

MODEL POLICY ON DATA 2000 AND TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE

Adopted as policy by the House of Delegates of the Federation of State Medical Boards

April 2013

INTRODUCTION

The profile of opioid addiction in the United States is changing, in that nonmedical use of prescription opioids has become a problem as significant as the use of heroin. Recent data indicate that approximately 1.6 million persons in the U.S. misused or were addicted to prescription opioids in 2010 [1], while 323,000 persons misused or were addicted to heroin [2]. Despite the dimensions of the problem, nearly 80% of opioid-addicted persons do not receive treatment for their addiction because of limited treatment capacity, financial obstacles, social stigma, and other barriers to care [3].

To address this need, researchers, federal health agencies, and pharmaceutical manufacturers have focused on developing medications that can be used to treat opioid addiction in medical office settings, rather than being limited to use only in specialized Opioid Treatment Programs (OTPs) [4]. As a result of those efforts, two major products are now available for use in office settings: buprenorphine (alone and in combination with naloxone) and naltrexone (in an oral formulation and an extended-release injectable formulation). These medications have been shown to be effective when used in office-based settings and thus to increase access to treatment for many patients who would not or cannot obtain care in OTPs [5-7].

Regardless of setting, the primary goals of addiction treatment are to reduce or stop opioid use, to improve the patient's overall health and social functioning, and to help the patient avoid some of the more serious consequences of opioid addiction. Treatment also can help the patient see his or her problems from a different perspective, improve self-reliance, and empower the individual to make positive changes in his or her life [8].

Buprenorphine: Buprenorphine is a partial opioid agonist that was approved by the FDA to treat opioid addiction in 2002. It is available in both tablet and film formulations for the treatment of addiction, either as buprenorphine alone (Subutex®) or in a 4:1 combination with naloxone (Suboxone®). The film formulation – which is similar to a dissolvable film strip of mouthwash – is marketed in unit-dose packaging with a serial number on each foil packet. (A transdermal formulation [BuTrans®] has been approved by the FDA, but only for the treatment of chronic pain.)

The addition of naloxone to buprenorphine does not reduce the efficacy of the medication when it is taken sublingually, yet it appears to serve as a deterrent to injection misuse [9]. For this reason, the buprenorphine/naloxone combination is the preferred formulation for most patients, with the exception of pregnant women, for whom current guidelines recommend use of the monoproduct [10]. Whenever the monoproduct is used, extra attention should be given to the risks of misuse and diversion.

Multiple studies have shown that, administered sublingually and at therapeutic doses in appropriately

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

selected patients, buprenorphine is safe and effective [11-15]. The blockade of the opioid receptor imposed by buprenorphine limits the effects of subsequently administered opioid agonists or antagonists, reducing the risk of opioid overdose, and the “ceiling effect” appears to confer a higher safety profile and generally milder withdrawal symptoms (compared to full agonists) when the drug is tapered after prolonged administration [16-17].

Nevertheless, overdoses and deaths due to buprenorphine can occur and have been reported [18]. Most overdoses, especially fatal ones, involve concurrent use of another CNS depressant such as benzodiazepines, other opioids, or alcohol [19-22]. Buprenorphine also poses a significant risk to non-tolerant individuals, especially children [23].

Relatively few serious adverse events have been associated with buprenorphine. Where such events have been reported, most have involved abuse of the drug by injection, rather than sublingual administration in a clinical setting [24-28]. A national evaluation of pharmacotherapies for opioid addiction in Australia involving more than 1,200 patients found no significant difference in rates of serious adverse events between methadone, LAAM, and buprenorphine, or between different doses of buprenorphine [29].

Although early reports based on animal studies suggested that buprenorphine would have a low potential for misuse to achieve euphoria, researchers have documented a measurable level of misuse and diversion of buprenorphine [30-31]. Varying levels of misuse and diversion were predicted by early investigators [32] because buprenorphine is prescribed to high-risk individuals who are addicted to opioids. Subsequent research confirms that misuse and diversion have been reported worldwide wherever buprenorphine has been used for the treatment of addiction [33-36].

The tablet form of buprenorphine has proved more vulnerable to diversion and nonmedical use than the sublingual film, so the pharmaceutical company that held the original patent stopped manufacturing the tablet form and petitioned the Food and Drug Administration (FDA) to require that all buprenorphine products be formulated as unit-dose sublingual filmstrips, thereby eliminating tablet formulations from the market. (As of January 2013, the FDA had not acted on the petition.)

Role of Federal Legislation: The use of buprenorphine for the treatment of opioid addiction is governed by the federal Drug Addiction Treatment Act of 2000, commonly referred to as “DATA 2000” (Public Law 106-310, Title XXXV, Sections 3501 and 3502). This legislation is of particular interest to state medical boards because, for the first time in almost a century, it allows physicians to treat opioid addiction with FDA-approved controlled drugs in office-based settings. Specifically, DATA 2000 allows physicians to use buprenorphine and other controlled substances in CSA Schedules III, IV, and V, which have been approved by the FDA for the treatment of opioid dependence, to treat patients in office-based settings, provided certain conditions are met.

DATA 2000 thus has enlarged treatment capacity by lifting the requirement that patients who need opioid agonist treatment can receive such treatment only in specially licensed opioid treatment programs (OTPs), often referred to as “methadone clinics.”

Implementation of DATA 2000 required changes in the oversight systems within the Department of Health and Human Services (HHS) and the Drug Enforcement Administration (DEA). The Secretary of HHS delegated authority in this area to the Center for Substance Abuse Treatment (CSAT) of the Substance Abuse and Mental Health Services Administration (SAMHSA).

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Role of State Medical Boards: The use of opioid agonist medications to treat opioid-addicted patients in the offices of individual physicians significantly increases the role of state medical boards in overseeing such treatment. For this reason, the Federation of State Medical Boards entered into an agreement with SAMHSA to develop model guidelines for use by state medical boards in regulating office-based treatment of addiction. This resulted in the Model Policy adopted by the Federation in 2002 [37].

The updated Model Policy presented here reflects the large body of research and experience accrued in the decade since buprenorphine was approved in 2002 for the treatment of opioid addiction. The Model Policy is designed to encourage state medical boards to adopt consistent standards, to promote the public health by making appropriate treatment available to opioid- addicted patients, and to educate the regulatory and physician communities about the potential of new treatment modalities for opioid addiction.

The Federation acknowledges with gratitude the efforts of the state Board members and directors who worked to update the Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The Federation also thanks SAMHSA for its support of this important project.

MODEL POLICY ON DATA 2000 AND TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE

SECTION I: PREAMBLE

The (*name of Board*) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the principles of high-quality medical practice dictate that the people of (name of state) have access to appropriate, safe and effective medical care, including the treatment of addiction. The application of up-to-date knowledge and evidence-based treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from addiction.

In this context, the Board recognizes the body of evidence for the effectiveness of buprenorphine in the office-based treatment of opioid addiction [38], when such treatment is delivered in accordance with current standards of care and the requirements of the Drug Addiction and Treatment Act of 2000 (DATA 2000) and state medical licensing boards.

Federal Requirements to Prescribe Buprenorphine for Addiction: Physicians who wish to treat opioid addiction with buprenorphine in their medical offices must demonstrate that they have met the requirements of the DATA 2000 legislation and obtained a waiver from SAMHSA.ⁱ To qualify for such a waiver, physicians must hold a current controlled substance registration with the Drug Enforcement Administration and a current license in the state in which they practice. They also must meet one or more of the following qualifications [39]:

- Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;
- Subspecialty board certification in addiction medicine from the American Osteopathic Association;
- Addiction certification from the American Board of Addiction Medicine;
- Completion of not less than eight hours of training related to the treatment and management of opioid addiction provided by the American Academy of Addiction Psychiatry, the American Society of Addiction Medicine, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or other approved organizations; or¹
- Participation as an investigator in one or more clinical trials leading to the approval of an opioid drug in Schedule III, IV, or V or a combination of such drugs for treatment of opioid- addicted patients.

