Strategies for Prescribing Opioids for the Management of Pain

INTRODUCTION

Since 2017, when the Federation of State Medical Boards (FSMB) adopted the document entitled *Guidelines for the Chronic Use of Opioid Analgesics,* new evidence has emerged regarding the risks and benefits associated with prescription opioid therapy, as well as risk mitigation strategies and patient harm associated with tapering and discontinuation of opioid therapy. Although overall prescriptions by clinicians for opioids decreased by more than 44% between 2011 and 2020, the drug-related overdose and death epidemic continues to be a leading public health priority in the United States, with overdose deaths rising to more than 107,000 in 2022. This is due in part to a marked increase in the use of illicit and synthetic opioids, most notably fentanyl, putting an increased focus among stakeholders and policymakers on harm-reduction strategies. At the same time, pain is one of the most common reasons patients present to healthcare providers, and national surveys indicate that one in five adults in the U.S. have chronic pain, underscoring the public health importance of evidence-based pain care.[1] Data have also emerged revealing disparities in access to pain care for certain populations, including historically minoritized and marginalized populations, women and patients residing in rural and underserved areas. Certain patients may also be at risk for inadequate pain treatment, including older patients, patients with cognitive impairment, those with substance use and mental disorders, sickle cell disease, cancer and patients at the end of life.[2] Despite earnest efforts to improve pain management and mitigate associated risks, the responsible and appropriate prescribing of opioids continues to be a lingering challenge for state medical boards, clinicians and patients.

To address these issues, in April 2022, FSMB Chair Sarvam P. TerKonda, MD, appointed the Workgroup on Opioid and Addiction Treatment to undertake a comprehensive review of FSMB recommendations related to opioids and update them as appropriate, with the goal of advancing pain care and improving the safe and appropriate prescribing of opioids for pain, eliminating stigmatizing language, and emphasizing that decisions regarding pain care should be shared between clinician and patient and individualized. In completing its work, the Workgroup conducted a thorough review and analysis of FSMB's existing opioid-related policies, related state and federal guidelines and policies, guidance documents from selected medical specialty organizations (e.g., the American Society of Addiction Medicine, American College of Obstetricians and Gynecologists) and a targeted literature review. Workgroup members included board members and staff who serve on state medical and osteopathic boards, health

[1] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[2] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

professionals from academia, and representatives of the National Association of Boards of Pharmacy, the National Council of State Boards of Nursing, the American Association of Dental Boards, the Centers for Disease Control and Prevention, the American Medical Association, and the American Osteopathic Association.

The Workgroup sought input from a diverse group of medical and health policy stakeholders that included experts in pain medicine and addiction treatment, government officials, patients living with pain, and thought leaders. A meeting was held in September 2022 with experts on a variety of topics related to pain management and the Workgroup met on several additional occasions to examine and explore key elements required to ensure that FSMB's recommendations remain timely and sufficiently comprehensive to serve as a meaningful guidance and resource for state medical and osteopathic boards, physicians, and other clinicians.

Policy makers and clinicians are working to maintain a balance between curbing the nation's overdose and death epidemic, which may be divided into two components (one caused by inappropriate prescribing leading to prolonged use, and the other due to illicit contamination of drugs with synthetic opioids like fentanyl) and ensuring that appropriate access to evidence-based care is available to patients with pain. The recommendations in this document have been revised to reflect the paramount importance of individualized, patient-centered care in the management of pain. It also reflects a more comprehensive inclusion of non-opioid, non-pharmacologic, and non-invasive treatment options, as well as additional information about patient populations not previously addressed. The definitions have also been updated to reflect current terminology and to remove stigmatizing language.

The strategies and recommendations in this document are intended as a helpful resource to provide overall guidance to state medical and osteopathic boards in assessing clinicians' management of pain in their patients and whether opioids are used in a medically appropriate manner. This guidance is not meant to establish a strict standard of care for all patients but rather to encourage a responsible, patient-centered and compassionate approach to caring for patients' pain.

