

# ARIZONA OPIOID PRESCRIBING GUIDELINES

A voluntary, consensus set of guidelines that promote best practices for prescribing opioids for acute and chronic pain

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Disclaimer: This document should not be used to establish any standard of care. No legal proceeding, including medical malpractice proceedings or disciplinary hearings, should reference a deviation from any part of this document as constituting a breach of professional conduct. These guidelines are only an educational tool. Clinicians should use their own clinical judgment and not base clinical decisions solely on this document. The following recommendations are not founded in evidence-based research but are based on promising interventions and opinion. Additional research is needed to understand the impact of these interventions on decreasing unintentional drug poisoning and on health care costs. All of the following recommendations should be implemented in concert and collaboration with public health entities and other relevant stakeholders.

# TABLE OF CONTENTS

<b>Purpose and Development of the Guidelines</b> .....	<b>2</b>
<b>Glossary of Terms and Abbreviations</b> .....	<b>3</b>
<b>Intended Audience and Scope</b> .....	<b>4</b>
<b>Safe, Cautious Opioid Prescribing</b> .....	<b>4</b>
<b>Summary of Arizona Opioid Prescribing Guidelines for the Treatment of Acute Pain</b> .....	<b>5</b>
<b>Summary of Arizona Opioid Prescribing Guidelines for the Treatment of Chronic Pain</b> .....	<b>6</b>
<b>Opioid Prescribing Guidelines for Acute Pain</b> .....	<b>7</b>
Acute Pain Guideline #1.....	7
Acute Pain Guideline #2.....	7
Acute Pain Guideline #3.....	7
Acute Pain Guideline #4.....	8
Acute Pain Guideline #5.....	8
Acute Pain Guideline #6.....	8
<b>Opioid Prescribing Guidelines for Chronic Non-Terminal Pain</b> .....	<b>9</b>
CNTP Guideline #1.....	9
CNTP Guideline #2.....	9
CNTP Guideline #3.....	10
CNTP Guideline #4.....	12
CNTP Guideline #5.....	13
CNTP Guideline #6.....	14
CNTP Guideline #7.....	14
CNTP Guideline #8.....	14
CNTP Guideline #9.....	15
CNTP Guideline #10.....	16
CNTP Guideline #11.....	17
CNTP Guideline #12.....	17
<b>Appendix A: Adjuvant Nonopioid Medications</b> .....	<b>18</b>
<b>Appendix B: Considerations for Opioid Use During Pregnancy</b> .....	<b>20</b>
<b>Appendix C: Opioid Risk Tool</b> .....	<b>21</b>
<b>Appendix D: Adjunctive Medications During Taper</b> .....	<b>22</b>
<b>Appendix E: Arizona &amp; National Resources</b> .....	<b>23</b>
<b>References</b> .....	<b>24</b>
<b>Special Acknowledgments</b> .....	<b>27</b>

## PURPOSE OF THE GUIDELINES

The abuse of prescription drugs is a serious societal and public health problem in the United States and in Arizona. According to data from Arizona's Controlled Substances Prescription Monitoring Program, there are approximately 10 million Class II-IV prescriptions written and 524 million pills dispensed each year. Prescription pain relievers account for more than half of the drugs dispensed in the state. As the use of these habit-forming drugs grows, so too does the likelihood of adverse outcomes related to misuse and abuse.

Overdose deaths from prescription analgesics increased more than four-fold from 1999 to 2010 in the U.S. The Centers for Disease Control and Prevention (CDC) declared it an epidemic, and Arizona is no exception. **Arizona ranked 6th highest in the nation in 2010 for drug overdose deaths and had the 5th highest opioid prescribing rate in the U.S.** in 2011.<sup>1</sup> Relieving pain and reducing suffering must be done in a manner that limits the personal and societal harm from prescription drug misuse and abuse. These guidelines are intended to help prescribers and patients by reducing the inappropriate use of controlled substances, improving safety, and reducing harm while preserving the vital roles of clinicians and patients in the management of acute and chronic pain.

## DEVELOPMENT OF THE GUIDELINES

National and state organizations, including the [Arizona Prescription Drug Misuse and Abuse Initiative](#), and practitioners across Arizona promote responsible prescribing practices as a key strategy to reduce prescription drug misuse and abuse. In March 2014, the Arizona Department of Health Services convened a summit for healthcare associations, academic institutions, health plans, federal healthcare providers, public health leaders, and other stakeholders to begin the development of voluntary, consensus guidelines to promote responsible, appropriate prescribing practices to reduce the misuse and abuse of opioid analgesics.

Existing national and state prescribing guidelines were utilized to inform the content of these guidelines including: VA/DoD Clinical Practice Guideline: [Management of Opioid Therapy for Chronic Pain](#); VA/DoD Factsheet: [Tapering and Discontinuing Opioids](#); American Pain Society/American Academy of Pain Medicine: [Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain](#); American Society of Interventional Pain Physicians: Guidelines for Responsible Opioid Prescribing in CNCP—[Part 1](#) and [Part 2](#); Washington State Agency Medical Directors' Group: [Interagency Guidelines on Opioid Dosing for CNCP](#); and [Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain](#). These guidelines build on and complement the existing Arizona Guidelines for Dispensing Controlled Substances and the Arizona Guidelines for Emergency Department Controlled Substance Prescribing.

As defined by the Institute of Medicine, guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." The **Arizona Opioid Prescribing Guidelines** are intended to provide general guidance to Arizona prescribers. They are not a substitute for appropriate assessment and professional judgment. *Thank you for reviewing and disseminating the Arizona Opioid Prescribing Guidelines and doing your part to protect the well-being of Arizonans.*

## GLOSSARY OF TERMS AND ABBREVIATIONS

- 1. 6 A's** – a key component of opioid monitoring and reassessment of risks versus benefits that include evaluation of the following domains: analgesia, activity, aberrant drug-related behaviors, adverse effects, affect, and adjunctive treatments.
- 2. ABERRANT DRUG-RELATED BEHAVIORS (ADRB)** – a set of behaviors suggestive of problematic prescription opioid use, including: aggressively requesting medications, reports of lost or stolen prescriptions, decreasing functionality or frequent accidents while using opioids, repeat noncompliance, unsanctioned dose escalations, early refill requests, obtaining opioids from multiples sources, and use of non-prescribed drugs.
- 3. ADDICTION** – 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. Addiction is characterized by the 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.<sup>2</sup>
- 4. ARIZONA STATE BOARD OF PHARMACY CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM (AZ CSPMP)** – prescription drug monitoring program.
- 5. CHRONIC OPIOID THERAPY (COT)** – opioid therapy prescribed for > 90 days.
- 6. CHRONIC PAIN** – pain persisting longer than 3-6 months and beyond the normal tissue healing time.
- 7. CHRONIC NON-CANCER PAIN (CNCP)** – chronic pain that is not due to malignancy.
- 8. CHRONIC NON-TERMINAL PAIN (CNTP)** – chronic pain that is not occurring at the end of life and is not due to malignancy. CNTP is inclusive of CNCP for the purpose of these guidelines.
- 9. HOSPICE** – a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life, and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.
- 10. PALLIATIVE CARE** – an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.<sup>3</sup>
- 11. PHYSICAL DEPENDENCE** – a state of adaptation 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.<sup>4</sup>
- 12. MORPHINE EQUIVALENT DOSE (MED)** – the equipotent dose of an opioid expressed as the equivalent dose of oral morphine determined by using the Washington State Agency Medical Directors' Group Opioid Dose Calculator (<http://www.agencymeddirectors.wa.gov/opioiddosing.asp>).
- 13. OPIOID THERAPY (OT)** – the use of opioid medications to treat pain.
- 14. SUBSTANCE USE DISORDER (SUD)** – the essential feature of a substance use disorder is a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems. SUD diagnosis is based on a pathological pattern of behaviors related to use of the substance. The diagnostic criteria can be considered to fit within the following groupings: impaired control, social impairment, risky use, and pharmacological criteria.<sup>5</sup>
- 15. TOLERANCE** – a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drugs' effects over time.<sup>4</sup>
- 16. URINE DRUG TESTING (UDT)** – testing of urine for various drugs and metabolites to provide objective documentation of adherence to an opioid treatment plan as well as aid in the diagnosis and treatment of addiction or substance use disorders.

## INTENDED AUDIENCE AND SCOPE

The **Arizona Opioid Prescribing Guidelines** are intended for use by clinicians in primary care and specialty outpatient settings who manage acute and chronic pain that is not occurring at the end of life and not due to malignancy. Chronic pain will be referred to as chronic non-terminal pain (CNTP) in these guidelines. Much of the existing literature and several existing guidelines for chronic opioid therapy (COT) use the term chronic non-cancer pain (CNCP). The use of the term CNTP is inclusive of CNCP for this guideline. These guidelines are not intended to apply to hospice or palliative care patients (as defined in the glossary of terms) or patients with end of life or cancer-related pain.

