947.htm

MEDICALLY SUPERVISED WITHDRAWAL

> 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.

Overdose prevention, including prescribing or dispensing naloxone, is an essential complement to both detoxification services as well as medically supervised withdrawal discussed in the following sections. For detailed guidance please refer to SAMHSA's Opioid Overdose Prevention Tool Kit found at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit/SMA13-4742. Similarly, patients should be advised of the risks of relapse following detoxification and offered a relapse prevention program that includes counseling, naloxone and opioid antagonist therapy.

Detoxification

Detoxification is a legal and regulatory term that has fallen into disfavor with the medical community and is generally viewed as a misnomer. For the purposes of compliance, refer to the definitions for "detoxification treatment, long-term detoxification and short-term detoxification" in 42 CFR § 8.2. Detoxification is specifically intended to describe a service provided to patients

to address dependence on their opioid drug of choice. A discussion of medically supervised withdrawal, which is the more accurate description of the gradual reduction or tapering of the medication dosage over time under the supervision of the physician, is included in this section. Medically supervised withdrawal may be either voluntary or involuntary. Its purpose is to eliminate physical dependence on opioid medications. Although medically supervised withdrawal is not specifically addressed in the regulations, these guidelines address the community standards for approaching this stage of treatment.

Detoxification can be considered the medically supported transition to a medication-free state or to antagonist therapy. Many OTPs do not provide a specific pathway for patients to go directly to a medication-free state because of the notoriously poor outcomes and high incidence of relapse to drug use. Please refer to TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf). With the decreased availability and insurance reimbursement for inpatient detoxification services and the advent of long-acting antagonist therapy, each program should evaluate the need to develop policies and procedures to provide this service so that treatment can be matched to the individual needs and preferences of the patient. Very careful review of the risks and benefits of detoxification must be provided and thorough informed consent obtained from patients choosing this treatment option. Because of the risk of fatal overdose if relapse occurs, detoxification services should be accompanied by relapse prevention counseling, overdose prevention education as well as a naloxone kit (naloxone dose and syringes) or an FDA-approved naloxone auto injector. The treatment and aftercare plans should always include a strategy to transition to medication-assisted treatment if needed.

Voluntary Medically Supervised Withdrawal

Voluntary medically supervised withdrawal is completely different from involuntary tapering, administrative withdrawal, or other types of medically supervised withdrawal. The physician initiates voluntary medically supervised withdrawal from medication-assisted treatment in collaboration with and at the request of the rehabilitated patient. In initiating voluntary medically supervised withdrawal, the physician reduces dosages of medication at a rate well tolerated by the patient and in accordance with sound clinical judgment and close observation of the patient. Please refer to TIP 43 for guidance (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf).

For women with childbearing potential, the physician conducts an assessment for pregnancy and reviews the results of a pregnancy test before initiating medically supervised withdrawal. For pregnant patients, the physician should not initiate withdrawal before 14 weeks or after 32 weeks of gestation. When the patient experiences intolerable withdrawal symptoms or actual or potential relapse, the physician should consider halting the withdrawal process and possibly restoring the patient to a previously effective dose. Patient and physician together may decide that an additional period of maintenance is necessary before further medically supervised withdrawal is attempted.

Regardless of whether medically supervised withdrawal is conducted with or against medical advice, very careful review of the risks and benefits of withdrawal from maintenance therapy must be provided and thorough informed consent obtained from patients choosing medically

supervised withdrawal. Because of the risk of fatal overdose if relapse occurs, medically supervised withdrawal services should be accompanied by relapse prevention counseling, overdose prevention education and naloxone prescription. The treatment and aftercare plans should always include a strategy to transition to medication-assisted treatment with antagonist or agonist therapy if needed. OTPs should offer a variety of supportive options as part of the transition from opioid agonist therapy. For example increased counseling should be available prior to discharge, and participants encouraged to attend a 12-step or other mutual-help program sensitive to the needs of patients receiving medication-assisted treatment.

Withdrawal against Medical Advice

A patient who requests voluntary medically supervised withdrawal from medication-assisted treatment against the medical advice (AMA) of the physician or program staff may receive it. A patient has the right to leave treatment when he/she chooses to do so. The program will offer all the same services to the patient voluntarily withdrawing from medication-assisted treatment regardless of whether the decision is AMA.

An OTP may readmit a patient who abruptly left the program within 30 days of his/her departure without repeating the initial assessment procedure required by 42 CFR § 8.12(f)(4). The program must fully document both the issue that caused the patient to seek discharge and the steps it took to avoid discharging the patient as well as the circumstances of the readmission. In the case of a pregnant patient, the program must keep the physician or agency providing prenatal care for the patient informed, consistent with the privacy standards of 42 CFR § 2.

Involuntary Withdrawal from Treatment

A major goal of an OTP is to retain patients for as long as they can benefit from and express a desire to continue treatment. Programs should make every effort to intervene productively in a patient's situation before resorting to administrative withdrawal. For example, patients with disruptive behavior should be screened and, if needed, referred for a full psychiatric evaluation. The type and quantity of behavioral services as well as the medical supervision for patients at risk for administrative withdrawal should be matched to address the degree of risk behavior.

Involuntary "administrative withdrawal" requires OTPs to define and follow due process. The underlying goal is for involuntary medically supervised withdrawal to reflect a humane partnership between the patient and the treatment program. The program policies and procedures must take into consideration, on a case-by-case basis, all factors affecting the patient and all the steps involved in the process must be documented. Because of the risk of fatal overdose if relapse occurs, medically supervised withdrawal services should be accompanied by relapse prevention counseling, overdose prevention education as well as a naloxone prescription. The treatment and aftercare plans should always include a strategy to transition to medication-assisted treatment including antagonist pharmacotherapy if needed.

42 CFR § 8.12 does not specify under what conditions administrative withdrawal is considered appropriate. Standard practice regarding involuntary discharge among OTPs provide for the following situations:

- Nonpayment of fees. Remedies may include referral to a more affordable OTP or other forms of medication-assisted treatment.

- Disruptive conduct or behavior. Disruptive behaviors include dealing drugs, repeated loitering, or violation of treatment program rules resulting in documented observable, negative effect on the individual, program, staff, and/or other patients not successfully addressed by more conservative means. Clinical interventions should be aimed at retaining these patients in treatment and may include, as appropriate, intensified counseling opportunities, special treatment plans addressing the behavior, and/or referrals for mental health evaluation.

- Violent conduct or threatening behaviors. Violent conduct or threatening behaviors include assaults or attempted assaults and direct and credible threats of violence towards other patients, program staff members, or visitors. If practical under the circumstances and with due regard for patient and OTP staff safety, before administrative discharge, it is recommended that the OTP conduct a crisis assessment to address suicide risk, danger to self or others, urgent or critical medical conditions, and immediate threats. Please refer to SAMHSA's Suicide Prevention App for Behavioral Health and Primary Care Providers (http://store.samhsa.gov/apps/suicidesafe/)

- Incarceration or other confinement that does not permit medically supervised withdrawal for patients receiving maintenance therapy with an opioid agonist.

Administrative discharge of a pregnant patient is a medically high-risk undertaking. As with all patients, interventions to address problematic behavior should be intensive and begin at the earliest suggestion of concern. Transfer to treatment in another program is preferable to medically supervised withdrawal in pregnancy. It may be helpful for the program to establish transfer agreements for treatment for this purpose in advance of the need. In the rare event a pregnant patient is administratively withdrawn and discharged, the program must ensure referrals are followed through to completion. Provider(s) should carefully follow up the patient's pregnancy and opioid use disorder.

When a patient is administratively discharged from an OTP, the program must employ the same principles as those used for voluntary medically supervised withdrawal from medication. The goal is to follow a withdrawal schedule that is based on sound clinical judgment and close patient monitoring. A schedule for medically supervised withdrawal for administrative withdrawal from treatment is generally a minimum of 21 days, but the physician may adjust this timeframe depending on clinical factors. The patient's condition during this medically supervised withdrawal and all steps to address it should be documented in the patient's record. Access TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf) for additional information.

Administrative withdrawal is usually involuntary and used only when all therapeutic options have been exhausted. Given the short timeframe in which administrative withdrawal occurs and the poor prognosis of patients who are involuntarily discharged, the preferred approach is for OTPs to refer or transfer patients to a suitable alterative treatment program. Because of the risks of relapse following detoxification, patients should be offered a relapse prevention program that includes counseling, naloxone and opioid antagonist therapy.

REQUIRED SERVICES

> 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.

OTPs must provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. Any assessments or treatments not directly provided at the facility must be assured via a formal documented agreement with the appropriate community providers.

Adequacy of services is manifest by a plan to manage and follow up each problem identified in the patient's history, physical exam, psychiatric evaluation, health risk assessments, and social support evaluations within 30 days of admission. An OTP should have appropriate information-sharing agreements with other providers, in accordance with federal regulations, in order for these services to be considered fully available to patients.

Assessment begins during program admission and continues throughout treatment. Its purpose is to address the whole health and well-being of the patient. Assessment begins with a personal substance use history, physical examination, laboratory evaluation, and determination of disease morbidity. Subsequently, professional staff will further assess the severity of disease in terms of patient response to pharmacotherapy, recovery resources, coping skills, and psychosocial morbidity. Assessment also may involve determining patient motivation and readiness for change as indicated on page 284 in TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf). Additional resources are available at http://www.samhsa.gov/sbirt. The SAMHSA SBIRT page has links to motivational interviewing and readiness for change.

Consulting the PDMP at admission and periodically (for example, every three months) thereafter should be one of the tools used in the ongoing assessment of the patient. The program should update each patient's assessment at least quarterly during the first year of continuous treatment and semi-annually in subsequent years unless another schedule is stipulated by state or local regulations.

INITIAL MEDICAL EXAMINATION SERVICES

42 CFR 8.12(f) *Required services*. (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.

All individuals who meet OTP admission criteria must receive a complete, fully documented physical evaluation prior to admission to the OTP. The initial medical examination should provide the basis upon which the admission criteria are satisfied and the justification for the pharmacotherapy selected. The patient re-entering treatment may need a repeat examination depending on the time elapsed since the original examination. The Evaluation and Management (E&M) definitions for an expanded problem-focused or detailed medical examination provide useful models of what would be considered adequate, in most cases, for fulfilling the regulatory requirements, but should not limit the examination of patients who, in the judgment of the physician, merit more comprehensive evaluation. E&M definitions can be found at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval_mgmt_serv_guide-ICN006764.pdf.

The purpose of the initial medical evaluation is to confirm the diagnosis of opioid use disorder and identify co-occurring medical and psychiatric conditions that may make medication-assisted treatment unsafe, limit its effectiveness, influence the selection of pharmacotherapy, or require prompt medical attention. Screening should be conducted for common co-occurring conditions even if the patient has no personal history of them. Screening should establish the risk of undiagnosed conditions such as Hepatitis C, the human immunodeficiency virus (HIV), sexually transmitted infections (STIs), cardio-pulmonary disease, and sleep apnea in order to determine what further diagnostic testing such as laboratory studies, a cardiogram, and others are needed. Opportunities for disease prevention should also be identified at this time; for example, the need for gynecologic care or vaccinations for Hepatitis A and B, Tetanus, Pneumococcal Disease, or Influenza. Positive screening results or disease risks must have a management plan that is seen through to completion regardless of whether this is accomplished via services provided directly on-site or by referral and care coordination.

