

Guidelines for the Chronic Use of Opioid Analgesics

*Adopted as policy by the Federation of State Medical Boards
April 2017*

INTRODUCTION

In April 2015, the Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to review the current science for treating chronic pain with opioid analgesics and to revise the Model Policy as appropriate.

To accomplish this charge, the workgroup conducted a thorough review and analysis of FSMB's existing policy document and other state and federal policies on the prescribing of opioids in the treatment of pain, including the March 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (<https://www.cdc.gov/drugoverdose/prescribing/guideline.html>)

In updating its existing policy, the FSMB sought input from a diverse group of medical and policy stakeholders that ranged from experts in pain medicine and addiction to government officials and other thought leaders. Over the course of the last 12 months, the workgroup met on several occasions to examine and explore the key elements required to ensure FSMB's policy document remains relevant and is sufficiently comprehensive to serve as a prescribing guideline and resource for state medical and osteopathic boards and clinicians.

This policy document includes relevant recommendations identified by the workgroup, and is in keeping with recent releases of advisories issued by the CDC and FDA. This policy is intended as a resource providing overall guidance to state medical and osteopathic boards in assessing physicians' management of pain in their patients and whether opioid analgesics are used in a medically appropriate manner.

FSMB GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS

Section 1 – PREAMBLE

The diagnosis and treatment of pain is integral to the practice of medicine^{2,18-21}. In order to implement best practices for responsible opioid prescribing, clinicians must understand the relevant pharmacologic and clinical issues in the use of opioid analgesics and should obtain sufficient targeted continuing education and training on the safe prescribing of opioids and other analgesics as well as training in multimodal treatments.

Section 2 – FOCUS OF GUIDELINES

The focus of the Guidelines that follow is on the general overall safe and evidence-based prescribing of opioids and treatment of chronic, non-cancer pain with the specific **limitation and restriction** that these Guidelines do not operate to create any specific standard of care, which standard must depend upon fact-specific totality of circumstances surrounding specific quality-of-care events. The Guidelines recognize that there is not just one appropriate strategy to accomplish the goals of these Guidelines. Effective means of achieving the goals of these Guidelines vary widely depending on the type and causes of the patient's pain, the preferences of the clinician and the patient, the resources available at the time of care, and other concurrent issues beyond the scope of these Guidelines.

These Guidelines that follow do not encourage the prescribing of opioids over other pharmacological and nonpharmacological means of treatment but rather the Guidelines recognize the responsibility of clinicians to view pain management as essential to quality of medical practice and to the quality of life for patients who suffer from pain.

Finally, the Guidelines that follow are not intended for the treatment of acute pain, acute pain management in the perioperative setting, emergency care, cancer-related pain, palliative care, or end-of-life care. These Guidelines may apply most directly to the treatment of chronic pain lasting more than three months in duration or past the time of normal tissue healing, however many of the strategies mentioned here are also relevant to responsible prescribing and the mitigation of risks associated with other controlled substances in the treatment of pain.

Section 3 – DEFINITIONS

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

Aberrant Behaviors: Certain behaviors may constitute aberrant behaviors. For example, obtaining prescriptions for the same or similar drugs from more than one clinician or other health care provider without the treating clinician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a pattern of drug use that exists despite adverse consequences or risk of consequences. Abuse of a prescription medication involves its use in a manner that deviates from accepted medical, legal, and social standards, generally to achieve a euphoric state ("high") or that is other than the purpose for which the medication was prescribed¹⁴. Please also see "Substance Use Disorder".

Addiction: A common definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors"¹⁴. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm¹⁴. 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"²⁴. (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.) Please also see "Substance Use Disorder".

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA)¹³, 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.

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 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, all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist¹⁴. 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 Behavioral Disorders, 10th Edition* (ICD-10) of the World Health Organization⁵⁰, and the *Diagnostic and Statistical Manual (DSM)* of the American Psychiatric Association⁵¹, In the DSM-IV-TR, a

diagnosis of “substance dependence” meant addiction. In the DSM-5, 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 ratings⁴⁹.

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”⁵⁰. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction^{51,52}. Please also see "Substance Use Disorder".

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution⁵³⁻⁵⁴. 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^{13,55}.

Pharmaceuticals that make their way outside this closed distribution system are said to have been “diverted”⁵⁵, and the individuals responsible for the diversion (including patients) are in violation of federal law, and often corresponding state laws as well.

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^{7,8,54}.

Misuse: The term misuse (also called nonmedical use) encompasses all uses of a prescription medication other than those that are directed by a clinician and used by a patient within the law and the requirements of good medical practice¹⁴. Please also see "Substance Use Disorder".

