



MATC Exam Form Number MA-100519

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**COURSE MATERIAL and EXAM for the
Medication-Assisted Treatment Counselor (MATC) Credential**

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A Primer on Opiate Addiction and Treatment¹

Randall L. Stenson, M.D.

Introduction: Opiate addiction has a long, chronicled history dating back to ancient times. Opium use has been associated with many cultures, religions and religious experiences, and political/economic wars. A number of important cycles of opiate addiction have occurred in the United States since the introduction of morphine in the Civil War. At present, opiate abuse is starting at an earlier age and is being fueled by both illicit and prescribed opiates.

Important background information: Prior to the Civil War, opium was the source of opiate use and abuse. Heroin, an acetylated form of morphine, is produced from the opium plant. Liquefying heroin powder and injecting it results in an intensification of the opiate induced euphoria, as this acetylated form rapidly crosses the blood-brain barrier. A number of short acting opiate painkillers have been developed since morphine was first manufactured. These medications are used widely for pain control and other medical conditions, but particularly for managing moderate to severe pain. The vast majority of individuals, who use these for managing acute pain, do not abuse or misuse them. There is a subset of the population that is vulnerable to opiate addiction. Approximately 1 to 3% of the population falls into this category.

¹ This article was prepared by Randall L. Stenson, MD, Medical Director at CORE Medical Clinic, Inc., located in Sacramento, California, who is a licensed psychiatrist practicing in the field of addiction medicine and psychiatry for over thirty years. This article is used with Dr. Stenson’s permission, which is appreciated.



The reasons for this vulnerability are complex and the subject of ongoing research, but there is clearly a genetic component. Quite often, opiate addiction is seen in genetically related individuals. Drs. Solomon Snyder and Hans Gosterlitz, leading addiction researchers in the early 1970s, independently discovered the opiate receptor within months of each other. Several subtypes of receptors have since been identified. The mu receptor is the one most involved with pain control and addiction. Subsequent research, led to the discovery of endogenous (brain produced) opiate compounds. These are most often called endorphins and enkephalins, and will be referred to as endorphins in the remainder of this paper. Endorphins are linked amino acids, which are the breakdown products of protein in our diets. They are relatively simple compounds that are metabolized in milliseconds (one 1000th of a second) with enzymes located throughout our body called peptidases. This rapid breakdown of endorphins protects us from becoming addicted to them. Exercise is a stimulator of endorphin production. Excessive exercise has been experienced by some as being addictive, which likely relates to excessive endorphin production and turnover in these individuals.

Endorphin activity in the brain has been linked to a variety of important biologic processes. These include regulation of pain, breathing (respiration), bowel activity, and body temperature as well as controlling or contributing to eye pupil size, sleep, motivation, and reward. The reward area of the brain is the area that tells us if we like something or not. Drugs of abuse have potent effects on the reward areas of the brain (the Nucleus Acumens is the most important neuroanatomic brain reward area). Animal models are excellent predictive sources for human addiction. Drugs that animals abuse will predictably be abused by humans. These drugs stimulate the reward area of the brain. Dopamine and endorphin are the two most important neurotransmitters related to stimulating the reward center of the brain.

Opiate Addiction and Treatment: Researchers have long noted that opiate addiction is associated with an extremely high rate of relapse. Good outcome data for treatment of various addictions is in its infancy, is evolving, and varies widely. Alcoholics Anonymous estimates that between 10 to 15% of individuals who initiate involvement will stay with the program. Various intensive, drug-free, alcohol oriented programs report one year success rates of 40 to 60%. Special populations, such as physicians or nurses who must engage in treatment to prevent loss of their license, have been associated with extremely high (90 to 95%) success rates at one year. Opiate dependent individuals, involved in drug-free rehabilitation, relapse at a rate that approaches 95%.



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This disparity in response to drug-free treatment, contributed to Drs. Solomon and Kosterlitz curiosity and their discovery of the opiate receptor. The grand patriarchs of opiate addiction, Drs. Vincent Dole and Marie Nyswander, were convinced that opiate addicted persons suffered from a biologic deficiency. Prior to the discovery of the opiate receptor and brain produced endorphins, they began using methadone - a synthetic, long acting opiate in the treatment of heroin addicts. They found that the right dose of methadone removed the craving for heroin and was not associated with euphoria or intoxication. They also found that a number of physiological variables normalized or greatly improved. For example, women using heroin often became amenorrheic (having no monthly menstruation) whereas on methadone, their menstrual cycle returned. Emergency room visits and concurrent medical problems diminished. The immune system's ability to fight infection was improved. They also found that individuals did not become tolerant to the beneficial effects of methadone. All short acting opiates are complicated by the development of tolerance. Why tolerance does not develop to methadone is the subject of current research. Drs. Dole and Nyswander's prime disciple, Mary Jeanne Kreek, reported in 2003 that methadone replicated some of the actions of endorphins on the cell membrane. Ongoing research is required to replicate this finding and to determine if the new, long acting opiate, buprenorphine (Subutex/Suboxone) behaves in the same manner at the receptor site.

Patients suffering from opiate addiction often report that methadone "makes me feel normal". The majority of opiate addicted individuals report a chronic withdrawal state after they have been detoxified from short acting opiates, such as heroin, vicodin, oxycodone, etc. This condition is now referred to as Chronic Endorphin Deficiency. Those in the field recognize a characteristic cluster of symptoms associated with this deficiency. These include: persistent drug craving and preoccupation; chronic insomnia; vague, migratory aches and pains; intensification of pain associated with any underlying medical condition; low energy; lack of motivation; loss of sense of humor; loss of interest in activities previously enjoyed; an absence of joy or passion; depressed mood; dope dreams associated with either an intoxicated feelings or withdrawal; spontaneous acute withdrawal "coming out of the blue" or associated with an old drug using stimulus (i.e. driving past an old connection); an uncomfortable increase in sex drive (often associated with unwanted promiscuity or unsatisfying sexual activity); and a feeling of depersonalization or being an outsider looking in.

This syndrome differs from major depression in that helplessness, hopelessness, and suicidal ideation are usually not present. The individual intuitively knows that using an opiate will reverse the syndrome. Some patients have gone to enormous degrees of sacrifice to deal with this syndrome without using. A patient once shared that she must exercise two to three hours every day to prevent



many of the above symptoms. Another person shared that they had not slept more than one hour in a 24-hour period for the previous eight months since stopping opiates. These examples illustrate the persistence and refractory nature of this syndrome.

Undoubtedly, this contributes to the very high rate of relapse with opiate addiction. This contrasts with a subjective experience that many experience when they stop alcohol, cocaine, methamphetamine, marijuana, and nicotine. If individuals abstain from these substances, they often feel gradually better, especially if they remain associated with other individuals in recovery. Clearly, chronic abstinence syndromes exist with these compounds as well, but likely are not as persistent and individuals see more tangible evidence of improvement, reinforcing their recovery. When this is not the case, the clinician should always look for a co-morbid psychiatric condition.

Co-morbid psychiatric conditions are extremely common with all addictions, including opiate addiction. It is commonly noted that 50 to 70% of individuals who suffer from addiction also suffer from other psychiatric conditions. Successful treatment requires accurate recognition and treatment of these co-existing conditions. Clearly overlap of symptoms exists and working with the individual in a holistic way is extremely important.

A significant percent of opiate dependent individuals will describe opiates as being therapeutic for an underlying psychiatric condition the very first time they took the drug. Such individuals may be born with or be genetically predisposed to endorphin deficiency. The opiate initially acts as a therapeutic agent. Because all short acting opiates develop rapid tolerance, addiction quickly clouds the issue. Methadone and buprenorphine, with their unique long acting, nontolerance developing properties, are associated with extremely high rates of recovery.

Individuals taking methadone for 10 years have a 95% chance of being in full recovery with no complicating illicit drug use problem. They must be watched closely for the development of addiction to other substances, especially if their motivation for recovery is limited. Regular urinalysis testing and recovery oriented counseling are extremely important part of methadone or buprenorphine (opiate replacement) treatment.

Drug counseling and recovery orientation are heavily emphasized in opiate replacement treatment programs. Individuals have often spent many years enmeshed in the drug using culture or in their drug seeking behaviors. Friends, family, and contacts may be heavily weighted towards those involved in the drug culture. The drug itself, with its potent effects upon the reward areas of the brain, is often "my best friend" when treatment is initiated. Many hours of intensive



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counseling are required to address these complex social and psychological variables.

Though individuals are dependent upon methadone and/or buprenorphine while on opiate replacement therapy (they will have an acute opiate abstinence reaction if they abruptly discontinue the medication), we view them as being in recovery and capable of using all available recovery tools to help them refrain from drugs of abuse and to modify their drug related behaviors. We are encouraging AA and NA to adopt the same view, so patients are comfortable disclosing that they are in opiate replacement therapy, as honesty is very important in recovery. Patients should be educated about the principles outlined above. Those wanting to stop methadone or buprenorphine are encouraged to do so. They are educated on the importance of counseling, acquiring recovery skills, and understanding the endorphin deficiency syndrome.

Individuals with the persistent endorphin deficiency syndrome, who choose to stay on opiate replacement therapy, are encouraged to do so without guilt or prejudice. We view relapse in an individual with endorphin deficiency syndrome who is trying to get off methadone or buprenorphine as one of life's great tragedies, especially if they do not fully understand the principals. They often have done quite well in treatment and are getting off due to self or other imposed pressure. We strongly encourage our patients to be the expert of himself or herself and not let others dictate their treatment.

Summary: Drs. Dole and Nyswander's careful clinical work with patients in the 1960s led to their conviction that opiate dependent individuals have or develop a persistent brain deficiency syndrome. Subsequent research and experience has strongly affirmed their theory. Addiction is a complex disorder with no cookie cutter solution. We strongly encourage students entering this field to educate themselves and treat each person as a unique individual, making no prediction as to how well they will or will not do in treatment. Rather, walk an individual path with each patient, to discover the tools and treatments that work best for him or her.



Quick Guide For Clinicians, Based on TIP 43²

Center for Substance Abuse Treatment, SAMHSA

This Quick Guide was developed to accompany *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, Number 43 in the Treatment Improvement Protocol (TIP) series published by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA). * * * This Quick Guide is based entirely on TIP 43 and is designed to meet the needs of the busy clinician for concise, easily accessed how-to information.

The Quick Guide is divided into 13 sections to help readers quickly locate relevant material. It presents current information about the nature and dimensions of opioid use disorders and their treatment in the United States, including basic principles of medication-assisted treatment for opioid addiction (MAT), regulatory requirements, and evidence-based best practices in opioid treatment programs (OTPs). For more information on the topics in this Quick Guide, readers are referred to TIP 43.

WHAT IS A TIP?

The TIP series has been in production since 1991. This series provides the substance abuse treatment and related fields with consensus-based, field-reviewed guidelines on substance abuse treatment topics of vital current interest.

TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*

- Is a guide to MAT in OTPs
- Is written for opioid addiction treatment providers and OTP administrators
- Revises TIPs 1, 10, 20, and 22
- Incorporates changes in MAT since publication of TIP 1 in 1993
- Examines related medical, mental, sociological, and substance use disorders and their treatment in a comprehensive maintenance treatment program
- Describes ethical considerations that arise in many OTPs
- Summarizes areas for emphasis in successfully administering MAT in OTPs

² Center for Substance Abuse Treatment. *Quick Guide For Clinicians. Based on TIP 43 - Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs* Treatment Improvement Protocol (TIP) Series 43. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005. (This article has been edited for inclusion within this MATC exam material.)



INTRODUCTION

Opioid addiction

- Is physical dependence on and subjective need and craving for opioid drugs
- Has similarities to other chronic medical disorders
- Is treated most successfully with a combination of pharmacological and behavioral interventions

MAT

- Is any opioid addiction treatment that includes a U.S. Food and Drug Administration (FDA)-approved medication for the detoxification or maintenance treatment of opioid addiction (i.e., methadone, levo-alpha acetyl methadol [LAAM], buprenorphine, buprenorphinenaloxone, naltrexone)
- May be provided in an OTP, a medication unit affiliated with an OTP, a physician's office, or another health care setting
- Includes comprehensive maintenance, medical maintenance, interim maintenance, detoxification, and medically supervised withdrawal
- Increases the likelihood for cessation of illicit opioid use or of prescription opioid abuse
- Is adversely affected by stigma

(For more information, see TIP 43, Chapter 1.)

