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Executive Summary

Federal statute, the Drug Addiction Treatment Act of 2000 (DATA 2000), has established a new paradigm for the medication-assisted treatment of opioid addiction in the United States (Drug Addiction Treatment Act of 2000). Prior to the enactment of DATA 2000, the use of opioid medications to treat opioid addiction was permissible only in federally approved Opioid Treatment Programs (OTPs) (i.e., methadone clinics), and only with the Schedule II opioid medications methadone and levo-alpha-acetyl-methadol (LAAM), which could only be dispensed, not prescribed.* Now, under the provisions of DATA 2000, qualifying physicians in the medical office and other appropriate settings outside of the OTP system may prescribe and/or dispense Schedule III, IV, and V opioid medications for the treatment of opioid addiction if such medications have been specifically approved by the Food and Drug Administration (FDA) for that indication. (The text of DATA 2000 can be viewed at <http://www.buprenorphine.samhsa.gov/fulllaw.html>.)

In October 2002, FDA approved two sublingual formulations of the Schedule III opioid partial agonist medication buprenorphine for the treatment of opioid addiction. These medications, Subutex[®] (buprenorphine), and Suboxone[®] (buprenorphine/naloxone), are the first and, as of this writing, the only Schedule III, IV, or V medications to have received such FDA approval and, thus, to be eligible for use under DATA 2000. Office-based treatment with buprenorphine promises to bring opioid addiction care into the mainstream of medical practice, thereby greatly expanding access to treatment and bringing new hope to thousands.

DATA 2000 directs the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop a Treatment Improvement

*Due to a number of factors, including the association of LAAM with cardiac arrhythmias in some patients, as of January 1, 2004, the sole manufacturer has ceased the production of the drug.

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Protocol (TIP) containing best practice guidelines for the treatment and maintenance of opioid-dependent patients. This TIP, *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*, is the product of that mandate. The TIP was developed by SAMHSA and a team of independent substance abuse treatment professionals, in consultation with the National Institute on Drug Abuse, the Drug Enforcement Administration (DEA), and FDA. The purpose of this TIP is to provide physicians with science-based clinical practice guidelines on the use of buprenorphine in the treatment of opioid addiction. The primary audience of this TIP is physicians who are interested in providing buprenorphine for the treatment of opioid addiction.

In developing this TIP, the consensus panel, made up of research and clinical experts in the field of opioid addiction treatment, recognized that while buprenorphine offers new hope to many individuals, pharmacotherapy alone is rarely sufficient for the long-term successful treatment of opioid addiction. As a result, these guidelines emphasize that optimally effective and comprehensive opioid addiction care is achieved when attention is provided to all of an individual's medical and psychosocial comorbidities.

This TIP is composed of 6 chapters and 10 appendices, including a complete list of references (Appendix A, Bibliography). Chapter 1, Introduction, describes the basic facts regarding opioid addiction, the traditional approaches to its treatment, and the new DATA 2000 treatment paradigm.

Chapter 2, Pharmacology, addresses, in-depth, the physiology and pharmacology of opioids in general, and of buprenorphine in particular. The chapter also provides a review of the research literature regarding the safety and effectiveness of buprenorphine for the treatment of opioid addiction.

Chapter 3, Patient Assessment, summarizes an approach to screening and assessment of individuals who are addicted to opioids and who may be candidates for treatment with buprenorphine.

Chapter 4, Treatment Protocols, provides detailed protocols on the use of buprenorphine for the treatment of opioid addiction, including both maintenance and withdrawal treatment approaches.

Chapter 5, Special Populations, discusses several special populations whose circumstances require careful consideration as they begin buprenorphine treatment. Treating these special populations requires an understanding of available resources and often involves collaboration with specialists in other areas of care.

Chapter 6, Policies and Procedures, discusses legal and regulatory issues pertaining to the provision of opioid addiction treatment, including the procedures and physician qualifications necessary to obtain the required waiver under DATA 2000 to provide office-based opioid addiction treatment, recommended office practice policies and procedures, the security and confidentiality of opioid addiction care information, and the use of buprenorphine in OTPs.

The following sections summarize the content of this TIP and are grouped by chapter.

Chapter 1, Introduction

Chapter 1 provides an overview of opioid addiction in the United States today, including the historical context of the current treatment environment, the scope of the opioid addiction problem, the traditional approaches to treatment, and an introduction to buprenorphine as an opioid addiction treatment.