Initial toxicology tests are a part of the admission process. At a minimum, admission samples are tested for opioids, methadone, buprenorphine, amphetamines, cocaine, marijuana, and benzodiazepines. If there is a history of prescription opioid analgesic abuse, an expanded toxicology panel that includes these opioids should be administered. Additional testing is based on individual patient need and local drug use patterns and trends. Furthermore, there are a variety of recommendations on the use of electrocardiograms (EKG) in patients receiving methadone. The most prominent guidance addresses cardiac risks with regard to the use of methadone for pain management.
SAMHSA has published the report of an expert panel on QT interval screening in methadone maintenance. The panel recommended that programs develop clear policies and procedures

describing a universal Cardiac Risk Management Plan that incorporates clinical assessment, electrocardiogram assessment, risk stratification, and prevention of drug interactions for all patients. Patient-specific risk minimization strategies such as careful patient monitoring; obtaining electrocardiograms as indicated by a particular patient's risk profile; and adjusting the methadone dose, as needed, for patients with identified risk factors for adverse cardiac events should also be included. The panel also suggested specific modifications to informed consent documents, patient education, staff education, and methadone protocols.

A patient's physical examination should document the presence of clinical signs of addiction, such as old and fresh needle marks and an eroded or perforated nasal septum and/or a state or symptoms of intoxication, such as constricted or (pinpoint) pupils, slowed heart or respiratory rate, or drowsiness or withdrawal, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea. There should be a high degree of concordance between the documented physical examination findings and the symptoms reported in the review of systems.

The assessment and plan resulting from this initial medical evaluation should summarize positive screening findings for which further evaluation is required and how this will be accomplished; deficiencies in health maintenance and how preventive services should be introduced, a list of all identified co-occurring problems and the plan to address them even if by referral; substance use diagnoses for each substance used along with severity; the medication selected and rationale for prescribing it and the expected impact of pharmacotherapy; and the education provided to the patient about his or her health conditions and any potential interactions or complications that may occur in regards to the planned medication-assisted treatment.

The results of laboratory work as well as the following services: psychosocial assessment; preliminary treatment plan; and patient orientation should be completed within 14 days of admission. Releases of information should be obtained at this time from other treating physicians or prescribers identified on the state PDMP. Also during this time, proper patient consent should be obtained by the program to seek medical records from other healthcare providers.

PREGNANT AND POSTPARTUM PATIENTS

> 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.

As of this writing, both methadone and buprenorphine are Pregnancy Category C drugs that call for a careful risk/benefit analysis, but for which there is no known teratogenic effects to the human fetus when medication is taken as directed and relapse is avoided. Both medications produce opioid dependence in the newborn which requires assessment and monitoring and may require specific medical care. Although the level of evidence supporting buprenorphine

maintenance during pregnancy is not as voluminous as that supporting methadone maintenance treatment, decisions need to factor in access and the specific needs and goals of the patient.

Pregnant women seeking treatment from an OTP must be given priority both for interim maintenance therapy and in the context of transfers from interim maintenance to comprehensive maintenance therapy. Reasons for denying admission to a pregnant applicant should be documented in the OTP's intake log or other enduring program records.

Every pregnant patient in an OTP should receive prenatal care, provided either onsite or by other healthcare providers. If appropriate prenatal care is neither available onsite nor by referral, or if the pregnant patient cannot afford care or refuses prenatal care services, an OTP, at a minimum, should offer basic prenatal instruction on maternal, physical, and dietary care as part of its counseling services. In cases where the OTP refers the patient elsewhere for prenatal care, the program should have formal documented agreements and informed consent procedures in place that ensure reciprocity in the exchange of pertinent clinical information regarding compliance with the recommended course of medical care. If a pregnant patient refuses the offered onsite or referred prenatal services, the treating physician or authorized healthcare professional, as appropriate, may use informed consent procedures to have the patient formally acknowledge, in writing, her refusal of these services. Policies forbidding children in the facility are not appropriate. Every attempt should be made to provide a safe and supportive environment for parents and their small children.

For pregnant women receiving methadone or buprenorphine, the OTP should have policies and procedures in place to assure the:

- Initial 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.

- Methadone dose is carefully monitored, especially during the third trimester when pregnancy induces changes, such as the rate at which methadone is metabolized or eliminated from the system, potentially necessitating either an increased or a split dose.

- Patients who become pregnant during treatment are maintained at their pre-pregnancy dosage, if effective, and are managed with the same dosing principles used with non-pregnant patients.

Pregnant women are encouraged to consider ongoing maintenance treatment after delivery. Medically supervised withdrawal after pregnancy should occur only when clinically indicated or requested by the patient. If a pregnant patient is discharged, the OTP must identifies the specific physician or authorized healthcare professional, as appropriate, to whom the patient is being discharged. The name, address, and telephone number of the provider caring for the patient after discharge are to be recorded in the patient record.

The OTP should establish and implement policies and procedures, including informed consent, to ensure appropriate follow-up and primary care for the new mother and well-baby care for the

infant. Informed consent refers to the patient's agreement to receive treatment as well as to release information to and obtain information from pertinent healthcare providers. Appropriate counseling and informed decision making between provider and patient must take place and be documented to ensure that issues mentioned in the latest patient information sheets and product inserts for the prescribed medication are covered and understood.

Pregnant women with concurrent HIV infection are subject to the same policies and procedures established for all HIV-infected patients in medication-assisted treatment and receive the same treatment opportunities and services, directly or by referral, as HIV-diagnosed patients who are not pregnant. OTPs 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. OTPs should have policies and procedures in place to support the decision to breastfeed during medication-assisted treatment, unless medically contraindicated by, for example, the presence of HIV, HTLV I or II, or untreated tuberculosis infection in the mother or if the mother is taking certain cancer chemotherapy agents, such as antimetabolites that interfere with DNA replication and cell division.

NEONATAL ABSTINENCE SYNDROME

Neonatal abstinence syndrome is a group of problems that occur in a newborn who was exposed to medications or drugs in utero. Babies of mothers who drink alcohol during pregnancy may have a similar condition. Infants prenatally exposed to opioids may experience hyperactivity of the central and autonomic nervous systems. This causes symptoms affecting the gastrointestinal tract and respiratory system. Signs of withdrawal from opioids may begin at any time, from minutes to hours to 2 weeks after birth; however, most appear within 72 hours. Neonatal abstinence syndrome will require management with a regimen of opioid agonist medication in tapering doses for approximately half of opioid-exposed infants. This often requires extended inpatient hospitalization and supportive care.

Programs should make certain the newborns of OTP patients receive prompt medical evaluation if signs or symptoms of neonatal abstinence syndrome appear after discharge from the hospital. (Access: http://vec.chop.edu/healthinfo/neonatal-abstinence-syndrome.html.) This means that mothers must be educated about neonatal abstinence syndrome, its symptoms, its potential effect on their infants, and need for treatment should it occur.

CLINICAL ASSESSMENT, TREATMENT PLANNING, AND EVALUATION OF PATIENT PROGRESS IN TREATMENT

> 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.

Assessment and Treatment Planning

The purpose of an assessment is to determine treatment eligibility, develop a treatment plan, and establish a measure for the response to treatment. "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.

The clinical assessment of each patient takes into account the natural history of opioid addiction as altered by time and treatment as well as the individual's past experience with treatment and recovery. In addition, all patients entering OTPs must be screened for other problem substance use and for mental health issues such as depression and anxiety. Positive screening results or disease risks must have a management plan that is seen through to completion regardless of whether this is accomplished via services provided directly on-site or by referral and care coordination. SAMHSA has supported a program of Screening, Brief Intervention, and Referral to Treatment (SBIRT) that can assist with screening for co-occurring behavioral health disorders. (Access: http://www.samhsa.gov/sbirt.)

A complete inventory of the individual's strengths and weakness as well as recovery resources is necessary to individualize the assessment. Based on the assessment and building upon the stage of treatment, an individualized treatment plan can then be designed. Assessment will need to occur repeatedly throughout the treatment experience as the stage of treatment as well as the

unique variables of the individual patient will change over time. For information on the stages of treatment, please visit: http://www.ncbi.nlm.nih.gov/books/NBK64208/.
The patient and therapist identify and agree upon a specific set of goals and develop a treatment plan to achieve them. The goals should be specific, measurable, realistically attainable, and patient centered. For more information, refer to *Decision in Recovery: Medication for Opioid Addiction*, a multimedia interactive decision support tool available soon on samhsa.gov.

Evaluation

Evaluation is the close examination or appraisal of a patient's health, including the patient's physical and mental capacity and potential. A patient who is being admitted to treatment should receive an intensive evaluation that includes a health history, medical exam, and screening. Evaluation results enable program staff 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. Program staff must use this information to determine the appropriate pharmacoptherapy and the initial dosage of medication and place the patient into the appropriate level of treatment. A full medical exam should be completed within 14 days of treatment initiation.

Evaluation of the effectiveness of the patient-centered treatment plan needs to be performed at regular intervals, such as quarterly, unless otherwise dictated by applicable regulations. The treatment plan should be revised based on ongoing assessment and evaluation of the plan's effectiveness. The effectiveness of the treatment plan should be based on the patient's progress toward the identified goal and the continued feasibility and appropriateness of the goals and their ongoing importance to the individual patient and his or her recovery. The patient's response to treatment determines his/her progression through each treatment stage. While some patients may remain in one stage for a considerable period of time, others may rapidly progress through one or more of the stages. In addition, it is not uncommon for a patient to relapse. Programs should ensure they adequately document all the services a patient receives in the patient's treatment plan. For information on assessment and treatment planning access: http://store.samhsa.gov/product/TAP-21-Addiction-Counseling-Competencies/SMA13-4171.

Patients unsuccessfully treated with methadone or buprenorphine/naloxone maintenance and continue the illicit use of opioids as well as patients who have misused benzodiazepines and alcohol to the extent that they have an increased risk for opioid overdose should be considered for possible opioid antagonist therapy.

Studies suggest that the duration of retention in treatment is directly related to success in outcome. For patients who drop out of treatment, the outcome often is negative, whereas patients who remain in treatment, despite continued excessive use of alcohol or illicit drugs, tend to benefit from the treatment experience.

Both psychosocial and medical treatment should be of sufficient intensity and duration so as to be effective for each treatment stage. In general, a greater intensity of services is desirable at the beginning of treatment, or when staff members identify a patient's relapse or relapse "trigger" conditions exist. Many patients often need psychosocial services for an extended period of time because of the multiplicity of their problems.