SCREENING, ADMISSION, AND ASSESSMENT

Initial screening of applicants for admission to an OTP includes

- Identification of and immediate assistance with crises
- Verification that applicants satisfy Federal and State regulations and OTP eligibility criteria
- Explanation of patient and program responsibilities
- Description of essential aspects of MAT and OTP operations
- Identification of treatment barriers for applicants

An applicant is eligible for admission to an OTP if all of the following are true:

- He or she is addicted to an opioid drug.
- He or she became opioid addicted at least 1 year before admission.
- He or she is at least 18 years old (or meets Federal and State requirements for younger admissions).

A physician can invoke an exception to the 1-year opioid addiction criterion for one of the following reasons:

- The applicant was released from a correctional facility within 6 months of applying for treatment admission.



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- The applicant is a previously treated OTP patient (up to 2 years after previous discharge).
- The program physician certifies that the applicant is pregnant.
- The underage applicant has undergone two attempts at detoxification or outpatient psychosocial treatment for addiction. (A parent, legal guardian, or other State-designated adult must provide written consent.)

Federal regulations provide for interim maintenance treatment—emergency dispensing of opioid medication by an OTP for up to 120 days before an individual is admitted to treatment (without formal screening and with only minimal drug testing)—if

- The individual is eligible for admission to an OTP (see above).
- There are no available programs within a reasonable geographic area or programs that will have openings for a new patient within 14 days of his or her applying.
- The OTP that will provide interim maintenance maintains reasonable criteria to prioritize admissions.

Types of assessment for MAT include

- Medical assessment. Opioid and other substance use and treatment history, medical history, physical exam, laboratory tests (including initial and random drug tests and possibly tests for tuberculosis [TB], hepatitis, HIV, and sexually transmitted diseases [STDs]), and women’s health assessment (including pregnancy testing). OTPs also must comply with State physical examination requirements.
- Induction assessment. At least daily checks for signs of overmedication or undermedication during initial dosing and to ensure that patient has not used benzodiazepines or alcohol recently, observed dosing to ensure that patient ingests medication, checks for dosage adjustment, and determination of steady-state dosage levels. *(For more information on induction with specific medications, see TIP 43, pages 65–70.)*
- Comprehensive assessment. Determination of patient motivation for treatment and substance use, cultural background, and psychosocial factors such as mental status and history, sociodemographic status, family and social networks, physical or sexual abuse history, housing situation, legal status, spirituality, employment and military history, sexual orientation, insurance and financial status, and recreational activities. *(For more information, see TIP 43, Chapter 4.)*

PHARMACOLOGY

Five medications are available for MAT in OTPs: methadone, LAAM, buprenorphine (Subutex®), buprenorphine-naloxone (Suboxone®), and naltrexone.



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Methadone

- Is the most frequently used medication for opioid addiction treatment in OTPs
- Is a full mu opioid agonist
- Is available as an oral solution, liquid concentrate, tablet/diskette, and powder (but is nearly always administered as an oral solution in U.S. OTPs)
- Suppresses pain for 4–6 hours; suppresses withdrawal and drug craving for 24–36 hours in most patients who are opioid addicted
- Is administered daily for opioid addiction treatment and may be given in split doses
- Has been shown to be safe and effective when used with appropriate safeguards and psychosocial services
- Has variable body clearance rates and elimination half-lives among individual patients
- Has an excellent safety profile when taken as directed by the manufacturer

LAAM

- Is a full mu opioid agonist
- Is provided in an oral solution, which is colored to distinguish it from methadone
- Is longer acting than methadone and cannot be administered daily
- Was the subject of an FDA warning in 2001 because of its association with potentially fatal cardiac arrhythmia in some patients
- Has not been manufactured since early 2004, and its continued availability is uncertain

Buprenorphine (Subutex)

- Was approved in 2002 for MAT in physicians' offices and other medical and health care settings and in 2003 for MAT in OTPs (physicians must obtain a waiver from SAMHSA; OTPs must receive SAMHSA certification to provide buprenorphine)
- May be used both for medical maintenance pharmacotherapy and for medically supervised withdrawal from an opioid addiction treatment medication
- Is available in sublingual tablets either alone (Subutex) or combined with naloxone (Suboxone [see below])
- Is a partial opioid agonist at the mu receptor and an antagonist at the kappa receptor
- Has a ceiling effect that prevents larger doses from producing greater agonist effects, although larger doses lengthen its duration of action
- Can be administered on a daily or less-than-daily basis



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- Can precipitate opioidlike withdrawal symptoms in patients with high levels of physical dependence
- Generally is safe and well tolerated when used as recommended by the manufacturer Buprenorphine-Naloxone Combination (Suboxone)
- Combines a partial mu opioid agonist (buprenorphine) and antagonist (naloxone)
- Was developed to prevent injection abuse of buprenorphine
- Is provided in tablet form for sublingual administration
- Has a ratio of 4 parts buprenorphine to 1 part naloxone

Naltrexone

- Is a full mu opioid antagonist
- Blocks the effects of heroin, morphine, and methadone
- Can precipitate opioid withdrawal but causes no withdrawal symptoms of its own when a patient stops using it
- Can block opioid effects for up to 72 hours
- Has had poor patient compliance
- Effectively prevents relapse in most patients when used as directed
- Generally is safe when used as recommended by the manufacturer

The most common side effects of these medications are

- Constipation
- Sweating
- Insomnia or early awakening
- Decreased libido or sexual performance
- Dizziness
- Nausea, vomiting, or stomach upset
- Anxiety, nervousness, headache, joint/muscle pain, or tiredness (naltrexone)

Drugs that inhibit or induce the activity of the cytochrome P34A enzyme system can cause clinically significant increases or decreases in serum and tissue levels of opioid medications. These include certain medications to treat HIV and some psychiatric medications. *(For more information on the pharmacology of MAT medications, see TIP 43, Chapter 3.)*

PHARMACOTHERAPY

Contraindications to OTP Admission and Opioid Pharmacotherapy

Inclusion rather than exclusion should be the guiding principle in OTPs. People who possibly should not be admitted to an OTP for MAT include those who



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- Are also dependent on central nervous system (CNS) depressants, based on *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-TR) criteria
- Have had allergic reactions to opioid medications
- Have cardiac abnormalities (for treatment with LAAM)
- Do not satisfy DSM-IV-TR criteria for opioid dependence
- Have been addicted to opioids for less than 1 year (except those receiving buprenorphine) and have no addiction treatment history
- Cannot attend treatment sessions regularly, especially for dosing (unless a clinical exception is obtained from SAMHSA or buprenorphine dosing will meet patient needs)

Stages of MAT in an OTP

Induction Stage

In general, induction procedures used for each patient depend on the unique properties of each medication, prevailing regulatory requirements, patient preferences, and safety.

- Initial goals are to eliminate opioid withdrawal symptoms and achieve steady-state medication levels in patients' blood between doses of medication.
- Induction normally begins when there are no signs of opioid intoxication or sedation and beginning signs of opioid withdrawal (especially for induction with buprenorphine).
- Presence of sedatives, tranquilizers, tricyclic antidepressants, benzodiazepines, alcohol, or CNS depressants should be ruled out before induction begins.
- Dosing should be observed.
- LAAM may not be used for induction.

With methadone. Initial dosing is typically 20–30 mg and cannot exceed 30 mg per dose and 40 mg on day 1, unless need is documented by a program physician.

With buprenorphine. Induction with buprenorphine monotherapy is effective for most patients. Typically, 4 mg is given, followed after 4 hours Pharmacotherapy 13 with up to 4 mg if needed, but the total on day 1 should not exceed 8 mg.

With buprenorphine-naloxone. Induction with the buprenorphine-naloxone combination is not recommended for patients withdrawing from longer acting opioids (it can cause withdrawal symptoms). For others, an initial 4/1 mg (buprenorphine/naloxone) is recommended, followed in 2 to 4 hours with an additional 4/1 mg if indicated.



With naltrexone. Patients should be abstinent from short-acting opioids for 7 days and longacting opioids for 10 days. Initial dosing is 25 mg followed by 50 mg on day 2 if no withdrawal symptoms occur, then 50 mg per day up to 350 mg per week.

Stabilization Stage

The goal is to eliminate the patient's drug-seeking behavior, craving, and illicit opioid use or prescription opioid abuse. Optimal dosage should be determined by patient response, but some guidelines exist for the following medications (*for LAAM, see TIP 43, page 72*):

- **Methadone.** Evidence supports a daily dose of 80 mg or more, but some patients do well on 14 Medication-Assisted Treatment less than 80 mg per day, and some patients require more than 120 mg per day.
- **Buprenorphine.** For most patients, the stabilization dosage is 12–16 mg per day, although some patients may need up to 32 mg per day. Increasing the dosage to 24 mg or more per day is usually necessary for every-other-day dosing schedules.
- **Naltrexone.** A daily 50 mg or thrice weekly 100–150 mg dose (totaling 350 mg per week) is recommended.

Maintenance Stage

The goal is for the patient to resume normal functioning while continuing to receive regular medication dosages, without the need for routine dosage adjustments.

Patients in this stage

- Are responding well to treatment and dosage
- Have stopped substance abuse
- Have resumed productive lifestyles
- Typically have received take-home medication privileges
- May remain at the same dosage for many months or years

Medically Supervised Withdrawal

The goal is to taper the amount of maintenance treatment medication a patient is taking.

- The likelihood of long-term success depends on individual patient factors.
- The relapse rate is high (80 percent or more in some studies).
- Methadone or buprenorphine may be used for tapering after detoxification.
- A common methadone-tapering practice is 5- to 10-percent incremental reductions every 1–2 weeks. (*For information on tapering from LAAM, see TIP 43, page 79.*)



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Take-Home Medication

Take-home maintenance medication is permitted for patient self-administration under specific conditions. Any patient in MAT may receive take-home medication doses for days when the OTP or physician's office is closed. For other take-home medication privileges, SAMHSA regulations require

- Absence of recent drug and alcohol abuse
- Regular OTP attendance
- Absence of behavioral problems in the OTP
- Absence of recent criminal activity
- Stable home, family, and social relationships
- Acceptable time in comprehensive maintenance treatment
- Assurance of safe storage of medication 16 Medication-Assisted Treatment
- Clear indicators that benefits of decreased OTP attendance outweigh risk of medication diversion

Physician's Office-Based Opioid Treatment With Methadone

An exception can be obtained from SAMHSA for patients to receive methadone maintenance via observed dosing by a private physician in cooperation with an OTP when the patient

- Has been stable in treatment for at least 1 year
- Has a history of negative drug tests
- Is socially stable
- No longer requires psychosocial services

Under this arrangement, the physician need not observe dosing for patients already on extended take-home medication schedules. *(For more on the stages of pharmacotherapy and common dosing considerations, see TIP 43, Chapter 5.)*

PHASES OF TREATMENT

MAT in OTPs may be conceptualized in phases so that interventions are matched to levels of patient progress and expected outcomes. At any point, patients may encounter a setback requiring a return to a previous phase. The consensus panel for TIP 43 identified the following phases.

