

**Model Policy on
the Use of Opioid
Analgesics in the
Treatment of
Chronic Pain**

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MODEL POLICY ON THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

INTRODUCTION

The Federation of State Medical Boards (FSMB) is committed to assisting state Medical Boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, the use of opioid analgesics. [1]. The FSMB updated its guidelines in 2003 [2] so that its Model Policy would reflect the best available evidence on management of pain and give adequate attention to both the undertreatment and overtreatment of pain and the inappropriate use of opioid analgesics.

Through these initiatives, the FSMB has sought to provide a resource for use by state medical boards in educating their licensees about cautious and responsible prescribing of controlled substances while alleviating fears of regulatory scrutiny. The FSMB recognizes that inappropriate prescribing can contribute to adverse outcomes such as reduced function, opioid addiction, overdose, and death [3-5]. By promulgating its Model Policies, the FSMB has sought to provide a framework for the legitimate medical use of opioid analgesics for the treatment of pain while emphasizing the need to safeguard against their misuse and diversion.

Since their publication, the 1998 and 2004 Model Policies have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The policies have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted all or part of the Model Policies.¹

The updated Model Policy presented here reflects the considerable body of research and experience accrued since the 2004 revision was adopted [2]. While recognizing that adequate evidence is currently lacking as to the effectiveness and safety of long-term opioid therapy, this Model Policy is designed to promote the public health by encouraging state medical boards to adopt consistent policy regarding the treatment of pain, particularly chronic pain, and to promote patient access to appropriate pain management and, if indicated, substance abuse and addiction treatment. The Model Policy emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate. It also includes references and the definitions of key terms used in pain management.

¹ As of March 7, 2012, 57 of 70 State Medical Boards have policy, rules, regulations or statutes reflecting the Federation's 1997 or 2004 *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.

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The FSMB encourages every state medical board to work with the state attorney general to evaluate the state's policies, regulations and laws in an effort to identify any barriers to the effective and appropriate use of opioids to relieve pain, while ensuring that adequate safeguards are in place to deter and rapidly detect those who would obtain opioid analgesics for nonmedical purposes [6-7].

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

ISSUES ADDRESSED IN THE NEW MODEL POLICY

There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated [8-10]. Since the 2004 revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffers from pain so intense as to interfere with the activities of daily living [4]. Pain arises from multiple causes and often is categorized as either *acute pain* (such as that from traumatic injury and surgery) or *chronic pain* (such as the pain associated with terminal conditions such as cancer or severe vascular disease or with non-terminal conditions such as arthritis or neuropathy) [4,8]. This model policy applies most directly to the treatment of chronic pain and the use of opioid analgesics but many of the strategies to improve appropriate prescribing and mitigate risks can be applied to the use of other controlled medications and to the treatment of acute pain.

Undertreatment of pain is recognized as a serious public health problem that compromises patients' functional status and quality of life [4,9]. A myriad of psychological, social, economic, political, legal and educational factors—including inconsistencies and restrictions in state pain policies—can either facilitate or impede the ability and willingness of physicians to manage patients with pain [6,10-11].

While acknowledging that undertreatment of pain exists, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment [4,8,12]. Indeed, some cases of intractable pain actually result from overtreatment in terms of procedures and medications.

Complicating the picture, adverse outcomes associated with the misuse, abuse and diversion of prescription opioids have increased dramatically since the FSMB's last review [3]. Physicians and other health care professionals have contributed—often inadvertently—to these increases.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioids by physicians may include: (1) physician uncertainty or lack of knowledge as to prevailing best clinical practices; (2) inadequate research into the sources of and treatments for pain; (3) sometimes conflicting clinical guidelines for appropriate treatment of pain; (4) physician concerns that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; (5) physician misunderstanding of causes and manifestations of opioid dependence and addiction; (6) fear on the part of physicians of causing addiction or being deceived by a patient who seeks drugs for purposes of misuse; (7) physicians practicing outside the bounds

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of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and (8) inadequate physician education about regulatory policies and processes [3-4,12,14-20]. Inappropriate treatment also can result from a mistaken belief on the part of patients and their physicians that complete eradication of pain is an attainable goal, and one that can be achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