Unless clinically indicated, there should be no limits on patients' duration of treatment or dosage level of medication. Likewise, there should be no limitations on the psychosocial services offered to patients, even when they no longer take medication.

Programs should make every effort to retain patients in treatment as long as it is clinically appropriate, medically necessary, and acceptable to the patient. Maintaining a patient on medication, even when psychosocial treatment or other clinic services may not be yielding optimum results, is beneficial to both the individual patient and the public health. In addition, pharmacotherapy may still benefit patients who no longer need ancillary services.

Co-occurring disorders, which include multiple drug use problems as well as psychiatric and medical disorders, are most effectively treated and managed at a single treatment site. If the appropriate level of expertise is not available within the program, staff members should arrange for the patient to receive appropriate care elsewhere, taking into consideration barriers to treatment, e.g., financial and transportation burdens and travel time to and from care.

Medication-assisted treatment providers should have an understanding of both substance use and co-occurring disorders. It is essential for OTPs 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 if those services are not offered onsite. Increasingly, it is expected that substance abuse and mental health treatment programs will integrate medical and behavioral health services into their clinical programs in order to address the needs of the whole person receiving treatment services. OTPs may be especially well positioned to do this because they are already required to offer medical and substance use disorder treatment in a single setting. Information exchange across this network must both facilitate treatment and protect patient privacy.

HIV and Hepatitis

Staff members should become knowledgeable about existing and emerging diseases of public health interest and educate patients about these conditions. OTPs should continually review and be prepared to modify clinical approaches while addressing patients' related mental health issues as the public health environment changes. Examples of these types of diseases include tuberculosis, viral hepatitis, and sexually transmitted infections. Programs should ensure that each patient has access to low-cost or free immunizations recommended by the CDC. Ongoing services should address the medical and emotional well-being of patients on medication-assisted treatment. Patients should receive risk assessment; testing (including HIV and viral hepatitis); and diagnostic workup and medical treatment for infectious and other medical or psychiatric problems. In cooperation with the medical and nursing staff, the clinical staff should assess the need to include goals related to these health concerns in the treatment plan. Programs should coordinate care appropriately with the providers and health departments caring for the patients with medical or psychiatric problems, taking into account informed patient consent consistent with 42 CFR § 2 if these services will not be offered in the OTP itself. For guidelines on HIV and viral hepatitis screening, testing, and treatment, access http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm as well as http://www.ncbi.nlm.nih.gov/books/NBK92036.

Patients with opioid use disorders who receive effective medication-assisted treatment have improved adherence to pharmacotherapy for HIV or other medical conditions. OTP staff should be able to offer options to patients living with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) that maximize the benefits of medication-assisted treatment and address medication side effects and toxicity during the course of HIV/AIDS treatment. It is important that clinical staff understand issues related to opioid-assisted pharmacotherapies and antiretroviral medications, such as the risk for drug-drug interactions with some of these therapies as this can be an important consideration in the choice of opioid therapy. For further information on opioid interactions with other medications, access http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3334287/.

Linkages established with community HIV/AIDS treatment, prevention programs and social support services facilitate the OTP's collaboration with a patient's primary physician and supports his/her continuation of medication-assisted treatment. This is especially important when HIV infection/AIDS becomes the primary health concern and there is a transfer of care. The OTP and the provider responsible for HIV/AIDS medication management work together to monitor and case manage medication adherence and adverse events. Programs arrange confidential information exchange—consistent with 42 CFR § 2—to ensure that appropriate information reaches the providers caring for the patient. For additional information, access: http://store.samhsa.gov/product/TIP-37-Substance-Abuse-Treatment-for-Persons-With-HIV-AIDS/SMA12-4137.

As with HIV, patients who test positive for viral hepatitis are referred for further evaluation including sexually transmitted infection screening and treatment, if necessary. Patients who test negative are immunized against hepatitis A and B, as appropriate. Many patients identified as positive for hepatitis C virus (HCV) may benefit from pharmacotherapy, but this determination will require a diagnostic workup. An OTP and the agency responsible for HCV and any other viral hepatitis medical treatment should work together to monitor and case manage medication adherence and adverse events. Formal documented agreements must be in place to ensure that the appropriate information reaches the providers caring for the patient. For additional information about HCV, access http://store.samhsa.gov/product/TIP-53-Addressing-Viral-Hepatitis-in-People-With-Substance-Use-Disorders/SMA11-4656.

Mental Health Disorders

An OTP identifies patients with mental health needs during the assessment process and refers them to appropriate treatment if such treatment is not available onsite. In addition, it monitors patients for the emergence of symptoms of mental illness when patients withdraw or are discharged from treatment.

Linkages with mental health providers in the community provide a mechanism for an OTP to jointly monitor and evaluate a patient's use of mental health medication. If possible and when indicated, programs may dispense these medications in conjunction with the daily dose of opioid medication. For additional information, access http://store.samhsa.gov/product/TIP-42-Substance-Abuse-Treatment-for-Persons-With-Co-Occurring-Disorders/SMA13-3992.

Trauma

According to the December 30, 2010, National Survey of Substance Abuse Treatment Services (N-SSATS) report on Mental Health Screenings and Trauma-Related Counseling in Substance Abuse Treatment Facilities (http://oas.samhsa.gov/2k10/313/313Trauma2k10Web.pdf), the experience of traumatic events and the possible sequela of posttraumatic stress disorder (PTSD) often co-occur with a substance abuse disorder and are present among many substance abuse treatment patients. Common types of trauma include being exposed to a natural disaster or violence in combat or noncombat situations and experiencing childhood, historical, sexual, and physical assault or domestic violence.

Because of the relationship between substance use and trauma-related mental health problems, it is recommended that OTPs use mental health screenings and assessments to determine if a patient is suffering from a trauma-related illness and/or has been involved in domestic violence. The program must be prepared to offer appropriate treatment or refer patients for appropriate clinical intervention. For additional information on trauma-informed care, please access http://store.samhsa.gov/product/TIP-57-Trauma-Informed-Care-in-Behavioral-Health-Services/SMA14-4816.

Tobacco Use Disorders

Tobacco use is a source of a great degree of morbidity and mortality for people with opioid use disorders. Addressing tobacco use saves lives and is a key part of holistic, individualized treatment planning. A growing body of evidence demonstrates that counselors and agencies can successfully help patients stop using tobacco, which improves patient health and saves lives. Furthermore, recent studies indicate that treating tobacco use actually helps patients address their alcohol and other drug problems. Integrating tobacco treatment into the mainstream of substance abuse treatment is rapidly becoming a nationwide best practice. (Access http://smokingcessationleadership.ucsf.edu/resources/toolkits). OTPs have the advantage of being able to prescribe medication-assisted treatment for tobacco use disorders as an ongoing part of patient care.

Alcohol Use Disorders

Alcohol is the most widely used psychotropic substance and its use is common among patients receiving medication-assisted treatment. Patients should be counselled against alcohol use while on medication-assisted treatment due to its depressant effects, which can interact adversely with opioids. For example, alcohol is associated with 22 percent of overdose deaths due to opioid pain relievers. Intervention should be provided for alcohol use disorders that by themselves cause a great deal of medical harm. Combined with the effects of hepatitis, alcohol can worsen liver disease. In addition to addressing alcohol use disorder behaviorally, OTPs should have the ability to assess recent use of alcohol via toxicology tests and Breathalyzer results as a means of establishing safety for dosing and take-homes. In addition, these tests are integral to assessing the need for concurrent treatment of an alcohol use disorder. Because of the availability of staff with prescribing authority, OTPs should provide medication-assisted treatment for alcohol use disorders, when appropriate, as well as provide counseling interventions for patients with a need for treatment. Extended-release injectable naltrexone is the only FDA-approved medication for the treatment of both alcohol and opioid use disorders. For additional information, access TIP

49: Incorporating Alcohol Pharmacotherapies Into Medical Practice (http://www.ncbi.nlm.nih.gov/books/NBK64041/pdf/TOC.pdf)

Program staff members are knowledgeable about current, effective strategies for treating alcohol, cocaine, and other drugs of abuse. An OTP manages a patient's concurrent abuse of substances other than opioids following the principles described in TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf). Even when patients are not fully abstinent from all drugs of abuse, they and their communities continue to benefit from medication-assisted treatment for opioid use disorders.

Patients engaging in polydrug abuse must receive careful evaluations. Decisions on the most therapeutic course of treatment are based on the patient's condition and the treatment team's best clinical judgment. Persons with polysubstance use are at increased risk of suicide. For additional information on screening for suicide risk and interventions, please visit http://www.samhsa.gov/suicide-prevention. Polydrug abusing patients may benefit from treatment with other FDA-approved medications. In addition, OTPs coordinate care with providers outside of the OTP who prescribe medications with abuse potential.

Benzodiazepine Use

The use and abuse of benzodiazepines is a growing problem nationally and within medication-assisted treatment populations. Benzodiazepine use that is not legitimately prescribed by a provider with whom the program has permission to communicate should be addressed as illicit. Benzodiazepines are highly associated with overdose fatalities when combined with opioids. Patients known to be using benzodiazepines even by prescription should be counselled as to their risk and provided with overdose prevention education and naloxone. For an evidence based strategy to address benzodiazepine use among OTP patients, refer to *Management of Benzodiazepines in Medication-Assisted Treatment: Final Report on the Development of Clinical Guidelines* (http://my.ireta.org/sites/ireta.org/files/Best%20Practice%20Guidelines%20for%20BZDs%20in%20MAT%202013_0.pdf) prepared by the Institute for Research, Evaluation and Training in Addictions with Support from Community Care Behavioral Health Organization.

Chronic Pain

In accordance with the regulations and treatment guidelines, OTP patients are permitted to receive both medication-assisted treatment and adequate doses of opioids or other analgesics for pain when medically necessary. OTPs should make careful diagnostic distinctions between the physical dependence associated with the chronic administration of opioids for pain relief and an opioid use disorder. Patients with co-occurring pain should receive treatment from both pain management and addiction medicine specialists who employ a multidisciplinary approach. When possible and appropriate, programs refer patients with chronic pain for consultation with a specialist in pain medicine. For further guidance, refer to TIP 54: Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders (http://store.samhsa.gov/shin/content//SMA12-4671/TIP54.pdf).

Aftercare Planning

Aftercare planning should begin upon admission. Taking a recovery oriented approach to care facilitates this process. Aftercare planning should include the need for ongoing management of medical and psychiatric problems. Untreated, these problems are associated with relapse to drug use. Antagonist medications (e.g., extended-release injectable naltrexone) should also be considered for inclusion in aftercare plans. For more information, refer to the *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide* (http://store.samhsa.gov/shin/content/SMA14-4892/SMA14-4892.pdf).

RECOVERY ORIENTED SYSTEMS OF CARE

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.