Acute Phase

- The acute phase begins immediately on patient admission to an OTP.
- Patients in this phase may be admitted for either maintenance treatment or detoxification.
- Treatment services usually are more intensive during this phase.
- Phase duration ranges from days (up to 180 for opioid detoxification in an OTP) to months and focuses on eliminating illicit substance use



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- (induction) and lessening the intensity of other immediate problems (e.g., co-occurring disorders; medical, legal, family, and psychosocial problems).
- Patient goals include eliminating withdrawal symptoms and opioid craving; feeling well throughout the day; abstaining from illicit opioid use and complying with treatment medication regimens, confirmed by drug tests; learning about drug and medication interaction risks; avoiding high-risk situations for relapse; actively engaging in recovery; satisfying food, shelter, and safety needs; completing medical and mental health assessments; and, for those entering maintenance treatment, developing a treatment plan.
 - Patients in detoxification have immediate access to maintenance treatment if medication tapering is unsuccessful or they change their minds about the type of treatment they want.
 - By the end of this phase, signs of opioid withdrawal are ameliorated, physical drug craving is reduced, illicit-opioid use is eliminated, other substance use is reduced, medical and mental health assessments are done, a treatment plan has been developed, and basic needs are satisfied.

Rehabilitative Phase

- Dosage stabilization is complete but may require adjustments; patients are comfortable at their established dosage for at least 24 hours before moving to this phase.
- Program policies, such as those about takehome medications and dosing hours, are more flexible, so patients can attend to other life domains.
- Frequency of drug testing depends on progress in treatment; consistent, negative drug tests lead to reduced random-testing frequency (e.g., once or twice per month).
- Efforts increase to promote patient participation in constructive activities such as employment, education, vocational training, child rearing, homemaking, and volunteer work.
- Information about outside support groups (i.e., faith-based, community, and mutual-help groups) is reviewed, and patients are urged to participate in them, assuming groups support MAT.
- Patients receive assistance in developing skills for coping with relapse triggers.
- The primary goal is to empower patients to cope with major life problems by discontinuing alcohol and prescription drug abuse and all illicit-drug use; recognizing and coping with relapse triggers; complying with medical/dental and mental health treatment and maintaining a stable health status; maintaining a positive social and family support system; accepting increased responsibility for dependents; resolving legal



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problems and ceasing all illegal activities; participating in support groups; and obtaining effective pain management treatment.

- By the end of this phase, patients are employed, seeking employment, or involved in constructive activities (e.g., school, child rearing, and volunteer work); legal problems are being resolved; co-occurring disorders are stabilized; a conflict-free social support system is in place; and alcohol abuse, illicit-drug use, and inappropriate use of other substances are eliminated.

Supportive-Care Phase

- Patients have discontinued alcohol and prescription drug abuse and all illicit-drug use, as well as any involvement in criminal activities.
- Patients receive take-home medication for longer periods and are permitted fewer OTP visits (as few as one visit every 2 weeks, if State policy allows).
- Patients continue counseling and other care as needed, but medical and mental health, family relationships, and financial and legal situations are stable.
- Care is often augmented through mutual-help, faith-based, community, and other groups.
- When ready, patients may progress to either the medical maintenance or tapering phase.

Medical Maintenance Phase

- Patients are allowed longer term supplies of take-home medication (up to 30 days, if State regulations permit, after patients have been substance free for 2 years of continuous treatment) and further reductions in treatment visits.
- Methadone maintenance may occur through OTPs, physicians' offices, or other health care settings that are SAMHSA-approved "medication units" formally linked to OTPs.
- Patients should have no alcohol use problems, live in a stable environment, have a stable income, be involved in productive activities, have had no legal involvement for at least 3 years and have no current parole or probation status, and have adequate social support systems.
- Continuation of random drug testing, callbacks of medication, and monitoring for relapse risks are recommended during this phase.
- Positive drug tests should cause a return to the rehabilitative phase.
- Patients may remain in methadone maintenance, transition to buprenorphine maintenance (in the OTP or via an offsite physician's office or another health care facility), or enter the tapering and readjustment phase.



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- Medication diversion by a patient in medical maintenance results in reclassification to the most appropriate previous phase and adjustment of treatment, other services, and privileges.

Tapering and Readjustment Phase

- Goal is gradual reduction or elimination of maintenance medication.
- Most patients try to taper from treatment medication at least once.
- Patients should continue receiving treatment support and assistance to adjust to a life free of both maintenance medication and substances of abuse.
- Patients should be advised that even gradual dose tapering will cause discomfort and that a return to treatment medication is not a failure.
- Major goals are to increase self-sufficiency, maintain a balanced lifestyle, and function well without medication.

Continuing-Care Phase

- Treatment comprises medical follow-up by a primary care physician, occasional check-ins with an OTP counselor, and participation in recovery groups.
- Appointments with the OTP should be scheduled for every 1–3 months.
- Some patients might need referral to a non-MAT outpatient program.

(For more information on treatment phases, see TIP 43, Chapter 7.)

PATIENT RETENTION

Retention may be the most important indicator of MAT outcomes. Patient characteristics, behavior, and other nontreatment-related factors appear to contribute relatively little to retention in MAT.

Several treatment-related steps have been found to improve patient retention:

- Individualization of medication dosages
- Clarification of program goals and treatment plans
- Simplified admission process
- Attention to patient financial needs
- Reduced attendance burden when possible
- Early provision of useful, high-intensity services
- Good staff–patient interactions
- Staff knowledge of, positive attitudes about, and confidence in MAT

Patients need to develop relapse prevention skills by

- Making lifestyle changes to decrease the need for drugs
- Recognizing relapse warning signs
- Developing positive coping methods
- Increasing participation in healthy, rewarding activities as alternatives to drug use



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

- Avoiding people and situations that might trigger use

Mutual-help programs vary in attitudes toward treatment medications. Counselors should help patients find mutual-help groups that accept opioid pharmacotherapy or start a group at the OTP.

Involuntary (or Administrative) Discharge

- Should be avoided if possible
- Should be handled fairly and humanely, when unavoidable
- Is indicated by SAMHSA only for violence or threats, drug dealing, repeated loitering, flagrant noncompliance with treatment, nonpayment of fees, and incarceration or confinement
- Should be preceded by other strategies such as clear communication of program rules, dosage adjustment, treatment of co-occurring disorders, intensified counseling, alternative medications, inpatient detoxification from other substances of abuse, change of counselors, rescheduling of dosing times, and family intervention
- Should include procedures for review and appeal, dosage protocol for withdrawal from medication, and a readmission procedure

(For more on patient retention and involuntary discharge from treatment, see TIP 43, pages 122–124 and 138–141, respectively.)

DRUG TESTING

Drug tests are performed or results are used in OTPs to

- Detect substances of abuse in patients
- Guide patient care
- Modify treatment plans
- Confirm clinical impressions
- Monitor patients' compliance with medication
- Evaluate OTP effectiveness
- Fulfill program quality assurance requirements
- Detect and monitor emerging substance use trends

Urine Drug Tests

Urine drug testing is the dominant testing method in OTPs because

- Obtaining specimens is relatively easy.
- Testing is affordable.
- The method is well studied with well-established cutoff levels and use guidelines.

Drawbacks of urine drug testing include

- The need for observed specimen collection negates trust.



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- The possibility of deliberate tampering exists.
- Patients with shy bladder syndrome need other arrangements.
- A patient's physical condition can affect test sensitivity and specificity.
- The method is not feasible if patient has renal failure or other bladder control problems.
- Some medications (e.g., HIV medications) can affect results.

Oral Drug Tests

Oral-fluid drug testing in OTPs

- Was approved in 2003
- Requires specimen analysis by a qualified offsite laboratory
- Must follow appropriate State laws and regulations
- Includes specimen collection with oral swabs, which most patients prefer to observed urine collection
- Is highly sensitive and specific for methadone and opioids of abuse
- Allows storage of samples
- Is less susceptible to tampering than urine testing
- Has lower detection limits than urine testing for some drugs
- Is recommended when specimen collection must be observed

Frequency of Drug Tests

SAMHSA requires eight drug tests per year for patients in long-term MAT, including one test at admission and random monthly tests. Patients in short-term detoxification must have one initial drug test. Some states require more frequent testing and may have specific drug-testing methodologies to follow. OTPs

- Should contact their State agency to determine their State's requirements
- Must follow the more stringent of either Federal or State regulations
- Should institute more frequent, random tests for patients who continue to abuse substances or test negative for treatment medication

Laboratory Considerations

A laboratory selected for specimen analysis should

- Be federally approved and in compliance with Clinical Laboratory Improvement Amendments and Health Insurance Portability and Accountability Act regulations
- Participate in external quality assessment
- Have adequately trained staff and supervisors, including a trained staff scientist
- Use appropriate analytical methods based on manufacturer's instructions
- Confirm positive findings and evaluate control samples for each analysis
- Collaborate with OTPs on confidentiality, reporting of and turnaround time for results (preferably within 2 or 3 days), and specimen retention for retesting



Interpreting and Using Drug Test Results

- Drug test results should not be the sole basis for treatment decisions, especially discharge.
- Numerous medications and substances can produce false-positive or false-negative results.
- Positive tests for substance abuse should be confirmed whenever possible.
- Patients should be informed of unfavorable test results as soon as possible.
- Patient denials should be taken seriously, and appropriate follow-ups should be performed.
- Results and subsequent treatment decisions should be documented in patient records.
- Results never should be used punitively but should be used to explore different interventions and treatment plans to improve compliance.
- Onsite testing kits allow the admission process to proceed while results are pending, but some recent studies have found drawbacks, and some States disallow onsite analysis.

(For more information on drug testing, see TIP 43, Chapter 9.)

ASSOCIATED MEDICAL PROBLEMS

Integration of medical and addiction treatment in an OTP is preferable but often beyond the means of the OTP. Each OTP should clearly define and communicate to patients the medical services offered on site versus by referral and should establish sound links with medical providers.

The following medical problems are more prevalent and often more severe in people addicted to opioids than in the general population:

- Acute, life-threatening infections. Cellulitis, abscesses, wound botulism, necrotizing fasciitis, and endocarditis
- Infectious diseases. TB, STDs, hepatitis (particularly hepatitis C), and HIV/AIDS
- Chronic diseases. Diabetes, asthma, hypertension, chronic obstructive pulmonary disease, and coronary artery disease
- Pain. Acute and chronic

OTPs should screen patients for these problems (HIV testing requires a patient's written permission) and provide patient education and treatment if possible or refer patients for medical care. OTPs should establish protocols for medical assessment and periodic reassessment.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

When a patient requires hospitalization, the OTP physician should communicate the following to the attending physician and other hospital health care professionals:

- The patient's addiction medication dosage
- The date on which addiction medication was last administered
- The patient's medical, co-occurring, or social problems
- That the patient may require larger doses of medication for anesthesia and pain relief
- Information about appropriate controls to prevent the patient from obtaining and abusing substances

(For more information on medical problems and their management in OTPs, see TIP 43, Chapter 10.)

MULTIPLE SUBSTANCE USE

Patients in MAT commonly use and may be dependent on one or more of the following:

- Alcohol. The effects of concomitant alcohol and MAT medication use are additive and more sedating than either alone. Patients who are alcohol dependent may have liver damage as well as more medical and mental disorders, greater criminality, and poorer social and family relationships than patients who are not alcohol dependent. Alcohol-related factors are a major cause of death in patients in MAT.
- Benzodiazepines/prescription sedatives. High doses can cause severe intoxication, high risks of injuries or fatal overdose, and sedation or respiratory depression. Patients have reported taking these drugs within 1 hour of their MAT medication to boost the treatment medication's effect. When used in prescribed doses, benzodiazepines are not dangerous for patients in MAT.
- Cocaine/other stimulants. Patients in MAT who use stimulants may be disruptive and exhibit severe mood swings. Adequate doses of methadone have been found to reduce cocaine use in some cases.
- Marijuana. Some studies have found that marijuana use does not affect MAT outcomes adversely.

Patients in MAT sometimes use marijuana to self-medicate for anxiety or insomnia. Marijuana use should be discouraged because it increases the likelihood of patients' engaging in activities that will lead to relapse.