To obtain a waiver, a physician must notify SAMHSA in writing of his or her intent to prescribe an approved opioid medication to treat addiction, certifying the physician's qualifications and listing his/her DEA registration number. SAMHSA will then notify DEA whether a waiver has been granted. If SAMHSA grants a waiver, DEA will issue an identification number no later than 45 days after receipt of the physician's written notification. (If SAMHSA does not act on the physician's request for a waiver within the 45-day period, DEA will automatically assign the physician an identification number.) This process is explained, and can be accessed at the following website: <http://buprenorphine.samhsa.gov/howto.html>.

¹ i The "waiver" allows an exception to the Harrison Narcotics Act of 1914, which made it illegal for a physician to prescribe an opioid to any patient with opioid addiction for the purpose of managing that addiction or acute withdrawal. Prior to DATA 2000, the only exception to the Harrison Act was federal legislation that allowed the establishment of methadone maintenance treatment (MMT) clinics, now referred to as Opioid Treatment Programs (OTPs). That exception only allowed the use of methadone to treat addiction or withdrawal within specially licensed and regulated facilities, but not in office-based medical practice.

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

If a physician wishes to prescribe or dispense an appropriately available and approved opioid medication for maintenance treatment or detoxification (so as to fulfill the requirements of DATA 2000) on an emergency basis before the 45-day waiting period has elapsed, the physician must notify SAMHSA and the DEA of his or her intent to provide such emergency treatment.

In addition to a waiver, a physician who wishes to prescribe buprenorphine or another approved opioid for the treatment of addiction in an office setting must have a valid DEA registration number and a DEA identification number that specifically authorizes him or her to engage in office-based opioid treatment.

Prescription Requirements: Prescriptions for buprenorphine and buprenorphine/naloxone must include full identifying information for the patient, including his or her name and address; the drug name, strength, dosage form, and quantity; and directions for use. Prescriptions for buprenorphine and/or buprenorphine/naloxone must be dated as of, and signed on, the day they are issued (21 CFR 1306.05[a]). Both the physician's regular DEA registration number and the physicians' DATA 2000 identification number (which begins with the prefix X) must be included on the prescription (21 CFR 1301.28 [d][3]). [39]

For detailed guidance, physicians are referred to the Buprenorphine Clinical Practice Guidelines published by CSAT/SAMHSA, which can be accessed at http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf.

State Medical Board Requirements: The (state medical board) will determine the appropriateness of a particular physician's prescribing practices on the basis of that physician's overall treatment of patients and the available documentation of treatment plans and outcomes. The goal is to provide appropriate treatment of the patient's opioid addiction (either directly or through referral), while adequately addressing other aspects of the patient's functioning, including co-occurring medical and psychiatric conditions and pressing psychosocial issues.

SECTION II: GUIDELINES

Multiple studies have shown that opioid addiction treatment with buprenorphine can be successfully integrated into office practice by physicians who are not addiction specialists. In such studies, patient outcomes are comparable to or better than outcomes of patients treated in specialized clinics [40-48]. However, as in the treatment of any medical disorder, physicians who choose to offer addiction treatment need to understand the nature of the underlying disorder, the specific actions of each of the available medications (as well as any associated contraindications or cautions), and the importance of careful patient selection and monitoring [40].

The Board has adopted the following guidelines for the treatment of opioid addiction in office-based settings. The guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of accepted professional practice.

Physician Qualifications: The diagnosis and medical management of opioid addiction should be based on current knowledge and research, and should encompass the use of both pharmacologic and nonpharmacologic treatment modalities. Thus, before beginning to treat patients for opioid addiction, the physician should become knowledgeable about opioid addiction and its treatment, including the use of approved pharmacologic therapies and evidence-based nonpharmacologic therapies [49-50].

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

As described in the Preamble, physicians who wish to prescribe or dispense buprenorphine for the treatment of opioid addiction must meet the requirements of DATA 2000 [51], which are that the physician must be licensed in the state, have a valid DEA controlled substances registration and identification number, comply with federal and state regulations applicable to controlled substances, and hold a current waiver [39].

In addition to these requirements, DATA limits the number of patients that a physician is permitted to treat at any one time to 30 in the first year after obtaining a waiver, and to 100 patients thereafter. The physician who wishes to treat more than 30 patients after the first year must file an application with the DEA to extend his or her waived capacity to do so [39,51].

DATA 2000 also requires that a physician who wishes to treat opioid addiction with buprenorphine in an office setting must demonstrate a capacity to offer (or refer patients for) appropriate counseling and other ancillary services, and to recognize when those services are needed [51].

Physicians are not permitted to delegate the prescribing of buprenorphine to non-physicians. Even physicians who hold DEA registrations to prescribe controlled substances for other conditions are not allowed to prescribe buprenorphine for the treatment of addiction unless they meet the DATA requirements and hold a waiver. However, non-physician professionals can play an active role in evaluating and monitoring patients and providing other elements of care, in accordance with state regulations and rules governing physician supervision [52].

Physicians should consult the DEA regulations (Title 21 US Code of Controlled Substances Act 1301.28 and 21 USC 823 9GO(2)(G) [51] and the resources available on the DEA's website (at www.deadiversion.usdoj.gov), as well as (*any relevant documents issued by the state medical board*) for specific rules governing the issuance of prescriptions for controlled substances.

Patient Assessment: The objectives of the patient assessment are to determine a given patient's eligibility for treatment, to provide the basis for a treatment plan, and to establish a baseline measure for use in evaluating a patient's response to treatment. Accordingly, the assessment should be designed to achieve the following [49,53]:

- Establish the diagnosis of opiate addiction, including the duration, pattern and severity of opioid misuse; the patient's level of tolerance; results of previous attempts to discontinue opioid use; past experience with agonist therapies; the nature and severity of previous episodes of withdrawal; and the time of last opioid use and current withdrawal status.
- Document the patient's use of other substances, including alcohol and other drugs of abuse.
- Identify comorbid medical and psychiatric conditions and disorders and to determine how, when and where they will be addressed.
- Screen for communicable diseases and address them as needed. Evaluate the patient's level of physical, psychological and social functioning or impairment;
- Assess the patient's access to social supports, family, friends, employment, housing, finances and legal problems.
- Determine the patient's readiness to participate in treatment.

Assessment usually begins at the time of the patient's first office visit and continues throughout treatment. While the evidence is not conclusive, consensus opinion is that an initial patient assessment is of higher quality when it includes a medical and psychiatric history, a substance abuse history, and an evaluation of family and psychosocial supports, as well as a pregnancy test for all women of childbearing age. The physical examination,

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

if performed during the initial assessment, can be focused on evaluating neurocognitive function, identifying sequelae of opioid addiction, and looking for evidence of severe hepatic dysfunction [10,53].

As a general rule, a urine drug screen or other toxicologic screen should be part of the initial evaluation to confirm recent opioid use and to screen for unreported use of other drugs. Ideally, this drug screen should include all opioids commonly prescribed and/or misused in the local community, as well as illicit drugs that are available locally [54]. It also is advisable to access the patient's prescription drug use history through the state's prescription drug monitoring program (PDMP), where available, both to confirm compliance in taking prescribed medications and to detect any unreported use of other prescription medications.

Information from family members and significant others can provide useful additional perspectives on the patient's status, as can contact with or records from clinicians who have treated the patient in the past [46].

Treatment Planning: There is an emerging consensus among addiction experts that treatment medications such as buprenorphine should be considered as an option for every opioid-addicted patient [38]. However, the failure to offer medication-assisted treatment does not in itself constitute substandard care. No single treatment is appropriate for all persons at all times. Therefore, an individualized treatment plan is critical to the patient's ultimate success in returning to productive functioning [5,54].

The treating physician should balance the risks and benefits of medication-assisted treatment in general – and treatment with buprenorphine in particular – against the risks associated with no treatment or treatment without medication [4,55]. The various options include:

- Simple detoxification and no other treatment;
- Detoxification followed by antagonist therapy;
- Counseling and/or peer support without medication-assisted therapy;
- Referral to short- or long-term residential treatment;
- Referral to an OTP for methadone maintenance; or
- Treatment with buprenorphine or buprenorphine/naloxone in an office-based setting.