Recovery-oriented systems of care (ROSC) are based on the substance use treatment community's concept of recovery and recovery management. Recovery is defined as a voluntary, self-directed, ongoing process where patients access formal and informal resources; manage their care and their addiction; and rebuild their lives, relationships, and health to lead full meaningful lives. While recovery is patient directed, recovery management comprises the clinically based structured processes used to coordinate and facilitate the delivery of recovery support services after the acute stage of treatment.

The ROSC framework is replacing the traditional approach to the treatment of substance use disorders characterized by brief interventions, crisis linked timing, and a focus on abstinence. When OTPs adopt the ROSC philosophy, their primary responsibility of dispensing medication onsite to treat opioid use disorders expands to include supporting patients' recovery within their own environment. In addition to forming long-term partnerships with patients and their families, other service providers, behavioral healthcare systems professionals, and community groups, recovery-oriented programs involve patients in all care decisions and help them identify and select the services and support they need at any point in the recovery process.

OTPs should include recovery support services in their patient's treatment plan. Recovery support services may involve follow-up phone calls; face-to-face meetings; e-mails; and connecting patients to peer-to-peer services, 12-step, faith-based, and community groups. Furthermore, under the ROSC framework, OTPs provide patients with continuing care. This includes a discharge plan, referrals to continuing outpatient care, procedures that address patients' physical and mental health problems following medically supervised withdrawal, plans for reentry to maintenance treatment if relapse occurs, and ongoing recovery management. OTPs also are encouraged to offer supportive counseling as a transitional service.

The organized provision of peer recovery support services is a newer concept within the field of medication-assisted treatment and a key component of ROSC. Peers are recovering men and women who have experienced the challenges and successes of the earlier stages of medication-assisted treatment. These individuals often have more credibility and impact on patients than do clinical staff.

Recovery coaches employed by the OTP help people on their pathway to recovery by providing:

- Emotional support—demonstrations of empathy, caring, and concern during activities such as peer mentoring, recovery coaching, or recovery support group meetings.
- Informational support—health and wellness information; educational assistance; and help acquiring life skills, job training, and citizenship restoration (e.g., voting rights, driver's license).
- Instrumental support—assistance completing tasks, especially those that are stressful or unpleasant (e.g., filling out applications, obtaining public benefits), or providing supports such as child care and transportation to support group meetings and clothing closets.
- Affiliation support—opportunity to establish positive social connections with others in recovery and learn social and recreational skills in an alcohol- and drug-free environment.

Cultural Competency

Programs are sensitive to the culture and values of patients and offer, as appropriate, treatment for groups organized with special needs in mind (e.g., gender, sexual orientation, older adults, Spanish language, co-occurring disorders, and developmental disabilities). All program staff, either by the OTP's hiring practices or through training, should be professionally and culturally competent and able to work effectively with the local community; accept input from minority community members; and/or receive the advice of individuals with knowledge of gender, ethnicity, and language issues. In addition, written nondiscrimination policies should 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, and all printed materials, electronic media, and course offerings should employ unbiased and non-prejudicial language.

HIV Prevention

Programs should develop and implement a plan for educating about and testing patients for HIV/AIDS. The information provided may address topics such as HIV/AIDS testing procedures, confidentiality, reporting, follow-up care, counseling, safer sex, social responsibilities, universal precautions, and sharing of drug injection equipment.

HCV Prevention

Consistent with resources, OTPs should screen and test for HCV and HBV either directly or by referral. Program staff should receive education on and teach patients how to treat and prevent the different forms of viral hepatitis, especially HCV, because it is the most common blood borne virus among persons who inject drugs. These viruses may affect patients' health, mental health, and dosage levels of opioid medications. Messages patients should receive regarding HCV include but are not limited to:

- HCV is four times as prevalent as HIV.
- You don't have to look sick to be sick.
- HCV medications can be given safely with methadone and buprenorphine.
- Patients can be treated and often cured.

Treatment of Adolescents

For the purpose of this document, adolescents are defined as youth ranging in age from 13 to 18. Programs develop and implement policies to ensure that adolescents are provided with developmentally appropriate treatment and evidence-based psychosocial support, such as family involvement, for that treatment. Screenings and assessments tailored to adolescents ensure that medication-assisted treatment is the most appropriate treatment for these patients.

Criminal Justice Issues

Programs develop procedures to coordinate and communicate with agents of the criminal justice system and advocate for the continuous treatment of patients who are incarcerated, on probation, or on parole.

Women in Treatment

OTPs' policies and procedures must reflect the specific needs of female patients and make provisions for the respectful and safe treatment of women. The option of single-sex group therapy based on gender identity or expression or sexual orientation should be available and each OTP's physical space, including restrooms, should meet the needs of female patients. In addition, all staff members should be intensively trained in the characteristics and needs of the women participating in their particular program.

Family Involvement

The involvement of family members contributes to positive treatment outcomes while also providing benefits to the family members. It is useful to expand the concept of family to include the patient's social network; significant others; persons in recovery, such as a sponsor; and resources from the community including the outpatient provider and others at the patient's request. An OTP provides opportunities for family and significant others to become involved in

therapy. Some OTPs use short-term groups to educate the family on medication-assisted treatment, substance use disorders and 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 follow-up to the referrals confirmed. If needed, identification of the ongoing need for collaboration should occur with the informed consent of the patient and a valid release of information.

Consistent with best practices for developmentally appropriate treatment, family involvement is an expectation of treatment for young adults (18-24 years). Onsite education and training for all patients who are parents should be available. 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. Children should be permitted inside the treatment program under parental supervision. When appropriate, program staff should refer patients who are parents to resources and services in parenting skills and child care as well as parent support groups.

OTPs also should provide reproductive health education for all patients and, when needed, make appropriate referrals for contraceptive services.

Alternative Therapies

Programs support patient choice in seeking alternative therapies, providing appropriate guidance in the process. This may include ensuring the therapies will not cause harm and that practitioners are trained/certified/licensed. Also, programs may provide some culturally appropriate alternative therapies when there is a need.

Orientation to Treatment

Patients may be in withdrawal or intoxicated during the first days of treatment; therefore, their orientation to treatment occurs at the time of admission and when they are stabilized. Orientation to treatment comprises continuous education via multiple modalities (e.g., verbal, written, video) in individual and/or group settings. Topics include:

- Signs and symptoms of overdose, use of the naloxone antidote (prescriptions should be given to patients on entry into treatment), and when to seek emergency assistance.
- The medication or modality of treatment being used, including side effects and common myths, and the expected outcomes.
- The nature of various addictive disorders.
- The benefits of treatment and nature of the recovery process, including stages of treatment.
- An OTP's guidelines, rules, regulations, fees, and billing procedures.
- Noncompliance and discharge procedures, including administrative withdrawal from medication.
- Patient rights (http://www.nlm.nih.gov/medlineplus/ency/article/001947.htm).
- Confidentiality and how release of information is permitted in accordance with 42 CFR § 2.
- Toxicology testing procedures.
- Dispensation and the appropriate storage of medications when receiving take-homes.
- HIV-spectrum and other infectious diseases such as HCV, tuberculosis, and sexually transmitted infections.

- Potential drug interactions.
- Agreements needed to exchange appropriate information within the network of consultants and referral agencies in accordance with HIPAA regulations and 42 CFR § 2.
- The prescription drug monitoring program (PDMP), if applicable, and how the OTP utilizes it.
- Central registries and how programs utilize them.

Substance Abuse Counseling

Appropriately trained, experienced, and certified or licensed substance abuse counselors should provide services at the intensity and for the duration required to meet each patient's needs as referenced in the individualized treatment plan. While there are no set patient-to-staff ratios specified in the federal regulations, states have set patient-to-staff ratios as high as 75:1 and as low as 30:1. States allow for an increase in the ratio under certain circumstances. Staff ratios should be sufficient to ensure that patients have reasonable and prompt access to counselors and receive counseling services at the required levels of frequency and intensity. An OTP's staffing of counselors is based on the characteristics and needs of particular patient populations and state requirements.

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 with appropriate medications.

Counseling for HIV, Hepatitis, and Other Infectious Diseases

OTPs should provide patients with counseling on HIV and other prevalent infectious diseases, such as hepatitis, sexually transmitted infections, and tuberculosis. Counseling also should include infectious disease prevention and risk reduction education for at-risk patients and emphasize the need for patients to adhere to treatment and communicate honestly with the provider when treatment has begun.

Medical Services

It is highly recommended, but not required, that OTPs provide basic primary care onsite. OTP physicians can prescribe medication as appropriate for co-occurring medical and psychiatric disorders.

Program staff should provide care coordination, making referrals for medical and psychiatric treatment when indicated. The staff members responsible for establishing linkages with other healthcare organizations and practitioners should be knowledgeable about pharmacotherapy treatment (e.g., drug interactions, acute withdrawal, and overdose), actively seek patient consent to talk with other providers, and check their state's PDMP.

OTPs may determine that directly observed therapy may enhance patients' compliance with their regimen for psychotropic medications, which may be subject to abuse, and medications for illness and chronic health conditions. These medications may be dispensed with the daily opioid dose.

TESTING AND SCREENING FOR DRUG USE

> 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.

Clinical drug testing is used for the purposes of diagnosis, monitoring, and evaluating progress in treatment and the promotion of long-term recovery. Through drug testing, patients' use of specific drugs as well as the absence of prescribed medications, which may be an indication of diversion, can be identified. After the patient's initial drug test at admission, clinicians should determine the frequency of toxicological testing by evaluating the clinical appropriateness in relation to the patient's stage of treatment. All maintenance patients must receive a minimum of eight toxicology tests per year. The results of toxicological tests are an essential component in making decisions regarding take-home medication privileges; however, treatment decisions should not be based solely on toxicology screening results.

Although testing panels typically include opioids (including prescription opioid analgesic compounds), benzodiazepines, barbiturates, cocaine, marijuana, methadone (and its metabolites), buprenorphine, amphetamines, and alcohol, they are not limited to these substances. Clinicians should determine the drug-testing regimen by analyzing community drug-use patterns and individual medical indications. It is strongly recommended that benzodiazepines, barbiturates, and alcohol (using the ethyl glucuronide test) be included in drug screening and testing panels. Alcohol is the most widely used mood-altering substance in the United States, and benzodiazepines and barbiturates are often prescribed for detoxification and chronic seizure disorders. Detection of benzodiazepines, barbiturates, or alcohol is important in ongoing assessment, treatment planning, and medication management.

OTPs often perform onsite point of collection (POC) tests using sensitive and automated immunoassay (IA) technologies that screen urine or oral fluid samples for a relatively narrow range of drug classes (e.g. amphetamines, barbiturates, benzodiazepines, opioids) and a limited number of specific drugs. POC tests such as IAs have a place in clinical decision making, but are not by themselves adequate to satisfy the regulatory requirements for drug use testing services.

Laboratory testing affords the opportunity to obtain confirmation testing such as gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-mass spectrometry (LC-MS) or tandem mass-spectrometry (LC-MS/MS.) This should form part of the OTP's established procedures for addressing potentially false positive and false negative urine or other toxicology test results as described in Chapter 9 in TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf).