- Nicotine. Although many OTPs avoid addressing nicotine dependence because it may create additional stress for patients, research has shown that a smoking intervention neither detracts from nor interferes with addiction recovery. Patients stabilized on MAT medication are less likely to abuse other substances than individuals who are unmedicated. OTPs can address multiple substance use by



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- Adjusting treatment medication dosages
- Increasing counseling and psychosocial services
- Increasing drug testing
- Detoxifying patients (through either outpatient or inpatient treatment) from other substances, especially from CNS depressants

Discharge from MAT because of other substance use should be done only when all reasonable alternatives have been exhausted. *(For more information on multiple substance use in MAT, see TIP 43, Chapter 11.)*

PATIENTS WITH SPECIAL NEEDS

To ensure that a patient can be matched to treatment as soon as the assessment indicates the patient has a special need, treatment planning should involve a team of

- Physicians
- Counselors
- Nurses
- Case managers
- Social workers

Patients Who May Require Special Treatment Services

- Patients with serious medical disorders should receive treatment on site or by referrals to medical centers.
- Patients with housing, family, or social problems may need help meeting basic needs.
- Patients with disabilities may be served best through mobile medication units, home-nursing services, or take-home privileges.
- Adolescents and young adults may require youth-oriented psychosocial services.
- Lesbian, gay, and bisexual patients may require help coping with problems related to their sexual orientation and additional HIV/AIDS counseling.
- Aging patients may require increased monitoring for medication interactions and dosage adjustments because of slower metabolisms.
- Patients with pain may have a higher tolerance for opioids and need higher doses. *(For more information on pain management, see TIP 43, pages 174–178.)*

(For more on these types of patients, see TIP 43, Chapter 6.)

Patients With Serious Co-Occurring Disorders

Many people who are opioid addicted have co-occurring mental disorders. The co-occurring mental disorder



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- May be caused by the patient’s substance abuse (i.e., primary substance use disorder and secondary mental disorder)
- May exist independently and may or may not be a significant cause of the substance use disorder (i.e., primary mental disorder and secondary substance use disorder)

These patients require more intensive services than most patients. It is best to stabilize patients’ opioid addiction while addressing their co-occurring disorders because each can influence the other.

Special care must be given to ensure that

- Patients’ opioid addictions are stabilized to make accurate diagnosis possible.
- The disorders are diagnosed correctly.
- Treatment medication for one disorder does not interfere with medication for the other. (*For more information on co-occurring mental disorders, see TIP 43, Chapter 12.*)

Pregnant Women and Newborns

Integration of a women’s overall health initiative into MAT is recommended to improve an OTP’s capacity to meet women’s needs. OTPs should assess women for physical and sexual abuse in current relationships. Referrals should be made to ensure a safe place for a woman and her children.

All women of childbearing age admitted to an OTP must receive a pregnancy test. Methadone currently is the only opioid medication approved by FDA to treat pregnant women in MAT, although buprenorphine is sometimes used when the prescribing physician believes that the potential benefits justify the risks. Several studies have found buprenorphine safe and effective for treating pregnant patients, but more research is needed.

A large percentage of pregnant women in MAT continue to use other substances that are harmful to maternal and fetal health, including alcohol, heroin, cocaine, barbiturates, and tranquilizers. Monitoring drug use and appropriate perinatal care are crucial.

Methadone dosages must be adjusted for women who are pregnant to prevent withdrawal symptoms in the patient and to minimize neonatal abstinence syndrome in the infant. Mothers maintained on methadone can breast-feed if they

- Are not HIV positive
- Are not abusing substances
- Have no other disease or infection for which breast-feeding is contraindicated



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An abstinence scoring system is recommended to monitor opioid-exposed newborns to

- Assess onset, progression, and diminution of withdrawal symptoms
- Determine whether pharmacotherapy is needed
- Monitor responses to such therapy

Research indicates that developmental sequelae for infants exposed to methadone in utero are well within the normal range. *(For more information on pregnancy in MAT, see TIP 43, page 93 and Chapter 13.)*

ADMINISTRATIVE CONSIDERATIONS

OTP staff members should meet the following qualifications:

- Appropriate licensing, certification, or credentialing under State regulations
- Evidence of empathy and sensitivity toward patients in MAT
- Recognition and avoidance of harmful transference relationships with patients
- Sensitivity to culture, gender, and age issues
- Multicultural and multilingual background when needed
- Flexibility in thinking, behavior, and attitudes

Staff retention should be a priority. Managers should do the following to retain staff:

- Maintain clear policies and apply them consistently
- Avoid excessive caseloads
- Encourage a team approach and a culture of mutual respect
- Establish clearly delineated job descriptions
- Establish objective performance standards
- Convene regular consulting sessions among program staff members
- Provide opportunities for professional training
- Establish personnel policies that reduce stress on staff (e.g., flexible work schedules)

OTP staff members should be kept up to date on the following:

- Facts about MAT and the health effects of treatment medications
- Drug abuse and communicable disease trends in the local community
- General skills training such as crisis management, communication, cultural diversity, and problem solving
- Training in sensitivity to patients and their needs OTPs must maintain diversion control plans to reduce the possibility of diversion by patients. This can be through random callbacks that require patients to return with their remaining take-home medication so that staff can inventory it, random drug testing to ensure that patients are taking their medication as directed, and a no-loitering policy.



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- Staff members. This can be through rigorous accounting and inventory policies, accurate recording in receipt and dispensing logbooks, and prompt investigation of any discrepancies in records.

Community resistance to OTPs can be addressed through

- Good community relations
- Community outreach to neighbors and local businesses
- Community education

Because SAMHSA-approved accrediting organizations require OTPs to demonstrate performance improvement, OTPs must establish procedures to monitor and evaluate program effectiveness. Several resources are available to assist administrators in setting up quality assurance procedures. *(For more information, see TIP 43, Chapter 14.)*



Treatment Improvement Protocol, Series 43 (TIP 43): Appendix C

Glossary of Terms³

A

abstinence. Nonuse of alcohol or any illicit drugs, as well as nonabuse of medications normally obtained by prescription or over the counter. Abstinence in this TIP does not refer to nonuse of or withdrawal from maintenance medications (methadone, buprenorphine, LAAM, or naltrexone) when they are used in MAT. Compare *medically supervised withdrawal*.

accreditation. Process of periodic review of an OTP for conformance with accrediting-body standards. Accrediting bodies and their standards are approved by SAMHSA. See 42 CFR, Part 8 § 2, for other accreditation-related terms and definitions.

acute phase. Initial and usually the most symptomatic intensive-treatment phase of MAT.

addiction. Combination of the physical dependence on, behavioral manifestations of the use of, and subjective sense of need and craving for a psychoactive substance, leading to compulsive use of the substance either for its positive effects or to avoid negative effects associated with abstinence from that substance. Compare *dependence*.

administrative discharge. Release or discharge of a patient from an OTP, often against the patient's wishes. See *involuntary discharge*.

admission. Formal process of enrolling patients in an OTP, carried out by qualified personnel who determine that the patient meets acceptable medical criteria for treatment. Admission can include orientation to the program and an introduction to peer support, patient rights, services, rules, and treatment requirements related to MAT.

agonist. See *opioid agonist*.

analgesic. A compound that alleviates pain without causing loss of consciousness. *Opioid analgesics* are a class of compounds that bind to specific

³ Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 06-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005, reprinted 2006.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

receptors in the central nervous system to block the perception of pain or affect the emotional response to pain. Such compounds include opium and its derivatives, as well as a number of synthetic compounds. Chronic administration or abuse of opioid analgesics may lead to addiction.

antagonist. See opioid antagonist.

assessment. Process of identifying the precise nature and extent of a patient's substance use disorder and other medical, mental health, and social problems as a basis for treatment planning. Assessment usually begins during program admission and continues throughout treatment. It includes a personal substance abuse history, physical examination, laboratory evaluation, and determination of disease morbidity. Severity of disease often is assessed further in terms of physiologic dependence, organ system damage, and psychosocial morbidity. Assessment also may involve determining patient motivation and readiness for change.

assessment tools. Instruments (e.g., questionnaires) used to capture the range of patient variables affecting treatment planning, methods, and outcomes. Valid assessment tools contain quantifiable indicators to measure patient progress and to track patients through treatment.

Axis I. DSM-IV-TR disorder classification comprising definitions and descriptions of major disorders (i.e., psychotic, mood, and substance use disorders) that may require clinical attention.

B

benzodiazepines. Group of medications having a common molecular structure and similar pharmacological activity, including antianxiety, sedative, hypnotic, amnestic, anticonvulsant, and muscle-relaxing effects. Benzodiazepines are among the most widely prescribed medications (e.g., diazepam, chlordiazepoxide, clonazepam, alprazolam, lorazepam).

best-treatment practices. Methods determined, often by a consensus of experts, to be optimal for defined therapeutic situations. Such guidelines usually are based on both an analysis of published research findings and the experience of experts.

blood testing. Identifying evidence of opioid and other psychoactive substance use and measuring the levels of substances or medications in the body by examining patient blood specimens for the presence and concentrations of identifiable drugs and their metabolites.



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buprenorphine. Partial opioid agonist approved by FDA for use in detoxification or maintenance treatment of opioid addiction and marketed under the trade names Subutex[®] and Suboxone[®] (the latter also containing naloxone).

C

certification. Process by which SAMHSA determines that an OTP is qualified to provide opioid addiction treatment under the Federal opioid treatment standards.

civil commitment. Legal process that permits individuals to be confined against their will in psychiatric or other treatment facilities, which usually is justified by determining that a patient is a threat to himself or herself or others. Although statutes permitting involuntary civil commitment may remain in some States, such laws rarely have been used to commit people who abuse substances and are not under criminal justice jurisdiction.

Commission on Accreditation of Rehabilitation Facilities (CARF). One of several SAMHSA-approved accreditation organizations charged with ensuring that OTPs meet the standards set forth in Federal regulations and SAMHSA guidelines. Also known as CARF... The Rehabilitation Accreditation Commission.

comprehensive maintenance treatment. Continuous therapy with medication in conjunction with a wide range of medical, psychiatric, and psychosocial services. Compare *medical maintenance*.

comprehensive treatment assessment. Evaluation made after formal admission to an OTP, in which trained staff members determine the range and severity of a patient's problems and the patient's service needs. These determinations are used to establish short- and long-term treatment goals in the patient's treatment plan.

confidentiality regulations. Rules established by Federal and State agencies to limit disclosure of information about a patient's substance use disorder and treatment (described in 42 CFR, Part 2 § 16). Programs must notify patients of their rights to confidentiality, provide a written summary of these rights, and establish written procedures regulating access to and use of patient records.

consent to treatment. Form completed with and signed by an applicant for MAT and by designated treatment program staff members, which verifies that the applicant has been informed of and understands program procedures and his or her rights and treatment goals, risks, and performance expectations.

contingency contracting. Use of preestablished, mutually agreed-on privileges (e.g., take-home dosing) or consequences (e.g., loss of privileges) to motivate



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improvements in treatment outcomes. Many experts agree that negative contingencies in MAT (e.g., reduction in medication) are neither effective nor ethical and should be avoided.

continuing-care phase. Optional phase of MAT in which patients who have completed medically supervised withdrawal from treatment medication and are leading socially productive lives continue to maintain regular contact with their treatment program.

co-occurring disorder. In this TIP, a mental disorder, according to DSM-IV diagnosis, that is present in an individual who is admitted to an OTP.

counseling. In MAT, a treatment service in which a trained counselor and a case manager evaluate both a patient's external circumstances and immediate treatment progress and offer appropriate advice and assistance or referral to other experts and services as needed. A major objective in MAT is to provide skills and support for a substance-free lifestyle and encourage abstinence from alcohol and other psychoactive substances. Compare *psychotherapy*.

craving. Urgent, seemingly overpowering desire to use a substance, which often is associated with tension, anxiety, or other dysphoric, depressive, or negative affective states.

cross-tolerance. Condition in which repeated administration of a drug results in diminished effects not only for that drug but also for one or more drugs from a similar class to which the individual has not been exposed recently.

cultural competence. Capacity of a service provider or organization to understand and work effectively in accord with the beliefs and practices of persons from a given ethnic/racial/religious/social group or sexual orientation. It includes the holding of knowledge, skills, and attitudes that allow the treatment provider and program to understand the full context of a patient's current and past socioenvironmental situation.

cultural diversity. Differences in backgrounds and beliefs that may affect the way groups of patients in OTPs and individuals within these groups view the world and their place in it, their substance use, and treatment.