Patients share with physicians a responsibility for appropriate use of opioid analgesics [21-22]. This responsibility encompasses providing the physician with complete and accurate information and adhering to the treatment plan. While many patients take their medication safely as prescribed and do not use opioids problematically, some patients—intentionally or unintentionally—are less than forthcoming or have unrealistic expectations regarding the need for opioid therapy or the amount of medication required. Other patients may begin to use medications as prescribed, then slowly deviate from the therapeutic regimen. Still others may not comply with the treatment plan because they misunderstood the physician's instructions. Some patients share their drugs with others without intending harm (a pattern of misuse that is seen quite often among older adults [15]). Then there are patients who deliberately misuse or are addicted to opioids, and who mislead, deceive or fail to disclose information to their physicians in order to obtain opioids to sustain their addiction and avoid withdrawal [19-23].

Patients often leave medications unsecured where they can be stolen by visitors, workers and family members, which is another important source of diversion. Thus a prescription that is quite appropriate for an elderly patient may ultimately contribute to the death of a young person who visits or lives in the patient's home. Therefore, the physician's duty includes not only appropriate prescribing of opioid analgesics, but also appropriate education of patients regarding the secure storage of medications and their appropriate disposal once the course of treatment is completed [18,23].

A more problematic individual is the criminal patient, whose primary purpose is to obtain drugs for resale. Whereas many addicted patients seek a long-term relationship with a prescriber, criminal patients sometimes move rapidly from one prescriber (or dispenser) to another. Such individuals often visit multiple practitioners (a practice sometimes characterized as "doctor shopping") and travel from one geographic area to another not for the purposes of relief of legitimate pain but in search of unsuspecting targets [19-21]. Physicians' attention to patient assessment and the routine use of state prescription drug monitoring programs (PDMPs), where available, have been cited as effective ways to identify individuals who engage in such criminal activities [20-23,45].

Conclusion: The goal of this Model Policy is to provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:

- **Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain:** Not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.
- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional

behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.

- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the physician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances or certain condition (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- **Unjustified dose escalation without adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.
- **Excessive reliance on opioids, particularly high dose opioids for chronic pain management:** Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic non-cancer pain only when safer and reasonably effective options have failed. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.
- **Not making use of available tools for risk mitigations:** When available, the state prescription drug monitoring program should be checked in advance of prescribing opioids and should be available for ongoing monitoring.

In addition, the Model Policy is designed to communicate to licensees that the state medical board views pain management as an important area of patient care that is integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that physicians will not be sanctioned solely for prescribing opioid analgesics or the dose (mg./mcg.) prescribed for legitimate medical purposes. However, prescribers must be held to a safe and best clinical practice. The federal Controlled Substances Act [25] defines a “lawful prescription” as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on physicians a responsibility to minimize the potential for misuse, abuse and diversion of opioids and all other controlled substances.

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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 (name of Board) recognizes that principles of high-quality medical practice dictate that the people of the State of (name of state) have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41, 80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

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Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

SECTION II: GUIDELINES

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For

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example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted

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to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance [21-23]. With all patients, the physician’s decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician’s own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community [21-23].

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient’s pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient’s surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a “treatment contract”) is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician’s prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician’s policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

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Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating Opioid Therapy: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29]and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial

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risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

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If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of

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treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, 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 [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

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 [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (*any relevant documents issued by the state medical board*).

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SECTION III: DEFINITIONS

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

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors" [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "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 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" [40].

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes 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. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (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. 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.

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The CSA does *not* limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in *Schedules II or III* under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications 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 [28]. 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 [70], and the *Diagnostic and Statistical Manual (DSM)* of the American Psychiatric Association [71]. 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 [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. 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” [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. 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 [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been “diverted” [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that 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 [17,19,74].

Misuse: The term *misuse* (also called *nonmedical use*) encompasses 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 [28].

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Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

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 term because it includes the entire class of agents that act at opioid receptors in the CNS, 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 be present in the sample that was analyzed [53,59-260].

Pain: An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic non-cancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

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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. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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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

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Model Policy for the Use of Opioid Analgesics In the Treatment of Chronic Pain

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

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

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

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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, ~~LAAMI~~, 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).

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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.¹ 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 | 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.

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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].

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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,

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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.

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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].

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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].

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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

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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].

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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

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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

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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].

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“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.

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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

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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].

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