## INTRODUCTION

Chronic pain is more prevalent in the U.S. than heart disease, cancer, and diabetes combined.<sup>6</sup> Chronic pain can cause a vicious cycle of suffering, reduced functioning, and reduced quality of life. Unfortunately, a medical cure is often not possible for many people with CNTP.<sup>6</sup> CNTP is a complex multidimensional experience with biological, social, psychological, and spiritual influences and effects. Because of this, a comprehensive, whole person, multimodal, interdisciplinary approach represents the most effective method for treating patients with CNTP.<sup>7</sup> The patient's active role in self-management forms the foundation for effective pain care.<sup>6</sup> Medications can offer modest to moderate benefit when used according to the principles of "rational polypharmacy"<sup>8</sup> as a part of a multimodal treatment plan. Psychosocial therapies and interventions targeting physical activation and functional restoration should be routinely incorporated into the care plan when prescribing COT for patients with CNTP.<sup>9</sup>

## SAFE, CAUTIOUS OPIOID PRESCRIBING

While opioid medications have a clear role in treating acute, post-operative, and cancer pain, the effectiveness of COT for CNTP is unclear. No randomized controlled trials (RCT) have evaluated the use of COT for CNTP for treatment periods greater than three to four months.<sup>10-12</sup> RCT data have shown opioids to be effective at reducing pain for very carefully selected patients with CNTP for time periods less than 16 weeks while functional improvement is unclear.<sup>13-16</sup> Epidemiological, population based data suggest that outcomes for patients with CNTP may be worse for patients on COT than for those not on COT.<sup>17,18</sup>

Despite the lack of data on the efficacy and safety of COT for CNTP, use of COT for CNTP increased dramatically from 1999-2010 in the United States, with opioid sales and overdose deaths from prescription analgesics increasing four-fold during this time frame.<sup>19,20</sup> Arizona ranked 6th highest in the nation in 2010 for drug overdose deaths and had the 5th highest opioid prescribing rate in the U.S. in 2011.<sup>1</sup>

Additional potential harms associated with COT include increased rates of falls,<sup>21</sup> fractures,<sup>22</sup> traffic accidents,<sup>23</sup> sleep disordered breathing,<sup>24</sup> endocrine dysfunction,<sup>25</sup> and addiction.<sup>26</sup> Because of the lack of data supporting COT for CNTP and the potential harms associated with COT for CNTP, caution should be used when prescribing COT for CNTP while safety and improved function should be prioritized.<sup>27,28</sup> When possible, opioid therapy should be limited to situations supported by reasonable quality evidence such as short term use in well-selected patients with CNTP,<sup>13,14</sup> acute pain,<sup>29</sup> peri-operative pain,<sup>29</sup> and cancer pain;<sup>30</sup> as well as pain treated in the hospice or palliative setting. Low to moderate dose opioid therapy may provide modest benefit for well-selected patients with CNTP in the primary care setting.

## **SUMMARY OF ARIZONA OPIOID PRESCRIBING GUIDELINES FOR THE TREATMENT OF ACUTE PAIN**

The goal of these guidelines is to balance the appropriate treatment of pain with approaches to more safely prescribe opioids. Thoughtful opioid prescribing for acute and post-operative pain can improve safety, reduce harm, and prevent the unintended or inappropriate long-term use of opioid medications.

Note: These guidelines are not intended to apply to hospice or palliative care patients (as defined by the World Health Organization), patients at end of life, or cancer-related pain.

1. Opioid medications should only be used for treatment of acute pain when the pain severity warrants that choice, and non-opioid pain medications or therapies do not provide adequate pain relief.
2. When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed. This should be based on the expected duration of pain severe enough to justify prescribing opioids for that condition.
3. When opioid medications are prescribed for acute pain, patient should be counseled that:
  - Sharing with others is illegal.
  - Medications should be stored securely.
  - Medications should be disposed of properly when the pain has resolved to prevent non-medical use of medications.
  - Opioids are intended for short-term use only.
  - Driving or operating machinery should be avoided if a patient is sedated or confused while using opioids.
4. Long acting opioids should not be used for treatment of acute pain, including post-operative pain, except in select opioid tolerant patients, and situations where monitoring and assessment for adverse effects can be conducted.
5. The continued use of opioids should be considered carefully, including assessing the potential for misuse. If pain persists beyond the anticipated treatment duration, the patient should be carefully reevaluated.
6. The Arizona Controlled Substances Prescription Monitoring Program should be checked prior to prescribing opioids and periodically if renewing opioid prescriptions.

## SUMMARY OF ARIZONA OPIOID PRESCRIBING GUIDELINES FOR THE TREATMENT OF CHRONIC NON-TERMINAL PAIN (CNTP)

1. A comprehensive medical and pain related evaluation that includes assessing for substance use, psychiatric comorbidities, and functional status should be performed before initiating opioid treatment for chronic pain.
2. A goal directed trial of opioid therapy is considered appropriate when pain is severe enough to interfere with quality of life and function and the patient has failed to adequately respond to indicated non-opioid and non-drug therapeutic interventions. Potential benefits should be determined to outweigh risks. The patient should agree to participate in other aspects of a pain care plan such as physical therapy and cognitive behavioral therapy when these therapies are recommended and available.
3. The provider should assess for risk of misuse, addiction, or adverse effects, and perform a risk stratification before initiating opioid treatment.
4. Initiating opioids in patients with CNTP should ideally be limited to the evidence-based indication of short term therapy with the purpose of facilitating participation in a comprehensive care plan; however, if chronic opioid therapy (COT) is considered, a goal directed trial lasting 30-90 days should be the starting point. Continuing opioid treatment after the treatment trial should be a deliberate decision that weighs the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult with a pain specialist may be useful.
5. When a trial of opioid therapy is determined to be appropriate, patients should be actively engaged in a process of education, shared decision-making, and informed consent. The provider should obtain and document informed consent including discussion of risks, benefits, and conditions under which opioids are prescribed or discontinued. Documentation of this discussion is ideally accomplished by using a signed Opioid Pain Care Agreement (OPCA).
6. Clinicians treating patients with opioids for chronic pain should obtain and review past records when possible. Ongoing medical records should document the patient evaluation, a treatment plan with clearly defined goals, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant drug-related behavior observed.
7. For patients on chronic opioid therapy (COT), monitoring progress and adherence to the treatment plan is essential to optimize patient care and the overall benefit to risk profile. Appropriate monitoring for COT includes, at a minimum: (1) regular assessment with face to face encounters (2) assessment of response to therapy including assessment of the 6 A's (analgesia, activity, aberrant drug related behaviors, adverse effects, affect, and adjuncts), (3) periodic query of the AZ Controlled Substances Prescription Monitoring Program, and (4) periodic completion of UDT. Frequency of monitoring should be determined by risk category.
8. Clinicians should consider consultation, when available, for patients with: complex pain conditions, serious co-morbidities including mental illness, a history or evidence of current drug addiction or abuse, patients who are pregnant or breastfeeding, or when the provider wants help managing the patient.
9. An opioid treatment trial should be tapered/discontinued if the goals are not met and opioid therapy should be tapered/ discontinued at any point if risks outweigh benefits or if dangerous or illegal behaviors are demonstrated.
10. COT should be used in the lowest possible doses to achieve treatment goals. Opioid related adverse events increase with doses >50-100 mg of morphine equivalent dose per day (MEDD) and reaching these doses should trigger a re-evaluation of therapy.
11. Combined use of opioids and benzodiazepines should be avoided if possible. If this combination is used, it should be with great caution and informed consent should be obtained. Particular caution should also be exercised when opioids are used with other sedatives/hypnotics.
12. Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use and who are prepared to conduct the necessary careful monitoring. Methadone should generally not be prescribed to opioid naïve patients, and particular caution should be used if methadone is prescribed for opioid naïve patients.

## OPIOID PRESCRIBING GUIDELINES FOR ACUTE PAIN

The goal of these guidelines is to balance the appropriate treatment of acute pain with approaches to more safely prescribe opioids. Thoughtful opioid prescribing for acute and post-operative pain can improve safety, reduce harm, and prevent the unintended or inappropriate long-term use of opioid medications. Note: These guidelines are not intended to apply to hospice or palliative care patients (as defined by the World Health Organization), patients at end of life, or cancer-related pain.