Urine or other toxicological specimens are collected in a therapeutic context that suggests trust and respect and minimizes falsification. Reliance on direct observation is neither necessary nor appropriate for all patients.

The physician or authorized healthcare professional interpreting toxicology results must have knowledge of physiological issues and a thorough understanding of the differences among laboratories and the factors that affect absorption, metabolism, and elimination of opioids and other drugs.

All OTP treatment personnel must understand the benefits and the limitations of toxicological testing procedures. In order for toxicology testing to be an effective therapeutic tool, OTPs must promptly address the results with patients and document both the results of toxicology tests and follow-up therapeutic interventions in the patient record. Clinicians should rapidly intervene to therapeutically address the disclosure of illicit drug use, a positive drug test, or possible diversion of opioid medication, as evidenced by the absence of opioids or related metabolites in drug toxicology test results.

Note: While federal regulations require initial toxicology screening and eight additional screens per year for patients enrolled in comprehensive maintenance therapy, patients on long-term detoxification are required to have testing monthly. For additional information, refer to TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf and TAP 32 Clinical Drug Testing in Primary Care (http://store.samhsa.gov/shin/content//SMA12-4668/SMA12-4668.pdf).

RECORDKEEPING AND DOCUMENTATION

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.

All records required by 42 CFR § 8.12(g) should be retained for a minimum of 3 years. It is strongly recommended that a program implement an electronic health record (EHR) system.

Patient Records

Patient records must be kept confidential and up to date. All entries must be legible and organized in a manner that facilitates access to specific elements of the record and document individual patient treatment outcomes. As required by HIPAA, patients have a right to access their medical records and other health information.

Programs must adhere to all requirements of the federal confidentiality regulations (42 CFR § 2) and HIPAA privacy, security, and breach notification regulations (45 CFR § 160 and § 164), as applicable.

In accordance with 42 CFR § 2, programs should have clear guidelines for the access, transfer, and disposal of records. They also should have record-retention policies and safeguards for the destruction of old containers, labels, printouts, and program records under normal operating conditions as well as in the event of a disaster or program closure.

Records of the identity, diagnosis, prognosis, or treatment of any patient that are maintained in connection with any activity relating to substance abuse education, prevention, training, treatment, or research that 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 § 2, be confidential. Information in these records can be disclosed only for the purposes or circumstances expressly authorized under subsection 42 CFR § 2(b).

Programs may use standard intake forms or identical data elements when possible. Programs should be efficient and avoid duplication in recordkeeping. 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. An individual patient record is typically comprised of: 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 and consistent with 42 CFR § 2 and HIPAA privacy regulations.
An individual patient record should contain:

- Documentation of compliance with the approved central registry system (if applicable) or an alternative mechanism to avoid dual registration.
- The initial assessment report.
- Narrative bio-psycho-social history prepared within approximately 30 days of the patient's admission or as required by state regulation.
- Medical reports, including results of the physical examination; past and family medical history; nursing notes; laboratory reports, including results of regular toxicology screens, a problem list, and list of medications updated as clinically indicated; and progress notes,

including documentation of all medications and dosages. Information in the medical record is entered by physicians and authorized healthcare professionals, as appropriate.

- Dated case entries of all significant contacts with patients, including a record of each counseling session, in chronological order.
- Dates and results of patient case conferences.
- 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; and in subsequent years, semiannual assessments; treatment plan updates; and counselor summaries, which include an evaluation of the existing treatment plan and the patient's response to treatment.
- Documentation that all services listed in the treatment plan are available and actually were provided or that the patient was referred to such services.
- A written report on the process used to make patient treatment decisions, such as privileges or changes in counseling sessions, frequency of drug tests, or any other significant treatment changes, either positive or negative, and the factors considered in the decisions.
- A record of correspondence with patient, family members, and other individuals.
- A record of each referral for service and the results.
- Documentation that the patient received a copy of the program's rules and regulations and a statement of patient rights and responsibilities and that these items were discussed with her or him.
- Consent forms; release(s) of information; and prescription, travel, employment, and take-home documentation.
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- A closing summary, including reasons for discharge and any referrals. In the case of death, the cause of death is documented.
- The PDMP reports, unless operating in a state with no PDMP.

Records for the Storage, Dispensing, and Administration of Opioid Medication

OTPs' policies and procedures must be consistent with DEA statutes and regulations pertaining to the recording of and accounting for the use of controlled substances. Other medications must be stored separately from methadone and buprenorphine. Medication orders and changes in dosage are written on an acceptable order sheet and signed by the physician or comparable electronic process.

As part of the process to create a perpetual and accurate inventory of all in-stock medications, including controlled substances, every dose administered or dispensed is captured electronically

or recorded on an administration sheet at the time the medication is administered or dispensed and recorded on the patient's individual medication dose history. The qualified person administering or dispensing the medication either signs or initials each notation. If initials are used, the full signature of the qualified person administering or dispensing the medication appears at the bottom of each page of the medication sheet. The number of dispensed medication doses is totaled in milligrams on a daily basis. Programs must calibrate their medication-dispensing instruments according to the manufacturer recommendations to ensure accurate patient dosing and medication tracking.

Multiple Program Enrollment Prevention

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 the 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. For guidance, access the regulation at http://www.ecfr.gov/cgi-bin/text-idx?SID=07521f1d15ff4661f403ec736facfdb7&node=42:1.0.1.1.2.3.1.4&rgn=div8.

GUIDELINES FOR THERAPEUTIC DOSAGE AND ADMINISTRATION

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.

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(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 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.

PHARMACOTHERAPY

The delivery of care in OTPs has been impacted by the availability of multiple pharmacotherapies. When pharmacotherapy is indicated, it is the responsibility of OTPs to match each patient to the appropriate medication even if it is not offered at the OTP. The choice of pharmacotherapy should reflect sound medical reasoning as applied to the specific patient. Programs providing treatment with multiple medications using both the OTP and office-based opioid treatment (OBOT) models of service delivery should develop clear policies and procedures for assigning patients to a specific model and establish criteria for determining a specific pharmacotherapy.

Appropriate OTP staff are authorized to dispense or administer methadone and buprenorphine to patients admitted for treatment. The federal opioid treatment standards apply equally to both methadone and buprenorphine with the sole difference spelled out in 42 CFR § 8.12(i)(3). Other pharmacotherapies may be provided in a manner consistent with the best medical practices for each medication. For example, the use of extended-release injectable naltrexone is clinically appropriate for some patients presenting to OTPs and is not subject to these regulations.

Physicians who have obtained waivers to prescribe buprenorphine under the rules spelled out in DATA 2000 may prescribe buprenorphine to the number of patients specified in the law. A physician may treat patients under DATA 2000 rules in an OTP facility, but the OTP must clearly distinguish between patients who are cared for by a physician in accordance with the rules under DATA 2000 and those who are cared for in an OTP facility in accordance with 42 CFR § 8.12.

General Dosage Principles

When a state PDMP is available, OTP physicians and other healthcare providers, as permitted, should register to use their respective state's PDMP and query it for each newly admitted patient prior to initiating dosing. The PDMP should be checked periodically (for example, quarterly) through the course of each individual's treatment and, in particular, before ordering take-home doses as well as at other important clinical decision points. Querying the PDMP will result in a range of possible results. In some cases, no use of scheduled prescription medications will be identified. In others, the history of prescription use reported by the patient will be confirmed. If the patient has ongoing relationships with prescribers from whom they may still acquire prescriptions for controlled substances or other psychotropics, strategies to prevent or limit this activity should be established. Ideally, releases of information should be obtained from each prescriber in order to coordinate needed medical care while avoiding the use of medications that may interact with the pharmacotherapy for a substance use disorder. Lastly, the PDMP may reveal ongoing receipt of prescriptions not reported to the program for substances known to be misused by the patient. An assertive strategy of care coordination combined with additional treatment strategies, such as medically supervised withdrawal from the misused prescription medications and intensive behavioral interventions, may need to be implemented. In some situations, the presence of active diversion may lead to discharge for reasons of patient safety or the safety of the community. Of particular concern is when a patient refuses to sign a release of information to allow care coordination with other prescribers.

OTP safety policy and procedures should include checking the PDMP prior to admitting a patient as well as periodically while the patient is enrolled in treatment. Additional information about PDMPs can be found at http://captus.samhsa.gov/access-resources/briefing-prescription-drug-monitoring-program-pdmp-effectiveness.

The program physician is the only practitioner authorized to order and/or change a patient's dosage of methadone or buprenorphine. The physician must make an individualized decision informed by the up-to-date product labeling and clinical judgment.

Standing orders are defined as orders that apply equally to all persons fulfilling certain criteria. Examples of standing orders in general medical practice are those that allow influenza immunization to be administered to all patients who meet specific criteria. Another example is the standing order that allows cardiopulmonary resuscitation to begin when a patient in the hospital experiences cardiac arrest. This is why "do not resuscitate" must be written as an order, otherwise resuscitation is conducted as per the standing order.

Standing orders regarding the dose, schedule, or re-administration of methadone are not appropriate because of the unique pharmacologic properties, the well-established potential for fatalities in the induction period, and the risk of relapse during medically supervised withdrawal. In an OTP, an unacceptable standing order is any formulaic policy generically applied to all patients meeting specific criteria or in specific situations without evaluation by a physician or other qualified healthcare provider. Common examples are dose adjustments made solely on the basis of a Clinical Opioid Withdrawal Scale (COWS) score and remedicating a patient who vomits after dosing based on the time between dose administration and vomiting using a fixed percentage of the dose.

The physician may choose to write a very short cascading order incorporating a COWS score or other objective measure in order to titrate the dose of a specific individual if appropriately trained and qualified staff (as determined by licensing criteria or credentialing) are available to evaluate the ongoing appropriateness of the physician's treatment plan and recognize the need for the patient to be re-evaluated prior to completion of the full course of the order. The physician must document the evidence and assessment supporting the planned use of a cascading order whenever one is use. The program as a whole needs to be acutely aware of the added risk to the patient such orders represent.

Program-wide dosage caps or ceilings are contrary to the current state of the medical literature and the principle of individualized treatment. Programs should eliminate their use. In addition, OTPs should avoid establishing procedures or policies that hinder the ability of physicians or authorized healthcare professionals, as appropriate, to adjust patient dosages whenever the need is indicated.

Effective medication-assisted treatment has the following desired outcomes:

- Prevention of the onset of subjective and/or objective signs of opioid abstinence syndrome for at least 24 hours (opioid agonists).

- Reduction or elimination of drug craving routinely experienced by the patient (opioid agonists or antagonists).
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- Blockage of the euphoric effects of any illicitly acquired, self-administered drug without the patient experiencing or observers noticing undesirable effects (opioid agonists or antagonists).