Patients may be suitable candidates for treatment with buprenorphine even if past treatment episodes were not successful [50].

If a decision is made to offer the patient treatment with buprenorphine, the risks associated with possible misuse and diversion are such that the combination buprenorphine/naloxone product is preferable for most patients [38,40,43]. The monoproduct should be used only rarely except in pregnant women, for whom it is the preferred formulation [53].

Psychosocial and other nonpharmacologic interventions often are useful components of treatment [48,50,55]. Such interventions typically work best in conjunction with medication-assisted therapies; in fact, there is some evidence that the combination of pharmacologic and non-pharmacologic interventions may be more effective than either approach used alone [56]. As noted earlier, the ability to offer patients psychosocial supports, either on-site or through referral, is a requirement of the DATA 2000 legislation.

Educating the Patient: Every patient to whom buprenorphine is prescribed should be cautioned to follow the directions exactly, particularly during the induction stage. Critical issues involve when to begin dosing, the frequency of subsequent doses, and the importance of avoiding the use of any other illicit or prescription opioid.

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Concurrent use of non-opioid sedating medications or over-the-counter products also should be discussed, and patients should be advised to avoid the use of alcohol [7].

Patients should be cautioned about potential sedation or impairment of psychomotor function during the titration phase of induction with buprenorphine [57].

Finally, because opioids can contribute to fatal overdoses in individuals who have lost their tolerance to opioids or in those who are opioid-naïve (such as a child or other family member), proper and secure storage of the medication must be discussed. Particularly where there are young people in the patient's home, the subject of safe storage and use should be revisited periodically throughout the course of treatment, with the discussions documented in the patient record [57].

Informed Consent: Although agonist medications such as buprenorphine clearly are effective for the treatment of opioid dependence, they do entail a substitute dependence on the prescribed medication to replace the prior dependence on the misused opioid [46]. This issue should be thoroughly discussed with the patient in terms of potential risks and benefits as part of the informed consent process. Patients and family members often are ambivalent about agonist treatment for this reason and their concerns may influence subsequent treatment choices. Possible topics of discussion include the difference between addiction and physical dependence (including an explanation of why agonist therapy is not simply “switching one addiction for another”), the likelihood of relapse with and without medication-assisted treatment, the projected duration of treatment, the potential for successfully tapering from agonist therapy at some point in the future, and the role and importance of adjunctive therapies such as counseling and peer support. With the patient's consent, this conversation could include family members, significant other(s), or a guardian [7].

A written *informed consent* document, discussed with and signed by the patient, can be helpful in reinforcing this information and establishing a set of “ground rules.” The practitioner should document the informed consent in the patient's medical record [58].

Treatment Agreement: The terms of treatment agreements vary widely, but typical provisions include an acknowledgement of the potential benefits and risks of therapy and the goals of treatment; identification of one provider and one pharmacy from whom the patient will obtain prescriptions; authorization to communicate with all providers of care (and sometimes significant others) and to consult the state's Prescription Drug Monitoring Program (PDMP), if one is available; other treatments or consultations in which the patient is expected to participate, including recovery activities; avoidance of illicit substances; permission for drug screens (of blood, urine, saliva or hair/nails) and pill counts as appropriate; mechanisms for prescription renewals, including exclusion of early renewals; expected intervals between office visits; and specification of the conditions under which therapy will be continued or discontinued [59].

The agreement also should include a statement instructing the patient to stop taking all other opioid medications unless explicitly told to continue. Such a statement reinforces the need to adhere to a single treatment regimen. Inclusion in the agreement of a pharmacy address and telephone number reinforces to the patient the importance of using one pharmacy to fill prescriptions.

Finally, the treatment agreement should set forth the objectives that will be used to evaluate treatment success, such as freedom from intoxication, improved physical and psychosocial function, and adherence to the treatment regimen [59].

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Copies of the treatment agreement and informed consent should be provided to the patient and all other care providers, and file in the patient's medical record. The agreement should be reviewed regularly and adjusted as needed [58].

Induction, Stabilization, and Follow-up: The goal of induction and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues or markedly reduces the use of other opioids without experiencing withdrawal symptoms, significant side effects, or uncontrollable craving for the drug of abuse [60].

The initial induction process requires a higher degree of attention and monitoring than the later maintenance phase [59]. Particular attention should be given to the timing of the initial doses so as to minimize untoward outcomes. Withdrawal symptoms can occur if either too much or too little buprenorphine is administered (i.e., spontaneous withdrawal if too little buprenorphine is given, precipitated withdrawal if buprenorphine is administered while the opioid receptors are substantially occupied by an opioid agonist). Undermedication or overmedication can be avoided through a flexible approach to dosing, which sometimes requires higher doses of treatment medication than expected, and by taking into account patient-reported symptoms [61].

The stabilization phase is focused on finding the right dose for an individual patient. A patient is stabilized when the dose allows him or her to conduct activities of daily living and to be aware of his or her surroundings without intoxication and without suffering withdrawal or distressing drug craving [61-62]. Although there is no precise way to determine in advance what the optimal dose for a particular patient will be [63], most patients are likely to stabilize on eight to 24 mg of buprenorphine per day, although some may need doses of up to 32 mg per day [64].

Buprenorphine blood concentrations stabilize after approximately seven days of consistent dosing [17]. If withdrawal symptoms subsequently emerge during any 24-hour dosing interval, the dose is too low and should be increased [64]. Medical factors that may cause a patient's dose requirements to change include (but are not limited to) starting, stopping, or changing the dose of other prescription medications; onset and progression of pregnancy; onset of menopause; progression of liver disease; and significant increase or decrease in weight [61].

Dose adjustments generally can be made in increments of 2 mg/day. Because buprenorphine has a long plasma half-life and an even longer duration of action at the mu opioid receptor, five days should be allowed between dose adjustments [53].

Patient adherence to medication regimens and session appointments is associated with better treatment outcomes, and regular monitoring can help patients plan for possible obstacles and teach them ways to handle any problems that occur [65]. Regular assessment of the patient's level of engagement in treatment and the strength of the therapeutic alliance allows for modification of the treatment plan and level of care in response to the patient's progress or lack thereof [56].

Early in treatment, medications should be prescribed and follow-up visits scheduled commensurate with the patient's demonstrated stability. Until patients have shown the ability to be compliant with the treatment plan and responsible with their medication supplies, and have discontinued high-risk behaviors and associated diversion risks, they should be seen more frequently and given supplies of medication only as needed until the next visit. As patients demonstrate stability and the risk declines, they can be seen less often (typically once a month) and prescribed larger supplies of medication [46,59].

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Patient monitoring during follow-up visits should address the following points [46,54,59,66]:

- Whether the patient continues to use alcohol or illicit drugs, or to engage in non-medical use of prescription drugs;
- The degree of compliance with the treatment regimen, including the use of prescribed medications as directed;
- Changes (positive or negative) in social functioning and relationships;
- Avoidance of high-risk individuals, situations, and diversion risk;
- Review of whether and to what degree the patient is involved in counseling and other psychosocial therapies, as well as in self-help activities through participation in mutual support meetings of groups such as Narcotics Anonymous;
- The presence or absence of medication side effects; and
- The presence or absence of medical sequelae of substance use and its remission.

The patient's compliance with regard to use of prescribed buprenorphine and avoidance of other opioids should be monitored through patient report, regular toxicologic analyses [54], reports from significant others, and regular checks of the state's Prescription Drug Monitoring Program, where available [46].

Individuals being treated with medication-assisted therapy often demonstrate dramatic improvement in addiction-related behaviors and psychosocial functioning. Such positive changes should be acknowledged and reinforced by the prescribing physician whenever possible. Reducing the frequency of monitoring visits, with their associated costs, and increasing the patient's responsibility for medications are examples of how positive, responsible behaviors can be reinforced [46,67].

Adjusting the Treatment Plan: Treatment outcomes typically are positive for patients who remain in treatment with medication-assisted therapies such as buprenorphine [46,68]. However, some patients struggle to discontinue their misuse of opioids or other drugs, are inconsistent in their compliance with treatment agreements, or succeed in achieving some therapeutic goals while not doing well with others [69].