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Opioid addiction includes not only misuse and abuse of heroin, but also the less commonly recognized issue of misuse and abuse of prescription opioid pain medications, such as hydrocodone, oxycodone, and meperidine.

Rates of addiction to prescription opioids have been increasing. The incidence of emergency department visits related to prescription opioid pain medications has more than doubled between 1994 and 2001. Recent data show that in at least 15 metropolitan areas, two or more narcotic pain medications—primarily oxycodone, hydrocodone, and codeine—were ranked among the 10 most common drugs involved in drug abuse deaths. (SAMHSA 2002*b*)

The prevalence of heroin addiction in the United States also has been increasing and currently is believed to be the highest it has been since the 1970s. According to the Office of National Drug Control Policy (ONDCP), an estimated 810,000 to 1,000,000 individuals in the United States were addicted to heroin in the year 2000 (ONDCP 2003).

Although well-run methadone maintenance programs—with programming that includes counseling services, vocational resources, referrals, and appropriate drug monitoring—have been shown to decrease opioid use and related crime, increase employment, improve physical and mental health, and decrease the incidence of human immunodeficiency virus (HIV) related to needle sharing, as well as decrease overall mortality rates from opioid addiction, the rise in opioid addiction has not been accompanied by a rise in treatment capacity. Currently, fewer than one-quarter of the Nation's individuals who are addicted to opioids receive any kind of treatment for their addiction (NIH Consensus Statement 1997). The hope of the new DATA 2000 treatment approach with buprenorphine is to greatly expand this number.

More than 20 years ago, buprenorphine was identified as a viable option for the maintenance treatment of individuals

addicted to opioids. Research conducted over the past two decades has documented the safety and effectiveness of buprenorphine for this indication. The enactment of DATA 2000 has now enabled physicians in the United States to offer specifically approved forms of buprenorphine for the treatment of opioid addiction.

Chapter 2, Pharmacology

Buprenorphine has unique pharmacological properties that make it an effective and well-tolerated addition to the available pharmacological treatments for opioid addiction. This chapter reviews the general pharmacology of opioid agonists and antagonists, as well as the opioid *partial agonist* properties of buprenorphine.

Drugs that activate opioid receptors on neurons are termed opioid *agonists*. Heroin and methadone are opioid agonists. The repeated administration of opioid agonists results in dose-dependent physical dependence and tolerance. *Physical dependence* is manifested as a characteristic set of withdrawal signs and symptoms upon reduction, cessation, or loss of an active compound at its receptors. *Addiction*, conversely, is a *behavioral* syndrome characterized by the repeated, compulsive seeking or use of a substance, despite adverse social, psychological, and/or physical consequences. Opioid addiction often, but not always, is accompanied by tolerance, physical dependence, and opioid withdrawal symptoms.

Opioids that bind to opioid receptors but block them, rather than activating them, are termed opioid *antagonists*. Examples of opioid antagonists are naltrexone and naloxone.

Opioid *partial agonists* are drugs that activate receptors, but not to the same degree as full agonists. Increasing the dose of a partial

agonist does not produce as great an effect as does increasing the dose of a full agonist. The agonist effects of a partial agonist reach a ceiling at moderate doses and do not increase from that point, even with increases in dosage. *Buprenorphine is an opioid partial agonist.* It is the partial agonist properties of buprenorphine that make it a safe and an effective option for the treatment of opioid addiction. Buprenorphine has sufficient agonist properties such that when it is administered to individuals who are not opioid dependent but who are familiar with the effects of opioids, they experience subjectively positive opioid effects. These subjective effects aid in maintaining compliance with buprenorphine dosing in patients who are opioid dependent.

Buprenorphine occupies opioid receptors with great affinity and thus blocks opioid full agonists from exerting their effects. Buprenorphine dissociates from opioid receptors at a slow rate. This enables daily or less frequent dosing of buprenorphine, as infrequently as three times per week in some studies.

Buprenorphine is abusable, consistent with its agonist action at opioid receptors. Its abuse potential, however, is lower in comparison with that of opioid full agonists. A formulation containing buprenorphine in combination with naloxone has been developed to decrease the potential for abuse via the injection route. Physicians who prescribe or dispense buprenorphine or buprenorphine/naloxone should monitor for diversion of the medications.