Opioid: An opioid is an opium-like compound that binds to one or more of the three opioid receptors of the body. The class includes naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides¹⁹. Most clinicians 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^{34,40-41}.

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 less². *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 cancer and does not occur at the end of life^{2,56}. *Opioid-induced hyperalgesia* may develop as a result of long-term opioid use in the treatment of 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 treatment⁵⁷.

Prescription Drug Monitoring Program: As a patient safety tool, 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^{1,12}. After analyzing the efficacy of PDMPs, the Government Accountability Office (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, overdose, and diversion by allowing clinicians to determine whether a patient is receiving prescriptions for controlled substances from other clinicians, as well as whether the patient has filled or refilled an order for an opioid the clinician has prescribed^{12,58-59}.

Substance Use Disorder: In the DSM-5, Substance Use Disorder encompasses what was previously classified as abuse, dependence, misuse, and tolerance. Under the DSM-5 definition of Substance Use Disorder a patient needs to meet any 2 of 11 criteria in the same 12 months. The severity is based on the number of criteria (i.e., mild is 2-3 criteria, moderate is 4-5 criteria, and severe is 6 or more criteria). Criteria are grouped into impaired control (i.e., taken in larger amounts or over longer time than was intended; persistent desire or unsuccessful efforts to cut down or control use; great deal of time spent in activities to obtain, use or recover from its effects; craving or strong desire to use); social impairment (i.e., use resulting in a failure to fulfill major role obligations at work, school, or home; continued use despite persistent or recurrent social or interpersonal problems caused by the use; important social, occupational, or recreational activities are given up or reduced due to use); risky use (i.e., recurrent use in situations in which it is physically dangerous; use despite knowledge of having a persistent physical or psychological problem that is caused or exacerbated by use); and pharmacological properties (i.e., tolerance; withdrawal).

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 and is not the same as addiction¹⁴. Please also see "Substance Use Disorder".

Section 3 - FSMB GUIDELINES

State medical boards may adopt the following criteria for use in evaluating a clinician's management of a patient with pain, including the clinician's prescribing of opioid analgesics. Such adoption is subject to the **Guidelines, Limitations and Restrictions** previously set forth.

Patient Evaluation and Risk Stratification

The medical record should document the presence of one or more recognized medical indications and absence of psychosocial contraindications for prescribing an opioid analgesic³ and reflect an appropriately detailed patient evaluation²². An evaluation should be completed and documented concurrent with the decision of 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. Assessment of the patient's pain should 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 functioning¹⁷.

For every patient, the initial assessment and evaluation should include a systems review and relevant physical examination, as well as objective markers of disease or diagnostic markers as indicated. Also, functional assessment, including social and vocational assessment, is useful in identifying supports and obstacles to treatment and rehabilitation.

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for substance use disorder also should be part of the initial evaluation^{5,6,9-11,27}, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics³⁷⁻³⁹. This can be done through a careful clinical interview, which should also inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance use disorder¹⁷. Use of validated screening tools for substance use disorder may be used for collecting and evaluating information and determining the patient's level of risk.

Patients who have a history of substance use disorder as defined by DSM-5 are at an elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for relapse. Treatment of a patient who has a history of substance use disorder may involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up, as needed). Additionally, patients who have a substance use disorder as defined by the DSM-5, require additional support if opioid therapy is necessitated and should not receive opioid therapy until they are established in a treatment/recovery program¹⁷ or alternatives are established, such as co-management with an addiction professional. Clinicians who treat patients with chronic pain are encouraged to also be knowledgeable about the identification and treatment of substance use disorder, including the

role of replacement agonists such as methadone and buprenorphine. Some non-addiction specialist clinicians may choose to directly treat patients with substance use disorder. This may include becoming eligible to treat substance use disorder using office-based buprenorphine as part of medication-assisted treatment.

Assessment of the patient's personal and family history of mental health disorders should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics. 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 disorders are at increased risk for misuse or abuse of controlled medications, including addiction and overdose. Additionally, untreated depression can interfere with the resolution of pain.

The patient evaluation may include information from family members and/or significant others^{10-11,31-32}. It is strongly recommended that the state prescription drug monitoring program (PDMP) be consulted prior to initiating opioid therapy and at appropriate intervals thereafter to determine whether the patient is receiving prescriptions from any other clinicians, and the results obtained from the PDMP should be reviewed.

In working with a patient who is taking opioids prescribed by another clinician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance⁹⁻¹¹. Therefore, to ensure a smooth transition of care, clinicians are encouraged to collaborate with the primary prescriber.