D

dependence. State of physical adaptation that is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, and/or decreasing blood level of a substance and/or administration of an antagonist. Compare *addiction*.



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detoxification. In this TIP, treatment for addiction to an illicit substance in which the substance is eliminated gradually from a patient's body while various types and levels of reinforcing treatment are provided to alleviate adverse physical or psychological reactions to the withdrawal process. This TIP avoids the term “detoxification” to designate the process of dose tapering from maintenance medication because that term incorrectly suggests that opioid treatment medications are toxic. Compare *medically supervised withdrawal*.

diagnosis. Classification of the nature and severity of the substance use, medical, mental health, or other problems present in a patient who is addicted to opioids. DSM-IV-TR and ICD-10 classifications commonly are used to classify substance use and mental disorders.

discharge. Release from or discontinuation of enrollment in treatment when maximum benefit has been achieved or when a patient is deemed no longer suitable for treatment. See *administrative discharge, involuntary discharge*.

diversion. Sale or other unauthorized distribution of a controlled substance, usually for a purpose other than the prescribed and legitimate treatment of a medical or mental disorder.

diversion control plan. Documented procedures to reduce the possibility that controlled substances are used for other than their legitimate use. Federal opioid treatment standards (42 CFR, Part 8 § 12(c)(2)) require a diversion control plan in an OTP as part of its quality assurance program

dosage determination. Process of identifying the amount of medication that will minimize withdrawal symptoms and craving in patients in MAT and eliminate their opioid abuse. Much evidence supports a linear relationship among the amount of medication provided, the timeframe over which it is allowed to act before another dose is administered (dose frequency), and treatment response.

dose tapering. See medically supervised withdrawal.

drug interaction. Action of one drug on the effectiveness or toxicity of another drug.

drug testing. Examination of an individual to determine the presence or absence of illicit or nonprescribed drugs or alcohol or to confirm maintenance levels of treatment medications, usually by a methodology that has been approved by the OTP medical director based on informed medical judgment. OTPs also must conform to State laws and regulations in this area. See *blood testing, oral-fluid drug testing, urine testing*.



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duration of action. Length of time that a treatment medication effectively prevents withdrawal symptoms or craving. Duration of action can be affected by many factors, including drug interactions, certain diseases and medical conditions, patient cross-tolerance, and the relative affinity of a medication for its targeted cell receptor.

E

eligibility. See treatment eligibility.

elimination half-life. Time required after administration of a substance (e.g., methadone) for one-half the dose to leave the body. Elimination half-life affects the duration of action of a substance or medication and can be influenced by patient factors such as absorption rate, variable metabolism and protein binding, changes in urinary pH, concomitant medications, diet, physical condition, age, pregnancy, and even use of vitamins and herbal products.

H

half-life. See elimination half-life.

hepatitis C. Viral disease of the liver that is the leading cause of cirrhosis in the United States and a particular concern in MAT because of the high incidence of the disease and spread of the infection among people who inject drugs.

high-risk behavior. Activity that increases the likelihood that a recovering patient in substance abuse treatment will relapse to substance use or contract a substance use-related disorder, such as an infectious disease.

hospital-based treatment. Treatment of opioid addiction and related complications that requires patient residency for some period in a hospital setting or outpatient treatment in a hospital-linked facility to ensure that necessary services and levels of care are available.

I

iatrogenic opioid addiction. Addiction resulting from medical use of an opioid (i.e., under physician supervision), usually for pain management.

induction. Initial treatment process of adjusting maintenance medication dosage levels until a patient attains stabilization.

induction stage. The period of opioid pharmacotherapy, usually during the acute phase of treatment, in which steady-state blood levels of a medication are achieved.



intake. Initial screening of applicants for admission to an OTP.

intensity of treatment. Frequency and method of delivery for therapeutic services. In this TIP and in American Society of Addiction Medicine Patient Placement Criteria, intensity of treatment is one component, along with treatment setting, that determines the level of care for a patient. Levels of care are adjusted during MAT based on patient needs and the treatment plan. See, for example, *intensive inpatient treatment* and *intensive outpatient treatment*.

intensive inpatient treatment. Level of care in which addiction professionals and clinicians provide a regimen of around-the-clock evaluation, care, and therapy in an inpatient setting. Involvement of physicians can range from monitoring multidisciplinary staff members to direct management of cases, depending on the severity of patients' problems.

intensive outpatient treatment. Level of care (possibly including partial hospitalization) in which addiction professionals and clinicians provide therapeutic services to clients who live at home or in special residences. Treatment is delivered in two to five regularly scheduled sessions per week totaling 6 to 24 hours per week. Many treatment services and levels of care are compatible with intensive outpatient treatment, but most programs include structured psychoeducation and group counseling.

interim maintenance treatment. Time-limited pharmacotherapeutic regimen in conjunction with appropriate medical services while a patient awaits transfer to an OTP that provides comprehensive maintenance treatment (42 CFR, Part 8 § 2).

intervention. The process of providing care to a patient or taking action to modify a symptom, an effect, or a behavior. Also the process of interacting after assessment with a patient who is substance addicted to present a diagnosis and recommend and negotiate a treatment plan. Also frequently used as a synonym for *treatment*. Types of intervention can include crisis intervention, brief intervention, and long-term intervention.

involuntary discharge. Formal discontinuation of a patient's enrollment in an OTP without patient consent, usually for reasons related to program operations, safety, or treatment compliance—for example, violence or threats of violence; buying and selling drugs; repeated loitering; flagrant noncompliance with program rules resulting in an observable, negative impact on the program, staff, and other patients; nonpayment of fees; and incarceration or other confinement. See *administrative discharge*.



J

Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

One of several SAMHSA-approved accreditation organizations charged with ensuring that OTPs meet the standards set forth in Federal regulations and SAMHSA guidelines.

L

LAAM. See levo-alpha acetyl methadol.

level of care. The setting or combination of settings in which the appropriate intensities and types of treatment services can be provided for individual patients.

levo-alpha acetyl methadol (LAAM; trade name ORLAAM). An opioid agonist medication derived from methadone that is effective for up to 72 hours. Reports in 2000 and 2001 of potential arrhythmogenic cardiac effects of LAAM led to tightening of guidelines, including recommendations that LAAM no longer be used for first-line therapy but only for treatment of patients who already have used it successfully or do not show an acceptable response to other addiction treatments. At this writing, LAAM's future availability for opioid pharmacotherapy is doubtful.

M

maintenance dosage. Amount of medication that is adequate to achieve desired therapeutic effects for 24 hours or more, with allowance for day-to-day fluctuations.

maintenance medication. Medication used for ongoing treatment of opioid addiction.

maintenance treatment. Dispensing of an opioid addiction medication at stable dosage levels for a period in excess of 21 days in the supervised treatment of an individual for opioid addiction (42 CFR, Part 8 § 2).

medical maintenance. (1) Phase of MAT and type of treatment by an OTP, medication unit, or physician affiliated with an OTP in which a person who has achieved a stable lifestyle and has remained abstinent from illicit drugs for at least 2 years (longer in some States) receives ongoing pharmacotherapy with methadone, buprenorphine, or LAAM but no longer requires the structure or frequency of psychosocial treatment services provided in an OTP, as determined by the OTP medical director. (2) Medical maintenance also can be provided by physicians using buprenorphine or naltrexone (42 CFR, Part 8 § 12(i)(3)(vi); 42 CFR, Part 8 § 11(h)).



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

medically supervised withdrawal. Dispensing of a maintenance medication in gradually decreasing doses to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of opioid drugs. The purpose of medically supervised withdrawal is to bring a patient maintained on maintenance medication to a medication-free state within a target period.

medication-assisted treatment for opioid addiction (MAT). Type of addiction treatment, usually provided in a certified, licensed OTP or a physician's office-based treatment setting, that provides maintenance pharmacotherapy using an opioid agonist, a partial agonist, or an antagonist medication, which may be combined with other comprehensive treatment services, including medical and psychosocial services.

medication unit. Facility established as part of, but geographically separate from, an opioid treatment program, from which certified private practitioners or community pharmacists may dispense or administer opioid agonist medications for observed ingestion (42 CFR, Part 8 § 11(i)(1)).

methadone. The most frequently used opioid agonist medication. Methadone is a synthetic opioid that binds to mu opiate receptors and produces a range of mu agonist effects similar to those of short-acting opioids such as morphine and heroin.

methadone maintenance treatment. Dispensing of methadone at stable dosage levels for more than 21 days in the supervised treatment of an individual for opioid addiction (42 CFR, Part 8 § 2).

mobile treatment services. Substance use treatment provided directly to patients from traveling units or vans, ranging from comprehensive maintenance services (with medication and counseling in one or several mobile units) to more limited care, usually medication maintenance therapy, in conjunction with a fixed-site program offering counseling and other psychosocial services.

multiple substance abuse. Concurrent opioid and other substance use—a serious problem in OTPs. Other substances commonly used by people addicted to opioids include alcohol, amphetamines, benzodiazepines (particularly alprazolam and diazepam), other prescription sedatives, cocaine, marijuana, and nicotine. Patterns of use range from periodic low doses to regular high doses that also can meet criteria for addiction. Some drugs—in particular, high-dose barbiturates—used in combination with opioids are immediately life threatening.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

mutual-help program. Program offering the benefits of peer support to people who are substance addicted, through attendance at group meetings and other activities. Twelve-Step programs are one type of mutual-help program.

N

naloxone. Short-acting opioid antagonist. Because of its higher affinity than that of opioids for mu opiate receptors, naloxone displaces opioids from these receptors and can precipitate withdrawal, but it does not activate the mu receptors, nor does it cause the euphoria and other effects associated with opioid drugs. Naloxone is not FDA approved for long-term therapy for opioid addiction, except in the combination buprenorphine-naloxone tablet. Some programs use naloxone to evaluate an individual's level of opioid dependence. See *naloxone challenge test*.

naloxone challenge test. Test in which naloxone is administered to verify an applicant's current opioid dependence and eligibility for admission to an OTP. Withdrawal symptoms evoked by naloxone's antagonist interaction with opioids confirm an individual's current dependence.

naltrexone. Derivative of naloxone and the only opioid antagonist approved for use alone in long-term treatment of people with opioid addiction. Naltrexone is used primarily after medically supervised withdrawal from opioids to prevent drug relapse in selected, well-motivated patients.

narcotic. See *opiod* (preferred usage).

not-in-my-backyard (NIMBY) syndrome. Informal name used to label opposition to the placement of OTPs in communities.