Due to the potential for serious drug-drug interactions, buprenorphine must be used cautiously with certain other types of medications, particularly benzodiazepines, other sedative drugs, opioid antagonists, medications metabolized by the cytochrome P450 3A4 system, and opioid agonists.

Chapter 3, Patient Assessment

This chapter provides an approach to the screening, assessment, and diagnosis of opioid addiction problems, and for determining when buprenorphine is an appropriate option for treatment. The necessary first steps in the medical management of opioid addiction are (1) the use of validated screening tools to identify patients who may have an opioid use problem and (2) further assessment to clearly delineate the scope of an opioid addiction problem when one is identified. When treatment is indicated, consideration must be given to the appropriate treatment approach, treatment setting, and level of treatment intensity, based on a patient's preferences, addiction history, presence of medical or psychiatric comorbidities, and readiness to change. Buprenorphine is a treatment option for many, but not for all.

Screening

The Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction Consensus Panel recommends that physicians periodically and regularly screen *all* patients for substance use and substance-related problems, not just those patients who fit the stereotypical picture of addiction. Several validated addiction screening instruments are discussed. The full text of selected screening instruments is provided in Appendix B, Assessment and Screening Instruments.

Assessment

If screening indicates the presence of an opioid use disorder, further assessment is indicated to thoroughly delineate the patient's problem, to identify comorbid or complicating medical or emotional conditions, and to determine the appropriate treatment setting

and level of treatment intensity for the patient. Complete assessment may require several office visits, but initial treatment should not be delayed during this period.

The Guidelines document provides recommendations on effective interviewing techniques and on the components of the complete history, physical, and recommended initial laboratory evaluation of patients with opioid addiction.

The consensus panel recommends that initial and ongoing drug screening should be used to detect or confirm the recent use of drugs (e.g., alcohol, benzodiazepines, barbiturates), which could complicate patient management. Urine screening is the most commonly used and generally most cost-effective testing method.

Diagnosis of Opioid-Related Disorders

After a thorough assessment of a patient has been conducted, a formal diagnosis can be made. As a general rule, to be considered for buprenorphine maintenance, patients should have a diagnosis of *opioid dependence*, as defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR)* (American Psychiatric Association 2000). This diagnosis is based not merely on physical dependence on opioids but rather on opioid addiction with compulsive use despite harm. (See DSM-IV-TR diagnostic criteria in Appendix C, DSM-IV-TR Material.)

Determining Appropriateness for Buprenorphine Treatment

A detailed approach to determining the suitability of buprenorphine as a treatment option for patients with opioid addiction is included in the Guidelines. The evaluation includes determining if appropriate patient motivation exists and ruling out contraindicating medical and psychiatric comorbidities.

Patients for whom buprenorphine may be an appropriate treatment option are those who

- Are interested in treatment for opioid addiction
- Have no contraindications to buprenorphine treatment
- Can be expected to be reasonably compliant with such treatment
- Understand the benefits and risks of buprenorphine treatment
- Are willing to follow safety precautions for buprenorphine treatment
- Agree to buprenorphine treatment after a review of treatment options

Patients less likely to be appropriate candidates for buprenorphine treatment of opioid addiction *in an office-based setting* are individuals whose circumstances or conditions include

- Comorbid dependence on high doses of benzodiazepines or other central nervous system depressants (including alcohol)
- Significant untreated psychiatric comorbidity
- Active or chronic suicidal or homicidal ideation or attempts
- Multiple previous treatments for drug abuse with frequent relapses (except that multiple previous *detoxification* attempts followed by relapse are a strong indication for long-term *maintenance* treatment)
- Poor response to previous treatment attempts with buprenorphine
- Significant medical complications

Chapter 4, Treatment Protocols

This chapter provides detailed protocols for the use of buprenorphine in the treatment of opioid addiction. A variety of clinical scenarios are addressed, including whether patients are addicted to long- versus short-acting opioids, and whether the

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approach selected is maintenance treatment or medically supervised withdrawal (which **must** be followed by long-term drug-free or naltrexone treatment to be useful to the patient).