### **#1: OPIOID MEDICATIONS SHOULD ONLY BE USED FOR TREATMENT OF ACUTE PAIN WHEN THE SEVERITY OF THE PAIN WARRANTS THAT CHOICE AND NON-OPIOID PAIN MEDICATIONS OR THERAPIES WILL NOT PROVIDE ADEQUATE PAIN RELIEF.**

Most acute pain is better treated with non-opioid medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAID), or therapies such as exercise, or specific stretching) than opioid medications which have less desirable adverse effect profiles in acute pain patients. Care should be taken so that opioid pain treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. When treating adolescents, important considerations include that the developing brain may be more susceptible to opioid addiction and nonmedical use is more common.<sup>31</sup>

See Appendix A for more information on non-opioid medications commonly prescribed to help manage pain.<sup>32,33</sup>

### **#2: WHEN OPIOID MEDICATIONS ARE PRESCRIBED FOR TREATMENT OF ACUTE PAIN, THE NUMBER DISPENSED SHOULD BE NO MORE THAN THE NUMBER OF DOSES NEEDED. THIS SHOULD BE BASED ON THE EXPECTED DURATION OF PAIN SEVERE ENOUGH TO JUSTIFY PRESCRIBING OPIOIDS FOR THAT CONDITION.**

Prescribing more medications than the amount likely to be needed leads to unused medications being available for non-medical use or abuse. Use of opioid pain medications should be stopped when pain severity no longer requires them.

### **#3: WHEN OPIOIDS ARE PRESCRIBED FOR ACUTE PAIN, THE PATIENT SHOULD BE COUNSELED ON THE FOLLOWING:**

- Sharing with others is illegal.
- Medications should be stored securely.
- Medications should be disposed of properly when the pain has resolved to prevent non-medical use of medications.
- Opioids are intended for short-term use only.
- Driving or operating machinery should be avoided if patient is sedated or confused while using opioids.

Patients need to understand why medications must be securely stored. Encourage patients to keep medications in a locked area rather than unsecured in typical locations, such as the bathroom or kitchen cabinet, where they are accessible to children, curious teenagers, visitors, or vulnerable to theft or diversion. Instruct patients to dispose of unused medication immediately to prevent misuse, abuse, accidental poisoning, overdose, death or theft.

## **FEDERAL GUIDELINES ON PROPER DISPOSAL OF PRESCRIPTIONS**

The Food and Drug Administration (FDA) worked with the White House Office of National Drug Control Policy to develop consumer guidance for proper disposal of prescription drugs. The guidelines are summarized below.

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medications. Do not flush medicines down the sink or toilet unless the information specifically instructs doing so.

- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.
- The Drug Enforcement Administration ([www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)) recently expanded options for proper disposal of controlled substances. Call 1-800-882-9539 to find a collection receptacle location nearby. Some communities have permanent drop-boxes; for a list of Arizona drug disposal and drop box locations, see: <http://www.azcjc.gov/acjc.web/rx/default.aspx>
- If no instructions are given on the drug label, and no take-back programs or drop-boxes are available in your area, take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash. Mix prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and put them in containers, such as empty cans or sealable bags to prevent the medication from leaking or breaking out of a garbage bag. Scratch out any identifying information on the prescription label to make it unreadable.
- Flush prescription drugs down the toilet only if the label or accompanying patient information specifically instructs doing so. Because a small number of medicines may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed, the FDA advises a few medicines be flushed down the sink or toilet as soon as they are no longer needed and when they cannot be disposed of through a medicine take-back program. Click here for an updated list of medicines recommended for disposal by flushing, or visit: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>

#### **#4: LONG ACTING OPIOIDS SHOULD NOT BE USED FOR TREATMENT OF ACUTE PAIN, INCLUDING POST-OPERATIVE PAIN, EXCEPT IN SELECT OPIOID TOLERANT PATIENTS, AND SITUATIONS WHERE MONITORING AND ASSESSMENT FOR ADVERSE EFFECTS CAN BE CONDUCTED.**

Prescribers should be aware that dose selection is critical, particularly when initiating therapy in opioid non-tolerant patients. Some extended-release/long-acting(ER/LA) opioid analgesics are only appropriate for opioid-tolerant patients. Dosage should be individualized in every case. Titration should be based on efficacy and tolerability. ER/LA opioid analgesics can cause serious side effects and death.<sup>57</sup>

#### **#5: THE CONTINUED USE OF OPIOIDS SHOULD BE CONSIDERED CAREFULLY, INCLUDING ASSESSING THE POTENTIAL FOR MISUSE. IF PAIN PERSISTS BEYOND THE ANTICIPATED TREATMENT DURATION, THEN THE PATIENT SHOULD BE CAREFULLY REEVALUATED.**

Patients with acute pain who fail to recover in the expected timeframe for their diagnosis should be carefully reevaluated. The continuation of opioid treatment may at that point represent the initiation of opioid treatment for chronic pain. The diagnosis and appropriateness of interventions should be reevaluated and the patient's medical history should be reviewed for comorbidities that could interact with opioid treatment and for risk factors for problems during opioid treatment, including substance abuse or history of substance abuse.

#### **#6: THE ARIZONA CONTROLLED SUBSTANCES PRESCRIPTION DRUG MONITORING PROGRAM SHOULD BE CHECKED PRIOR TO PRESCRIBING OPIOIDS AND PERIODICALLY IF RENEWING OPIOID PRESCRIPTIONS.**

The primary function of the Arizona Controlled Substances Prescription Monitoring Program (AZ CSPMP) is to provide a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances. It allows prescribers (and their authorized delegates) access to a database to assist in treating patients, identifying patients who might be doctor shopping to feed a drug addiction, and in identifying and deterring drug diversion.

# OPIOID PRESCRIBING GUIDELINES FOR CHRONIC NON-TERMINAL PAIN (CNTP)

## **#1: A COMPREHENSIVE MEDICAL AND PAIN RELATED EVALUATION THAT INCLUDES ASSESSING FOR SUBSTANCE USE, PSYCHIATRIC COMORBIDITIES, AND FUNCTIONAL STATUS SHOULD BE PERFORMED BEFORE INITIATING OPIOID TREATMENT FOR CHRONIC PAIN.**

Prior to initiating or continuing COT, a comprehensive assessment should be performed including the following:

- Obtain a medical, pain-related, and social history with a pain focused physical exam
- Assess for past, present, or family history of substance use disorder (SUD)
- Assess for psychiatric disorders; if present assess current treatment and degree of control
- Assess suicide risk
- Assess for the presence of sleep disordered breathing
- Assess for pregnancy or likelihood of becoming pregnant (see Appendix B)
- Assess for the use of other medications that may have life threatening drug-drug interactions.
- Use urine drug testing (UDT) to screen for illegal drugs, unreported prescribed medications, or unreported alcohol use.
- Use the Arizona State Board of Pharmacy Controlled Substances Prescription Monitoring Program (AZ CSPMP) to screen for adherence to COT and the use of unreported prescribed medications.
- Formulate a diagnosis (or diagnostic impression if a specific diagnosis is not possible) and generate a differential diagnosis.

## **#2: A GOAL DIRECTED TRIAL OF OPIOID THERAPY IS CONSIDERED APPROPRIATE WHEN PAIN IS SEVERE ENOUGH TO INTERFERE WITH QUALITY OF LIFE AND FUNCTION AND THE PATIENT HAS FAILED TO ADEQUATELY RESPOND TO INDICATED NON-OPIOID AND NON-DRUG THERAPEUTIC INTERVENTIONS. POTENTIAL BENEFITS SHOULD BE DETERMINED TO OUTWEIGH RISKS. THE PATIENT SHOULD AGREE TO PARTICIPATE IN OTHER ASPECTS OF A PAIN CARE PLAN SUCH AS PHYSICAL THERAPY AND COGNITIVE BEHAVIORAL THERAPY WHEN THESE THERAPIES ARE RECOMMENDED AND AVAILABLE.**

A patient is considered an appropriate candidate for a trial of opioid therapy if **all** of the following criteria are met (the ethical imperative is to provide the pain treatment with the best benefit to harm profile for the individual patient):

- Pain is severe enough to limit the quality of life or function that has failed to adequately respond to indicated non-opioid and non-drug therapeutic interventions
- The potential benefits of opioid therapy are likely to outweigh the risks
- The patient is fully informed and consents to the therapy
- The patient has no absolute contraindications to opioid therapy
- Clear and measureable treatment goals are established
- The patient agrees to participate in a comprehensive pain care plan

**Absolute Contraindications** to COT include:

- Severe respiratory instability
- Acute psychiatric instability or uncontrolled suicide risk
- Diagnosed substance use disorder (SUD) not in remission and/or active treatment
- Opioid allergy (that cannot be resolved by switching agents)
- Co-administration of a drug capable of inducing a life-threatening drug-drug interaction.
- QTc interval > 500 milliseconds (for methadone) on an electrocardiogram (ECG)
- Active diversion of controlled substances (providing medication to someone for whom it was not intended)
- Prior opioid trials that were discontinued due to intolerance, non-treatable serious adverse effects or lack of efficacy

**Relative Contraindications** to COT include (opioid trial may be considered only if determination that benefits outweigh risks):

- Co-occurring SUD in treatment
- Medical condition in which OT may cause harm (e.g. sleep apnea, COPD)
- QTc interval 450-500 milliseconds (for methadone) on an ECG
- Paralytic ileus
- Risk for suicide or unstable psychiatric disorder
- Complicated pain (e.g. headache not responsive to other pain treatment modalities)
- Conditions that may impact adherence to OT (e.g. cognitive impairment)
- Unwillingness or inability to comply with treatment plan (e.g. lack of social support, social instability)
- Pregnancy/breastfeeding

COT should not be used as an isolated therapy and should be part of a comprehensive and multimodal treatment plan focused on the whole person management of CNTP.<sup>9</sup>

### **#3: THE PROVIDER SHOULD ASSESS FOR RISK OF MISUSE, ADDICTION, OR ADVERSE EFFECTS, AND PERFORM A RISK STRATIFICATION BEFORE INITIATING OPIOID TREATMENT.**

A risk stratification should be performed as part of a risk/benefit assessment prior to initiating or continuing COT in patients with CNTP. The purpose is to determine the most appropriate treatment, how much structure to provide, and how closely to monitor the patient during COT. With patient consent, third party sources of information such as family, other medical providers, and outside medical records should be included, when possible, in the process of risk assessment. Risk assessment can be accomplished either by using existing opioid risk assessment tools (structured risk assessment) such as the Opioid Risk Tool (ORT), the Screener and Opioid Assessment for Patients with Pain (SOAPP®), or the Current Opioid Misuse Measure (COMM™), or by using Tables 1 and 2 (global risk assessment).