GUIDELINES FOR PRESCRIBING OPIOIDS FOR THE MANAGEMENT OF PAIN

Section 1 – PREAMBLE Opioids can be essential for the management of pain; however, they carry considerable potential risks, including misuse and the development of opioid use disorder (OUD), among other risks.[3] In order to implement best practices for opioid prescribing, medical students, residents and practicing clinicians must understand the relevant pharmacologic and clinical issues in the use of opioids and should obtain sufficient targeted continuing education and training about the safe prescribing of opioids and other controlled substances, as well as training in multimodal treatments for pain. The clinical determination of whether opioids are

[3] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.
DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

used as part of a treatment protocol is one that should be made between the individual and clinician based on the factors and considerations unique to that individual as discussed in these guidelines.

Section 2 – FOCUS OF GUIDELINES

The focus of the guidelines that follow is on the overall safe and evidence-based treatment of pain, including the prescribing of opioids with the specific **limitation** that these guidelines do not create any specific standard of care or basis for disciplinary action, as the provision of care should be individualized and patient-centered with the goal of optimizing function and quality of life. 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, patient demographics, and other concurrent issues beyond the scope of these guidelines.

The guidelines that follow are not intended to encourage or discourage the prescribing of opioids over other pharmacological and nonpharmacological means of treatment, but rather to recognize the responsibility of clinicians to view pain management as essential to the quality of medical practice and to the quality of life for patients living with pain.

While all care should be individualized and patient-centered, the guidelines that follow are applicable to the prescribing of opioids for the management of pain not generally associated with urgent or emergency care, cancer care, sickle cell-related care, palliative care or end of life care. Although these guidelines apply most directly to the use of opioids in the treatment of pain, many of the strategies described here may also be relevant to responsible prescribing and the mitigation of risks associated with other controlled substances that carry increased risks, including, but not limited, to overdose and misuse.

Section 3 – DEFINITIONS

For the purposes of these guidelines, the following terms are defined as shown.

Aberrant Behaviors: Aberrant behavior is irregular behavior that deviates from what is considered proper or normal. Suspected aberrant behavior should be discussed directly with the patient.

Abuse: Abuse is an older but stigmatizing term[4] used to describe a pattern of drug use that exists despite adverse consequences or risk of consequences. Abuse of a prescription medication includes its use in a manner that deviates from accepted medical, legal and social standards,

[4] *See* Kelly, John F. and Westerhoff, Cassandra, "Does it matter how we refer to individuals with substance-related condition? A randomized study of two commonly used terms." *International Journal of Drug Policy*, Vol. 21, Issue no.3, pages 202-207. Retrieved from: https://www.sciencedirect.com/science/article/abs/pii/S0955395909001546?via%3Dihub.

generally to achieve a euphoric state ("high") or that is other than the purpose for which the medication was prescribed. The term "misuse" is now preferred over "abuse."

Addiction: Addiction is a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.[5]

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA), which is designed to ensure both the availability and control of regulated substances. [6] 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 Drug Enforcement Administration (DEA). In granting regulatory authority to these agencies, Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, 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 a drug that is being considered for rescheduling or removal from control.

Most potent opioids are classified in Schedule II under the CSA, indicating that they have a significant potential for misuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions). Although the scheduling system provides a rough guide to misuse potential, all controlled medications have some potential for misuse.

Corresponding Responsibility: A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility also rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment, or in legitimate and authorized research, is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[7]

[5] American Society of Addiction Medicine, *The ASAM National Practice Guideline For the Treatment of Opioid Use Disorder 2020 Focused Updated*

[6] Controlled Substance Act of 1970(CSA). Federal Register (CFR). Public Law 91-513, 84 Stat. 1242.

[7] 21 C.F.R. Section 1306.04.

Dependence: Used in different ways:

- Physical dependence is a state of neurological adaptation that is manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
- Psychological dependence is a subjective sense of need for a specific psychoactive substance, either for its positive effects or to avoid negative effects associated with its abstinence.[8]

Diversion: Distribution of a controlled substance outside of the closed system of distribution.[9]

Harm Reduction: A comprehensive set of policies and initiatives to help prevent death, injury, disease, overdose, and substance misuse. Harm reduction is effective in addressing the public health epidemic involving substance use as well as infectious disease and other harms associated with drug use. Specifically, harm reduction services can:

- Connect individuals to overdose education, counseling, and referral to treatment for infectious diseases and substance use disorders.
- Distribute opioid overdose reversal medications (e.g., naloxone) to individuals at risk of overdose, or to those who might respond to an overdose.
- Lessen harms associated with drug use and related behaviors that increase the risk of infectious diseases, including HIV, viral hepatitis, and bacterial and fungal infections.
- Reduce infectious disease transmission among people who use drugs, including those who inject drugs by equipping them with accurate information and facilitating referral to resources.
- Reduce overdose deaths, promote linkages to care, facilitate co-location of services as part of a comprehensive, integrated approach.
- Reduce stigma associated with substance use and co-occurring disorders
- Promote a philosophy of hope and healing by utilizing those with lived experience of recovery in the management of harm reduction services, and connecting those who have expressed interest to treatment, peer support workers and other recovery support services.[10]

Misuse: The use of illegal drugs and/or the use of prescription drugs in a manner other than as directed by the prescriber, such as use in greater amounts, more frequently, or longer than told to take a drug or using someone else's prescription.[11] Misuse, by itself, is not a reason to

[8]American Society of Addiction Medicine, *The ASAM National Practice Guideline For the Treatment of Opioid Use Disorder 2020 Focused Updated*

[9] *See* Controlled Substances Act of 1970.

[10] Substance Abuse and Mental Health Services Administration. *Harm Reduction.* https://www.samhsa.gov/find-help/harm-reduction

[11] Center for Disease Control and Prevention, *Commonly Used Terms*, available at: https://www.cdc.gov/opioids/basics/terms.html#:~:text=Drug%20misuse%20%E2%80%93%20The%20use%20of,term%20is%20substance%20use%20disorder.

discontinue or alter a course of therapy or treatment; it also is not, by itself, a reason to discharge a patient from a practice.

Opioid: A current term for any psychoactive chemical that resembles morphine in pharmacological effects, and which includes opiates and synthetic/semisynthetic agents that exert their effects by binding to highly selective receptors in the brain where morphine and endogenous opioids affect their actions.[12]

Opioid Use Disorder: A problematic pattern of opioid use that causes significant impairment or distress. A diagnosis of opioid use disorder is based on specific criteria such as unsuccessful efforts to decrease or control use, or use resulting in social problems and a failure to fulfill obligations at work, school, or home, among other criteria. Opioid use disorder (OUD) is preferred over older terms with similar definitions, such as "opioid abuse or dependence" or "opioid addiction."[13]

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:** Pain that is usually sudden in onset and time limited (having a duration of less than one (1) month) and often is caused by injury, trauma, or medical treatments such as surgery
- **Subacute Pain:** Unresolved acute pain or subacute pain (pain that has been present for one to three (1–3) months) can evolve into chronic pain
- **Chronic Pain:** Pain that typically lasts more than three (3) months and can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause.[14]

Prescription Drug Monitoring Program: Prescription Drug Monitoring Programs (PDMPs) offer information about controlled prescription medications, including opioids, that are dispensed to an individual. They can serve as important resources for clinicians' use in completing full patient clinical assessments of opioid and other controlled substance use history.[15] A PDMP history or report should not, by itself, be used as the basis for discontinuing care, discharging a patient or non-consensually changing a course of treatment.

Substance Use Disorder: Substance use disorder (SUD) is a health condition marked by a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues to

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[12] *See* The ASAM National Practice Guideline For the Treatment of Opioid Use Disorder 2020 Focused Updated

[13] Center for Disease Control and Prevention, *Commonly Used Terms*, available at: https://www.cdc.gov/opioids/basics/terms.html#:~:text=Drug%20misuse%20%E2%80%93%20The%20use%20of,term%20is%20substance%20use%20disorder.

[14] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[15] *See* American Society of Addiction Medicine, *The ASAM National Practice Guideline For the Treatment of Opioid Use Disorder 2020 Focused Updated*

use alcohol, nicotine, and/or other drugs despite significant related problems.[16] Individuals with a SUD also may have pain, which should be assessed and treated. Coordination of care with a clinician specializing in SUD care may be appropriate.