Maintenance Treatment

Maintenance treatment with buprenorphine for opioid addiction consists of three phases: (1) induction, (2) stabilization, and (3) maintenance. Induction is the first stage of buprenorphine treatment and involves helping patients begin the process of switching from the opioid of abuse to buprenorphine. The goal of the induction phase is to find the minimum dose of buprenorphine at which the patient discontinues or markedly diminishes use of other opioids and experiences no withdrawal symptoms, minimal or no side effects, and no craving for the drug of abuse. The consensus panel recommends that the buprenorphine/naloxone combination be used for induction treatment (and for stabilization and maintenance) for most patients. The consensus panel further recommends that initial induction doses be administered as observed treatment; further doses may be provided via prescription thereafter.

To minimize the chances of precipitated withdrawal, patients who are transferring from long-acting opioids (e.g., methadone or sustained release morphine, oxycodone) to buprenorphine should be inducted using buprenorphine monotherapy, but switched to buprenorphine/naloxone soon thereafter. Because of the potential for naloxone to precipitate withdrawal in both mother and fetus, pregnant women who are deemed to be appropriate candidates for buprenorphine treatment should be inducted and maintained on buprenorphine monotherapy.

The stabilization phase has begun when a patient is experiencing no withdrawal symptoms, is experiencing minimal or no side effects, and no longer has uncontrollable cravings for opioid agonists. Dosage adjustments may be necessary during early

stabilization, and frequent contact with the patient increases the likelihood of compliance.

The longest period that a patient is on buprenorphine is the maintenance phase. This period may be indefinite. During the maintenance phase, attention must be focused on the psychosocial and family issues that have been identified during the course of treatment as contributing to a patient's addiction.

Medically Supervised Withdrawal ("Detoxification")

Buprenorphine can be used for the medically supervised withdrawal of patients from both self-administered opioids and from opioid agonist treatment with methadone or LAAM. The goal of using buprenorphine for medically supervised withdrawal from opioids is to provide a transition from the state of physical dependence on opioids to an opioid-free state, while minimizing withdrawal symptoms (and avoiding side effects of buprenorphine).

Medically supervised withdrawal with buprenorphine consists of an induction phase and a dose-reduction phase. The consensus panel recommends that patients dependent on short-acting opioids (e.g., hydromorphone, oxycodone, heroin) who will be receiving medically supervised withdrawal be inducted directly onto buprenorphine/naloxone tablets. The use of buprenorphine (either as buprenorphine monotherapy or buprenorphine/naloxone combination treatment) to taper off long-acting opioids (e.g., methadone, LAAM) should be considered only for those patients who have evidence of sustained medical and psychosocial stability, and should be undertaken in conjunction and in coordination with patients' OTPs.

Nonpharmacological Interventions

Pharmacotherapy alone is rarely sufficient treatment for drug addiction. For most

patients, drug abuse counseling—individual or group—and participation in self-help programs are necessary components of comprehensive addiction care. As part of training in the treatment of opioid addiction, physicians should at a minimum obtain some knowledge about the basic principles of brief intervention in case of relapse. Physicians considering providing opioid addiction care should ensure that they are capable of providing psychosocial services, either in their own practices or through referrals to reputable behavioral health practitioners in their communities. In fact, DATA 2000 stipulates that when physicians submit notification to SAMHSA to obtain the required waiver to practice opioid addiction treatment outside the OTP setting, they must attest to their capacity to refer such patients for appropriate counseling and other nonpharmacological therapies.

Treatment Monitoring

Patients and their physicians together need to reach agreement on the goals of treatment, and develop a treatment plan based on the patient's particular problems and needs. During the stabilization phase, patients receiving maintenance treatment should be seen on at least a weekly basis. Once a stable buprenorphine dose is reached and toxicologic samples are free of illicit opioids, the physician may determine that less frequent visits (biweekly or longer, up to 30 days) are acceptable. During opioid addiction treatment with buprenorphine, toxicology tests for relevant illicit drugs should be administered at least monthly.

Chapter 5, Special Populations

This chapter discusses the approach to patients who have certain life circumstances or comorbid medical or behavioral conditions that warrant special

consideration during the assessment and treatment of opioid addiction.

Patients With Medical Comorbidities

Patients who are addicted to opioids often have other medical comorbid problems as a consequence of both high-risk behaviors and of direct toxic effects of the active and inert ingredients in illicit drugs. In patients being treated with buprenorphine for opioid addiction, it is important to screen for and manage common comorbid medical conditions and to anticipate known and potential drug interactions.