#### **STRUCTURED RISK ASSESSMENT**

The ORT (Appendix C) is a brief, 5-question survey using patient self-report to assess aberrant drug related behavior (ADRB) risk prior to initiating COT. The strengths of this tool include being widely accessible, brief, and easy to administer. The primary limitation is a low sensitivity for predicting ADRB (0.18-0.45).<sup>35,36</sup> The SOAPP® (<http://www.painedu.org/soapp.asp>) also uses patient self-report to predict the risk of ADRB. The SOAPP® is more extensive (24 items) and is associated with a sensitivity of 0.41-0.72)<sup>35,36</sup> for predicting ADRB. The COMM™ (<http://www.painedu.org/soapp.asp>) is a 17-item self-report survey that is designed to identify ADRB that may be associated with opioid misuse in patients who are currently on chronic opioid therapy. The ORT may be a more appropriate screening tool for clinics with a higher volume of low risk patients, while the SOAPP® may be more appropriate as an initial screening tool in higher risk patient populations.<sup>37</sup>

Patients determined to be high risk by either the ORT, COMM™ or the SOAPP® require more rigorous evaluation, treatment structure, and monitoring. Appropriate consultation with psychiatric, SUD, behavioral health, or pain specialty services should be considered. It may not be appropriate to prescribe COT for high-risk patients in a primary care setting without readily available consultation and support services.

## GLOBAL RISK ASSESSMENT

Global risk assessment can be accomplished by using the clinical interview and assessing both risk for medication misuse/addiction as well as risk for adverse effects such as fracture and unintentional overdose. Examples of these risk characteristics are listed in Table 1. A semi-structured clinical interview by a behavioral health specialist is more time intensive but is associated with a higher sensitivity (0.69 - 0.77)<sup>35,36</sup> for predicting ADRB than either the ORT or the SOAPP®.<sup>35,36</sup>

**TABLE 1 RISK CHARACTERISTICS ASSOCIATED WITH OPIOID RELATED ADVERSE EVENTS**

Risk Characteristics	Examples/details
Substance use history	Alcohol, marijuana, tobacco, recreational, and illicit drug use
Risk factors for medication misuse/addiction	Age < 45 y/o, prior personal or family history of addiction, legal problems, psychiatric illnesses
Risk factors for adverse medical effects	Age > 65 y/o, medical comorbidities such as sleep disordered breathing, respiratory disease, concomitant use of sedative medications, and cognitive impairment
Aberrant drug-related behaviors (ADRB)	Decreasing functionality or frequent accidents while using opioids, repeat noncompliance, unsanctioned dose escalations, early refill requests, obtaining opioids from multiple sources, using non-prescribed drugs, or other misuse
Urine drug testing	Frequency determined by overall risk category
Query of the AZ CSPMP	Frequency determined by overall risk category

Table 2 is then used to determine risk category based on the presence or absence of risk characteristics.

**TABLE 2**

Risk of Misuse	Condition/Situation	Treatment Setting for Opioid Therapy
Low (no moderate or high risk characteristics)	<ul style="list-style-type: none"> <li>• Diagnosis with concordant physical exam, medical imaging, laboratory findings</li> <li>• High levels of pain acceptance and active coping strategies</li> <li>• Well motivated patient willing to participate in multimodal treatment plan</li> <li>• Attempting to function at normal levels and making progress toward treatment goals</li> <li>• UDT and CSPMP are appropriate</li> <li>• No aberrant drug related behaviors (ADRB) (e.g. lost prescriptions, multiple requests for early refills, unauthorized dose escalation, apparent intoxication, frequent accidents etc.)</li> </ul>	<ul style="list-style-type: none"> <li>• Provide OT in primary care setting in conjunction with multimodal treatment plan</li> <li>• CSPMP and UDT yearly or more often as indicated</li> <li>• Follow up interval should be no longer than 2-4 weeks after opioid dosage modification and no longer than 3 months for patients on stable opioid doses</li> </ul>

Risk of Misuse	Condition/Situation	Treatment Setting for Opioid Therapy
Moderate (high risk characteristics absent)	<ul style="list-style-type: none"> <li>• Diagnosis with concordant physical exam, medical imaging, laboratory findings and pain in &gt; 3 regions of body</li> <li>• Moderate co-morbid psychological and medical problems well-controlled by active treatment</li> <li>• Risk factors for medication misuse/abuse (e.g. history of substance use)</li> <li>• Any positive UDT or CSPMP with no repeat behavior</li> <li>• Moderate levels of pain acceptance and coping strategies</li> </ul>	<ul style="list-style-type: none"> <li>• Provide OT in primary care setting with escalated monitoring and caution or in pain specialty setting</li> <li>• Perform updated risk/benefit assessment</li> <li>• Increase frequency of follow up and monitoring to determine stability or if there is a pattern of ADRB</li> <li>• Consider consultation with addiction or behavioral health specialist</li> <li>• CSPMP and UDT every 6 months or more often as indicated</li> </ul>
High	<ul style="list-style-type: none"> <li>• Widespread pain without objective signs and symptoms</li> <li>• Unstable or untreated substance abuse or psychiatric disorder or high suicide or homicide risk</li> <li>• History of or current troublesome aberrant drug related behaviors</li> <li>• Unwilling to participate in multimodal therapy and not functioning close to a normal lifestyle</li> <li>• Pattern of CSPMP reports or UDT that is inconsistent with expected results, or failure to submit UDT when requested</li> </ul>	<ul style="list-style-type: none"> <li>• For one or more high risk situations/ conditions, OT may not be appropriate</li> <li>• Additional evaluation by psychiatric, SUD, behavioral health, or pain specialty services may be indicated</li> <li>• If OT is used, it should be provided in a structured setting with escalated monitoring such as a specialty pain clinic</li> <li>• Consider tapering OT</li> <li>• Consider non-opioid treatment strategies</li> <li>• CSPMP and UDT every 3 months or more often as indicated</li> </ul>

**#4: INITIATING OPIOIDS IN PATIENTS WITH CNTP SHOULD IDEALLY BE LIMITED TO THE EVIDENCE-BASED INDICATION OF SHORT TERM THERAPY WITH THE PURPOSE OF FACILITATING PARTICIPATION IN A COMPREHENSIVE CARE PLAN; HOWEVER, IF CHRONIC OPIOID THERAPY (COT) IS CONSIDERED, A GOAL DIRECTED TRIAL LASTING 30-90 DAYS SHOULD BE THE STARTING POINT. CONTINUING OPIOID TREATMENT AFTER THE TREATMENT TRIAL SHOULD BE A DELIBERATE DECISION THAT WEIGHS THE RISKS AND BENEFITS OF CHRONIC OPIOID TREATMENT FOR THAT PATIENT. A SECOND OPINION OR CONSULT WITH A PAIN SPECIALIST MAY BE USEFUL.**

Opioid therapy is only one potential component of a comprehensive pain care plan that should emphasize functional improvement by developing a foundation of robust self-management strategies (a healthy lifestyle, exercise, coping strategies, stress management, sleep hygiene, weight management, etc.). It should include paced increases in activity and treatment of mental health conditions. Effective management of depression can result in a significant improvement in pain without the addition of analgesics.<sup>38</sup> Active patient participation in self-management strategies is the foundation for effective treatment.

Initiation of opioid therapy should include the development of an “exit strategy”<sup>39</sup> that specifies anticipated duration of therapy and indications for discontinuation (see below). If goals of improved quality of life, improved function, and improved analgesia are achieved, and prominent adverse effects are not present during an opioid trial, COT may then be considered beyond 30-90 days. If treatment goals are not met, function or quality of life declines or is not improved, or prominent adverse effects including significant ADRB are present, opioid medications should be tapered and discontinued and other strategies for pain care should be pursued. Patients who do not achieve satisfactory results at low to moderate opioid doses are unlikely to respond to high opioid doses.<sup>40,41</sup> (See CNTP Guideline #10 for opioid dosing discussion.)