Caution should be used with the administration of chronic opioids in women of childbearing age, as chronic opioid therapy during pregnancy increases risk of harm to the newborn. Opioids should be administered with caution in breastfeeding women, as some opioids may be transferred to the baby in breast milk. When chronic opioid therapy is used for an elderly patient, clinicians should carefully consider the initial dose, titrating slowly upwards if necessary, using a longer dosing interval, and monitoring more frequently. Patients at risk for sleep disordered breathing are at increased risk for harm with the use of chronic opioid therapy. Clinicians should consider the use of a screening tool for obstructive sleep apnea and refer patients for proper evaluation and treatment when indicated.

The patient evaluation should include most of the following elements:

- Medical history and physical examination targeted to the pain condition
- Nature and intensity of the pain
- Current and past treatments, including interventional treatments, with response to each treatment
- Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e. obesity, renal disease, sleep apnea, COPD, etc.)
- Effect of pain on physical and psychological functioning
- Personal and family history of substance use disorder
- History of psychiatric disorders (bipolar, ADD/ADHD, sociopathic, borderline, major depressive disorder)

- Post-traumatic stress disorder (PTSD)
- Medical indication(s) for use of opioids
- Review of the PDMP results
- Obtain consultation with other clinicians when applicable
- Urine, blood or other types of biological samples and diagnostic markers

Development of a Treatment Plan and Goals

The goals of pain treatment include reasonably attainable improvement in pain to decrease suffering and to increase function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; screening for side effects of treatment; and avoidance of unnecessary or excessive use of medications^{2,4}. There should be a balance between monitoring for efficacy and side effects with the use of medications for the shortest duration appropriate.

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 therapies²² for both the clinician and the patient.

The treatment plan may contain information supporting the selection of therapies, both pharmacologic (medications other than opioids to include anti-inflammatories, acetaminophen, and selected antidepressants and anticonvulsants) interventional, and non-pharmacologic therapies such as cognitive behavioral therapy, massage, exercise, multimodal pain treatment, and osteopathic manipulative treatment. The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered to the extent they are available.

Informed Consent and Treatment Agreement

The decision to initiate chronic opioid therapy is a shared decision between the clinician and the patient. The clinician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient. If opioids are prescribed, the patient (and possibly family members) should be counseled on the potential risks and anticipated benefits, adverse effects of opioids, including but not limited to dependence, substance use disorder, overdose and death, as well as the safe ways to store and dispose of medications.

Use of a written informed consent and treatment agreement is recommended for long-term chronic opioid therapy^{9-11,19,22}. Treatment agreements outline the joint responsibilities of the clinician and patient, including the patient's agreement to periodic and unannounced drug testing for opioids and other medications when deemed appropriate by the clinician with potential for substance use disorder as well as discuss with the patient how and when the PDMP will be reviewed as part of the patient's care.

Informed consent may address:

- Limited evidence as to the benefit of opioids or other pharmaceutical therapies in the management of chronic pain (except for cancer)

- Potential risks and benefits of opioid therapy
- Potential side effects (both short and long term), such as cognitive impairment and constipation
- The likelihood that tolerance to and physical dependence on the medication will develop
- Risk of drug interactions and over-sedation
- Risk of impaired motor skills (affecting driving and other tasks)
- Risk of substance use disorder, overdose and death
- The clinician's prescribing policies and expectations, including the number and frequency of prescription refills, early refills and replacement of lost or stolen medications
- Reasons for which drug therapy may be changed or discontinued (including violation of the treatment agreement) or that treatment may be discontinued without agreement by the patient.
- Education of the patient that the complete elimination of pain is not to be expected.

Treatment agreements outline the joint responsibilities of the clinician and patient¹⁹⁻²¹ and are indicated for opioid or other medications with potential for substance use disorder. It is strongly recommended that treatment agreements include:

- Treatment goals in terms of pain management, restoration of function and safety
- Patient's responsibility for safe medication use (not taking more than prescribed; dangers of using in combination with alcohol, cannabis, or other substances like benzodiazepines unless closely monitored by the prescriber, etc.)
- Secure storage and safe disposal
- Patient's responsibility to obtain prescribed opioids from only one clinician or practice
- Patient's responsibility of getting the prescriptions filled at only one pharmacy
- Patient's agreement to periodic drug testing
- Clinician's responsibility to be available or to have a covering clinician available to care for unforeseen problems and to prescribe scheduled refills.

Clinicians are recommended to refrain from referring patients to the emergency department to obtain prescriptions for opioids for chronic pain that is not cancer-related or as part of palliative care or end-of-life care.

