



COLORADO

**Department of
Regulatory Agencies**

Division of Professions and Occupations

Guidelines for the Safe Prescribing and Dispensing of Opioids

Colorado Dental Board, Colorado Medical Board, State Board of Nursing, State Board of Optometry, Colorado Podiatry Board and State Board of Pharmacy

In collaboration with the Nurse-Physician Advisory Task Force for Colorado Healthcare and Endorsed by the Colorado State Board of Veterinary Medicine.

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PREAMBLE

The effective and safe management of pain is a primary concern for both Colorado healthcare providers and patients. In 2012, over 25 million adults in the United States reported experiencing pain on a daily basis.¹ That same year, over 259 million prescriptions for opioids were written.² In 2013, the misuse and abuse of prescription opioids in Colorado and across the United States evolved into a public health epidemic³ leading to drug addiction,⁴ overdose deaths,⁵ and increased costs to society.⁶

In order to address this public health crisis, the Colorado Dental Board, Colorado Medical Board, State Board of Nursing, State Board of Pharmacy, and the Nurse-Physician Advisory Task Force for Colorado Healthcare collaborated to develop a policy providing meaningful guidance to prescribers and dispensers of opioids in Colorado. The *Policy for Prescribing and Dispensing Opioids* (“Policy”) was adopted by the four boards in 2014. The Policy was subsequently adopted by The State Board of Optometry and the Colorado Podiatry Board and endorsed by the Colorado State Board of Veterinary Medicine.⁷

In 2016, the Boards⁸ embarked on a process of evaluating the Policy - soliciting statewide stakeholder feedback, consulting with experts in the field of pain management, addiction and mental health, and reviewing current literature, policy, and guidelines related to the safe prescribing and dispensing of opioids for pain. The Boards then collaborated to revise the Policy to both harmonize the guidelines with current policies and provide Colorado prescribers and dispensers with current, evidence-based guidance.

Today’s prescribers have dual obligations: to effectively manage pain and improve function while reducing opioid-related adverse outcomes such as diversion, addiction, overdose, and death. Pharmacists share a corresponding responsibility with the prescriber to assure that a prescription order is valid in all respects and is appropriate for the patient and condition. The Boards acknowledge the complexities faced by Colorado prescribers and dispensers in the appropriate management of pain, including the demands on practitioners considering opioid therapy. These demands differ depending on the practice setting, the patient diagnosis and condition, and the patient’s access to care.

¹ Nahlin RI. Estimates of Pain Prevalence and severity in adults—United States. 2012. *J. Pain*.2015;16:769-80, <http://dx.doi.org/10.1016/j.jpain.2015.05.002>.

² LJ. Mack KA, Hockenberry JM. *Vital Signs: variations among states in prescribing opioid pain relievers and benzodiazepines-- United States*. 2012. *MMWR Morb Mortal Wkly Rep*2014;63 563-8.

³ *Weighted National Survey on Drug Use and Health* (NSDUH) estimates suggest that, in 2016, 11.5 million U.S. civilian, noninstitutionalized adults misused prescription opioids. Christie, C, Baker, C, Cooper, R, Kennedy, P, Madras, B, Bondi, P. President’s Commission on Combatting Opioid Addiction and the Opioid Crisis. (2017) Washington D.C.

⁴ Nearly 1 in 4 patients using prescription opioids for chronic, non-cancer pain in primary care settings struggles with addiction. Boscarino JA, Rukstalis M, Hoffman SN, et al. *Risk factors for drug dependence among outpatients on opioid therapy in a large US health-care system*. *Addiction* 2010;105:1776-82. <http://dx.doi.org/10.1111/j.1360-0443.2010.03052>.

⁵ In 2015, more than 15,000 people died in the United States from prescription opioid overdose. Rudd RA, Seth P, David F, Scholl L. *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*. *MMWR Morb Mortal Wkly Rep*. ePub: 16 December 2016. DOI: <http://dx.doi.org/10.15585/mmwr.mm6550e1>;

⁶ In 2013, the estimated economic burden of prescription opioid abuse, dependence and overdose was estimated \$78.5 billion. Christie, C, Baker, C, Cooper, R, Kennedy, P, Madras, B, Bondi, P. President’s Commission on Combatting Opioid Addiction and the Opioid Crisis. (2017) Washington D.C.