**#5: WHEN A TRIAL OF OPIOID THERAPY IS DETERMINED TO BE APPROPRIATE, PATIENTS SHOULD BE ACTIVELY ENGAGED IN A PROCESS OF EDUCATION, SHARED DECISION MAKING, AND INFORMED CONSENT. THE PROVIDER SHOULD OBTAIN AND DOCUMENT INFORMED CONSENT INCLUDING DISCUSSION OF RISKS, BENEFITS, AND CONDITIONS UNDER WHICH OPIOIDS WILL BE PRESCRIBED OR DISCONTINUED. DOCUMENTATION OF THIS DISCUSSION IS IDEALLY ACCOMPLISHED BY USING A SIGNED OPIOID PAIN CARE AGREEMENT (OPCA).**

A signed OPCA can serve as documentation of an informed consent discussion. Patient refusal to sign the OPCA should be documented in the medical record and considered as part of the ongoing assessment of the patient’s ability to adhere to treatment plan and level of risk for adverse outcomes. The rationale for prescribing opioids without a signed agreement should be documented.

Patient responsibilities while using opioids for CNTP should be discussed with the patient, and family if appropriate. The spirit of this discussion should be patient-centered to maximize patient safety and quality of care. The up-front clear communication of patient responsibilities will be helpful in determining the clinical significance of subsequent patient behavior in relation to opioid therapy.

The following issues should be reviewed with the patient (and family if appropriate):

- Treatment goals
- The requirement for a single prescribing provider or treatment team
- Patients should not change dosing without talking with the prescribing provider
- Discuss role of monitoring tools such as UDT, “pill counts”, AZ CSPMP
- Alcohol and illegal substances should not be used
- All medications (including over the counters and medical marijuana) from other sources should be discussed and documented in the medical record
- Agreement not to drive or operate heavy machinery or do any activity that requires alertness until abatement of medication-related drowsiness
- Responsibility to keep medication safe and secure
- Prohibition of selling, lending, sharing, or giving any medication to others
- Limitations on refills: clinic policy on refills should be reviewed. In general, early or urgent refills will not be given. New or increased pain should be evaluated
- Compliance is expected with all components of overall treatment plan
- Adverse effects and safety issues such as the risk of dependence and addictive behaviors
- Need for periodic re-evaluation of treatment
- Reasons for stopping opioid therapy
- Consequences of non-adherence with the treatment agreement
- The option of sharing information with family members and other providers, as necessary, with the patient’s consent
- Risks during pregnancy and after delivery (see Appendix B)

**#6: CLINICIANS TREATING PATIENTS WITH OPIOIDS FOR CHRONIC PAIN SHOULD OBTAIN AND REVIEW PAST MEDICAL RECORDS WHEN POSSIBLE. ONGOING MEDICAL RECORDS SHOULD DOCUMENT THE PATIENT EVALUATION, TREATMENT PLAN WITH CLEARLY DEFINED GOALS, DISCUSSION OF RISKS AND BENEFITS, INFORMED CONSENT, TREATMENTS PRESCRIBED, RESULTS OF TREATMENT, AND ANY ABERRANT DRUG-RELATED BEHAVIOR OBSERVED.**

**#7: FOR PATIENTS ON CHRONIC OPIOID THERAPY (COT), MONITORING PROGRESS AND ADHERENCE TO THE TREATMENT PLAN IS ESSENTIAL TO OPTIMIZE PATIENT CARE AND THE OVERALL BENEFIT TO RISK PROFILE. APPROPRIATE MONITORING FOR COT INCLUDES, AT A MINIMUM: (1) REGULAR ASSESSMENT WITH FACE TO FACE ENCOUNTERS (2) ASSESSMENT OF RESPONSE TO THERAPY INCLUDING ASSESSMENT OF THE 6 A'S (ANALGESIA, ACTIVITY, ABERRANT DRUG RELATED BEHAVIORS, ADVERSE EFFECTS, AFFECT, AND ADJUNCTS), (3) PERIODIC QUERY OF THE AZ CSPMP, AND (4) PERIODIC COMPLETION OF UDT. FREQUENCY OF MONITORING SHOULD BE DETERMINED BY RISK CATEGORY.**

The concept of “universal precautions” from the infectious disease literature refers to using a set of protective practices for all patients because the risk of a blood borne pathogen cannot be known prior to contact with the patient. In pain medicine, the term universal precautions refers to using a set of safe practices with all patients because the risk of addiction, medication misuse, adverse effects, or diversion cannot be known prior to treating a patient.<sup>42</sup>

Following the practices described in this guideline for all patients on COT will assure that the prescriber is using universal precautions.

CNTP and patient risk characteristics are not static. Change should be anticipated and lead to appropriate adjustments in the treatment plan as indicated. Clinician and patient inertia can often result in continuing a plan of care that is not ideal or even poses significant risk to the patient. Routine monitoring facilitates a proactive approach to optimizing the pain care plan. Particular attention should always be focused on maximizing a comprehensive, whole person, non-opioid approach based on a solid foundation of patient self-management. If pain levels improve, a gradual dose reduction or discontinuation of opioids should be considered.

Frequency of UDT and AZ CSPMP monitoring should be determined by risk category. High risk patients should be monitored quarterly or more frequently as indicated. Moderate risk patients should be monitored twice yearly or more frequent as indicated. Low risk patients should be monitored yearly or more frequent as indicated.

**#8: CLINICIANS SHOULD CONSIDER CONSULTATION, WHEN AVAILABLE, FOR PATIENTS WITH: COMPLEX PAIN CONDITIONS, SERIOUS CO-MORBIDITIES INCLUDING MENTAL ILLNESS, A HISTORY OR EVIDENCE OF CURRENT DRUG ADDICTION OR ABUSE, PATIENTS WHO ARE PREGNANT OR BREASTFEEDING, OR WHEN THE PROVIDER WANTS HELP MANAGING THE PATIENT.**

## **#9: AN OPIOID TREATMENT TRIAL SHOULD BE TAPERED/DISCONTINUED IF THE GOALS ARE NOT MET AND OPIOID THERAPY SHOULD BE TAPERED/DISCONTINUED AT ANY POINT IF RISKS OUTWEIGH BENEFITS OR IF DANGEROUS OR ILLEGAL BEHAVIORS ARE DEMONSTRATED.**

The decision to taper or discontinue opioid therapy should be made by the prescribing provider, often with input from other team members involved in the patient's care, after a discussion with the patient, and if appropriate with the family/caregiver. The tapering treatment plan should be individualized and developed after careful consideration of the potential outcomes and a psychosocial assessment including assessment of suicide risk should be completed when possible. Ongoing monitoring should be anticipated. Every attempt should be made to engage and support the patient during the tapering process. For patients at high ADRB risk (e.g. suicide gestures, dealing/selling medications, those with severe impulse control disorders), tapering opioids in a primary care setting is not appropriate. These patients should be referred to a specialist in pain or SUD.

### **REASONS TO TAPER AND DISCONTINUE OPIOIDS INCLUDE, BUT ARE NOT LIMITED TO:**

- Absolute contraindications to OT
- Severe unmanageable adverse effects
- Serious non-adherence to the treatment plan
- Evidence of illegal or unsafe behaviors
- Misuse suggestive of addiction to prescribed medication
- Lack of therapy effectiveness
- Goals of treatment are not met
- The medication fails to show partial analgesia with incremental dose titration
- Trials with different agents provide inadequate analgesia
- There is other evidence that the pain may not be opioid responsive
- Real or potential harms outweigh real or potential benefits
- A desire on the part of the patient to discontinue therapy
- Decreased level of pain in stable patients

More than 50% of patients started on opioids may choose to discontinue them due to lack of efficacy and/or intolerable side effects.<sup>14</sup> Patients who continue COT are more likely to have high risk characteristics and receive opioid doses > 120mg MED, a process termed "adverse selection."<sup>43-45</sup> Taken together, these data suggest that prescribers of COT for CNTP should frequently reevaluate the appropriateness and risks versus benefits. A re-evaluation of patients with CNTP on COT is an opportunity to maximize whole person, team-based, interdisciplinary non-opioid options for pain care. When patients on COT for CNTP are carefully evaluated for analgesic and functional improvement from COT, the composite picture is not uncommonly one of poor function, a high degree of pain related disability, and high levels of pain. If this is the case, a compassionate, patient-centered conversation should follow and include a recommendation to gradually taper COT and maximize whole person, team-based, interdisciplinary non-opioid approaches. Complex patients with multiple mental health comorbidities will often require specialty consultation and assistance.