Initiating an Opioid Trial

Non-opioid and non-pharmacologic treatments should be considered before initiating opioid therapy for chronic or acute pain lasting beyond the expected duration.

When a decision is made to initiate opioid therapy, it should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 30 days) and with specified evaluation points including improvement in pain and function.

The clinician 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 safety³³.

As noted by the FDA, when initiating opioid therapy for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, it is highly recommended that the lowest dose possible be given, beginning with a short acting opioid and/or rotating to a long acting/extended release, if indicated. Prescribers may download a medication guide of all extended-release opioids for patients at <http://www.accessdata.fda.gov/scripts/cder/daf/>. A patient counseling document available in English and Spanish through the extended-release, long-acting Risk Evaluation and Mitigation Strategy (REMS) is also available for download at <http://www.er-la-opioidrems.com/lwgUI/remis/pcd.action>.

The concurrent use of benzodiazepines and opioids, recently added as a Black Box warning by the FDA, greatly increases the risk of adverse events including death. Given this increased risk, clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

While there is clinical variation in response by patients to opioid therapy at any given dosage, the CDC and some states have recommended specific dosing guidelines for opioids. Clinicians need to be aware that increasing opioid dosage beyond the current recommended guidelines may result in increased risk for substance use disorder and/or diversion. A clinician should clearly state in the medical records the rationale for using higher dosages than the current recommended guidelines, recognizing that genetic variations can significantly alter drug response, and monitor those patients prescribed such a dose with increased vigilance to assure the risks of diversion and/or overdose are minimized. The clinician should also be aware that maximum benefit to the patient may have already been obtained and increasing the dosage may not result in further therapeutic benefit, and can result in harm to the patient. Referral to, or consultation with a pain specialist for patients on higher than recommended dosages, may be considered, and dosages should not be escalated without re-evaluation of the benefits and risks.

Before prescribing methadone for its analgesic effect, it is strongly recommended that clinicians have specific training and/or experience as individual responses to methadone vary widely increasing the risk of overdose. There is a complex relationship between dose, half-life, duration of analgesic effect, and duration of respiratory depression. Specifically, the duration of analgesic effect is generally shorter than the duration of respiratory depression. The long half-life of methadone and the longer duration of respiratory depression relative to analgesia places patients at risk for overdose when titrating methadone dose for pain management.

Clinicians should consider co-prescribing naloxone for home use for all patients with opioid prescriptions in case of accidental or intentional overdose by the patient or household contacts. Patients at greatest risk of overdose include patients with a history of substance use disorder, history of prior overdose, clinical depression, patients who are taking opioids with other central nervous system depressants, or when evidence of increased risk by other measures exists (behaviors, family history, PDMP, risk assessment results).

Ongoing Monitoring and Adapting the Treatment Plan

The clinician 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^{19,31-32}. When possible, collateral information about the patient's response to opioid therapy may be obtained from family members or other close contacts, as well as review of the state PDMP. The patient may be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted²⁶⁻³³. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled as indicated by stability and risk level. Monitoring plans for a given patient should take into account the generally increased risk for dependence developing a substance use disorder and misuse the longer the patient uses them.

Continuation, modification or termination of opioid therapy for pain is contingent on the clinician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as signs of substance use disorder and/or diversion^{9-11,27}. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life¹⁵. Information from family members or other caregivers may be considered in evaluating the patient's response to treatment^{6,19-20}. Use of measurement tools to assess the patient's level of pain, function, and quality of life may be helpful in documenting therapeutic outcomes^{6,31}.

Periodic and Unannounced Drug Testing

Periodic and unannounced drug testing (including chromatography) are useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs³⁴⁻³⁵. Drug testing is an important monitoring tool because self-reporting of medication use is not always reliable and behavioral observations may detect some problems but not others³⁶⁻⁴⁰. It is strongly recommended that patients being treated for addiction 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 testing³⁴. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place. Collection is preferably observed especially in pain clinics; however, chain-of-custody protocols are not followed. To help ensure a valid specimen, the urine should be warm and urine specific gravity and creatinine should be measured. 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 metabolites³⁴. In drug testing in a pain practice, it is important to identify the specific drug and metabolites, not just the class of the drug.

Clinicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately³⁵. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed³⁴. 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 pathologist⁴⁰⁻⁴¹.

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 point of care testing may not be appropriate for making definitive changes in medication management in populations at high risk for adverse outcomes until the results of confirmatory testing with more accurate methods such as liquid chromatography tandem mass spectrometry (LC-MS/MS) are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in substance use disorder treatment settings found very high rates of “false negatives and positives”^{34,60}.