Tolerance: A decrease in response to a drug dose that occurs with continued use. If an individual is tolerant to a drug, increased doses are required to achieve the effects originally produced by lower doses. Both physiological and psychosocial factors may contribute to the development of tolerance. Physiological factors include metabolic and functional tolerance. In metabolic tolerance, the body can eliminate the substance more readily, because the substance is metabolized at an increased rate. In functional tolerance, the central nervous system is less sensitive to the substance. An example of a psychosocial factor contributing to tolerance is behavioral tolerance, when learning or altered environmental constraints change the effect of the drug. Acute tolerance refers to rapid, temporary accommodation to the effect of a substance after a single dose. Reverse tolerance, also known as sensitization, refers to a condition in which the response to a substance increased with repeated use. Tolerance is one of the criteria of the dependence syndrome.[17]

Section 4 - GUIDELINES

State medical boards may use 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 use 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 in consideration of relevant psychosocial contraindications for prescribing an opioid and reflect an appropriately detailed patient evaluation.[18] An evaluation should be completed and documented concurrent with the decision of whether to prescribe an opioid. Evaluation of the patient is critical to appropriate management. Evaluation can identify reversible causes of pain and underlying etiologies with potentially serious sequelae that require urgent action. To guide patient-specific selection of therapy, clinicians should evaluate patients and establish or confirm the diagnosis. Clinicians are encouraged to maximize the use of nonopioid therapies if benefits outweigh the risks, and consider nonpharmacological, noninvasive approaches to managing pain. This does not mean that patients should be required to sequentially fail nonpharmacologic and nonopioid pharmacologic therapy or be required to use any specific treatments before

[16] American Psychiatric Association. (2022). *Diagnostic and statistical manual of mental disorders* (5th ed., text rev.). https://doi.org/10.1176/appi.books.9780890425787

[17] American Society of Addiction Medicine, *The ASAM National Practice Guideline For the Treatment of Opioid Use Disorder 2020 Focused Updated*

[18] Gourlay DL & Heit HA. Universal precautions in pain medicine: A rational approach to the treatment of chronic pain. *Pain Medicine.* 2005;6:107-112.

proceeding to opioid therapy.[19] Patients may not have affordable or ready access to all forms of pain treatment due to insurance or other payer limitations as well as barriers due to social determinants of health, including employment, child care, transportation and other concerns.

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 (including underlying mental and substance use disorders), social determinants of health, and the effect of the pain on the patient's physical and psychological functioning. [20]

For every patient, the initial assessment and evaluation should include a systems review (e.g., cardiovascular, pulmonary, neurologic) 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 potential supports and obstacles to treatment and rehabilitation. Clinicians should, to the extent possible, provide culturally and linguistically appropriate communications, including communications that are accessible to persons with disabilities.[21]

Assessment of the patient's personal and family history and relative risk for substance use disorder should be part of the initial evaluation and considered prior to a decision as to whether to prescribe opioids.[22] Assessment can be performed through a careful clinical interview, which should also inquire into any history of physical, emotional, or sexual abuse which are potential risk factors for substance use disorder.[23] Use of validated screening tools for substance use disorder may be useful to supplement the collecting and evaluating of information in determining the patient's level of risk.[24] The presence of a prior, adverse experience should not by itself constitute a reason to deny a particular therapy.

[19] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.
DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[20] Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA). *Treatment Improvement Protocol (TIP) 54: Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders*. DHHS Pub. No. (SMA) 12-4671. Rockville, MD: CSAT, SAMHSA, 2012.

[21] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.
DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[22] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.
DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[23] Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA). *Treatment Improvement Protocol (TIP) 54: Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders*. DHHS Pub. No. (SMA) 12-4671. Rockville, MD: CSAT, SAMHSA, 2012.

[24] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95.
DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

Patients with substance use disorders are likely to experience greater risks for opioid use disorder and overdose than persons without these conditions.[25] Treatment of a patient who has a history of substance use disorder may involve consultation with an addiction specialist before opioid therapy is initiated, as well as follow-up, as needed. Although substance use disorders can alter the expected benefits and risks of opioid therapy for pain, patients with co-occurring pain and substance use disorder require ongoing pain management that maximizes benefits relative to risks. All clinicians, particularly those who treat patients with chronic pain, are encouraged to be knowledgeable about the identification and treatment of substance use disorder, including the role of medications for treatment of opioid use disorder, such as methadone, buprenorphine and naltrexone.