The initial full-day dose of medication is based on the physician's assessment of the patient's overall condition. The physician must take into account the overall medical and psychiatric condition of the patient; the patient's risk for undiagnosed complicating conditions based on behavior, family history, age, and gender; the patient's life history and current substance use; and any physical finding on examination. The physician should take into account local conditions, such as the relative purity of available drugs and the source of the drugs, regardless of whether the patient illicitly purchased or obtained them from friends or family members. Medication dosage must also take into account over-the-counter (OTC) drugs, prescription medications, and prescription medications containing controlled substances. For a full discussion of appropriate dosing with methadone, refer to TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf), and for buprenorphine, refer to TIP 40 (http://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/TOC.pdf).

Regulations stipulate that the initial dose of methadone should not exceed 30 mg. The physician must document the carefully thought out justification for exceeding 30 mg. The total amount of methadone administered on day one must not exceed 40 mg.

Methadone has a long half-life and accumulates in the body with repeated dosing. The full effect of a single dose increase may not be appreciated for several days. Consequently a "start low and go slow" approach to induction or increases needed at any time during treatment is urged. For more information on the pharmacologic properties of methadone and how they guide clinical decision making, refer to TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf).

The total dose of medication and the interval between doses may need to be adjusted for patients with comorbid health conditions or atypical metabolic patterns, or if the patient takes other prescribed medications that have detectably altered the rate at which the opioid medication is metabolized.

Programs must 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 result in a decreased dosage. Such a situation may actually indicate the need for an increased dosage.

Medication-assisted treatment should continue as long as the patient desires and derives benefit from treatment. There should be no fixed length of time in treatment. For some patients, indefinite medication-assisted treatment may be clinically indicated.

Initial doses of buprenorphine and methadone should be based on the package insert. The physician will document the justification for any deviations from this principle.

If a program switches from one generic formulation to another and differences in the effective dose cause clinically relevant complaints, the physician needs to assess the patient and adjust the medication dosage. Additionally, caution should be exercised when a patient has missed several doses of medication because his/her tolerance may have changed. Under no circumstances should standing orders be used to address these situations.

The program should have the capability to obtain medication blood levels when clinically indicated.

UNSUPERVISED APPROVED USE (TAKE-HOME) OF MEDICATION

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;

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(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.

(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.)).

Note: In the context of 42 CFR § 8.12(i)(5) "container" refers to a child-proof medication bottle.

Take-home medication is a valuable therapeutic tool and an important means of individualizing treatment. Program policies that do not permit take-homes for any patients are unacceptable because these policies preclude individualized patient care. Take-home medication often is a critical issue for patients who are deciding whether to enter into and remain in treatment. The OTP medical director, therefore, should ensure that policies for the approval of take-home medication do not create barriers to patients continuing in treatment.

A multidisciplinary team, typically led by the primary clinician, assembles the documentation that a given patient has meaningfully fulfilled the eight take-home criteria and has done so for a period sufficiently long to suggest likely ongoing compliance. If on methadone, the patient also must meet the time-in-treatment requirements for the level of take-homes being considered. The team provides a summary of the documentation, makes recommendations regarding the patient's

ability to responsibly handle unsupervised use of medication, and attests that the therapeutic benefit outweighs any risk of diversion to the medical director. The medical director considers this information and his or her own assessment of the patient to make the final decision to approve or reinstate a patient's use of take-home medication.

The OTP medical director and program staff should take into consideration the best interest of each patient when customizing take-home medication schedules. Public health issues (e.g., preventing diversion, ensuring safe storage and security of medication, preventing overdoses) also are considered when determining a patient's eligibility for take-homes. Physicians and OTP staff periodically, and when clinically necessary, review a patient's unsupervised use of medication and document their decisions and actions in the patient's record.

Patients who need to travel but do not meet criteria for take-home medications should be considered for guest dosing. Guest dosing is not specifically provided for in the regulations but is consistent with SAMHSA's approach to both medication safety and supporting recovery. A sample policy for guest dosing was developed by the American Association for the Treatment of Opioid Dependence.

Whenever a physician wishes to deviate from the federal opioid treatment standards regarding unsupervised use of medication set forth in 42 CFR § 8.12, an OTP must submit an Exception Request and Record of Justification form (SMA-168) to SAMHSA for approval. The two most common reasons for submitting an exception request are to temporarily increase the number of take-home doses otherwise permitted for a patient for unsupervised use or when a patient does not meet the time-in-treatment or eight-point criteria for receiving take-home doses. On occasion, a trusted third-party may need to be involved in the management of an individual's take-home medication, whether as a condition of receiving an exemption from take-home dose requirements or to deliver dispensed doses to the individual patient's care givers in a skilled nursing facility or correctional institution. Programs should develop a standard process to record chain-of-custody of dispensed take-home doses. A sample form is provided in the appendices of this document.

OTPs monitor patients' use of take-home medications in a manner that complies with federal regulations. Monitoring patients' use of take-home medication ensures the security of the medications and serves as a mechanism for preventing diversion. As part of a program's policies related to medication security, patients are informed of their rights and the responsibility they have to store take-home opioid medications in a child-proof container in a secure location. Monitoring patients receiving medication for unsupervised use requires the physician or authorized healthcare professional, as appropriate, to have knowledge of physiological issues and a thorough understanding of the differences among laboratories and the factors that affect absorption, metabolism, and elimination of opioids. Knowledge and understanding in these areas are essential, for example, to interpret a negative methadone and/or a toxicology test for methadone metabolites.

Medication Security

Guidelines for Security of Take-Home Medication: Patients receiving unsupervised (take-home) medication should use a locked container to inconspicuously and safely transport take-home medication packaged in individual bottles that are labeled in accordance with the regulations and

store the medication at home. The regulations do not mandate that patients use a specific type of locking container.

Although the locking container is a reasonably safe place for the medication at home, it presents two regulatory challenges when transporting the medication from the program to the patient's home: (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 ease of discrete transport home, OTPs should dispense dry medication diskettes or tablets in one single bottle to patients who report to the clinic once or twice per month and receive 15- to 30-day supplies of medication. Programs also should consider medication diskettes or tablets for patients using air transportation. Dispensing dry medications mitigates any potential for bacterial growth in liquid media.

Provision of 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 also ensuring appropriate handling and delivery of medication to the patient is a challenge for clinical staff. One solution is to use a chain-of-custody record, which is a document containing the signatures of all people who have handled the medication (see page 78 in Appendix D. Samples of Standard Forms). This record also should contain spaces for the patient to initial each day that the medication is administered, as well as spaces 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 responsible person maintains a chain-of-custody record and takes charge of the medication, placing 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. Because, at the time of this writing, 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 diverted for illegal use.

To get permission for a family member who does not have a history of an alcohol or drug use disorder and with whom the OTP staff members have met and screened to pick up the medication for patients who are homebound, the OTP should use the SMA-168 and forward the exception request to the relevant state and federal government authorities.

INTERIM MAINTENANCE

FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS

42 CFR § 8.12 (j) Interim maintenance treatment. (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of §8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions: (i) The opioid agonist treatment medication is required to be administered daily under observation; (ii) Unsupervised or "take-home" use is not allowed; (iii) An initial treatment plan and periodic treatment plan evaluations are not required; (iv) A primary counselor is not required to be assigned to the patient; (v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and (vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

Mortality among individuals wait-listed for medication-assisted treatment is high. Rather than maintaining a waiting list for admission, program should consider offering interim maintenance. Provision of interim maintenance requires authorization from SAMHSA. For instructions on

how to obtain authorizations refer to 42 CFR § 8.11(g). All of the requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions: no take-home doses are permitted; an initial and periodic treatment plan are not required; a primary counselor is not required; and the rehabilitative and other services described in 42 CFR § 8.12(f)(4), (f)(5)(i) and (f)(5)(iii) are not required. Interim maintenance cannot be provided for more than 120 days in any 12-month period. To receive interim maintenance, a patient must be fully eligible for admission to comprehensive maintenance. Interim maintenance treatment is for those patients who cannot be enrolled in comprehensive maintenance treatment in a reasonable geographic area within 14 days of application for admission. During interim maintenance, the initial toxicology and at least two additional toxicology screening tests should be obtained.

Programs offering interim maintenance must develop clear policies and procedures governing the admission to interim maintenance and transfer of patients to comprehensive maintenance. Consideration should be given to the offering of interim maintenance with access to antagonist therapy and the transfer of patients to comprehensive maintenance. Priorities such as admission for pregnant women should be established.

EXEMPTIONS

> (h) Exemptions. An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and §8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

Any deviation from the opioid treatment standards put forth in 42 CFR § 8.12 requires the submission and approval of an Exception Request and Record of Justification (SMA-168) form that can be accessed via http://www.dpt.samhsa.gov/pdf/SMA-168.pdf.

Exception Request and Record of Justification (SMA-168) Form

On occasion, patients may need exceptions from the federal opioid treatment standards due to transportation hardships, employment, vacation, medical disabilities, etc. In these instances, the physician should submit the completed SMA-168 form to SAMHSA and, if applicable, the SOTA, for approval to change the patient's dosing regimen from the requirements specified in 42 CFR § 8.12. At times, it may be necessary to involve a trusted third-party in the management of take-home doses in order to receive the exemption. In this case, each program is encouraged to develop a standard process for monitoring the chain of custody of take-home medications.

Failure to submit an SMA-168 exception request to and obtain approval from SAMHSA and, if applicable, the SOTA, prior to providing care that deviates from the federal opioid treatment standards constitutes a serious regulatory violation, which may threaten a program's federal and state compliance, accreditation, and certification.

SMA-168 exception requests may be submitted to SAMHSA on-line, by fax, or by mail. For fastest processing, SAMHSA strongly recommends on-line submission. SAMHSA's decision on on-line exception requests is typically viewable by the submitting OTP within one hour of submission.

The most common reasons for submitting exception requests are to request:

- A temporary increase in the number of take-home doses permitted for unsupervised use.
- A change to the detoxification standards outlined in the regulation.

Eligible patients may be provided take-home medication according to this schedule with no exception request required. In cases where a treating physician believes it would be in the best interest of an individual patient to receive a temporary increase in the number of take-home medications, such as when there is a family or health emergency, approval of an SMA-168 exception request by SAMHSA and, if applicable, the SOTA, is required.

It should be noted that the take-home schedule defined in 42 CFR § 8.12(i)(3) represents a minimum standard. States and treatment programs may choose a more stringent standard, e.g., require longer time periods of stability or provide fewer total take-home doses. In addition, it is important to recognize that simply because an individual patient meets the time-in-treatment criteria for take-home doses according to the schedule, the patient is not automatically eligible to receive those take-home medications. The decision as to whether or not an individual patient should receive take-home medication is a medical decision that is made by the medical director (physician) of the program. The physician must assess each patient's progress and determine whether the rehabilitative benefit derived from decreasing the frequency of attendance outweighs any potential risks. While programs are being encouraged to individualize treatment and utilize the SAMHSA take-home schedule, this does not mean that they are required to do so.