Behaviors that are not consistent with the treatment agreement should be taken seriously and used as an opportunity to further assess the patient and adapt the treatment plan as needed. In some cases, where the patient's behavior raises concerns about safety or diversion of controlled medications, there may be a need to refer the patient for treatment in a more structured environment (such as an OTP) [69]. However, behavior that violates the treatment agreement or a relapse to nonmedical drug use do not constitute grounds for automatic termination of treatment. Rather, they should be taken as a signal to reassess the patient's status, to implement changes in the treatment plan (as by intensifying the treatment structure or intensity of services), and to document such changes in the patient's medical record [46].

Whenever the best clinical course is not clear, consultation with another practitioner may be helpful. The results of the consultation should be discussed with the patient and any written consultation reports added to the patient's record [59].

Patients with more serious or persistent problems may benefit from referral to a specialist for additional evaluation and treatment. For example, the treatment of addiction in a patient with a comorbid psychiatric disorder may be best managed through consultation with or referral to a specialist in psychiatry or addiction

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

psychiatry [10]. In other instances, aberrant or dysfunctional behaviors may indicate the need for more vigorous engagement in peer support, counseling, or psychotherapies, or possibly referral to a more structured treatment setting [56].

Preventing and Managing Relapse: Relapse always should be ruled out as a reason for loss of stability [56]. Relapse to drug use has been described as “an unfolding process in which the resumption of substance abuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli” [70]. It rarely is caused by any single factor; rather, it is a dynamic process in which the patient’s readiness to change interacts with other external and internal factors [59, 71]. Patients in relapse vary in the quantity and frequency of their substance use, as well as the accompanying medical and psychosocial sequelae.

Clinical strategies to prevent and address relapse generally encompass the following steps [10,61,71]:

- Identify environmental cues and stressors that act as relapse triggers.
- Help patients develop skills to cope with or manage negative emotional states;
- Help the patient work toward a more balanced lifestyle.
- Understand and manage craving.
- Identify and interrupt lapses and relapses. Patients should have an emergency plan to address a lapse so that a full-blown relapse can be avoided. If relapse does occur, be prepared to intervene.
- Develop a recovery support system. Families are more likely to provide such support if they are engaged in the treatment process and have an opportunity to ask questions, share their concerns and experiences, and learn practical coping strategies and behaviors to avoid.

It should be noted that lack of adherence to pharmacologic regimens occurs in a substantial portion of patients being treated for addiction, with some studies reporting that a majority of patients fail to follow the treatment plan at some point in their care. Retention in treatment also is a problem [72]. This is no different from the challenges encountered in managing any chronic disease, such as diabetes, hypertension, epilepsy, and other potentially life-threatening disorders [46], and is not an indicate to terminate treatment.

Patients who continue to misuse opioids after sufficient exposure to buprenorphine and ancillary psychosocial services or who experience continued symptoms of withdrawal or craving at 32 mg of buprenorphine should be considered for therapy with methadone [5,7,52,73].

Duration of Treatment: Available evidence does not support routinely discontinuing medication-assisted treatment once it has been initiated and the patient stabilized. However, this possibility frequently is raised by patients or family members. When it is, the physician and patient should carefully weigh the potential benefits and risks of continuing medication-assisted treatment and determine whether buprenorphine therapy can be safely discontinued [74].

Studies indicate that opioid-dependent patients are at high risk for relapse when medication-assisted therapy is discontinued, even after long periods of stable maintenance [7,74]. Research also shows that longer duration of treatment is associated with better treatment outcomes [75]. Such long-term treatment, which is common to many medical conditions, should not be seen as treatment failure, but rather as a cost-effective way of prolonging life and improving the quality of life by supporting the natural and long-term process of change and recovery. Therefore, the decision to discontinue treatment should be made only after serious consideration of the potential consequences [3,7-8].

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

As with other disease processes, the continuation of medication-assisted treatment should be linked directly to the patient's response (for example, his or her attainment of treatment goals). Relapse risk is highest in the first six to 12 months after initiating abstinence, then diminishes gradually over a period of years. Therefore, it is reasonable to continue treatment for at least a year if the patient responds well [3,7,10].

If buprenorphine is discontinued, the patient should be tapered off the medication through use of a safely structured regimen, and followed closely [46]. It may be necessary to reinstate pharmacotherapy with buprenorphine or a different medication or other treatment services if relapse appears imminent or actually occurs [59]. Such relapse poses a significant risk of overdose, which should be carefully explained to the patient [74]. Patients also should be assured that relapse need not occur for them to be reinstated to medication-assisted therapy [46].

Medical Records: Accurate and up-to-date medical records protect both the physician and the patient. In the event of a legal challenge, detailed medical records that document what was done and why are essential elements of the practitioner's defense [75-76].

A written informed consent and a treatment agreement articulating measurable treatment goals are key documents. The treatment agreement should be updated as new information becomes available. Both the informed consent and treatment agreement should be carefully explained to the patient and signed by both the patient (or guardian) and the treating physician [76]. The medical record should clearly reflect the decision-making process that resulted in any given treatment regimen.

The first page of the patient's chart should contain a summary of the information needed to understand the treatment plan, even without a thorough knowledge of the patient. This includes some demographic data, the names of other practitioners caring for the patient, all diagnoses, therapies employed, and a list of all medications prescribed. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [10,76].

Other documents that should be part of the medical record, where available, include [10,74,76]:

- Diagnostic assessments, including the patient history, physical examination, and any laboratory tests ordered, with their results;
- Actual copies of, or references to, medical records of past hospitalizations or treatments by other providers;
- The treatment plan, treatment agreement, and informed consent;
- Authorization for release of information to other treatment providers;
- Documentation of discussions with and consultation reports from other health care providers; and
- Medications prescribed and the patient's response to them, including any adverse events.

The medical record also must include all prescription orders, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [75].

Monitoring visits should be carefully documented in the medical record, along with any subsequent changes to the treatment plan [10,76]. The patient's record also should contain documentation of steps taken to prevent the diversion of treatment medications, including any communications with other treating physicians and, where

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

available, use of the state's prescription drug monitoring program to verify that all prescribed medicines have been obtained and that no other prescriptions for controlled drugs have been dispensed without the physician's knowledge [77-78].

Records (including drug logs, if buprenorphine is dispensed in the office) should be up-to-date and maintained in an accessible manner, readily available for review [75]. Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [10,74,76].

Physicians who treat patients for addiction must observe the special confidentiality requirements of federal law 42 CFR, Part 2, which addresses the confidentiality of patients being treated for alcohol or drug addiction. 42 CFR includes a prohibition against release of records or other information without the patient's consent or a valid court order, or in cases of a bona fide medical emergency, or in the course of mandatory reporting of child abuse [7].

SECTION III: DEFINITIONS

Accurate use of terminology is essential to understanding office-based treatment of opioid addiction [70]. However, terminology in this area is changing. For many years, the most commonly used terms have been "drug abuse" and "drug dependence," with the latter indicating a severe condition considered synonymous with the term "addiction" (the chronic brain disease). The terms "abuse" and "dependence," in use since the third edition of the *Diagnostic and Statistical Manual of Mental Disorders* [79] will be replaced in the forthcoming fifth edition [80] by the term "substance use disorder." Other new terms include "opioid use" for the activity of using opioids benignly or pathologically, and "opioid use disorder" for the disease associated with compulsive, out-of-control use of opioids.

For the purposes of this Model Policy, the following terms are defined as shown.

Abuse: The definition of "abuse" varies widely, depending on the context in which it is used and who is supplying the definition. For example, in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* [81], the American Psychiatric Association defines drug abuse as "a maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by one or more behaviors." The *DSM V*, to be published in 2013, replaces the term "abuse" with "misuse" [80].

Addiction: Addiction is widely defined as a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm [56]. (As discussed below, physical dependence and tolerance are normal physiological consequences of extended opioid therapy and are not the same as addiction.)

A recent definition of addiction, adopted by the American Society of Addiction Medicine in 2011, reads as follows: "Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death” [82].