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). It is recommended that both the test results and subsequent discussion with the patient be documented in the medical record³⁴.

Adapting Treatment

As noted earlier, clinicians are encouraged to consult the state’s PDMP before initiating opioids for pain and during ongoing therapy. A PDMP is important in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers, and patients who may be at increased risk for overdose^{9-11,36,42}.

If the patient’s progress is unsatisfactory, the clinician 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^{19-21,42-43}.

Evidence of misuse of prescribed opioids demands prompt evaluation by the clinician, including assessment for opioid use disorder or referral to a substance use disorder treatment specialist for such assessment, and arranging for evidence-based treatment of opioid use disorder if present. 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 clinician’s knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors¹¹.

When a drug test shows the presence of illicit drugs or drugs not prescribed by a clinician, this requires action on the part of the clinician. Some aberrant behaviors are more closely associated with substance use disorder. Of greatest concern is a pattern of behavior that suggests substance use disorder, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan⁴⁴.

Documented drug diversion or prescription forgery, and abusive or assaultive behaviors require a firm, immediate response^{10-11,22,28}, which may include properly discharging a patient from the clinician's practice. 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^{11,45-47}.

Consultation and Referral

It is important to consider referral to an interdisciplinary pain management program which includes modalities such as interventional pain management, physical and occupational therapy, acupuncture, or other non-pharmacologic therapies to avoid unnecessary reliance on opioids as the sole therapy for chronic or complex pain issues.

Specialty consultation should be considered if diagnosis and/or treatment for the condition manifesting as pain is outside the scope of the clinician's comfort with dosing requirements. Opioid dose level, in and of itself, does not indicate a referral. However, there is some risk associated with higher doses, and therefore, that may be an indication for consultation, depending on the clinician's training, resources and comfort level. The treating clinician, if possible, should seek a consultation with, or refer the patient to a pain, psychiatric, addiction or mental health specialist as needed.

Clinicians should be aware of treatment options for opioid use disorder and addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced clinician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed^{11,17,21,23}.

Discontinuing Opioid Therapy

Throughout the course of opioid therapy, the clinician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate²⁸.

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 use¹⁰⁻¹¹.

Discontinuing or tapering of opioid therapy may be required for many reasons, and ideally, clinicians will have an end strategy for patients receiving opioids at the outset of treatment. 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, failure to achieve expected pain relief or functional improvement, failure to comply with the treatment agreement, or significant aberrant medication use, including signs of addiction. Additionally, clinicians should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

If opioid therapy is discontinued, the patient who has become physically dependent should be provided a safely structured tapering regimen. Withdrawal can be managed either by the prescribing clinician or by referring the patient to an addiction specialist⁴³. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate⁹⁻¹¹.

Discontinuing opioids is not an easy process for some patients; therefore, a referral may be needed as clinicians have an obligation to provide transition therapy in order to minimize adverse outcomes.

Medical Records

Every clinician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following:^{10, 11,22,25-26}

- 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.
- Results of queries to the state PDMP.
- 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^{9-11,16,22,27,48}. 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 record¹³. The name, telephone number, and address of the patient's primary pharmacy should also be recorded to facilitate contact as needed¹¹. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review¹³.

Compliance with Controlled Substance Laws and Regulations

To prescribe, dispense or administer controlled substances, the clinician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations¹³.

Clinicians 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).

Section 4 – CONCLUSION

The goal of this Model Policy is to provide state medical and osteopathic boards with an updated guideline for assessing a clinician's 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 appropriate management of pain, particularly as related to the prescribing of opioid analgesics may include the following:

- **Adequate 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.
- **Adequate monitoring during the use of potentially abusable medications:** Opioids may be associated with substance use disorder and other dysfunctional behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.
- **Adequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain is a shared decision of the clinician 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 (such as benzodiazepines, alcohol, cannabis, or other central nervous system depressants) or certain conditions (e.g., sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- **Justified dose escalation with 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.
- **Avoid excessive reliance on opioids, particularly high dose opioids for chronic pain management:** It is strongly recommended that prescribers be prepared for risk

management with opioids in advance of prescribing, and should use opioid therapy for chronic pain that is not cancer-related, or part of palliative care or end-of-life care, only when non-opioid and non-pharmacological options have not been effective. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.

- **Utilization of available tools for risk mitigations:** The state prescription drug monitoring program should be checked in advance of prescribing opioids and should be utilized for ongoing monitoring.

GUIDELINES FOR THE CHRONIC USE OF OPIOID ANALGESICS

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