O

office-based opioid treatment (OBOT). MAT provided in a physician's office or health care setting other than an OTP (42 CFR, Part 8 § 11(i)(1)). See *medication unit*.

opiate receptors. Areas on cell surfaces in the central nervous system that are activated by opioid molecules to produce the effects associated with opioid use, such as euphoria and analgesia. Opiate receptors are activated or blocked by opioid agonist or antagonist medications, respectively, to mediate the effects of opioids on the body. Mu and kappa opiate receptor groups principally are involved in this activity.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

opioid. Natural derivative of opium or synthetic psychoactive substance that has effects similar to morphine or is capable of conversion into a drug having such effects. One effect of opioid drugs is their addiction-forming or addiction-sustaining liability.

opioid addiction. Cluster of cognitive, behavioral, and physiological symptoms resulting from continuation of opioid use despite significant related problems. Opioid addiction is characterized by repeated self-administration that usually results in opioid tolerance, withdrawal symptoms, and compulsive drug taking.

opioid addiction treatment. Dispensing of approved medication to prevent withdrawal and craving during the elimination of opioid use by a patient in MAT, with or without a comprehensive range of medical and rehabilitation services or medication prescribed when necessary to alleviate the adverse medical, psychological, or physical effects. This term encompasses medically supervised withdrawal, maintenance treatment, comprehensive maintenance treatment, and, under restricted timeframes, interim maintenance treatment (adapted from 42 CFR, Part 8 § 2).

opioid agonist. Drug that has an affinity for and stimulates physiologic activity at cell receptors in the central nervous system normally stimulated by opioids. Methadone and LAAM are opioid agonists.

opioid antagonist. Drug that binds to cell receptors in the central nervous system that normally are bound by opioid psychoactive substances and that blocks the activity of opioids at these receptors without producing the physiologic activity produced by opioid agonists. Naltrexone is an opioid antagonist.

opioid partial agonist. Drug that binds to, but incompletely activates, opiate receptors in the central nervous system, producing effects similar to those of a full opioid agonist but, at increasing doses, does not produce as great an agonist effect as do increased doses of a full agonist. Buprenorphine is a partial opioid agonist.

opioid treatment program (OTP). SAMHSA-certified program, usually comprising a facility, staff, administration, patients, and services, that engages in supervised assessment and treatment, using methadone, buprenorphine, LAAM, or naltrexone, of individuals who are addicted to opioids. An OTP can exist in a number of settings, including, but not limited to, intensive outpatient, residential, and hospital settings. Services may include medically supervised withdrawal and/or maintenance treatment, along with various levels of medical, psychiatric, psychosocial, and other types of supportive care.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

oral-fluid drug testing. Method of identifying evidence of opioid and other psychoactive substance use and measuring the levels of substances or medications in the body by examining patient saliva for the presence and concentrations of identifiable drugs and their metabolites. Oral-fluid testing must be approved for drug testing by the OTP medical director for patient and program needs.

orientation. See patient orientation.

outcome-based evaluation. Measurement of program effectiveness based on patient response to treatment, such as measures of reduction in opioid and nonopioid drug use and improvement in social function. An outcome-based evaluation system requires that the measures and instruments that are used reflect a consensus of the field, provide incentives to programs to submit data, and include ways to validate and aggregate clinic-level data for national and regional evaluation purposes. Compare *process-based evaluation*.

outpatient psychosocial program. In this TIP, an approach to MAT that may involve the use of opioid addiction treatment medication for medically supervised withdrawal but not for ongoing maintenance pharmacotherapy. Counseling and other psychosocial interventions are the primary features of outpatient psychosocial treatment programs.

OxyContin[®]. Long-acting class II opioid drug usually obtained by prescription for treatment of pain. OxyContin is one of several prescription opioids increasingly obtained by illicit means and abused by people addicted to opioids.

P

pain management. Treatment of acute or chronic pain by various treatment methods, often including administration of opioid medications.

patient. Any individual undergoing MAT in an opioid treatment program (42 CFR, Part 8 § 2).

patient advocacy. Term applied to two levels of activity in addiction treatment: (1) a social or political movement working for changes in legislation, policy, and funding to reflect patient concerns and protect their rights (i.e., *advocacy for* patients) and (2) a philosophy of substance abuse treatment practice maintaining that patients should be involved actively in their own treatment and have rights in its planning and implementation (i.e., *advocacy by* patients). Much of advocacy is about shifting the system from the directive model to one in which the patient is an empowered, involved participant in treatment decisions. This fits with the growing emphasis on individualized treatment.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

patient exception. Special permission requested from and decided by SAMHSA for a substance abuse treatment program to dispense or arrange for the offsite delivery of maintenance medication to a patient in an emergency or hardship situation when the patient does not meet regulatory requirements for such services. Patient exceptions are requested on SAMHSA form SMA-168. In most States, patient exceptions are contingent on the approval of the appropriate State Methadone Authority.

patient handbook. Document provided to a patient in an OTP that contains the information he or she should know to understand MAT, program offerings, program structure, and patient limits and privileges, as well as rights and responsibilities of patients and treatment providers.

patient matching. See patient-treatment matching.

patient motivation for change. Relative readiness to modify one's lifestyle and the sincerity and purposefulness of a patient in an OTP toward achieving the goals of MAT.

patient orientation. Planned introduction to the structure, services, offerings, and methods used in an OTP and to patients' and treatment providers' rights and responsibilities within the program.

patient referral. Alternative to providing all necessary treatment services and levels of care at the program site by collaboratively outsourcing some services to other settings and providers. When a patient must obtain comprehensive services in multiple settings, treatment program staff members should arrange the referrals, monitor patient progress, and coordinate care.

patient-treatment matching. Process of individualizing therapeutic resources to patient needs and preferences, ideally by a participatory process involving both the treatment provider and patient. Because many people addicted to opioids have multiple needs, effective patient-treatment matching in an OTP is a three-step process: (1) assessing, (2) selecting the most suitable treatment modality and site, and (3) identifying the most appropriate services.

pharmacology. Science that addresses the origin, nature, chemistry, effects, and uses of medications and drugs.

pharmacotherapy. Treatment of disease with prescribed medications.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

preliminary assessment. Basic assessment occurring before admission to a treatment program, in which an individual's eligibility for entry and level of any psychosocial crisis are determined.

prevalence. Number of cases of a disease in a population, either at a point in time (point prevalence) or over a period (period prevalence). *Prevalence rate* is the fraction of people in a population who have a disease or condition at one time (the numerator of the rate is the number of existing cases of the condition at a specified time and the denominator is the total population).

process-based evaluation. Evaluation of program effectiveness based on compliance with procedural standards. Compare *outcome-based evaluation*.

psychiatric comorbidity. See *co-occurring disorder*.

psychoactive drug. A substance that affects the mind, thoughts, feelings, and sometimes behaviors.

psychotherapy. Treatment service provided to patients in a comprehensive opioid treatment program, either directly or by referral, in which a trained therapist evaluates and treats patients for diagnosed psychiatric problems. Compare *counseling*.

R

readmission. Reenrollment of a patient who previously left an opioid treatment program. Readmission usually is preceded by a review of the patient's records to determine whether and how the individual's treatment plan should be modified.

referral. See patient referral.

rehabilitative phase. Phase of MAT in which patients who are stabilized on opioid treatment medication continue to eliminate addictive substances from their lives while gaining control of other major life domains (e.g., medical problems, co-occurring disorders, vocational and educational needs, family circumstances, legal issues).

relapse. Breakdown or setback in a person's attempt to change or modify a particular behavior; an unfolding process in which the resumption of compulsive substance use is the last event in a series of maladaptive responses to internal or external stressors or stimuli.

remission. State in which a mental or physical disorder has been overcome or a disease process halted.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

residential treatment. Therapy received within the context of a cooperative living arrangement. Residential treatment programs vary in duration and intensity of services and general philosophy.

retention in treatment. Period during which a patient is able and willing to remain in therapy, which is influenced by a combination of patient and program characteristics. Retention in treatment should be considered the product of a continuing therapeutic relationship between recovering patients and their treatment providers.

S

saliva testing. See oral-fluid drug testing.

screening. Process of determining whether a prospective patient has a substance use disorder before admission to treatment. Screening usually involves use of one or more standardized techniques, most of which include a questionnaire or a structured interview. Screening also may include observation of known presenting complaints and symptoms that are indicators of substance use disorders.

sedative. Medication with central nervous system sedating and tranquilizing properties. An example is any of the benzodiazepines. Most sedatives also promote sleep. Overdoses of sedatives can lead to dangerous respiratory depression (slowed breathing).

self-help program. See *mutual-help program*.

self-medication. Medically unsanctioned use of drugs by a person to relieve any of a variety of problems (e.g., pain, depression).

serum half-life. Time required for the amount of a compound (e.g., an opioid) in blood serum to be halved through metabolism or excretion.

side effect. Consequence (especially an adverse result) other than that for which a drug is used—especially the result produced on a tissue or organ system other than that being targeted.

stabilization (stability). Process of providing immediate assistance (as with an opioid agonist) to eliminate withdrawal symptoms and drug craving.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

stand-alone clinic. Facility that generally offers a comprehensive range of medication and psychosocial services for patients who are opioid addicted, including all levels of care and phases of treatment. Compare *hospital-based treatment*.

State Authority. Agency (sometimes referred to as a “Single State Agency”) designated by the governor or another official assigned by the governor to exercise the responsibility and authority within a State or territory for governing the treatment of addiction to opioid drugs (adapted from 42 CFR, Part 8 § 2).

stigma. Negative association attached to an activity or condition; a cause of shame or embarrassment. Stigma commonly is associated with opioid addiction and MAT.

stimulant. Agent, drug, or medication that produces stimulation. In this TIP, stimulant usually refers to drugs that stimulate the central nervous system (e.g., amphetamines, cocaine).

substance addiction. See *opioid addiction*.

substance dependence. See *dependence*.

substance use disorder (frequently referred to as substance abuse or dependence). Maladaptive pattern of drug or alcohol use manifested by recurrent, significant adverse consequences related to the repeated use of these drugs or alcohol. The substance-related problem must have persisted and occurred repeatedly during a 12-month period. It can occur sporadically and mainly be associated with social or interpersonal problems, or it can occur regularly and be associated with medical and mental problems, often including tolerance and withdrawal.

supportive-care phase. Phase of MAT in which patients maintain abstinence from substances and continue on maintenance medication while receiving other types of intervention as needed to resume primary responsibility for other aspects of their lives.

T

take-home medication. Opioid addiction treatment medication dispensed to patients for unsupervised self-administration.

tapering phase. Phase of MAT in which patients receiving medication maintenance attempt gradually to eliminate their treatment medication (e.g., methadone) while remaining abstinent from illicit substances.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

therapeutic alliance. Joining of patients and their treatment providers in an effective collaboration to assess and treat patients' substance use disorders.

therapeutic community (TC). Consciously designed social environment or residential treatment setting in which social and group processes are harnessed with treatment intent. A TC promotes abstinence from substance use and seeks to decrease antisocial behavior and effect a global change in lifestyle, including attitudes and values. A TC views substance abuse as a disorder of the whole person, reflecting problems in conduct, attitudes, moods, values, and emotional management. Treatment focuses on drug abstinence, coupled with social and psychological change requiring a multidimensional effort along with intensive mutual help and support.

therapeutic dosage. Combination of amount of medication and frequency and timing of administration that is determined by laboratory analysis, professional observation, or patient self-report to be beneficial to control and ameliorate symptoms of withdrawal from addiction and drug-seeking behavior. Therapeutic dosage levels should be determined by what each patient needs to remain stable.

tolerance. Condition of needing increased amounts of an opioid to achieve intoxication or a desired effect; condition in which continued use of the same amount of a substance has a markedly diminished effect.

treatment barrier. Anything that hinders treatment. Examples include financial problems, language difficulties, ethnic and social attitudes, logistics (caring for children, transportation), and unhelpful patient behaviors (tardiness, missed appointments).

treatment efficacy. Ability of an intervention or medication in expert hands and under ideal circumstances to produce the desired therapeutic effect.

treatment eligibility. Relative qualification of a prospective patient for admission to an OTP according to Federal, State, or third-party payer requirements. In general, Federal guidelines are minimum requirements and restrict admission to individuals who have been demonstrably dependent on opioids for 1 year; however, certain high-risk populations including pregnant women are admitted more quickly.

treatment intensity. Frequency and methods for delivery of therapeutic services. OTPs aim to establish levels of treatment intensity that match patients' needs.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

treatment outcomes. Observable results of therapy, including decreased use of illicit psychoactive substances, improved physical and emotional health, decreased antisocial activities, and improved social functioning; considered the best indicator of treatment program effectiveness.

treatment plan. Documented therapeutic approach for each patient that outlines attainable short-term goals mutually acceptable to the patient and the OTP and that specifies the services to be provided and their frequency and schedule (adapted from 42 CFR, Part 8 § 2).

treatment retention. See *retention in treatment*.

12-Step program. Self-help program requiring mastery of a set of steps to achieve and maintain abstinence, based on the program of Alcoholics Anonymous. Many addiction treatment programs use a 12-Step structure or philosophy as a construct for treatment design.

U

urine drug testing. Most common laboratory assessment technique in addiction treatment, which involves analysis of urine samples from patients for the presence or absence of specific drugs. Originally used as a measure of program effectiveness, urine testing now is used to make programmatic decisions, monitor psychoactive substance use, adjust medication dosage, and decide whether a patient is responsible enough to receive take-home medication. Methods of urine testing vary widely.