Assessment of the patient's personal and family history of mental disorders should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioids. All patients should be screened for depression and other mental disorders as part of a risk evaluation. Patients with untreated depression and other mental disorders may be at increased risk for opioid use disorder and drug overdose. Additionally, untreated depression can interfere with the resolution of pain.[26]

The evaluation of the patient may include information from family members and/or significant others. The state's PDMP should be reviewed prior to initiating opioid therapy and at appropriate intervals thereafter to determine whether the patient is receiving prescriptions from other clinicians, and the results obtained from the PDMP should be reviewed. Information obtained from the PDMP could indicate a need for referral to a treatment provider.

In working with a patient who is prescribed opioids by another clinician—particularly a patient on high doses—the evaluation and risk stratification assumes even greater importance. Therefore, to ensure appropriate care, clinicians should collaborate with the primary prescriber for a clear understanding of the indications for the high dosage and strategies to mitigate risk associated with the current dosage, including whether tapering may be pursued, in collaboration with the patient.

Pregnant, postpartum, and parenting persons should receive compassionate, evidence-based care for pain or opioid use disorder.[27] A cautious approach to prescribing opioids should be balanced with the need to address pain, and pregnancy should not be a reason to avoid treating

[25] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[26] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[27] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

acute pain.[28] At the same time, opioid use during pregnancy may be associated with risks to both the pregnant person and the fetus.[29] For pregnant persons already receiving opioids, clinicians should access appropriate expertise if tapering is being considered because of possible risks to the pregnant patient and the fetus if the patient goes into withdrawal.[30] Opioids should be administered with caution in breastfeeding persons, as some opioids may be transferred via breast milk.

When opioid therapy is used for patients above the age of 65, clinicians should use additional caution and increase the frequency and extent of monitoring to ensure pain is addressed and to minimize risks of opioids prescribed. Clinicians should review all current medications, over-the-counter drugs and any natural remedies before prescribing any new drugs.[31]

Patients at risk for sleep-disordered breathing are at increased risk for harm with the use of 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, review of systems, and physical examination targeted to the pain condition
- A review of current medications, including over the counter drugs and natural remedies
- A description of the nature and intensity of the pain
- A review of 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 (e.g., obesity, renal disease, sleep apnea, COPD, etc.)
- The effect of pain on physical and psychological functioning
- Personal and family history of substance use disorder
- History of mental disorders, including post-traumatic stress disorder (PTSD)
- Medical indication(s) for use of opioids
- A review of PDMP results
- Consultation with other clinicians, including specialists, when applicable

[28] The American College of Obstetricians and Gynecologists, Committee Opinion, Opioid Use and Opioid Use Disorder in Pregnancy, Number 711, August 2017, Reaffirmed 2021; Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[29] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[30] *Recommendation 5 and Recommendation 8* of Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[31] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

- Tests of 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 functionality and quality of life; 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.[32] Although improvement in function is a primary goal, function can improve even when pain is not eliminated. 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, to provide clear-cut, individualized objectives to guide the choice of therapies through shared decision-making for both the clinician and the patient.

The treatment plan may contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids, such as non-steroidal anti-inflammatory drugs, 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.) Clinicians are encouraged to recognize the role that social determinants of health have on an individual patient's access to specific therapies and to help identify effective strategies and other options to help individuals obtain treatment. The treatment plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered, to the extent they are available. The plan should also include an exit strategy, including thoughtful consideration of the potential risks and benefits for opioid tapering, should opioid therapy be unsuccessful.[33]

Informed Consent and Treatment Agreement

The decision whether to initiate opioid therapy, like the decision about how to treat an individual's substance use disorder or opioid use disorder, 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 or other pharmacologic or nonpharmacologic modalities) with the patient. If opioids are prescribed, the patient (and possibly family members

[32] Institute of Medicine (IOM) of the National Academy of Sciences (NAS). *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research*. Washington, DC: National Academies Press, 2011; Noble M, Treadwell JR, Tregear SJ et al. *Cochrane Database of Systematic Reviews, Issue 1. Long-term Opioid Management for Chronic Noncancer Pain.* New York, NY: The Cochrane Collaborative, John Wiley & Sons, Ltd., 2010. Review.