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act [75], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs [83]. Civil and criminal sanctions for serious violations of the statute are part of the government’s drug control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA [75], confers responsibility for scheduling controlled substances on the FDA and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other, but that both are necessary to ensure the public welfare. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

Most opioids are classified as Schedule II or III drugs under the CSA, indicating that they have a high potential for abuse and a currently accepted medical use in treatment in the U.S., and that abuse of the drug may lead to psychological or physical dependence [75]. (Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled substances have some potential for abuse.)

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [76]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (ICD- 10) of the World Health Organization (WHO) [84] and the *Diagnostic and Statistical Manual* (DSM) of the American Psychiatric Association [80,81]. In the DSM-IV-TR, a diagnosis of “substance dependence” meant addiction. In the upcoming DSM V, the term dependence is reestablished in its original meaning of physiological dependence; when symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings [80].

It may be important to clarify this distinction during the informed consent process, so that the patient understands that physical dependence and tolerance are likely to occur if opioids are taken regularly for a period of time, but the risk of addiction is relatively low unless the patient has additional risk factors. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid” [8].

Detoxification: Detoxification (also termed “medically supervised withdrawal”) refers to a gradual reduction, or tapering, of a medication dose over time, under the supervision of a physician, to achieve the elimination of tolerance and physical dependence [85].

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

“Detoxification” is a legal and regulatory term that has fallen into disfavor with some in the medical community; indeed, some experts view “detoxification” as a misnomer because many abusable drugs are not toxic when administered in proper doses in a medical environment [86].

Diversion: The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [75].

Pharmaceuticals that make their way outside this closed system are said to have been “diverted” from the system, and the individuals responsible for the diversion (including patients) are in violation of the law. The degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [30,87].

Maintenance Treatment: Maintenance treatment involves the dispensing or administration of an opioid medication (such as methadone or buprenorphine) at a stable dose and over a period of 21 days or more, for the treatment of opioid addiction. When maintenance treatment involves the use of methadone, such treatment must be delivered in an Opioid Treatment Program (OTP). However, maintenance treatment with buprenorphine may be delivered in either an OTP or a medical office by a properly credentialed physician [7].

Medication-Assisted Treatment (MAT): MAT is any treatment for opioid addiction that includes a medication (such as methadone, buprenorphine, or naltrexone) that is approved by the FDA for opioid detoxification or maintenance treatment. MAT may be provided in a specialized OTP or, for buprenorphine or naltrexone, in a physician’s office or other health care setting [7,55].

Misuse: The term misuse (also termed non-medical use) incorporates all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [56].

Opioid: An opioid is any compound that binds to an opioid receptor. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [7,51,83]. Most physicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader, more appropriate term because it includes the entire class of agents that act at opioid receptors in the nervous system, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM); drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for, including the most common currently used and misused prescription opioids, may well be present in the sample that was analyzed.

Opioid agonists are compounds that bind to the mu opioid receptors in the brain, producing a response that is similar in effect to the natural ligand that would activate it. With full mu opioid agonists, increasing the dose produces an more intense opioid effect. Most opioids that are misused, such as morphine and heroin, are full mu opioid agonists, as is methadone.

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Opioid partial agonists occupy and activate the opioid receptors, but the activation they produce reaches a plateau, beyond which additional opioid doses do not produce a greater effect. It should be noted that the plateau (or “ceiling effect”) may limit a partial agonist’s therapeutic activity as well as its toxicity. Buprenorphine is a partial mu opioid agonist.

Opioid antagonists bind to and block the opioid receptors and prevent them from being activated by an opioid agonist or partial agonist. Naltrexone and naloxone both are opioid antagonists, and both can block the effect of opioid drugs.

Opioid Treatment Program (OTP) (sometimes referred to as a “methadone clinic” or “narcotic treatment program”): An OTP is any treatment program certified by SAMHSA in conformance with 42 Code of Federal Regulations (CFR), Part 8, to provide supervised assessment and medication- assisted treatment of patients who are addicted to opioids. An OTP can exist in a number of settings, including intensive outpatient, residential, and hospital facilities. Treatments offered by OTPs include medication-assisted therapy with methadone, buprenorphine or naltrexone, as well as medically supervised withdrawal or detoxification, accompanied by varying levels of medical and psychosocial services and other types of care. Some OTPs also can provide treatment for co-occurring mental disorders [58].

Recovery: A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential [88]. As used in the ASAM Patient Placement Criteria, “recovery” refers to the overall goal of helping a patient achieve overall health and well-being [56]. SAMHSA’s 10 guiding principles recognize that recovery [89]:

1. Emerges from hope;
2. Is person-driven;
3. Occurs via many pathways;
4. Is holistic;
5. Is supported by peers and allies;
6. Is supported through relationship and social networks
7. Is culturally-based and influenced;
8. Is supported by addressing trauma;
9. Involves individual, family and community strengths and responsibility;
10. Is based on respect.

Relapse: Relapse has been variously defined as “a breakdown or setback in a person’s attempt to change or modify any target behavior” and as “an unfolding process in which the resumption of substance misuse is the last event in a long series of maladaptive responses to internal or external stressors or stimuli” [70]. Relapse rarely is caused by any single factor and often is the result of an interaction of physiologic and environmental factors [59].

The term *lapse* (sometimes referred to as a *slip*) refers to a brief episode of drug use after a period of abstinence. A lapse usually is unexpected, of short duration, with relatively minor consequences, and marked by the patient’s desire to return to abstinence. However, a lapse also can progress to a full-blown relapse, marked by sustained loss of control [56].

Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug’s effects over time [76]. Tolerance may occur both to an opioid’s

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

analgesic effects and to its unwanted side effects, such as respiratory depression, sedation, or nausea. Most investigators agree that absolute tolerance to the analgesic effects of opioids does not occur. In general, tolerance to the side effects of opioids develops more rapidly than does tolerance to the drug's analgesic effects.

Tolerance may or may not be evident during treatment with opioids and is not the same as addiction [70].

Trial Period: A period of time, which can last weeks or even months, during which the efficacy of a medication or other therapy for the treatment of addiction is tested to determine whether the treatment goals can be met. If the goals are not met, the trial should be discontinued and an alternative approach (i.e., a different medication or non-pharmacologic therapy) adopted [76].

Waiver: A documented authorization from the Secretary of Health and Human Services, issued by SAMHSA under the DATA 2000 regulations, that exempts a qualified physician from the rules applied to OTPs and allows him or her to use buprenorphine for the treatment of addiction in office-based practice [51].

REFERENCES

1. Office of National Drug Control Policy (ONDCP). *Epidemic: Responding to America's Prescription Drug Abuse Crisis*. Washington, DC: ONDCP, Executive Office of the President, The White House, 2011.
2. Becker WC, Sullivan LE, Tetrault JM et al. Non-medical use, abuse and dependence on prescription opioids among U.S. adults: Psychiatric, medical and substance use correlates. *Drug and Alcohol Dependence*. 2008 Apr 1;94(1-3):38-47.
3. Arfken CL, Johanson CE, diMenza S et al. Expanding treatment capacity for opioid dependence with buprenorphine: National surveys of physicians. *Journal of Substance Abuse Treatment*. 2010 Sep;39(2):96-104.
4. Gunderson EW & Fiellin DA. Office-based maintenance treatment of opioid dependence: How does it compare with traditional approaches? *CNS Drugs* 2008;22(2):99-111.
5. National Institute on Drug Abuse (NIDA). *Topics in Brief: Medication-Assisted Treatment for Opioid Addiction*. Bethesda, MD: NIDA, National Institutes of Health, April 2012.
6. Korthis PT, Gregg J, Rogers WE et al. Patients' reasons for choosing office-based buprenorphine: Preference for patient-centered care. *Journal of Addiction Medicine*. 2010;4(4):204-210.
7. McNicholas LF, chair, for the CSAT Expert Panel. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol [TIP] Series Number 40. DHHS Publication No. [SMA] 04-3939. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 2004.
8. World Health Organization (WHO). *Guidelines for the Psychologically Assisted Pharmacological Treatment of Opioid Dependence*. Geneva, Switzerland: WHO, 2009
9. Soyka M, Kranzler HR, Van den Brink W et al. The World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for the Biological Treatment of Substance Use and Related Disorders—Part 2: Opioid

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Dependence. *World Journal of Biological Psychiatry*. 2011 Apr;12(3):160-187.