Pregnant Women and Neonates

The scant evidence available does not show any causal adverse effects on pregnancy or neonatal outcomes from buprenorphine treatment, but this evidence is from case series not from controlled studies. Methadone is currently the standard of care in the United States for the treatment of opioid addiction in pregnant women. Pregnant women who present for treatment of opioid addiction should be referred to specialized services in methadone maintenance treatment programs. If such specialized services are refused by a patient or are unavailable in the community, maintenance treatment with buprenorphine may be considered as an alternative.

Adolescents/Young Adults

Buprenorphine can be a useful option for the treatment of adolescents with opioid addiction problems. The treatment of addiction in adolescents, however, is complicated by a number of medical, legal, and ethical considerations. Physicians intending to treat addiction in adolescents should be thoroughly familiar with the laws regarding parental consent in their States. Physicians who do not specialize in the treatment of opioid addiction

should strongly consider consulting with, or referring adolescent patients to, addiction specialists. Additionally, State child protection agencies can be a valuable resource when determining the proper disposition for adolescent patients addicted to opioids.

Geriatric Patients

Literature on the use of buprenorphine in geriatric patients is extremely limited. Due to potential differences in rates of metabolism and absorption compared to younger individuals, care should be exercised in the use of buprenorphine in geriatric patients.

Patients With Significant Psychiatric Comorbidity

The presence and severity of comorbid psychiatric conditions must be assessed prior to initiating buprenorphine treatment, and a determination made whether referral to specialized behavioral health services is necessary. The psychiatric disorders most commonly encountered in patients addicted to opioids are other substance abuse disorders, depressive disorders, posttraumatic stress disorder, substance-induced psychiatric disorders, and antisocial and borderline personality disorder.

As with medical comorbidities, it is important to explore the medications used to treat the other psychiatric conditions. Assessing for drug interactions is a critical part of the process.

Polysubstance Abuse

Abuse of multiple drugs (polysubstance abuse) by individuals addicted to opioids is common. Pharmacotherapy with buprenorphine for opioid addiction will not necessarily have a beneficial effect on an individual's use of other drugs. Care in the prescribing of buprenorphine for patients who abuse alcohol and for those who abuse sedative/hypnotic drugs (especially benzodiazapines) must be

exercised because of the documented potential for fatal interactions.

Patients With Pain

Physicians may encounter particular complexities with regard to abuse and addiction in the use of opioids to treat patients with pain. Some patients move from needing prescription opioids for the treatment of pain to abusing them. Physicians concerned about this changing diagnostic picture now may legally use an opioid—buprenorphine—to help facilitate a controlled detoxification in order to manage the physical dependence of the patient who no longer has pain that requires an opioid, but who continues to take the opioid for its mood-altering effects.

Patients who need treatment for pain *but not for addiction* should be treated within the context of a medical or surgical setting. They should not be transferred to an opioid maintenance treatment program simply because they have become physically dependent on prescribed opioids in the course of medical treatment.

Patients who *are* being treated for addiction also may experience pain due to illness or injury unrelated to drug use. Pain in patients receiving buprenorphine treatment for opioid addiction should be treated initially with nonopioid analgesics when appropriate.

Patients maintained on buprenorphine whose acute pain is not relieved by nonopioid medications should receive the usual aggressive pain management, which may include the use of short-acting opioid pain relievers. While patients are taking opioid pain medications, the administration of buprenorphine generally should be discontinued. When restarting buprenorphine, to prevent acutely precipitating withdrawal, administration generally should not begin until sufficient time has elapsed for the opioid pain medication to have cleared from the patient's system, as demonstrated by the onset of early withdrawal

symptoms. Patients who are receiving long-acting opioids for chronic severe pain may not be good candidates for buprenorphine treatment because of the ceiling effect on buprenorphine's analgesic properties.

Patients Recently Discharged From Controlled Environments

A number of issues should be considered in determining the most appropriate treatment modalities for patients with addiction who are recently released from controlled environments (e.g., prison). Intensive buprenorphine monitoring activities are required, and treating physicians may be called upon to verify and explain treatment regimens (e.g., to parole and probation officers); to document patient compliance; and to interact with the legal system, employers, and others. If an OTP alternative is available, physicians should determine if any patient factors preclude referral.