V

voluntary discharge. Departure from an OTP that is initiated by the patient. Tapering from medication is negotiated among the patient, program physician, and treatment providers.

W

withdrawal. Reduction and elimination of substance use. See *medically supervised withdrawal*, *withdrawal syndrome*.

withdrawal syndrome (or withdrawal). Predictable constellation of signs and symptoms after abrupt discontinuation of or rapid decrease in use of a substance that has been used consistently for a period. Signs and symptoms of withdrawal are usually opposite to the direct pharmacological effects of a psychoactive substance.



Treatment Improvement Protocol – Series 43 (TIP 43): Appendix D

*Ethical Considerations in MAT*⁴

Medication-assisted treatment for opioid addiction (MAT) is firmly rooted in medical treatment models. Treatment decisions by MAT providers should be based on four accepted principles of medical ethics, which can be listed briefly as beneficence, autonomy, nonmaleficance, and justice (Beauchamp and Childress 2001).

Fundamental Ethical Principles

Beneficence (Benefit)

According to Beauchamp and Childress (2001), the medical principle of beneficence emphasizes that treatment providers should act for the benefit of patients by providing competent, timely care within the bounds of accepted treatment practice. The principle of beneficence is satisfied when treatment providers make proper diagnoses and offer evidence-based treatments, that is, treatments drawn from research that provides statistical data about outcomes or from consensus-based standards of care. Beneficence is compromised when diagnoses are questionable or when outcome data do not validate a diagnosis or treatment. When MAT is carried out according to best-practice standards, the principle of beneficence is satisfied (Bell and Zador 2000).

Autonomy

Autonomy, like beneficence, springs from the ideal of promoting patients' best interests. However, whereas beneficence emphasizes the application of provider knowledge and skills to improve patient health, autonomy emphasizes respect for patients' rights to decide what treatment is in their best interests (Beauchamp and Childress 2001).

Standard medical practice places great value on patient autonomy. Usually, patients' and physicians' goals for treatment are identical, but, when they differ, physicians generally accord patients the right to make their own choices and accept the fact that patients' values may differ from physicians' values. For

⁴ Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 06-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005, reprinted 2006.



example, a physician might focus on extending a patient's life, whereas the patient might be more concerned with the quality of that life.

Exceptions to the principle of autonomy in standard medical practice are limited to circumstances in which patients' decisions might endanger themselves or others or in which patients may lack the capacity (because of physical or mental impairment) to make rational choices. Normally, standard medical practice does not permit an exception when patients make the “wrong” choice and the physician “knows better.” The physician may educate or perhaps attempt to persuade a patient but may not make decisions for the patient.

Nonmaleficance—“First, Do No Harm”

The principle of nonmaleficance emphasizes that health care providers should not harm or injure patients (Beauchamp and Childress 2001). Opioid treatment programs (OTPs) are on strong footing in terms of this principle. Before entering MAT, patients have been ingesting illicit opioids (and often other substances) and exposing themselves to serious health risks. Patients entering MAT are also at risk of arrest and imprisonment for illegal activities to support their addictions.

Once enrolled in OTPs, patients begin ingesting medications that have been manufactured in a regulated setting. The risks associated with injecting or otherwise ingesting substances of abuse produced under unknown conditions are gradually eliminated. Patients come under the care of professionals who monitor adverse drug reactions and attend to other health care needs. However, MAT carries risks of its own, including an increased risk of death in the induction phase of pharmacotherapy if medication dosage is not adjusted carefully.

Justice

The principle of justice emphasizes that treatment providers should act with fairness (Beauchamp and Childress 2001). Sometimes this principle is expressed as the duty of providers to treat patients in similar circumstances equally and to use resources equitably. When treatment resources are limited, it may be unclear how to apply this principle in MAT. The principle of justice also applies when treatment providers consider the involuntary discharge of patients.

Besides emphasizing that clinicians should act fairly toward patients, the principle of justice imposes a responsibility to advocate politically and socially for resources (including adequate funding and better treatment by other medical providers) to meet the needs of patients in MAT.



Ethics in Practice

Conflict Between Beneficence and Autonomy

A conflict arises between the principles of beneficence and autonomy when a treatment provider and a patient disagree about what is in the patient's best interest and how treatment should progress. Exhibit D-1 describes such a clash in which a provider believes that stopping all illicit drug use is feasible and in the patient's best interest but the patient disagrees or cannot comply. One or both of the following questions express the source of controversy:

- What is the proper balance between respect for a patient's autonomy and a provider's responsibility for that patient's health?
- Should the patient or the clinician decide what is in a patient's best interests?

Exhibit D-1. Case Example

R.S., a 35-year-old man who has been in MAT for 18 months, is in his second MAT episode. The first ended when he was arrested and imprisoned for armed robbery. R.S. has not missed medication appointments but is less attentive to counseling sessions. He regularly uses alcohol and marijuana and occasionally cocaine. R.S. is unwilling to stop using alcohol and drugs. His position is that he has stopped his use of illicit opioids entirely, which was his goal entering treatment. His other drug use is his choice, and the clinic should “get off his back.”

Patients in MAT who stop their opioid abuse but not their abuse of other substances (i.e., “noncompliant” or “nonresponding” patients) are a major research focus. The literature is replete with studies of strategies, such as contingency contracting (see chapter 8), that use patients' dependence on their treatment medication to compel their compliance with treatment-related mandates. These strategies “are based on the assumption that patients have the necessary skills to produce drug-free urine samples but often lack sufficient motivation” (Iguchi et al. 1996, p. 315). Examples of mandates enforced by contingency contracting include adoption of and adherence to a drug-free lifestyle (Iguchi et al. 1997), attendance at additional therapy-related sessions (with or without a significant other) (Iguchi et al. 1996; Kidorf et al. 1997), and performance of employment-related tasks (Kidorf et al. 1998). Training in substance abuse treatment provides treatment providers with an awareness and understanding of patients' tendencies toward denial, minimization, and rationalization of their substance use. A working familiarity with such studies provides treatment providers with a reasonable basis to choose beneficence over



autonomy when they conclude that they know better than patients what is in patients' best interest.

The conflict between beneficence and autonomy is not unique to MAT, but it is especially acute in MAT because of the fundamental power imbalance between treatment providers and patients. Patients in OTPs depend on their medication and may fear the effects of withdrawal from it. That dependence gives providers (and the principle of beneficence) the upper hand. Patients who refuse to comply with provider views of what is in their best interests risk administrative discharge or other sanctions. Until recently, only an OTP could provide patients with medication, ensuring the OTP's hold over patients. Often no other facility exists from which to obtain MAT.

Why do treatment providers in OTPs lean toward the principle of beneficence and away from the principle of autonomy in their approach to patients? The following factors may apply:

- A longstanding, complex regulatory system that favors a rule-governed perspective in OTPs
- Belief that patients in denial cannot act in their best interests
- Disagreement about goals between patients and treatment providers
- Attention to community concerns
- Effects of noncompliant patients on staff, patients in compliance, and new patients
- Discomfort with the disease model (see below)
- View of patients in MAT as failures
- Limited research examining the precept that complete abstinence is in patients' best interests.

Clinicians Who Are Uneasy With the Disease Model

MAT providers generally embrace the concept of addiction as a chronic relapsing disease; however, unlike medical professionals treating other chronic illnesses, some providers appear uncomfortable with the idea of alleviation of symptoms without cure (Hunt and Rosenbaum 1998, p. 202). These providers might draw on lessons from physicians caring for patients with other chronic diseases. How do they deal with noncompliant patients who fail to alter their diets or lifestyles, for example? Based on the disease model underlying comprehensive maintenance treatment, total abstinence may be unrealistic in the short run for some patients. When OTPs refuse to recognize that immediate abstinence is unrealistic and punish patients for the continuing but reduced presence of symptoms, they are not defining addiction as a disease. The long-term goal is always reducing or eliminating the use of illicit opioids and other illicit drugs and



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

the problematic use of prescription drugs; but, in the short run, patients should be supported as they reduce their substance use.

Research suggests that many patients are aware that they may relinquish their autonomy when they enter MAT. A study about the attitudes of patients receiving methadone found that many see OTPs as institutions that control and punish more than they help—OTPs are agents of conventional society (Hunt and Rosenbaum 1998).

Some Patients' Perspectives

“[C]lients often felt that the relationship between themselves and their counselors was less focused on therapy than power; less about psychological growth, getting help and a sense of well-being than about social control, conforming to rules and regulations, and punishment.” (Hunt and Rosenbaum 1998, p. 209)

“[Study participants] were also aware and fearful that having once adopted the culture of the clinic they would become dependent on it, and more significantly on the goodwill of individual counselors. This dependence was particularly troubling to them because of the increasing insecurity of subsidized slots. Many users expressed concern about once having entered the system and accepting its lifestyle with little or no warning they would be ejected from it. ... [M]any study participants felt, precisely because of the asymmetrical relationship between the client and the clinic, the staff used this as a way of exacting compliance.” (Hunt and Rosenbaum 1998, pp. 200–201)

In the opinion of Bell (2000, p. 1741), “Patients need protection because many are reluctant to complain because they have a sense of powerlessness and do not want to jeopardize their treatment.” Providers at OTPs should be aware of any bias toward the principle of beneficence and away from the principle of autonomy. Rather than assuming that the tilt toward beneficence is always correct, treatment providers and administrators should ask themselves in each case whether they are striking a proper balance between these two fundamental principles.

Other Conflicts Among the Four Principles of Medical Ethics

Involuntary discharge

An OTP's decision to discharge a patient against his or her wishes calls into question all four ethical principles. Involuntary discharge appears to breach practitioners' duties to put patient health first, do no harm, and respect patients' wishes, as well as to avoid harm to the community from reintroducing the effects



of untreated opioid use (especially criminal behavior and potential disease transmission). Yet an OTP often must balance the interests of individuals facing discharge with those of other patients, staff, future patients, and the larger community and society.

Threats to safety

When a patient commits or threatens an act of violence against another patient (on OTP premises) or against staff (on or off OTP premises), comes to treatment armed with a weapon, or deals drugs at or near an OTP, that patient poses a threat to the safety of the program, its staff, and its patients. Involuntary discharge of such a patient, although not in his or her best interests, takes into account the OTP's ethical responsibility to the rest of its patients (current and future), its staff, and others. The consensus panel believes that patient behavior threatening the safety of patients and staff or the status of the program in the community is grounds for patient discharge. OTP administrators may need to make difficult judgments about what constitutes threatening behavior (especially in light of deficits in interpersonal skills and possible untreated co-occurring disorders) and evidence of drug dealing. But an OTP's responsibility to provide good treatment for its other patients—indeed, its responsibility to remain a viable resource in the community—requires that these limits be set and enforced.

Failure to pay

Involuntary discharge for failure to pay treatment fees presents a more difficult ethical issue involving the limited financial resources of many patients and the uneven public funding of MAT. Patients discharged for inability to pay or because their OTPs have lost funding might have been doing well, and terminating treatment, in most cases, will halt their recovery or precipitate relapse ([Knight et al. 1996a](#)). Although involuntary discharge for failure to pay fees appears to violate the principles of autonomy, beneficence, and nonmaleficence, the unfortunate reality is that OTPs must operate within fiscal constraints. If OTPs continue to deliver uncompensated care, they may face financial ruin—a consequence that would jeopardize treatment for all patients (including those who continue to pay). Nonetheless, OTPs considering patient discharge for nonpayment should address the principle of nonmaleficence, at least in part, by mitigating harm to patients, for example, by working out payment schedules, assisting with access to insurance or other funding sources, or facilitating transfer to lower cost facilities. In 2003, the American Association for the Treatment of Opioid Dependence (AATOD) released new recommendations addressing involuntary withdrawal from treatment for nonpayment of fees (www.dmh.state.ct.us/opioid/withdrawal.htm).