[33] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

or caregivers) 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 overdose mitigation strategies, 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 subacute and chronic opioid therapy.[34] Treatment agreements outline the joint responsibilities of the clinician and patient. In addition, the clinician should discuss with the patient how and when the PDMP will be reviewed as part of the patient's care and how that information will be used.

Informed consent may address:

- Potential risks and benefits of opioid therapy
- Potential risks and benefits of non-opioid pharmacologic therapies
- 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 (i.e., 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 under certain circumstances
- Education of the patient that the complete elimination of pain may not occur
- The possible impact of therapeutic opioid use on drug testing in the workplace, etc.
- Risks for household members and other persons if opioids are intentionally or unintentionally shared with others for whom they are not prescribed

Treatment agreements outline the joint responsibilities of the clinician and patient 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, quality of life, but may not imply that the patient is absent of pain
- 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, overdose prevention and naloxone use, etc.)
- Secure storage and safe disposal

[34] Gourlay DL & Heit HA. Universal precautions in pain medicine: A rational approach to the treatment of chronic pain. *Pain Medicine.* 2005;6:107-112.

- Patient's responsibility to obtain prescribed opioids from only one clinician or practice, if possible (recognizing that this may not be possible for all patients)
- Patient's responsibility of getting the prescriptions filled at only one pharmacy, if possible (recognizing that this may not be possible for all patients)
- Patient's agreement to periodic drug testing, if applicable
- 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 related to cancer, sickle cell crisis, or as part of palliative or end-of-life care.

Initiating an Opioid Trial

Non-opioid, non-pharmacologic, and non-invasive treatments (such as cognitive behavioral therapy, massage, exercise, multimodal pain treatment and osteopathic manipulative treatment) should be considered before initiating opioid therapy for subacute and chronic pain.[35] This does not mean that patients should be required to sequentially fail nonpharmacologic and nonopioid pharmacologic therapy or be required to use any specific treatments before proceeding to opioid therapy.[36] Patients may not have affordable or ready access to all forms of pain treatment due to insurance or other payer limitations as well as barriers due to social determinants of health, including employment, child care, transportation and other concerns.

When a decision is made to initiate opioid therapy, it should be presented to the patient as a "therapeutic trial" or as a "test for a defined period of time" (usually no more than 30 days) and with specified evaluation points, including those to assess changes 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 safety.[37] When initiating opioid therapy for acute, sub-acute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release and long-acting (ER/LA) opioids.[38]

[35] *See* Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[36] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[37] Nicolaidis C, Chianello T & Gerrity M. Development and preliminary psychometric testing of the Centrality of Pain Scale. *Pain Medicine*. 2011 Apr;12(4):612-617.

[38] *Recommendation 3,* Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

The concurrent use of benzodiazepines and opioids is included as a boxed warning by the FDA as it greatly increases the risk of adverse events, including death. Clinicians should use caution when prescribing opioid pain medication and benzodiazepines (or other central nervous system depressants) concurrently and consider whether benefits outweigh risks.[39]

While there is clinical variation in response by patients to opioid therapy at any given dosage and there is need for patient flexibility and individualization with respect to opioid dosages, some states have specific dosing guidelines for opioids that are statutory in nature. The CDC has removed numeric thresholds from its recommendations due to reports of patient harm and to support individualized, patient-centered care. When considering whether to increase opioid dosage, a clinician should clearly state in the medical record the rationale for using higher dosages and monitor those patients prescribed such a dose with increased vigilance to assure that the medication is helping patients achieve their pain and functional goals and that 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 opioid dosages, may be considered, and dosages should not be escalated without re-evaluation of the benefits and risks in consultation with the patient.

Before prescribing methadone for its analgesic effect, clinicians are strongly recommended to 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, in particular when titrating methadone dose for pain management.

Clinicians should prescribe naloxone for home use where appropriate and with patient education for all patients with opioid prescriptions in case of unintentional poisoning or intentional overdose by the patient or household contacts. In most states, naloxone is available from the pharmacist without a prescription.

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 functioning. When possible, additional information about the patient's response to opioid therapy may be obtained from family members or other close contacts, as well by a review of the state PDMP. The patient may be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted.