Health Care Professionals Who Are Addicted to Opioids

There is a substantial problem of addiction to prescription opioids among physicians and other health professionals, especially within certain specialties. Prescription opioid addiction in health professionals should be viewed as an occupational hazard of the practice of medicine. Health professionals with substance abuse disorders often require specialized, extended care.

Chapter 6, Policies and Procedures

This chapter presents information on a number of administrative and regulatory issues pertaining to the use of controlled substances in the treatment of opioid addiction that are beyond the general

medico-legal responsibilities that govern most other types of medical practice. Physicians should become thoroughly familiar with these issues prior to undertaking the treatment of opioid addiction.

The DATA 2000 Waiver

To practice office-based treatment of opioid addiction under the auspices of DATA 2000, physicians must first obtain a waiver from the special registration requirements established in the Narcotic Addict Treatment Act of 1974 and its enabling regulations. To obtain a DATA 2000 waiver, a physician must submit notification to SAMHSA of his or her intent to begin dispensing and/or prescribing this treatment. The Notification of Intent form must contain information on the physician's qualifying credentials and must contain additional certifications, including that the physician (or the physician's group practice) will not treat more than 30 patients for addiction at any one time. Notification of Intent forms can be filled out and submitted online at the SAMHSA Buprenorphine Web site at <http://www.buprenorphine.samhsa.gov>. Alternatively, the form can be printed out from the site and submitted via ground mail or fax. (The site contains detailed information about buprenorphine, the DATA 2000 paradigm, and the physician waiver process.) Physicians who meet the qualifications defined in DATA 2000 are issued a waiver by SAMHSA and a special identification number by DEA.

To qualify for a DATA 2000 waiver, physicians must have completed at least 8 hours of approved training in the treatment of opioid addiction or have certain other qualifications as defined in the legislation (e.g., clinical research experience with the treatment medication, certification in addiction medicine) and must attest that they can provide or refer patients to the necessary, concurrent psychosocial services. The consensus panel recommends that all physicians who plan to practice opioid

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addiction treatment with buprenorphine attend a DATA 2000-qualifying 8-hour training program on buprenorphine. SAMHSA maintains a list of upcoming DATA 2000-qualifying buprenorphine training sessions on the SAMHSA Buprenorphine Web site. Additional information about DATA 2000 and buprenorphine also can be obtained by contacting the SAMHSA Buprenorphine Information Center by phone at 866-BUP-CSAT (866-287-2728) or via e-mail at info@buprenorphine.samhsa.gov.

Preparing for Office-Based Opioid Treatment

Prior to embarking on the provision of office-based addiction treatment services, medical practices that will be new to this form of care should undertake certain preparations to ensure the highest quality experience for patients, providers, and staff. Providers and practice staff should have an appropriate level of training, experience, and comfort with opioid addiction treatment. Linkages with other medical and mental health professionals should be established to ensure continuity of treatment and the availability of comprehensive, community-based, psychosocial services.

Privacy and Confidentiality

The privacy and confidentiality of individually identifiable drug or alcohol treatment information is protected by

SAMHSA confidentiality regulation Title 42, Part 2 of the Code of Federal Regulations (42 C.F.R. Part 2). This regulation mandates that addiction treatment information in the possession of substance abuse treatment providers be handled with a greater degree of confidentiality than general medical information. Among other stipulations, regulation 42 C.F.R. Part 2 requires that physicians providing opioid addiction treatment obtain signed patient consent before disclosing individually identifiable addiction treatment information to any third party. The requirement for signed patient consent extends to activities such as telephoning or faxing addiction treatment prescriptions to pharmacies, as this information constitutes disclosure of the patient's addiction treatment. A sample consent form with all the elements required by 42 C.F.R. Part 2 is included as Appendix D, Consent to Release of Information Under 42 C.F.R. Part 2.

Buprenorphine Use in OTPs

In May 2003, the Federal OTP regulations (42 C.F.R. Part 8) were amended to add Subutex[®] and Suboxone[®] to the list of approved opioid medications that may be used in federally certified and registered OTPs (i.e., methadone clinics). OTPs that choose to use Subutex[®] and Suboxone[®] in the treatment of opioid addiction must adhere to the same Federal treatment standards established for all medications under 42 C.F.R. Part 8.