10. Community Care Behavioral Health (CCBH) & Institutes for Research Education and Training in Addictions (IRETA). *Buprenorphine Treatment for Opioid Dependence*. Pittsburgh, PA: CCBH & IRETA, May 2011.

11. O'Connor PG. Advances in the treatment of opioid dependence: Continued progress and ongoing challenges. *Journal of the American Medical Association*. 2010;304:1612-1614.

12. Amato L, Davoli M, Perucci CA et al. An overview of systematic reviews of the effectiveness of opiate maintenance therapies: Available evidence to inform clinical practice and research. *Journal of Substance Abuse Treatment* 2005; 28:321-329.

13. Umbricht A, Huestis M, Cone EJ et al. Effects of high-dose intravenous buprenorphine in experienced opioid abusers. *Journal of Clinical Psychopharmacology*. 2004 Oct;24(5):479-487.

14. Teesson M, Ross J, Darke S et al. One year outcomes for heroin dependence: Findings from the Australian Treatment Outcome Study (ATOS). *Drug and Alcohol Dependence*. 2006 Jun 28;83(2):174-180.

15. Ducharme S, Fraser R, Gill K. Update on the clinical use of buprenorphine in opioid-related disorders. *Canadian Family Physician*. 2012 Jan;58(1):37-41.

16. Gordon AJ, Kunins HV, Rastegar DA et al. Update in addiction medicine for the generalist. *Journal of General Internal Medicine*. 2011;26(1):77-82.

17. Chiang CN & Hawks RL. Pharmacokinetics of the combination tablet of buprenorphine and naloxone. *Drug and Alcohol Dependence*. 2003;70:S39-S47.

18. Bauer SM, Loipl R, Jagsch R et al. Mortality in opioid-maintained patients after release from an addiction clinic. *European Addiction Research*. 2008;14(2):82-91.

19. Gibson AE, Degenhardt LJ, Mattick RP et al. Exposure to opioid maintenance treatment reduces long-term mortality. *Addiction*. 2008;103(3):462-468.

20. Nielsen S, Dietze P, Lee N et al. Concurrent buprenorphine and benzodiazepines use and self-reported opioid toxicity in opioid substitution treatment. *Addiction*. 2007 Apr;102(4):616-622.

21. Sporer KA. [Buprenorphine: A primer for emergency physicians](#). *Annals of Emergency Medicine*. 2004 May;43(5):580-584. Review.

22. Auriacombe M, Lagier G, Mallaret M et al. *French experience with buprenorphine*. In WL Dewey, LS Harris (eds.) *Problems of Drug Dependence, 2002: Proceedings of the 64th Annual Scientific Meeting, The College on Problems of Drug Dependence*. NIDA Research Monograph. 183. National Institutes of Health (NIH) Publication No. 03-5339. Rockville, MD: National Institute on Drug Abuse., 2003.

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

23. Boyer EW, McCance-Katz EF, Marcus S. Methadone and buprenorphine toxicity in children. *American Journal of Addiction*. 2010 Jan-Feb;19(1):89-95
24. Seet RC, Rathakrishnan R, Chan BP et al. Diffuse cystic leukoencephalopathy after buprenorphine injection. *Journal of Neurology, Neurosurgery and Psychiatry*. 2005 Jun;76(6):890-891.
25. Loo HW, Yam AK, Tan TC et al. Severe upper limb complications from parenteral abuse of Subutex. *Annals of the Academy of Medicine of Singapore*. 2005 Oct;34(9):575-578.
26. Albotins CA, Allen P, Daffy JR. Fungal endophthalmitis in intravenous drug users injecting buprenorphine contaminated with oral *Candida* species (Letter). *Medical Journal of Australia*. 2005;182(8):427.
27. Etchepare F, Coutaux A, Edel Y et al. Enterobacter cloacae spondylodiscitis through misuse of high dose intravenous buprenorphine. *Presse Medicines*. 2005; 34(10):725-727.
28. Cazorla C, Grenier de Cardenal D, Schumacher H et al. Infectious complications and misuse of high-dose buprenorphine. *Presse Medicines*. 2005; 34(10):719-724.
29. Diguisto E, Shakeshaft A, Ritter A et al. Serious adverse events in the Australian National Evaluation of Pharmacotherapies for Opioid Dependence (NEPOD). *Addiction* 2004; 99(4):450–460.
30. Johnson CE, Arfken CL, DiMenza S et al. Diversion and abuse of buprenorphine: Findings from national surveys of treatment patients and physicians. *Drug and Alcohol Dependence*. 2012 Jan 1;120(1-3):190-195.
31. Maxwell JC & Wilford BB, for the Substance Abuse and Mental Health Services Administration. *Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators. Final Report*. Silver Spring, MD: JBS International, Inc., 2006.
32. Jaffe JH & O’Keeffe C. From morphine clinics to buprenorphine: Regulating opioid agonist treatment of addiction in the United States. *Drug and Alcohol Dependence*. 2003 May 21;70(2 Suppl):S3-11.
33. Dasgupta N, Kramer ED, Zalman MA et al. Association between non-medical and prescriptive usage of opioids. *Drug and Alcohol Dependence*. 2006 Apr 28;82(2):135-142.
34. Bazazi AR, Yokell M, Fu JJ et al. Illicit use of buprenorphine/naloxone among injecting and noninjecting opioid users. *Journal of Addiction Medicine*. 2011 Sep;5(3):175-180.
35. Johansen CE, Arfken CL, di Menza S et al. Diversion and abuse of buprenorphine: findings from national surveys of treatment patients and physicians. *Drug and Alcohol Dependence*. 2012 Jan 1;120(1-3):190-195.
36. Lofwall MR & Havens JR. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. *Drug and Alcohol Dependence*. 2012 Dec 1;126(3):379-383.
37. Federation of State Medical Boards (FSMB). *Model Policy on Opioid Addiction Treatment in the Medical Office*. Dallas, TX: The Federation, 2002

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

38. O'Brien CP. Toward a rational selection of treatment for addiction. *Current Psychiatry Reports*. 2007 Dec;9(6):441-442.
39. Salsitz EA & Wunsch MJ, for the Physician Clinical Support System for Buprenorphine (PCSS-B). *PCSS-B Guidance on Drug Enforcement Administration Requirements for Prescribers and Dispensers of Buprenorphine and Buprenorphine/Naloxone*. East Providence, RI: American Academy of Addiction Psychiatry, January 25, 2010.
40. Bruce RD. Medical interventions for addictions in the primary care setting. *Topics in HIV Medicine*. 2010 Feb-Mar;18(1):8-12.
41. Barry DT, Irwin KS, Jones ES et al. Integrating buprenorphine treatment into office-based practice: A qualitative study. *Journal of General Internal Medicine*. 2009 Feb;24(2):218-225.
42. Jones ES, Moore BA, Sindelar JL et al. Cost analysis of clinic and office-based treatment of opioid dependence: Results with methadone and buprenorphine in clinically stable patients. *Drug and Alcohol Dependence*. 2009 Jan 1;99(1-3):132-140.
43. Fiellin DA, Moore BA, Sullivan LE et al. Long-term treatment with buprenorphine/naloxone in primary care: Results at 2-5 years. *American Journal on Addiction*. 2008 Mar-Apr;17(2):116-120.
44. Sullivan LE & Fiellin DA. Narrative review: Buprenorphine for opioid-dependent patients in office practice. *Annals of Internal Medicine*. 2008 May 6;148(9):662-670. Review.
45. Walley AY, Alperen JK, Cheng DM et al. Office-based management of opioid dependence with buprenorphine: Clinical practices and barriers. *Journal of General Internal Medicine*. 2008 Sep; 23(9):1393-1398.
46. Finch JW, Kamien JB & Amass L. Two-year experience with buprenorphine-naloxone (Suboxone) for maintenance treatment of opioid dependence within a private practice setting. *Journal of Addiction Medicine* 2007 Jun;1(2):104-110.
47. Magura S, Lee SJ, Salsitz EA et al.. Outcomes of buprenorphine maintenance in office-based practice. *Journal of Addictive Diseases*. 2007;26(2):13-23.
48. Torrington M, Domier CP, Hillhouse M et al. Buprenorphine 101: Treating opioid dependence with buprenorphine in an office-based setting. *Journal of Addictive Diseases*. 2007;26(3):93-99.
49. Gordon AJ, Krumm M, for the Buprenorphine Initiative in the VA (BIV). *Buprenorphine Resource Guide, Version 8*. Washington, DC: Department of Veterans Affairs, April 2008.
50. Meier BR & Patkar AA. Buprenorphine treatment: Factors and first-hand experiences for providers to consider. *Journal of Addictive Diseases*. 2007;26(1).
51. Drug Addiction Treatment Act of 2000 (DATA). *Federal Register* (CFR). Public Law No. 106-310, Title XXXV, Section 3501 and 3502.