[39] *Recommendation 11,* Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

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 consider the generally increased risk for dependence, and for developing a substance use disorder and misuse the longer the patient is receiving opioid therapy and may include referral to treatment programs or harm-reduction services, as clinically indicated.

Clinicians should not dismiss patients from their practice based solely on PDMP information. Doing so may adversely affect patient safety and result in missed opportunities to provide potentially lifesaving information (e.g., about risks of prescription opioids and about overdose prevention) and interventions (e.g., safer prescriptions, nonopioid pain treatment, naloxone, and effective treatment for substance use disorders).[40]

Continuation, modification, or termination of opioid therapy for pain should be discussed with the patient and 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.[41] A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, improved quality of life, or a reduction in the further decline of the patient. Information from family members or other caregivers may be considered in evaluating the patient's response to treatment. Use of measurement tools to assess the patient's level of pain, function, and quality of life may be helpful in documenting therapeutic outcomes.

Toxicology Testing

When prescribing opioids for subacute or chronic pain, clinicians should consider the benefits and risks of toxicology testing to assess for prescribed medications as well as other prescribed and nonprescribed controlled substances.

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, in order 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 record.[42]

Toxicology testing should not be used in a punitive manner but should be used in the context of other clinical information to inform and improve patient care. Clinicians should not dismiss patients from care based solely on a toxicology report. Dismissal could have adverse

[40] Recommendation 9, Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[41] Isaacson JH, Hopper JA, Alford DP et al. *Prescription drug use and abuse: Risk factors, red flags, and prevention strategies*. Postgraduate Medicine. 2005;118:19.

[42] Gourlay D, Heit HA & Caplan YH. *Urine Drug Testing in Clinical Practice; The Art & Science of Patient Care*. John Hopkins University School of Medicine; 6th Edition, August 2015.

consequences for patient safety, potentially including the patient obtaining opioids or other drugs from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.[43]

Adapting Treatment

As noted earlier, clinicians should 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.

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.[44] Such decisions should be made in consultation with the patient.

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 providing or arranging for evidence-based treatment of opioid use disorder, in particular medications for opioid use disorder (MOUD), if present. Patient behaviors that require such evaluation may include 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 behaviors.

When a toxicology test shows the presence of illicit drugs or drugs not prescribed by a clinician, this requires discussion of the test results with the patient and action on the part of the clinician. Changes to the patient's treatment plan may be required depending on the discussion and further evaluation of the totality of the patient's medical history and treatment plan. In some cases, the physician may need to run a confirmatory test if the patient evaluation does not clarify the initial test results. Importantly, toxicology testing should not be used in a punitive manner, and clinicians should not dismiss patients from care based on a toxicology test result. Dismissal could have adverse consequences for patient safety and result in missed opportunities to facilitate treatment changes or treatment for substance use disorder.

[43] Recommendation 10, Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[44] Passik SD, Kirsh KL. *Assessing aberrant drug-taking behaviors in the patient with chronic pain.* Curr Pain Headache Rep. 2004 Aug;8(4):289-94. doi: 10.1007/s11916-004-0010-3. PMID: 15228888.

Documented drug diversion or prescription forgery, and abusive or assaultive behaviors require a firm, immediate response,[45] which may include properly discharging a patient from the clinician's practice and/or referral to a treatment program or harm-reduction service. 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.[46]

Consultation and Referral

It is important to consider, if available, 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 may be considered if diagnosis and/or treatment for the condition manifesting as pain is outside the scope of the clinician's skills to manage the patient's medical condition(s). Opioid dose level, in and of itself, does not always warrant a referral. However, there is 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. While such a referral may not always be possible in every setting, clinicians should be knowledgeable about other options and resources that may be available and suggested.

Clinicians should be knowledgeable about evidence-based treatment options for substance use disorder and opioid use disorder (including those available in licensed opioid treatment programs [OTPs] and those offered in office-based settings) to make appropriate referrals when needed.

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 appropriate.

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.

Discontinuing or tapering of opioid therapy may be required for many reasons and clinicians should discuss with patients a strategy at the outset of treatment for approaching a taper and/or discontinuation of opioids if clinically indicated. Reasons for discontinuing opioid therapy include

[45] Smith MY & Woody G. Nonmedical use and abuse of scheduled medications prescribed for pain, pain-related symptoms, and psychiatric disorders: Patterns, user characteristics, and management options. *Current Psychiatry Reports.* 2005 Oct;7(5):337-343.