⁷ The Colorado State Board of Veterinary Medicine subsequently adopted the *Veterinary Policy for Prescribing and Dispensing Opioids* in 2016, balancing the need for coordinated efforts by all prescribers to reverse the trend of opioid misuse and abuse and the nuances of prescribing opioids, through human clients, for animal patients.

⁸ “Boards” as used in this policy means the Boards overseeing prescribing and dispensing of opioids and involved in the drafting and/or revision of this policy: the Colorado Dental Board; the Colorado Medical Board; the State Board of Nursing; the State Board of Optometry; the Colorado Podiatry Board; and, the State Board of Pharmacy.

Pain management, mental and behavioral health and addiction specialists play an important role in the treatment of chronic, non-cancer pain. Many of the tools and practices referenced in this policy were developed by such specialists. While the need for therapeutic care of pain in Colorado exceeds the supply of specialists in the state, other types of providers can successfully treat many painful conditions and achieve the function and relief the patient seeks. Accordingly, this Policy is intended to educate a broad range of prescribers and dispensers by providing guidelines, resources and tools that may be referenced at the point-of-care to support clinical decision making.

The Boards further recognize that reversing the trend of opioid misuse and abuse requires a coordinated, multimodal approach. This approach should include: increasing public awareness; the provision of constructive, collaborative policies aimed at improving prescriber education and practice; strategies to increase healthcare providers' use of the Prescription Drug Monitoring Program ("PDMP"); tactical harm reduction and diversion prevention initiatives; enhanced addiction treatment and recovery options; research and development related to tamper resistant opioids; and, efforts by law enforcement to reduce the illicit opioid supply.

Toward this end, the Boards have adopted this Policy to ensure consistent, evidence-based guidance for all Colorado prescribers and dispensers treating patients over 18 years of age suffering from acute, subacute or chronic, non-cancer pain. For the purpose of this Policy, the terms "chronic pain" or "chronic non-cancer pain" refer to pain that lasts longer than 90 days or beyond the time of normal tissue healing and is non-terminal. It does not include conditions such as cancer, scleroderma, multiple sclerosis, muscular dystrophy, rheumatoid arthritis or other conditions that may require palliative⁹ or end-of-life care.

This Policy provides guidelines and represents the Boards' current thinking on this topic. It does not set a standard of care for prescribers or dispensers.¹⁰ Practitioners may use an alternative approach provided the approach satisfies the requirements of the applicable statutes, regulations, and standard of care.¹¹ The Boards will refer to generally accepted standards of practice and expert review in approaching cases involving opioid therapy in the management of pain.

⁹ The term "palliative care" as used in this policy refers to care that provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness.

¹⁰ A "policy" is adopted by a board to provide guidance to licensees regarding the board's position on various subjects. Policies do not have the force of law. Conversely, "rules" have the force of law and set forth requirements to which licensees must adhere.

¹¹ Opioid prescribers and dispensers must conform to the regulations set forth by the respective licensing board and other applicable law.

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EXECUTIVE SUMMARY

Purpose

Prescribers and dispensers have an obligation to effectively manage pain and improve function while reducing opioid-related adverse outcomes. To assist healthcare professionals in discharging this duty, the Boards have adopted this Policy to ensure consistent, evidence-based guidance for all Colorado prescribers and dispensers in their treatment of patients 18 years of age and older suffering from acute, subacute or chronic, non-cancer pain. For the purpose of this Policy, the terms “chronic pain” or “chronic non-cancer pain” refer to pain that lasts longer than 90 days or beyond the time of normal tissue healing and is non-terminal. It does not include conditions such as cancer, scleroderma, multiple sclerosis, muscular dystrophy, rheumatoid arthritis or other conditions that may require palliative or end-of-life care.