Failure to respond

Another difficult ethical issue occurs when an OTP proposes to discharge a patient involuntarily for failure to respond to treatment. No matter which principle the OTP follows, it will fail to uphold another—perhaps even the very principle it is seeking to uphold. An OTP has at least two choices, and all four ethical principles are implicated.

- **To discharge.** When an OTP discharges a noncompliant patient, it risks violating the principle of beneficence because discharge might lead to a poorer health outcome for that patient and perhaps repercussions for the community. Indeed, because research has shown that discharge from MAT leads to poor outcomes, by pursuing the principle of beneficence to its logical conclusion of involuntary discharge, the OTP may be putting a patient's health at greater risk. The OTP may be violating the principle of nonmaleficence as well, especially if it is unaware of the possible consequences of involuntary discharge.

Involuntary discharge of noncompliant patients often occurs when OTPs have waiting lists. When limited slots exist—because of the limits of public sector funding or regulatory caps on slots—and applicants are waiting for treatment, pressure mounts to discharge patients who are not fully compliant with treatment regimens. Concerns about the fairness of continuing to treat a patient who is unwilling or unable to take full advantage of treatment appeal to the principle of justice.

- **Not to discharge.** Arguably, when treatment providers do not discharge noncompliant patients but continue treating them, they risk violating the principle of beneficence because they are not providing care they believe will promote patient health. By ignoring the effect noncompliant patients have on the therapeutic milieu for other patients, providers are violating the principle of beneficence for those other patients. Treatment providers who continue to treat noncompliant patients also violate the principle of justice by denying treatment to potential patients on the waiting list.

OTPs should decide how to respond to treatment noncompliance based on factors and principles discussed above and patients' specific circumstances. No single decision is correct in all cases. The OTP has an ethical responsibility to consider these principles and the effect of discharge on patients and the program.



Take-home privileges

The decisions a medical director makes about take-home privileges, although not as stark as those related to involuntary termination, also require that all four ethical principles be weighed. Patients are usually interested in increasing their autonomy and ability to carry out normal daily activities by reducing visits to their OTP for medication, but the medical director must consider what is safest for patients. Take-home medication privileges might benefit a patient by reducing his or her exposure to an OTP's less stable patients and making it easier for the patient to lead a normal life, by providing an incentive to further enhance recovery, and by expressing a program's confidence in the patient's progress. However, increased take-home privileges may pose a risk to a patient of overmedication and lethal use and to people in the community of drug diversion or accidental life-threatening ingestion by intolerant individuals (e.g., children). Federal regulations governing OTPs require that a medical director deciding whether to allow or increase patient take-home privileges consult the principle of nonmaleficence by considering the risk of harm to patients or others (42 Code of Federal Regulations, Part 8 § 12(i)(2)).

The longstanding concern with methadone diversion also is rooted in the principle of justice. OTPs are under considerable public scrutiny. If an OTP gives take-home privileges to irresponsible patients and those patients, their family members, or others in the community are harmed, the OTP's operations may be restricted or the OTP might be shut down. When an OTP closes its doors, its responsible patients—and the staff and ultimately the community—suffer. Therefore, it is important to consider a patient's behavior carefully—not just the time in treatment—before allowing take-home medication.

A word about due process

The decision to discharge a patient involuntarily or adjust take-home privileges might require that a treatment provider or administrator resolve factual disputes or differences in interpretation between a staff member and a patient or between two patients. It is important that an OTP provide a forum so that patients can receive a fair hearing on their versions of disputed events, including a review of the evidence and proposed sanctions. Some States require additional due-process procedures.

Ethics: Conclusion

OTP staff members can avoid or minimize some ethical dilemmas by remaining aware of sources of potential conflict, keeping ethical principles in mind, familiarizing themselves with the ethical standards of their profession, and



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

discussing potential conflicts with patients and other staff members. The goal always is reducing or eliminating the use of illicit opioids and other illicit drugs and the problematic use of prescription drugs. Exhibit D-2 presents the canon of ethics adopted by AATOD. Exhibit D-3 provides Internet links to the ethical guidelines of other treatment-centered organizations.

Exhibit D-2. AATOD Canon of Ethics

- Ensure that patients are treated with compassion, respect, and dignity regardless of race, creed, age, sex, handicaps, or sexual orientation.
- Retain competent and responsible personnel who adhere to a strict code of ethics, including but not limited to prohibiting of fraternization with patients, exploitation of patients, and criminal behavior.
- Subscribe to the treatment principles published in TIP 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*, which serves as a resource in making therapeutic decisions.
- Provide patients with accurate and complete information regarding methadone treatment, the nature of available services, and the availability of alternative treatment modalities before admission and throughout the treatment process.
- Ensure that discharge from treatment is conducted in accordance with sound and medically acceptable practice. The patient is assured of due process if the discharge is administrative in nature.
- Provide a safe and clean environment for patients and staff that is conducive to the therapeutic process.
- Remain in compliance with the required Federal, State, and local operating standards.
- Take all necessary and appropriate measures to maintain individual patient records and information in a confidential and professional manner.
- Strive to maintain good relations with the surrounding community, and pursue every reasonable action to encourage responsible patient behavior and community safety.



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

Exhibit D-3. Ethical Codes of Selected Treatment-Oriented Organizations and Their Web Sites

American Medical Association's Code of Ethics

www.ama-assn.org/ama/pub/category/8600.html

American Nurses Association's Code of Ethics

nursingworld.org/ethics/chcode.htm

American Psychological Association's Code of Ethics

www.apa.org/ethics

Mental Health Counselors' Code of Ethics

www.counseling.org

National Association of Alcohol and Drug Abuse Counselors' Code of Ethics

www.naadac.org

National Association of Social Workers' Code of Ethics

www.socialworkers.org/pubs/code/code.asp

Public Policy of the American Society of Addiction Medicine, Principles of Medical Ethics

www.asam.org/ppol/Principles%20of%20Medical%20Ethics.htm



Examination Questions

The correct answers to the questions on this exam are based on the information contained within this Course Material. Each question has four possible answers. Select the most correct answer to each question. If there is a conflict between the information contained within this Course Material and what you have learned from other sources, answer the questions based upon the information contained within this Course Material.

1. What was the source of opiate use and abuse prior to the Civil War?
 - a. heroin
 - b. opium
 - c. codeine
 - d. morphine

2. What receptor is most involved with pain control and addiction?
 - a. mu receptor
 - b. opioid2 receptor
 - c. endorphin receptor
 - d. enkephalin receptor

3. What do patients suffering from opiate addiction often report that methadone does?
 - a. "makes me high"
 - b. "makes me happy"
 - c. "makes me feel normal"
 - d. "makes me feel like heroin does"

4. Chronic Endorphin Deficiency is a chronic withdrawal state that opiate addicted individuals report symptoms of after they have been detoxified from short acting opiates. What are the symptoms?
 - a. lack of motivation and an absence of joy or passion
 - b. persistent drug craving, depressed mood and low energy
 - c. loss of interest in activities previously enjoyed and chronic insomnia
 - d. all of the above

5. When is an applicant eligible for admission to an OTP?
 - a. the applicant became opioid addicted at least 1 year before admission
 - b. the applicant is addicted to an opioid drug
 - c. the applicant is at least 18 years old (or meets Federal and State requirements for younger admissions)
 - d. if all of the above are true



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Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

6. Which type of MAT assessment includes observed dosing and daily (minimum) checks to ensure that the patient has not used benzodiazepines or alcohol recently?
 - a. medical assessment
 - b. induction assessment
 - c. comprehensive assessment
 - d. all of the above

7. Which of the five medications available for MAT in and OTP is no longer manufactured?
 - a. LAAM
 - b. Subutex
 - c. Suboxone
 - d. Naltrexone

8. Which medication has a ceiling effect that prevents larger doses from producing greater agonist effects?
 - a. Suboxone
 - b. naltrexone
 - c. methadone
 - d. buprenorphine

9. How long does Methadone suppress drug craving in most opioid addicted patients?
 - a. 6-8 hours
 - b. 10-12 hours
 - c. 12-24 hours
 - d. 24-36 hours

10. Which medication is a full mu opioid antagonist and can block opioid effects for up to 72 hours?
 - a. naltrexone
 - b. methadone
 - c. buprenorphine
 - d. all of the above

11. What should be a guiding principle in an OTP with regard to admission?
 - a. selection
 - b. inclusion
 - c. exclusion
 - d. elimination



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12. What is a key issue in the induction stage regardless of the medication?
- safety
 - attendance
 - compliance
 - detoxification
13. During which stage of treatment is the patient responding well to treatment and dosage and continues to receive regular medication dosages without the need for routine dosage adjustments?
- stabilization
 - maintenance
 - take home stage
 - medically supervised withdrawal
14. What are some of the criteria that “take homes” are based on?
- absence of recent drug use and regular OTP attendance
 - stable home environment and assurance of safe storage
 - clear indicators that benefits outweigh diversion risk
 - all of the above
15. In what treatment phase are program policies more flexible, so patients can attend to other areas of their life?
- acute
 - tapering
 - rehabilitative
 - medical maintenance
16. Gradual reduction or elimination of maintenance medication is the goal in which phase?
- acute
 - stabilization
 - tapering and readjustment phase
 - this is the goal in all phases
17. What type of mutual help groups should counselors help patients to locate?
- any 12-step group
 - only Methadone Anonymous groups
 - groups that accept opioid pharmacotherapy
 - groups that will insist on elimination of all medication to help them with real recovery



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

18. How many drug tests does SAMHSA require per year for patients in long-term MAT?
- a. 6
 - b. 8
 - c. 10
 - d. 1 per month
19. Which of the following is true when interpreting and using drug test results?
- a. drug test results should be the sole basis for treatment decisions
 - b. positive results should always be use punitively
 - c. patients should not be informed of positive test results
 - d. numerous medications produce a false-positive result
20. Which two medications can cause death when used in combination with their MAT medication?
- a. alcohol
 - b. benzodiazepines
 - c. cocaine/other stimulants
 - d. both a. and b.
21. Which patient might require increased monitoring for medication interactions and dosage adjustments because of slower metabolisms?
- a. aging patients
 - b. patients with pain
 - c. adolescent patients
 - d. patients with disabilities
22. What is the only opioid medication approved by the FDA to treat pregnant women in MAT?
- a. methadone
 - b. buprenorphine
 - c. Suboxone
 - d. no opioid medication is approved by the FDA
23. What fundamental principle of ethics springs from the ideal of promoting patients' best interest and emphasizes respect for a patients right to decide what treatment is in their best interest?
- a. justice
 - b. autonomy
 - c. beneficence
 - d. nonmalfeasance



Be sure that you are using the Answer Sheet that corresponds to the Exam Form identified above.

24. What fundamental medical principle of ethics emphasizes that a treatment provider should act for the benefit of patients by providing competent, timely care within the bounds of accepted treatment practice?
- justice
 - autonomy
 - beneficence
 - nonmalfeasance
25. What is common terminology for nonmalfeasance?
- First, do no harm.
 - The duty to treat patients equally.
 - Respect, always.
 - Identical goals, identical treatment.
26. Which of the following presents a difficult ethical issue involving discharge?
- bringing a gun into the facility
 - a patient threatening a staff member
 - dealing drugs in the OTP parking lot
 - involuntary discharge for failure to pay treatment fees
27. The long-term goal is always reducing or eliminating the use of illicit opioids and other illicit drugs and the problematic use of prescription drugs; but, in the short run, what should patients be supported in?
- relinquishing their autonomy
 - the reduction of their substance use
 - embracing the medication they are on
 - acceptance that they are not part of mainstream society
28. Why are patients in OTP treatment reluctant to complain?
- compliance issues
 - a sense of authority
 - a "don't rock the boat" attitude
 - fear of jeopardizing their treatment
29. Which of the following would not be an ethical reason for involuntary discharge?
- threatening staff
 - three (3) "dirty" urine tests
 - punching another patient in the clinic
 - none of the above



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30. What is an ethical consideration regarding take home privileges?
- a. risk of diversion
 - b. risk of lethal use
 - c. risk of over medication
 - d. all of the above