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

52. Alford DP, LaBelle CT, Kretsch N et al. Collaborative care in opioid-addicted patients in primary care using buprenorphine. *Archives of Internal Medicine*. 2011;171(5):425-431.
53. Kraus ML, Alford DP, Kotz MM et al. Statement of the American Society of Addiction Medicine Consensus Panel on the Use of Buprenorphine in Office-Based Treatment of Opioid Addiction. *Journal of Addiction Medicine*. 2011 Dec;5(4):254-263.
54. Gourlay D, Heit HA & Caplan Y. *Urine Drug Testing in Clinical Practice*. Stamford, CT: PharmaCom Group, Inc., for the American Academy of Family Physicians, 2010.
55. Amato L, Minozzi S, Davoli M et al. Psychosocial and pharmacological treatments versus pharmacological treatments for opioid detoxification. *Cochrane Database System Review*. 2011 Sept 7;(9):CD005031.
56. Fishman MJ, Mee-Lee D, Shulman G Detal., eds. *Supplement to the ASAM Patient Placement Criteria on the Management of Alcohol Use Disorders*. Baltimore, MD: Lippincott, Williams & Wilkins, Inc., 2010.
57. Lingford-Hughes AR, Welch S, Peters L et al., for the British Association for Psychopharmacology (BAP) Expert Reviewers Group. BAP updated guidelines: Evidence-based guidelines for the pharmacological management of substance abuse, harmful use, addiction and comorbidity: Recommendations from BAP. *Journal of Psychopharmacology*. 2012 July; 26(7):899-952.
58. Center for Substance Abuse Treatment (CSAT). *Substance Abuse: Administrative Issues in Outpatient Treatment*. Treatment Improvement Protocol [TIP] 46. Rockville, MD: CSAT, Substance Abuse and Mental Health Services Administration, 2006.
59. McNicholas L. Clinical guidelines for the use of buprenorphine in the treatment of opioid addiction. *A Tool for Buprenorphine Care*. 2008 May;1(12):12.
60. Gunderson EW, Levin FR, Rombone MM et al. Improving temporal efficiency of outpatient buprenorphine induction. *American Journal on Addiction*. 2011;20:397-404.
61. Baxter LE, chair, for the ASAM Methadone Action Group. *Clinical Guidance on Methadone Induction and Stabilization*. Chevy Chase, MD: American Society of Addiction Medicine, Inc., in press 2013.
62. Joseph H, Stancliff S, Lagrod J. [Methadone maintenance treatment](#) (MMT): A review of historical and clinical issues. *Mt Sinai Journal of Medicine*. 2000 Oct-Nov; 67(5-6):347-64. Review.
63. Marsch LA, Bickel WK, Badger GJ, Jacobs EA. Buprenorphine treatment for opioid dependence: The relative efficacy of daily, twice and thrice weekly dosing. *Drug and Alcohol Dependence*. 2005 Feb 14;77(2): 195-204.
64. Fareed A, Vayalapalli S, Casarella A et al. Effect of buprenorphine dose on treatment outcome. *Journal of Addictive Diseases*. 2012;31(1):8-18
65. Anton RF, O'Malley SS, Ciraulo DA et al., for the COMBINE Study Research Group. [Combined pharmacotherapies and behavioral interventions for alcohol dependence: the COMBINE study: A randomized](#)

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

[controlled trial](#). *Journal of the American Medical Association*. 2006 May 3;295(17):2003-2017.

66. Gordon AJ, Trafton JA, Saxon AJ et al., for the Buprenorphine Work Group of the Substance Use Disorders Quality Enhancement Research Initiative. Implementation of buprenorphine in the Veterans Health Administration: Results of the first 3 years. *Drug and Alcohol Dependence*. 2007 Oct 8;90(2-3):292-296.

67. Stotts AL, Dodrill CL & Kosten TR. Opioid addiction treatment: Options in pharmacotherapy. *Expert Opinions in Pharmacotherapy*. 2009 Aug;10(11):1727-1740.

68. Fiellin DA, Kleber H, Trumble-Hejduk JG et al. Consensus statement on office-based treatment of opioid dependence using buprenorphine. *Journal of Substance Abuse Treatment*. 2004;27:153-159.

69. Fiellin DA, Friedland GH & Gourevitch MN. Opioid dependence: Rationale for and efficacy of existing and new treatments. *Clinics of Infectious Diseases*. 2006 Dec 15;43(Suppl)4:S173-177. Review.

70. Heit HA. Addiction, physical dependence, and tolerance: Precise definitions to help clinicians evaluate and treat chronic pain patients. *Journal of Pain and Palliative Care Pharmacotherapy* 2003;17(1):15-29.

71. Marlatt G & Gordon JR, eds. *Relapse Prevention: Maintenance Strategies in the Treatment of Addictive Behaviors*. New York, NY: Guilford Press, 1985.

72. Fared A, Vayalapalli S, Byrd-Sellers J et al. Safety and efficacy of long-term buprenorphine maintenance treatment. *Addictive Disorders & Their Treatment*. 2011 Sep;10(3):123-130.

73. Batki SL, Kauffman JF, Martion I et al., eds. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol [TIP] 43. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 2005.

74. Stephenson DK, for the CSAM Committee on Treatment of Opioid Dependence. *Draft Guidelines for Physicians Working in California Opioid Treatment Programs*. San Francisco, CA: California Society of Addiction Medicine, 2008.

75. Controlled Substances Act of 1970 (CSA). *Federal Register* (CFR). Public Law No. 91-513, 84 Stat. 1242.

76. Utah Department of Health (UDOH). *Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain*. Salt Lake City, UT: The Department, February 2009.

77. Alliance for Model State Drug Laws (AMSDDL). *State Prescription Monitoring Statutes and Regulations Citation List*. Alexandria, VA: The Alliance, 2006.

78. Brushwood DB. Maximizing the value of electronic prescription monitoring programs. *Journal of Law, Medicine & Ethics* 2003;31:41-54.

79. American Psychiatric Association (APA). *Diagnostic and Statistical Manual of Mental Disorders, Third Edition (DSM-III)*. Washington, DC: American Psychiatric Publishing, Inc., 1980.

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

80. American Psychiatric Association (APA). *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V)*. Washington, DC: American Psychiatric Publishing, Inc., 2013.
81. American Psychiatric Association (APA). *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition-Text Revision (DSM-IV-TR)*. Washington, DC: American Psychiatric Publishing, Inc., 2000.
82. American Society of Addiction Medicine (ASAM). *Definition of Addiction*. Chevy Chase, MD: ASAM, 2011.
83. Drug Enforcement Administration (DEA). Office of Diversion Control. *Physician's Manual: An Informational Outline of the Controlled Substances Act of 1970*. Washington, DC: DEA, U.S. Department of Justice, 1990.
84. World Health Organization (WHO). *International Classification of Diseases, 10th Edition (ICD-10)*. Geneva, Switzerland: WHO, 1996.
85. Amato L, Minozzi S, Davoli M et al. Psychosocial and pharmacological treatments versus pharmacological treatments for opioid detoxification. *Cochrane Database System Review*. 2008a Oct 8;(4):CD005031.
86. Center for Substance Abuse Treatment (CSAT). *Guidelines for the Accreditation of Opioid Treatment Programs, Revised*. Rockville, MD: CSAT, Substance Abuse and Mental Health Services Administration, July 20, 2007.
87. Cicero TJ & Inciardi JA. Potential for abuse of buprenorphine in office-based treatment of opioid dependence. *New England Journal of Medicine*. 2005;353(17):1863-1865.
88. White W. Addiction recovery: Its definition and conceptual boundaries. *Journal of Substance Abuse Treatment*. 2007;33:229-241.
89. Substance Abuse and Mental Health Services Administration (SAMHSA). *SAMHSA's Working Definition of Recovery: 10 Guiding Principles of Recovery*. PEP12-RECDEF. Rockville, MD: SAMHSA, 2012.