[46] Turk DC, Swanson KS & Gatchel RJ. Predicting opioid misuse by chronic pain patients: A systematic review and literature synthesis. *Clinical Journal of Pain.* 2008 Jul-Aug;24(6):497-508.

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, patient desire to discontinue treatment, failure to comply with the treatment agreement, or significant aberrant medication use. Additionally, clinicians should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement, improvement in quality of life, or at least a reduction in the patient's decline.

Tapering and discontinuation of opioid therapy carry significant risks. Unless there are indications of a life-threatening issue such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), opioid therapy should not be discontinued abruptly.[47] In addition, if a tapering strategy is pursued, the goal should not necessarily be to discontinue opioid therapy, but to identify the appropriate level of therapy required to obtain an optimal level of benefit that outweighs risk. Clinicians should carefully weigh both the benefits and risks of continuing opioids and the benefits and risks of tapering opioids in collaboration with the patient. If opioid therapy is discontinued, the patient who has become physically dependent should be provided a safely structured tapering regimen. Clinicians should collaborate with the patient on the plan for tapering, including how quickly to taper and when pauses in tapering might occur. 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 appropriate.

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

Clinicians who treat patients for pain should maintain accurate and complete medical records. Information that should appear in the medical record may include the following:

- 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

[47] Recommendation 9, Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. *CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States*, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

- 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.[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 as required by law

The medical record must include all prescription orders for opioids and other controlled substances, whether written, electronically prescribed, or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record.[49] The name, telephone number, and address of the patient's primary pharmacy should also be recorded to facilitate contact as needed. Records should be up-to-date and maintained in an accessible manner to be readily available for review.[50]

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 regulations.[51]

Clinicians should be aware that while they are responsible for the proper prescribing and dispensing of controlled substances, pharmacists are legally bound by a corresponding responsibility when filling prescriptions for controlled substances. Questions that arise about a prescription should be discussed professionally between the physician and pharmacist.

Clinicians are referred to the *Practitioner's 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, as well as from (any relevant documents issued by the state medical board).

Section 5 – CONCLUSION

The goal of this document is to provide state medical and osteopathic boards with updated recommendations for assessing a clinician's management of pain, to determine whether opioids are used in a manner that is both medically appropriate and in compliance with applicable state

[48] American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine (ASRAPM). *Practice Guidelines for Chronic Pain Management: An Updated Report by the ASA Task Force on Chronic Pain Management and ASRAPM*. Washington, DC: ASA & ASRAPM, 2010.
[49] Controlled Substances Act of 1970 (CSA). *Federal Register* (CFR). Public Law No. 91-513, 84 Stat. 1242.
[50] Controlled Substances Act of 1970 (CSA). *Federal Register* (CFR). Public Law No. 91-513, 84 Stat. 1242.
[51] Controlled Substances Act of 1970 (CSA). *Federal Register* (CFR). Public Law No. 91-513, 84 Stat. 1242.

and federal laws and regulations. The appropriate management of pain, particularly as related to the prescribing of opioids and other controlled substances with potential for misuse 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 medications with misuse potential to assess for ongoing benefit and mitigation of potential harms:** Opioids may be associated with increased risks, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid when done in an intentional manner based on a foundation of shared decision making. However, tapering or discontinuation carry signfiicant risks and should be approached through shared decision-making with the patient.

- **Adequate attention to patient education and informed consent:** The decision to begin opioid therapy is a shared decision of the clinician and patient after a discussion of the potential benefits and 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 benzodiazpines, 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 for adverse events and harms.

- **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 generally associated with emergency care, cancer care, sickle cell-related care, palliative, or end of life care. Maintain opioid dosage as low as possible and continue 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 can be a valuable tool for ongoing monitoring.

- **Emphasis should be placed on individualized decision-making:** The decision to initiate, continue, taper or discontinue opioid therapy is one that must be made on an individualized basis. There is no specific numeric threshold or single indicator that applies equally to all patients. Patients with pain deserve the same care and compassion as any other patient with complex medical conditions.