***Also consider decreasing the opioid dose when the pain level decreases in stable patients.***

### **WHEN THERE IS CONCERN FOR A SUBSTANCE USE DISORDER:**

- Document and offer referral to addiction specialty services for patients demonstrating behaviors suggesting addiction to prescribed opioids or substance use disorders.
- Discuss pharmacologic options to treat SUD for all patients with opioid and/or alcohol use disorders.
- Discontinue opioid prescribing immediately and address withdrawal if there is clear evidence of unsafe or illegal behaviors.

## WHEN A PATIENT IS PREGNANT:

Chronic opioid therapy in pregnancy is a special situation where the discontinuation of opioids, even in a slowly tapered fashion, may not be the optimal treatment and may put the fetus at risk of multiple complications, including stillbirth (see Appendix B). Because of these risks, providers should consider consultation with an appropriately trained pain specialist, perinatologist, or other expert for their pregnant patients on COT.

## WHEN DISCONTINUING COT:

When a decision is made to discontinue COT in an opioid dependent patient, the clinician should determine the pace and setting for the opioid taper. Opioids should not be abruptly discontinued except in the rare situations where illegal or dangerous behaviors are occurring. Patient safety should be the primary factor in determining the pace and setting of the opioid taper and should be balanced with consideration of available resources, as well as patient preference and comfort. An outpatient opioid taper consisting of a 10% dose reduction every one to four weeks is generally well tolerated. More rapid tapering of COT (10-50% reduction in dose every one to seven days) can be considered when patient safety or preference dictate. Opioid tapering should occur in a structured, specialized outpatient or inpatient setting for patients with serious medical or psychiatric comorbidities that preclude tapering in the primary care setting or in patients with severe withdrawal symptoms, unstable living situations, suicidal ideation, or parasuicidal behavior.

Patients are at risk of unintentional opioid overdose death during opioid tapering, if they resume a higher opioid dose on their own. Loss of tolerance to a higher opioid dose can occur within 1-2 weeks of taking a lower dose of opioids during an opioid taper. Once tolerant to a lower opioid dose, a patient deciding to use a higher dose is at risk for overdose, respiratory depression, and death. This risk should be discussed with patients prior to initiating an opioid taper.

Clonidine and other adjunctive medications may be helpful to treat symptoms of opioid withdrawal with appropriate monitoring for hypotension and anticholinergic side effects if there are no contraindications (see Appendix D).

Benzodiazepines should not be used to treat symptoms of opioid withdrawal during an opioid taper or after opioids have been discontinued.

## **#10: COT SHOULD BE USED IN THE LOWEST POSSIBLE DOSES TO ACHIEVE TREATMENT GOALS. OPIOID RELATED ADVERSE EVENTS INCREASE WITH DOSES > 50-100 MG OF MORPHINE EQUIVALENT DOSE PER DAY (MEDD) AND REACHING THESE DOSES SHOULD TRIGGER A RE-EVALUATION OF THERAPY.**

Opioid related adverse effects including unintentional overdose, death, falls, fractures, traffic accidents, sleep disordered breathing, endocrine dysfunction, are dose related with risk increasing significantly at doses > 50 – 100 mg MEDD.<sup>21-25,42-45</sup> When COT is used for CNTP, the lowest possible doses to achieve treatment goals should be prescribed. In the primary care setting, if COT is prescribed for CNTP, it should generally be used in low to moderate doses (<50-100 mg MEDD).

When patients show evidence of poor pain control or functioning despite being treated with COT doses above 50-100 mg MEDD, rather than increase or maintain opioid doses, it is recommended that a comprehensive, interdisciplinary assessment be performed either within primary care or by referral to specialty services. Switching opioids, or tapering and discontinuing COT will likely be part of the overall care plan in this situation.

For patients receiving COT in primary care on opioid doses above 50-100 mg MEDD and who are functioning well and obtaining good analgesic benefit without significant adverse effects, a gradual dose reduction should be considered to improve the safety profile. Alternatively, referral to specialty services may be considered.

***When an opioid dose reduction or cessation is completed within the context of a comprehensive pain rehabilitation care plan, patients can experience an improvement in pain, function, and mood.<sup>49,50</sup>***

Short acting opioid medications for “breakthrough pain” should not be routinely added to long acting opioids when treating CNTP. However, combination of short acting opioids with long acting opioids may be considered during the titration or taper phases of COT.

MEDD calculations are based on the Washington State Agency Medical Directors’ [Group Opioid Dosing Calculator](#) that can be accessed online or downloaded.

**#11: COMBINED USE OF OPIOIDS AND BENZODIAZEPINES SHOULD BE AVOIDED IF POSSIBLE. IF THIS COMBINATION IS USED, IT SHOULD BE WITH GREAT CAUTION AND INFORMED CONSENT SHOULD BE OBTAINED. PARTICULAR CAUTION SHOULD ALSO BE EXERCISED WHEN OPIOIDS ARE USED CONCURRENTLY WITH OTHER SEDATIVE/HYPNOTICS.**

Combined use of benzodiazepines with opioids increases the risk of respiratory depression and overdose death.<sup>51-55</sup> Benzodiazepines are involved in 30-60% of prescription opioid overdose deaths.<sup>53,56</sup> Caution should be used when opioids are co-prescribed with any sedatives/hypnotics. Carisoprodol is metabolized to meprobamate and its use should be avoided.

**#12: METHADONE SHOULD ONLY BE PRESCRIBED BY CLINICIANS WHO ARE FAMILIAR WITH ITS RISKS AND APPROPRIATE USE AND WHO ARE PREPARED TO CONDUCT THE NECESSARY CAREFUL MONITORING. METHADONE SHOULD GENERALLY NOT BE PRESCRIBED TO OPIOID NAÏVE PATIENTS AND PARTICULAR CAUTION SHOULD BE USED IF METHADONE IS PRESCRIBED FOR OPIOID NAÏVE PATIENTS.**

Methadone has a unique pharmacologic profile and requires a particularly cautious approach when used in the outpatient setting. Methadone has a long and variable half-life, multiple drug-drug interactions, variable equianalgesic dose conversion ratios depending on dose, and is associated with prolongation of the corrected QT interval (QTc). Torsades de pointes is a potentially fatal, polymorphic ventricular arrhythmia that is usually preceded by QTc interval prolongation. Torsades de pointes primarily occurs in patients with QTc intervals >500 ms, though risk is increased starting around QTc intervals of 450 ms.

Methadone can be considered when the decision has been made to use COT with a long acting opioid. However, methadone should generally not be used in opioid naïve patients. An electrocardiogram (ECG) should be obtained prior to initiation in patients with known risk factors for QTc interval prolongation and should be considered in all patients prior to initiation. For patients with risk factors for QTc prolongation such as any prior ECG with a QTc > 450 milliseconds (ms) or a history of syncope, prescribers should perform a follow-up ECG 2 to 4 weeks after initiation of methadone therapy and following significant dose increases. In addition, follow-up ECGs should be obtained if the methadone dose is increased beyond 30-40 mg/d, again if doses are increased beyond 80-100 mg/d, and if new risk factors for QTc prolongation or signs and symptoms of arrhythmia develop.

For QTc > 450 ms and < 500 ms, the prescriber should consider using an alternate opioid or reducing the dose of methadone. For QTc > 500 ms, the prescriber should immediately reduce the dose of methadone or switch to an alternate opioid.

When prescribed in the primary care setting, methadone doses < 30 mg/d should be used. Methadone doses should not be increased more frequently than every 7 days.<sup>57</sup>

The [VA/DoD CPG for the Management of Opioid Therapy for Chronic Pain Appendix F on Methadone dosing](#) (page 135) and the [American Pain Society’s Methadone Safety Guidelines](#) may be referenced when using methadone for CNTP.

## APPENDIX A

**Adjuvant Nonopioid Medications:**<sup>32</sup> Please note this list is not all-inclusive; it is only a list of the most commonly prescribed medications to help with managing pain.