Exception Request for Variation from Detoxification Standards

42 CFR § 8.12 specifies that a program may not admit a patient for more than two detoxification treatment episodes in one year. 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. If, after this assessment, a physician believes it would be in the best interest of an individual patient to receive a third (or greater) detoxification treatment episode in one year, approval of an SMA-168 exception request by SAMHSA and (where applicable) the SOTA is required. On the SMA-168 submission, the physician must justify the reason for requesting more than two detoxification episodes per year and attest that the patient has been assessed for other forms of treatment.

Exception Request for Other Reasons

Programs should submit an SMA-168 exception request for approval of any treatment that differs from the federal opioid treatment standards set forth under 42 CFR § 8.12(i)(3). Programs do not need to submit SMA-168 exception requests to SAMHSA for the provision of care that is in compliance with the treatment standards set forth in Regulation 42 CFR § 8.12. For example, a common misperception is that a program must obtain approval from SAMHSA when treating a patient with methadone at doses greater than 100mg. Because 42 CFR § 8.12 places no such limit on the maximal allowed dose of methadone for a patient in treatment, no SMA-168 exception request is required by SAMHSA in this case. State rules, however, may differ.

42 CFR § 8.12 does specify a limit of 30 mg of methadone for the initial dose and 40 mg for the total daily dose for new a patient on the first day of treatment. Thus, treatment on the first day with methadone doses greater than these amounts would require SAMHSA to approve an SMA-168 form along with approval from the SOTA, where applicable.

When in doubt, submit. If a program has consulted the text of the federal opioid treatment standards in 42 CFR § 8.12 and is unsure if the care it intends to provide for a patient is in compliance with the standards, the program should submit an SMA-168 exception request. There are no penalties for submitting an exception request when one is not required. Failure to submit and obtain approval from SAMHSA (and the SOTA where applicable) prior to providing care that deviates from the federal opioid treatment standards constitutes a serious regulatory violation, which may threaten a program's federal certification.

Submit an SMA-168 Exception Request

SMA-168 exception requests can be submitted on-line from the SAMHSA OTP Exception Request Web site at http://otp-extranet.samhsa.gov. Assistance with on-line exception requests and requests for a physician account on the OTP Exception Request Web site can be obtained by calling the SAMHSA OTP Exception Request Information Center at 1-866-OTP-CSAT (1-866-687-2728) or by sending an email to otp-extranet@opioid.samhsa.gov.

APPENDIX A. REFERENCES

American Society of Addiction Medicine. (2013) *Drug Testing: A White Paper of the American Society of Medicine*. Chevy Chase, MD: American Society of Addiction Medicine.

American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental Disorders 5th ed.,* Arlington, VA: American Psychiatric Association.

Baxter L.E. Sr, Campbell A., Deshields M., Levounis P., Martin J.A., McNicholas L., Payte J.T., Salsitz E.A., Taylor T, Wilford B.B. Safe methadone induction and stabilization: Report of an expert panel. *J Addict Med.* 2013 Nov-Dec; 7(6), 377–386.

Center for Substance Abuse Treatment. (2005). *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP) Series 43. (DHHS Publication No. SMA 05-4048). Rockville, MD: Substance Abuse and Mental Health Services Administration.

Center for Substance Abuse Treatment. (2004). *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction.* Treatment Improvement Protocol (TIP) Series 40. (DHHS Publication No. SMA 04-3939) Rockville, MD: Substance Abuse and Mental Health Services Administration.

French, M. T., & Zarkin, G. A. (1992). The effects of drug abuse treatment on legal and illegal earnings. *Contemporary Policy Issues, 10*(2), 98–110.

French, M. T., Zarkin, G. A., Hubbard, R. L., & Rachal, J. V. (1993). The effects of time in drug abuse treatment and employment on posttreatment drug use and criminal activity. *American Journal of Drug and Alcohol Abuse, 19*(1), 19–33.

Gerstein, D. R., Johnson, R. A., Harwood, H. J., Fountain, D., Suter, N., & Malloy, K. (1994). *Evaluating Recovery ervices: The California Drug and Alcohol Treatment Assessment (CALDATA).* Sacramento, CA: California Department of Alcohol and Drug Programs.

Hubbard, R. L., Marsden, M. E., Rachal, J. V., & Cavanaugh, E. R. (1989). *Drug abuse treatment: A national study of effectiveness*. Chapel Hill, NC: The University of North Carolina Press.

Institute of Medicine. (1990). *Broadening the Base of Treatment for Alcohol Problems.* Washington, DC: National Academy Press.

Institute of Medicine. (1995). *Federal Regulation of Methadone Treatment.* Washington, DC: National Academy Press.

Institute of Medicine. (1996) *Telemedicine: A Guide to Assessing Telecommunications for Health Care*. Washington, DC: The National Academies Press.

Simpson, D. D., Joe, G. W., Lehman, W. E. K., & Sells, S. B. (1986). Addiction Careers:

Etiology, Treatment, and 12-Year Follow-Up Outcomes. *Journal of Drug Issues, 16*(1), 107–121.

U.S. Government Printing Office. (2006). *Code of Federal Regulations.* Washington, DC: GPO.

APPENDIX B. GUIDELINES PANEL

On January 25, 2012, SAMHSA convened a panel of experts in Linthicum, MD, to review and begin to revise the 2007 *Guidelines for the Accreditation of Opioid Treatment Programs*.

The key objectives of the meeting were to:

- Share information and data about the current state of the field of opioid treatment.
- Discuss the impact of state regulations and oversight, private-for-profit programs, and multi-state providers on the opioid treatment field.
- Determine how buprenorphine and office-based treatment are impacting opioid treatment services.
- Identify factors that will increase the accountability, capacity, and effectiveness of opioid treatment services in specific settings or populations.
- Recommend revisions and updates to the guidelines that will improve the overall accountability, capacity, and effectiveness of opioid treatment service delivery.

Within the context of the 2007 Guidelines, the expert panel members were asked to consider the following 17 emerging topics:

1. Approaches to address the use of benzodiazepines and/or alcohol in opioid treatment programs
2. Electronic health records and opioid treatment programs
3. Treatment in rural areas and the use of telemedicine in medication-assisted treatment
4. Interface between opioid treatment programs and state prescription drug monitoring programs
5. Best practices when addressing medical and psychiatric disorders
6. Pain management in medication-assisted treatment
7. Methods for working with younger patients with prescription opioid addiction
8. New treatments (e.g., extended release injectable naltrexone and new buprenorphine formulations)
9. Medication-assisted treatment and home health models of care
10. Strategies for integrating tobacco cessation
11. Pregnancy and post-partum care of women maintained on methadone/buprenorphine
12. Expanded admission practices and emergency procedures
13. Use of authorized healthcare professionals
14. Recovery
15. Standing orders
16. Cardiac assessment
17. Hepatitis

Other topics added by attendees included:

1. Methadone-related deaths
2. Medical marijuana
3. Take-home doses and drug charges

4. Homelessness/unemployment/patients on supplemental security income and social security disability insurance
5. Standards to help coordinate care between a methadone patient and residential treatment
6. Medical director qualifications

The participants were divided into small workgroups to discuss and provide feedback on each topic. Comments were collected, inserted into the 2007 guidelines, and distributed to the panel. Subsequently, the document was reviewed and revised during multiple 2-hour conference calls.

Accreditation Guidelines Expert Panel January 25, 2012

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APPENDIX C. FREQUENTLY ASKED QUESTIONS

COMMUNICATION WITH SAMHSA

What is the preferred method of submitting paperwork to SAMHSA?

SAMHSA prefers paperless communication. In light of this, SAMHSA has online versions of the SMA-162 and SMA-168 forms available for electronic submission and provides certified OTPs with access to the SAMHSA OTP Extranet, located at http://otp-extranet.samhsa.gov.

To begin using the online system, request the appropriate account at http://otp-extranet.samhsa.gov/request/.

Existing OTPs may submit the SMA-168 form (exception requests) as well as personnel change and renewal requests via SAMHSA's OTP Extranet located at http://otp-extranet.samhsa.gov. Requests for help with the Extranet should be emailed to the OTP Extranet Information Center at otp-extranet@opioid.samhsa.gov, or OTPs can call 1-866-OTP-CSAT between 8:30 and 5:00 pm EST, Monday through Friday.

How does a new OTP request provisional certification and obtain a number from SAMHSA?

OTPs should use the online SMA-162 form located at http://dpt2.samhsa.gov/sma162/sma162.aspx to apply for provisional certification and notify SAMHSA of program changes.

The OTP accesses, fills out, and electronically submits the online SMA-162 found on http://dpt2.samhsa.gov/sma162/sma162.aspx to SAMHSA. The Provisional Certification box on the SMA-162 form should be checked. SAMHSA will carefully review the form and application packet for completeness and notify the OTP of the need for additional information or clarification. Incomplete, inadequate, or poor quality applications will require a longer time to process. Applicants are urged to adhere closely to the instructions provided on the SAMHSA Web site, particularly, the checklist for documents to be submitted with the SMA-162. Electronic submission of all parts of the application will expedite evaluation of the application. After both the state where the OTP is located and the DEA complete their OTP approval process, SAMHSA will finalize its review and, upon approval of the program, assign the OTP a certification number.

What does an existing OTP do to find out its SAMHSA certification number?

An existing OTP can find out its SAMHSA number by emailing the OTP Extranet Information Center at otp-extranet@opioid.samhsa.gov, by calling 1–866-OTP-CSAT, or by contacting the SAMHSA compliance officer for the state where the program is located. To identify the correct compliance officer and find his or her contact information, access http://www.dpt.samhsa.gov/regulations/certification.aspx.

How does an OTP inform SAMHSA of program changes?

Existing OTPs should log in via the extranet (http://otp-extranet.samhsa.gov) and complete either the SMA-168 form (exception requests) or the SMA-162, which is used to notify SAMHSA of personnel changes and renewal requests. If the change at the program does not correspond to those provided on the form, an explanation should be attached. Or, the program may send a letter to the appropriate compliance officer informing SAMHSA of the change. The compliance officer's contact information is found at http://www.dpt.samhsa.gov/regulations/certification.aspx.

If I have a problem enrolling or getting on the extranet what should I do?

Requests for help with the Extranet should be emailed to the OTP Extranet Information Center at otp-extranet@opioid.samhsa.gov, or OTPs can call 1-866-OTP-CSAT between 8:30 am - 5:00 pm EST, Monday through Friday.

Does an existing medication unit have to submit an SMA-162 separately from the original OTP when renewing its program's SAMHSA certification or recertification?

No, SAMHSA requires only a single submission. Medication units are defined under federal regulations as facilities, including community pharmacies that dispense treatment medications under the auspices of an existing OTP. The SAMHSA-certified OTP assumes all responsibilities for medication units. If the OTP 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 form with 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.

How does an OTP apply to open a new medication unit?