PARTICIPANTS ON THE MODEL POLICY ON DATA 2000 AND TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE

Participation by federal agency representatives and third parties was in an advisory capacity only and does not imply endorsement of any draft or final version of the policy

Chair

Janelle Rhyne, MD
Former Board Chair
Federation of State Medical Boards
Cape Fear Health Net Health Net Clinic
Wilmington, North Carolina

Medical Board Representatives

Alfred (Al) Anderson, MD
Member, Minnesota Board of Medicine
Medical Pain Management Ltd.
St. Louis Park, Minnesota

J. Daniel Gifford, MD
Member, Alabama Board of Medicine
Nephrology of North Alabama
Decatur, Alabama

William L. Harp, MD
Executive Director
Virginia Board of Medicine
Richmond, Virginia

Lynn S. Hart
Executive Director
New Mexico Medical Board
Santa Fe, New Mexico

Stancel M. Riley, MD
Executive Director
Massachusetts Board of Registration in Medicine
Wakefield, Massachusetts

Joel B. Rose, DO
Member, Florida Board of Osteopathic Medicine
Tampa, Florida

Dana Shaffer, DO
Member, Iowa Board of Medicine
Exira, Iowa

C. Michael Sheppa, MD
Associate Medical Director
North Carolina Medical Board
Chapel Hill, North Carolina

Rosaire Verna, MD
Member, Maryland Board of Physicians
Easton, Maryland

Advisors to the Work Group

James W. Finch, MD
Director of Physician Education
Governor's Institute on Alcohol and Drug Abuse,
and Medical Director, Changes by Choice, Inc.
Durham, North Carolina

Laura McNicholas, MD, PhD
Clinical Associate Professor of Psychiatry
University of Pennsylvania and
Veterans Administration Medical Center
Philadelphia, Pennsylvania

Eric C. Strain, MD
Professor and Medical Director
Behavioral Pharmacology Research Unit, and
Director, Johns Hopkins Center for Substance Abuse
Treatment and Research
Johns Hopkins University School of Medicine
Baltimore, Maryland

Stephen A. Wyatt, DO
Medical Director, Dual Diagnosis Program
Middlesex Hospital
Old Lyme, Connecticut

Federal Agency Representatives

H. Westley Clark, MD, JD, MPH, CAS, FASAM
Director, Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services
Administration
Rockville, Maryland

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Cathy A. Gallagher
Office of Diversion Control
Drug Enforcement Administration
Arlington, Virginia

Sharon Hertz, MD
Deputy Director
Division of Anesthesia, Analgesia, and
Rheumatology Products
Food and Drug Administration
Silver Spring, Maryland

Regina LaBelle
Deputy Chief of Staff for Policy
Office of National Drug Control Policy
Executive Office of the President, The White
House
Washington, DC

Robert Lubran, M.S., M.P.A.
Director, Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services
Administration
Rockville, Maryland

Sandrine Pirard, MD, PhD, MPH
Medical Advisor, Division of Pharmacologic
Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services
Administration
Rockville, Maryland

Nicholas Reuter, MPH
Team Leader, Certification and Waiver Team
Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services
Administration
Rockville, Maryland

Alina Salvatore, R.Ph., M.A.
Public Health Advisor, Division of
Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services
Administration
Rockville, Maryland

Project Staff: FSMB

Lisa A. Robin
Chief Advocacy Officer
Federation of State Medical Boards
Washington, DC

Project Staff: JBS International

Bonnie B. Wilford, M.S.
Director, Center for Health Services &
Outcomes Research and Senior Principal
JBS International, Inc.
North Bethesda, Maryland

Field Reviewers

Chinazo O. Cunningham, MD, M.S.
*(for the Association for Medical Education and Re-
search in Substance Abuse: AMERSA)*
Associate Professor
Department of Family and Social Medicine
Albert Einstein College of Medicine and
Montefiore Medical Center
Bronx, New York

David A. Fiellin, MD
Professor of Medicine, Investigative Medicine
and Public Health Yale University School of
Medicine
New Haven, Connecticut

Michael H. Gendel, MD
*(for the American Academy of Addiction Psychiatry:
AAAP)*
Private Practice of Psychiatry
Denver, Colorado

Judith A. Martin, MD
*(for the California Society of Addiction Medicine:
CSAM)*
Deputy Medical Director, Community Behavioral
Health Services, and Medical Director of Substance
Abuse Services
Department of Public Health
City and County of San Francisco, California

William Morrone, DO, M.S.
*(for the American Academy of Osteopathic Addiction
Medicine: AOAAM)*
Department of Family Medicine
Central Michigan University
Saginaw, Michigan

Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office

Jennifer McNeely, MD, M.S.
*(for the Society of General Internal Medicine
Substance Abuse Interest Group: SGIM)*
Division of General Internal Medicine
New York University School of Medicine
New York, New York

Michael M. Miller, MD, FASAM, FAPA
Past President, American Society of Addiction
Medicine
Medical Director, Herrington Recovery
Center
Rogers Memorial Hospital
Oconomowoc, Wisconsin

William Morrone, DO, M.S.
*(for the American Academy of Osteopathic Addiction
Medicine: AOAAM)*
Department of Family Medicine
Central Michigan University
Saginaw, Michigan

John D. Patz, DO, FAAFP, FASAM, ABAM
*(for the American Academy of Osteopathic Addiction
Medicine: AOAAM)*
Behavioral Health Unit
PRMC Everett
Everett, Washington

Darius A. Rastegar, MD
*(for the Society of General Internal Medicine
Substance Abuse Interest Group: SGIM)*
Associate Professor of Medicine
Johns Hopkins University School of Medicine
Baltimore, Maryland

John A. Renner, Jr., MD
(for the American Psychiatric Association: APA)
Associate Professor of Psychiatry
Boston University School of Medicine
Boston, Massachusetts

Richard N. Rosenthal, MD
*(for the American Academy of Addiction Psychiatry:
AAAP)*
Arthur J. Antenucci Professor of Clinical
Psychiatry Chairman, Department of Psychiatry
St. Luke's Roosevelt Hospital Center, and Senior
Associate Dean for the St. Luke's Roosevelt

Hospital Affiliation
New York, New York

Andrew J. Saxon, MD
(for the American Psychiatric Association: APA)
Department of Psychiatry
University of Washington Puget Sound
Seattle, Washington

Joanna L. Starrels, MD, M.S.
*(for the Association for Medical Education and Re-
search in Substance Abuse: AMERSA)*
Division of General Internal Medicine
Albert Einstein College of Medicine
and Montefiore Medical Center
Bronx, New York

Jeanette Tetrault, MD
*(for the Society of General Internal Medicine
Substance Abuse Interest Group: SGIM)*
Department of Internal Medicine
Yale University School of Medicine
New Haven, Connecticut

Alexander Walley, MD, M.Sc.
*(for the Society of General Internal Medicine
Substance Abuse Interest Group: SGIM)*
Assistant Professor of Medicine
Boston University School of Medicine, and
Medical Director, Opioid Treatment Program
Boston Public Health Commission, and
Medical Director, Opioid Overdose Prevention
Program
Massachusetts Department of Public Health
Boston, Massachusetts

Norman Wetterau, MD, FASAM
*(for the Society of Teachers of Family Medicine:
STFM)*
University of Rochester/Highland Hospital
Tricounty Family Medicine
Nunda, New York