Class	Drug	Dosage
<b>Antidepressants</b>		
Serotonin-norepinephrine reuptake inhibitors	Venlafaxine (Effexor)	25-375 mg divided 2-3x/d
	Desvenlafaxine (Pristiq)	50 mg qd
	Duloxetine (Cymbalta)	20-60 mg qd
	Milnacipran (Savella)	12.5-100 mg 1-2x/d
Tricyclic Antidepressants	Amitriptyline	10-300 mg qd
	Desipramine	10-150 mg qd
	Nortriptyline	10-150 mg qd
Selective serotonin receptor agonists	Buspirone	5-30 mg 1-2x/d
	Vilazodone	10-40 mg qd with food
Selective serotonin reuptake inhibitors	Fluoxetine	10-80 mg qd
	Paroxetine	10-50 mg qd
Mixed receptor activity	Bupropion	IR 75-100 mg 1-3x/d SR 100-200 mg 1-2x/d XR 150-450 mg qd
<b>Anti-inflammatory Drugs</b>		
Oral Agents: Propionic acids	Naproxen	220-500 mg bid
	Ibuprofen	200-800 mg qid
	Ketoprofen	25-50 mg qid
	Flurbiprofen	50-100 mg tid
	Oxaprozin	600-1,200 mg qd
Acetic acids	Diclofenac	50-75 mg bid
	Indomethacin	25-50 mg tid
	Ketorolac	15-30 mg qid
	Etodolac	200-400 mg tid
	Sulindac	150-200 mg bid
	Tolmetin	400-600 mg tid
Oxicams (enolic acids)	Meloxicam	7.5 15 mg qd
	Piroxicam	10-20 mg qd
COX-2-selective inhibitors	Celecoxib	100-200 mg 1-2x/d
Salicylates (nonacetylated)	Salsalate	500-1000 mg up to 3x/d
	Diflunisal	500 mg up to 3x/d
	Choline magnesium trisalicylate	500 – 1,500 mg up to 3 x/d or 3,000 mg at bedtime
Fenamates (anthranilic acids)	Meclofenamate	50 mg qd
Nonacidic	Nabumetone	500-750 mg 2-3x/d

Class	Drug	Dosage
Anticonvulsants	Carbamazepine	100-1200 mg 1-4x/d
	Gabapentin	100-800 mg 1-3x/d
	Pregabalin	25-300 mg 1-3x/d
	Topiramate	25-200 mg 1-2x/d
	Zonisamide	25-200 mg 1-2x/d
	Ethosuximide	250-1,500 mg 1-2x/d
	Lamotrigine	25-500 mg 1-2x/d
	Oxcarbazepine	150-600 mg 1-2x/d
Muscle relaxants	Methocarbamol	500-1,500 mg up to 4x/d
	Orphenadrine	100 mg 1-2x/d
	Tizanidine	2-8 mg up to 3x/d
	Metaxalone	400-800 mg up to 4x/d
	Baclofen	10-20 mg up to 4x/d
	Cyclobenzaprine	5-10 mg qd-tid up to 30 mg/day Alt: 15-30 mg ER po qd
Topicals <sup>33</sup>		
Nonsteroidal anti-inflammatory agents	Diclofenac epolamine 1.5% patch (Flector Patch)	Apply one patch bid (every 12 h)
	Diclofenac sodium 1.5% topical solution (Pennsaid; Covidien)	Apply 40 drops to each knee qid
	Diclofenac sodium 1% gel (Voltaren Gel)	Lower extremities: apply 4 g qid; do not apply more than 16 g Upper extremities: apply 2 g qid; do not apply more than 8 g daily
Local Anesthetics	Lidocaine patch 5% (Lidoderm)	Apply up to 12h/d, 3 patches at a time
	Lidocaine 70 mg/tetracaine (Synera)	Venipuncture or cannulation: apply 20-30 min prior to procedure; dermatologic procedures: apply 30 min prior
Counterirritants	Capsaicin 8% patch (Qutenza; NeurogesX)	Apply for 60 min and repeat every 3 mo or as warranted; do not apply more frequently than every 3 mo
	Capsaicin 0.025%, 0.075% lotion, cream, gel, patch	Apply 3 to 4 times a day
	Methylsalicylate 15%, 30% cream and ointment (Ben Gay)	Apply 3 to 4 times a day; do not use longer than 7 d
	Menthol 2.5%, 5%, 10%, 16% cream, gel, ointment, patch (Icy Hot)	Apply 3 to 4 times a day; do not use longer than 7 d
	Trolamine salicylate 10% cream, lotion (Apercream, Sportscreme)	Apply 3 to 4 times a day; do not use longer than 7 d
	Camphor 11%, menthol 11% (Tiger Balm)	Apply 3 to 4 times a day; do not use longer than 7 d

## APPENDIX B

### CONSIDERATIONS FOR USE OF OPIOIDS DURING PREGNANCY

The significant increase in Neonatal Abstinence Syndrome (NAS) nationally and in Arizona has caused concern about the use of opioids during pregnancy. An [analysis](#) conducted by the Arizona Department of Health Services demonstrated a 205% increase in the rate of infants born exposed to narcotics between 2008 and 2013. In 2013, 645 newborns were identified with the presence of narcotics. This same analysis found that newborns in Arizona with NAS were three times more likely to be low birthweight; four times more likely to have respiratory symptoms; 17 times more likely to have seizures; and five times more likely to have feeding difficulties compared to those without NAS. Arizona newborns with NAS had a median length of stay of 13 days in the hospital compared to a non-NAS newborn with a median length of stay of two days.

While little is known about the long-term effects of exposure to opioids during pregnancy, clinicians are advised to consider the risk of pregnancy when prescribing opioids to women of childbearing age, and to avoid opioids, if at all possible, among pregnant women. Initiating chronic opioid therapy in a patient who is pregnant should be done in consultation with the healthcare provider overseeing the pregnancy and pain specialist as appropriate.

The American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel included recommendations regarding the use of opioids in pregnancy in their [Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain](#):

“Clinicians should counsel women of childbearing potential about the risks and benefits of COT during pregnancy and after delivery. Clinicians should encourage minimal or no use of COT during pregnancy, unless potential benefits outweigh risks. If COT is used during pregnancy, clinicians should be prepared to anticipate and manage risks to the patient and newborn (strong recommendation, low-quality evidence).”

Patient education and informed consent should include information on risks related to pregnancy. Patients of childbearing age should be advised to tell their provider if pregnant or planning to become pregnant. Patients on chronic opioid therapy who are pregnant should be advised of risks of potential harm to the infant, and advised that stopping opioids suddenly when pregnant can lead to complications during pregnancy.

[ACOG Committee Opinion No. 524](#) offers additional guidance on providing care to pregnant women experiencing opioid abuse, dependence, and addiction:

“The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone, but emerging evidence suggests that buprenorphine also should be considered. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use. Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise.”

2 Hussaini SK. Neonatal Abstinence Syndrome: 2008-2013 Overview. Research Brief, 2014. Accessed at: <http://azdhs.gov/phs/phstats/meddir/pdf/neonatal-abstinence-syndrom-research.pdf>

3 Chou R, Fanciullo GJ: Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. J Pain. Feb 2009; 10(2): 113-130. Accessed at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4043401/>

## APPENDIX C

Date \_\_\_\_\_

Patient Name \_\_\_\_\_

### OPIOID RISK TOOL

		Mark each box that applies	Item score if Female	Item Score if Male
1. Family History of Substance Abuse	Alcohol	<input type="checkbox"/>	1	3
	Illegal Drugs	<input type="checkbox"/>	2	3
	Prescription Drugs	<input type="checkbox"/>	4	4
2. Personal History of Substance Abuse	Alcohol	<input type="checkbox"/>	3	3
	Illegal Drugs	<input type="checkbox"/>	4	4
	Prescription Drugs	<input type="checkbox"/>	5	5
3. Age (Mark box if 16–45)		<input type="checkbox"/>	1	1
4. History of Preadolescent Sexual Abuse		<input type="checkbox"/>	3	0
5. Psychological Disease	Attention Deficit Disorder Obsessive Compulsive Bipolar Schizophrenia	<input type="checkbox"/>	2	2
	Depression	<input type="checkbox"/>	1	1
<b>TOTAL</b>		<input type="checkbox"/>		

**Total Score Risk Category**

Low Risk 0–3

Moderate Risk 4–7

High Risk ≥8

## APPENDIX D

### CONSIDER USE OF ADJUNCTIVE MEDICATIONS DURING TAPER<sup>57,58</sup>

Withdrawal symptoms	Clonidine 0.1 mg every 6 to 12 hours as needed
Anxiety, dysphoria, lacrimation, rhinorrhea	Hydroxyzine 25-50 mg every 6 hours as needed Diphenhydramine 25 mg every 6 hours as needed
Myalgias	NSAIDs or acetaminophen
Sleep disturbance	Trazodone (50 -100 mg) or gabapentin (300 -1800 mg) as needed Hydroxyzine 25-50 mg every 6 hours as needed Diphenhydramine 25 mg every 6 hours as needed
Nausea, dyspepsia	Antiemetics <ul style="list-style-type: none"><li>• Ondansatron 4-8 mg every 8 hours as needed</li><li>• Prochlorperazine 5-10 mg every 4 hours as needed</li><li>• Promethazine 12.5-25 mg every 6 hours as needed</li></ul> Calcium carbonate 500 mg 1–2 tabs every 8 hours as needed
Abdominal cramps	Dicyclomine 20 mg every 6 hours as needed
Diarrhea	Antidiarrheal agent such as Bismuth subsalicylate or Loperamide