Submit an SMA-162 with all requested attachments and signed documents to SAMHSA; this can be done online using SAMHSA's Extranet at http://otp-extranet.samhsa.gov. In Item 14 of the application, "Purpose of Application," check off "Medication Unit." SAMHSA will process the form and forward it for approval to the DEA, which will arrange an inspection. The program also should submit all required materials to the SOTA to seek state approval, as appropriate. Once the DEA approves the medication unit, it will assign a new DEA registration number for that medication unit. The SAMHSA-assigned number will stay the same for both the original site and the medication unit(s). The required documents are:

- A description of how the medication unit receives the medication supply from the primary facility.
- An affirmative statement that the medication unit is limited to administering and dispensing the narcotic treatment drug and collecting samples for drug testing or analysis.

- An affirmative statement that the sponsor agrees to retain responsibility for patient care.
- A diagram and description of the facilities to be used as a medication unit.
- Total number of patients to be served by the primary facility and medication unit.
- Total number of patients that will be served only at the medication unit.
- A justification for need to establishing a medication unit.
- Are there any other active medication units attached to this primary facility? If yes, please provide the name of the medication unit(s) and address.

Does "Program Sponsor" on the SMA-162 refer to a program or a person?

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

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

Within 3 weeks of a program change (e.g., medical director or program sponsor), an OTP should fill out the appropriate sections of the online SMA-162 and submit it to SAMHSA.

What are the differences between accreditation, provisional certification, and 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 42 CFR § 8.3 to accredit OTPs that use opioid agonist treatment medications. An OTP must receive accreditation before it may be certified by SAMHSA.

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 and satisfies all of the requirements of SAMHSA's application process. Provisional certification is granted to OTPs that have submitted form SMA-162 along with a statement identifying the accreditation body to which the OTP has applied, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification may be granted for 1 year, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification.

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 § 8.12.

When a new OTP is just getting started, how much time does it have to become accredited?

OTPs have up to 1 year to become accredited. New OTPs must apply for accreditation with a SAMHSA-approved accreditation body and request provisional certification from SAMHSA by filling out and electronically submitting the online SMA-162 as part of the process for receiving SAMHSA certification. Information an OTP provides on the online SMA-162 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 as well as all the other application requirements. 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.

TAKE-HOME PRIVILEGES

How does an OTP request an exception to take-home requirements from SAMSHA?

To request an exception to any of the take-home related regulations, an OTP physician must login to SAMHSA's extranet with his or her account and complete the SMA-168 online. For detailed instruction, please go to: http://www.dpt.samhsa.gov/regulations/exrequests.aspx.

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 a patient's weekly take-home include days adjacent to the day the clinic is closed?

Sometimes a patient's weekly take-home may include days adjacent to the day the clinic is closed; however, an OTP 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, the program is acknowledging that the eight criteria in the regulations for take-home medication have been reviewed. The take-home schedule must be tailored to each patient. Programs should consider patient risk for relapse and diversion when making take-home decisions.

Our program is considering dispensing tablets for patients who have take-home privileges. Is this a diversion risk?

All opioid treatment medications pose a risk of diversion. The medical director 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.

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 a Sunday?

An exemption request is needed to dispense take-home doses to short-term detoxification patients for holidays and days when the program is closed. SAMHSA will consider annual program-wide exemption requests for short-term detoxification patients, although the exemption should not be applied universally. The exemption permits only those patients deemed stable enough to safely take the medication unsupervised and who present a minimal risk for diversion to be granted a take-home dose in this situation. With a program-wide exemption in place, the program may provide a take-home for such patients without requesting an individual exemption for each one on each occasion.

If a patient is in a comprehensive maintenance program, is on take-home status, and requests a medically supervised withdrawal, can he/she remain on take-homes during the withdrawal period?

Yes, because the patient was admitted to maintenance treatment, take-homes would be permitted.

A few states and OTPs have recognized that the medication take-home schedule outlined under 42 CFR § 8.12(i) is different from schedules outlined in some state regulations. Which take-home schedule takes precedence?

Programs should adhere to the take-home schedule that is the most restrictive. Exemption requests should be submitted to SAMHSA or the state if there is a need to deviate from either of the schedules.

DETOXIFICATION PROGRAMS

Is a detoxification program considered to be an OTP?

Yes, a detoxification program is considered to be an OTP. 42 CFR § 8.12 defines an OTP as a "program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication." 42 CFR § 8.11(a)(1) states that an OTP must have a current, valid certification from SAMHSA to be considered qualified by the Secretary of DHHS to dispense methadone or buprenorphine for the treatment of addiction. A unit of a hospital that intends to offer new detoxification services using methadone or buprenorphine should apply to SAMHSA for provisional certification.

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?

Yes, SAMHSA requires inpatient detoxification programs that use methadone to be accredited and certified. 42 CFR § 8.12 addresses all forms of opioid treatment, including maintenance and detoxification treatment.

Will the accreditation and certification processes differ in any way from what is being required of maintenance programs?

No, detoxification programs are subject to the same standards as maintenance programs. Standards are detailed in 42 CFR § 8.12. 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.

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.

No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use (42 CFR § 8.12(i)(4)).

TREATMENT

42 CFR § 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 or authorized healthcare professional, as appropriate, any time within that 14-day period, or must he/she see the physician or authorized healthcare professional, as appropriate, before treatment commences?

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 or under the supervision of a physician or authorized healthcare professional, as appropriate, 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.

When a person in treatment for opioid addiction is abstinent from illicit opioids but tests positive for another drug, can we keep him or her in treatment?

Yes, a person who tests positive for drugs other than opioids may be kept in treatment. SAMHA encourages OTPs to ensure that the abuse of drugs other than opioids 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 TIP 43.

If detox, what are alternatives?

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

The regulations require that OTPs perform adequate testing services at minimum intervals. SAMHSA guidelines recommend that drug-screening tests should include tests for opioids, methadone, amphetamines, cocaine, and benzodiazepines. 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 to forgo testing for drugs that are not commonly used in that particular community or population. The accreditation bodies may offer additional guidance on this subject.

What happens when drug testing reveals use of specific drugs such as amphetamines and barbiturates?

The OTP should provide appropriate counseling and other treatment if abuse of other drugs is identified as a problem. When necessary, the OTP should coordinate with treatment programs offering higher levels of care to address the individual's polysubstance use.

Scenario: Within a few days of 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?

The patient does not have to use drugs again to be admitted. He/she may be readmitted after the physician or authorized healthcare professional, as appropriate, examines him or her and writes an admission order.

MEDICATION

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

Although there is no foolproof way to determine whether a person is legally medicated or using illicit drugs, a patient should be asked to sign a release of information to allow the pain management clinic to verify to the OTP that he/she is receiving opioid analgesics. Prescription drug monitoring programs (PDMPs), where available, will be helpful in this area.

What can we do about the dose cap restriction?

The *Federal Guidelines for Opioid Treatment Programs* advises against dosage caps. Medical evidence does not support their use. For additional information, access TIP 43 (http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf). Educating OTP physicians and staff appears to be the best approach for encouraging individualized treatment without dosage cap restrictions.

What is meant by the 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))?

Only oral forms of methadone should be dispensed. Parenteral and non-oral forms are prohibited in opioid addiction treatment. Previous regulations restricted dispensing methadone for addiction treatment to liquid only; however, the current regulations removed the liquid-only restriction and now permit solid forms of the medication. Diskettes and tablets are formulated to conform to standards and are acceptable forms of methadone for use in OTPs. Diskettes formulated to reduce the potential for intravenous administration pose less risk of diversion than tablets.

What is the federal regulation regarding the initial opioid medication dose?

The regulation is 42 CFR § 8.12 (h)(3)(ii)), and it states that "For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 mg and the total dose for the first day shall not exceed 40 mg, unless the program physician documents in the patient's record that 40 mg did not suppress opiate abstinence symptoms."

DRUG TESTING

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?

The federal regulations do not specify urine as the only type of biological sample that can be tested. Instead, 42 CFR § 8.12 (f)(6) says: "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." A CSAT letter to the field dated July 18, 2003, stated that offsite drug testing using oral fluids may be adequate, at least in some populations. It is SAMHSA'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.

Drug testing is considered a medical service and an important component of 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 remains responsible for the adequacy of drug abuse testing services and all other medical services provided by the program. 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.

SAMHSA expects that accreditation bodies will review these Guidelines and adopt all or part for inclusion in the accreditation standards they apply to OTPs. States may, however, adopt specific language regarding the type of biological specimen acceptable for testing. As always, OTPs should be careful to comply with any regulations imposed by the state that exceed the federal standards.

APPENDIX D. SAMPLES OF STANDARD 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.

EXAMPLE OF MEDICATION CHAIN-OF-CUSTODY RECORD

Date: _____

Name of Treatment Program: _____

Name of Treatment Program Dispensing Nurse: _____

Medication To Be Delivered (Methadone/Buprenorphine/Buprenorphine +Naloxone):

_____

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
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

APPENDIX E. PROGRAM RESPONSIBILITIES

Programs should develop and implement policies and procedures to promote and protect patients' rights as well as their health and well-being. Both the OTP's responsibilities and patient rights should be posted at the treatment site and reviewed with the patient following admission, at the end of the stabilization period, and when changes occur. For patients unable to read, program staff should verbally explain the patient's rights and the program's rules and regulations and document this interaction. In addition, programs should have accommodations in place for patients who do not speak English.

Program responsibilities include:

- Provide treatment that is fair and impartial, regardless of race, sex, age, and source of payment, and convey a sense of dignity and trust to the patient.
- Provide treatment according to accepted clinical practice and community standards of care.
- Ensure patients receive full disclosure of information about treatment and medication.
- Inform patients about potential interactions with and adverse reactions to other substances, including alcohol, other prescribed or OTC pharmacological agents, food, and medical procedures.
- Inform patients about the financial aspects of treatment, including the consequences of nonpayment of required fees. An OTP should establish payment expectations and work with the patient on following agreed-upon procedures to ensure payment for services rendered is received. Also, processes that help patients resolve financial difficulties that might occur over the course of treatment should be explained.
- Advise patients of their right to give informed consent before becoming involved in research projects and to retain a copy of the informed consent form.
- Provide an adequate number of competent, qualified, and experienced professional clinical staff to implement and supervise the treatment plan, consistent with patient needs.
- Inform patient about alternative medications, treatment alternatives, alternative modalities, and scientific advances affecting treatment.
- Protect patients, staff, and the public from another patient who acts in a manner that disrupts the safety of the clinic environment. Programs, however, also have a responsibility to attempt to determine the cause of the patient's behavior so an appropriate referral may be made to an alternative method of care.
- Do not deny treatment and services to patients who refuse to participate in research activities.

- Develop and display patient grievance policies and procedures that specify the minimum elements of due process applicable to the program setting and resources used to prevent, investigate, and resolve patient complaints. Program administration should obtains and be responsive to patients' feedback concerning their care.

- 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 the chain of custody for transporting methadone to the new program may be required. Please see Appendix D. Samples of Standard Forms for an example of the chain-of-custody form.

- Accommodate the patient's desire to remain in opioid therapy at an alternative program before the patient is discharged.

- Obtain patient consent before changing the patient's dose of opioids or other medications unless the patient signs a document waiving such consent.

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