## APPENDIX E

### ARIZONA RESOURCES

1. Arizona Department of Health Services website for clinicians: <http://azdhs.gov/clinicians/index.htm>
2. Arizona Prescription Drug Misuse and Abuse Initiative: <http://www.azcjc.gov/acjc.web/rx/default.aspx>
3. Arizona Controlled Substances Prescription Monitoring Program: <https://pharmacympm.az.gov/>
4. Arizona Emergency Department Prescribing Guidelines: <http://www.azdhs.gov/phs/owch/ipcfr/injuryprev.htm>
5. Arizona Guidelines for Dispensing Controlled Substances:  
<http://azpharmacy.org/displaycommon.cfm?an=1&subarticlenbr=112>
6. Arizona Living Well Institute – Chronic Disease Self-Management: <http://azlwi.org/>
7. Arizona Smokers Helpline: [www.ASHLine.org](http://www.ASHLine.org)
8. Behavioral Health Services: [www.azdhs.gov/bhs/](http://www.azdhs.gov/bhs/)
9. Drug Disposal & Drop Box locations: <http://www.azcjc.gov/acjc.web/rx/default.aspx>
10. Online Training to incorporate the Arizona Opioid Prescribing Guidelines (including 2 free credits of CME):  
<http://www.vlh.com/AZPrescribing> (as of January 2015)

### NATIONAL RESOURCES

1. American Academy of Pediatrics Clinical Report on Neonatal Drug Withdrawal:  
<http://pediatrics.aappublications.org/content/129/2/e540.abstract>
2. American College of Occupational & Environmental Medicine (ACOEM) Guideline on Opioids:  
[http://www.acoem.org/uploadedFiles/Knowledge\\_Centers/Practice\\_Guidelines/Chronic%20Pain%20Opioid%202011.pdf](http://www.acoem.org/uploadedFiles/Knowledge_Centers/Practice_Guidelines/Chronic%20Pain%20Opioid%202011.pdf)
3. American Pain Society and American Academy of Pain Medicine:  
<http://download.journals.elsevierhealth.com/pdfs/journals/1526-5900/PIIS1526590008008316.pdf>
4. American Society of Interventional Pain Physicians 2012 Opioid Guideline:  
<http://painphysicianjournal.com/2012/july/2012;%2015;S67-S116.pdf>
5. Association of State & Territorial Health Officials Prescription Drug Misuse & Abuse Strategies and Resources:  
<http://www.astho.org/Rx/>
6. Boston University School of Medicine CME courses: [www.opioidprescribing.com](http://www.opioidprescribing.com)
7. CDC Common Elements in Guidelines for Prescribing Opioids for Chronic Pain:  
<http://www.cdc.gov/HomeandRecreationalSafety/overdose/guidelines.html>
8. Emory University Center for Maternal Substance Abuse and Child Development Factsheet on Opiate Use in Pregnancy:  
<http://www.emory.edu/msacd/documents/Factsheets/Opiate%20Use%20During%20Pregnancy.pdf>
9. Federation of State Medical Boards: [http://library.fsmb.org/pdf/pain\\_policy\\_july2013.pdf](http://library.fsmb.org/pdf/pain_policy_july2013.pdf)
10. National VA guidelines: ([http://www.va.gov/PAINMANAGEMENT/docs/CPG\\_opioidtherapy\\_summary.pdf](http://www.va.gov/PAINMANAGEMENT/docs/CPG_opioidtherapy_summary.pdf))
11. National Institute of Drug Abuse Opioid Prescribing Resources:  
<http://www.drugabuse.gov/nidamed-medical-health-professionals/tool-resources-your-practice/opioid-prescribing-resources>
12. Partnership for Drug-free Kids: <http://www.drugfree.org/>
13. Providers' Clinical Support System for Medication Assisted Treatment: [www.pccsmat.org](http://www.pccsmat.org)
14. SAMSHA Opioid Overdose Toolkit:  
<http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>

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## SUMMARY OF ARIZONA OPIOID PRESCRIBING GUIDELINES FOR THE TREATMENT OF ACUTE PAIN

The goal of these guidelines is to balance the appropriate treatment of pain with approaches to more safely prescribe opioids. Thoughtful opioid prescribing for acute and post-operative pain can improve safety, reduce harm, and prevent the unintended or inappropriate long-term use of opioid medications.

Note: These guidelines are not intended to apply to hospice or palliative care patients (as defined by the World Health Organization), patients at end of life, or cancer-related pain.

- #1:** Opioid medications should only be used for treatment of acute pain when the severity of the pain warrants that choice, and non-opioid pain medications or therapies will not provide adequate pain relief.
- #2:** When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed. This should be based on the expected duration of pain severe enough to justify prescribing opioids for that condition.
- #3:** When opioid medications are prescribed for acute pain, the patient should be counseled on the following:
  - Sharing with others is illegal.
  - Medications should be stored securely.
  - Medications should be disposed of properly when the pain has resolved to prevent non-medical use of medications.
  - Opioids are intended for short-term use only.
  - Driving or operating machinery should be avoided if a patient is sedated or confused while using opioids.
- #4:** Long acting opioids should not be used for treatment of acute pain, including post-operative pain, except in select opioid tolerate patients and situations where monitoring and assessment for adverse effects can be conducted.
- #5:** The continued use of opioids should be considered carefully, including assessing the potential for misuse. If pain persists beyond the anticipated treatment duration, then the patient should be carefully reevaluated.
- #6:** The Arizona Controlled Substances Prescription Drug Monitoring Program should be checked prior to prescribing opioids and periodically if renewing opioid prescriptions.

For more information on the Arizona Opioid Prescribing Guidelines, visit <http://azdhs.gov/clinicians/clinical-guidelines-recommendations/>



## SUMMARY OF ARIZONA OPIOID PRESCRIBING GUIDELINES FOR THE TREATMENT OF CHRONIC NON-TERMINAL PAIN (CNTP)

- #1:** A comprehensive medical and pain related evaluation that includes assessing for substance use, psychiatric comorbidities, and functional status should be performed before initiating opioid treatment for chronic pain.
- #2:** A goal directed trial of opioid therapy is considered appropriate when pain is severe enough to interfere with quality of life and function and the patient has failed to adequately respond to indicated non-opioid and non-drug therapeutic interventions. Potential benefits should be determined to outweigh risks. The patient should agree to participate in other aspects of a pain care plan such as physical therapy and cognitive behavioral therapy when these therapies are recommended and available.
- #3:** The provider should assess for risk of misuse, addiction, or adverse effects, and perform a risk stratification before initiating opioid treatment.
- #4:** Initiating opioids in patients with CNTP should ideally be limited to the evidence-based indication of short term therapy with the purpose of facilitating participation in a comprehensive care plan; however, if chronic opioid therapy (COT) is considered, a goal directed trial lasting 30-90 days should be the starting point. Continuing opioid treatment after the treatment trial should be a deliberate decision that weighs the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult with a pain specialist may be useful.
- #5:** When a trial of opioid therapy is determined to be appropriate, patients should be actively engaged in a process of education, shared decision-making, and informed consent. The provider should obtain and document informed consent including discussion of risks, benefits, and conditions under which opioids are prescribed or discontinued. Documentation of this discussion is ideally accomplished by using a signed Opioid Pain Care Agreement (OPCA).
- #6:** Clinicians treating patients with opioids for chronic pain should obtain and review past records when possible. Ongoing medical records should document the patient evaluation, a treatment plan with clearly defined goals, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant drug-related behavior observed.
- #7:** For patients on chronic opioid therapy (COT), monitoring progress and adherence to the treatment plan is essential to optimize patient care and the overall benefit to risk profile. Appropriate monitoring for COT includes, at a minimum: (1) regular assessment with face to face encounters (2) assessment of response to therapy including assessment of the 6 A's (analgesia, activity, aberrant drug related behaviors, adverse effects, affect, and adjuncts), (3) periodic query of the AZ Controlled Substances Prescription Monitoring Program, and (4) periodic completion of UDT. Frequency of monitoring should be determined by risk category.
- #8:** Clinicians should consider consultation, when available, for patients with: complex pain conditions, serious comorbidities including mental illness, a history or evidence of current drug addiction or abuse, patients who are pregnant or breastfeeding, or when the provider wants help managing the patient.
- #9:** An opioid treatment trial should be tapered/discontinued if the goals are not met and opioid therapy should be tapered/discontinued at any point if risks outweigh benefits or if dangerous or illegal behaviors are demonstrated.
- #10:** COT should be used in the lowest possible doses to achieve treatment goals. Opioid related adverse events increase with doses > 50-100 mg of morphine equivalent dose per day (MEDD) and reaching these doses should trigger a re-evaluation of therapy.
- #11:** Combined use of opioids and benzodiazepines should be avoided if possible. If this combination is used, it should be with great caution and informed consent should be obtained. Particular caution should also be exercised when opioids are used with other sedatives/hypnotics.
- #12:** Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use and who are prepared to conduct the necessary careful monitoring. Methadone should generally not be prescribed to opioid naïve patients and particular caution should be used if methadone is prescribed for opioid naïve patients.





**ONLINE ACCESS:** This document can be accessed electronically at [www.azdhs.gov/clinicians/clinical-guidelines-recommendations/](http://www.azdhs.gov/clinicians/clinical-guidelines-recommendations/)