Overview of Recommendations

- ✦ Prior to Prescribing or Dispensing Opioids
 - ✓ Develop and Maintain Competence
 - ✓ Diagnose and Evaluate Patient
 - ✓ Consider Alternatives to Opioids
 - ✓ Collaborate with the Healthcare Team
 - ✓ Patient Education
 - ✓ Develop an Exit Strategy
- ✦ When Prescribing or Dispensing Opioids
 - ✓ Verify a patient-provider relationship
 - ✓ Prescribing Safeguards
 - ⊛ **Dosage-** When prescribing a dosage **above 50 mme/day, STOP:** 1) Ensure the patient’s condition warrants the higher dose; 2) Ensure the benefits of a higher dose outweigh the risks; and, 3) Ensure additional risk mitigation strategies are in place.
 - ⊛ **Formulation-** When prescribing a **long-acting or extended relief formulation, STOP:** 1) Ensure the patient’s condition warrants this formulation; 2) Ensure the benefits of this formulation outweigh the risks; 3) Consider concurrent medications that may potentiate the effects of the formulation; 4) Ensure the patient has been treated with immediate release opioids for at least one week prior to prescribing or dispensing this formulation; and, 5) Ensure additional risk mitigation strategies are in place.
 - ⊛ **Duration-**
 - When treating acute, **non-traumatic or non-surgical pain, STOP:** 1) Ensure the amount of medication prescribed or dispensed does not exceed the expected duration of the pain, typically **3-7 days**.
 - When prescribing opioids for subacute pain and the treatment of chronic, non-cancer pain **STOP:** 1) **Reassess pain and function within 30 days of initiating therapy** to ensure a clear benefit; and, 2) Ensure the benefits of continued opioid therapy outweigh the risks.
 - If the opioid treatment **exceeds 90 days for chronic, non-cancer pain, STOP:** 1) Ensure the patient continues to show clinical improvement with opioid therapy; 2) Ensure the benefits of continued opioid therapy outweighs the risk; and 3) Ensure additional risk mitigation strategies are in place.
- ✦ Risk Mitigations Strategies
 - ✓ Tools and Trials
 - ✓ Referral to Pain Management Specialist
 - ✓ Monitoring
 - ✓ Treatment Agreements
 - ✓ Concurrent Naloxone Prescribing
 - ✓ Patient Education
- ✦ Discontinuing Opioid Therapy
- ✦ Treatment for Opioid Use Disorder

BEFORE PRESCRIBING OR DISPENSING

Develop and maintain competence

Prescribers, including prescribers who dispense, must maintain competence to assess and treat pain to improve function. This includes understanding current, evidenced-based practices and using other resources and tools related to opioid prescribing and dispensing. Pharmacists must maintain competence in the appropriateness of therapy. Prescribers and dispensers should incorporate education courses specific to pain management and opioid prescribing and/or dispensing practices into their maintenance of competence plan.

See the Appendix for a list of resources, courses and tools for developing and maintaining competence.

Diagnose and Evaluate

The decision to prescribe or dispense opioid medication to patients may be made only after a proper diagnosis and complete evaluation, which should include an assessment of the pain, functionality and risk, and review of relevant PDMP data. These safeguards should be used prior to initiating treatment for both acute¹² and chronic, non-cancer pain.

1. Diagnose

Prescribers should establish a diagnosis and legitimate medical purpose appropriate for the initiation of treatment for pain management including opioid therapy through a history, physical exam, and/or laboratory, imaging or other studies. A bona fide provider-patient relationship must exist.

2. Assess Risk

Prescribers should conduct a risk assessment prior to prescribing opioids, periodically during continuation of opioid therapy, and before increasing dosage or the addition of other medications or upon learning of any factors that may lead to adverse outcomes. Risk assessment is defined as the identification of factors that may lead to adverse outcomes that may include:

- Patient and family history of substance use (drugs including prescription medications, alcohol and marijuana);
- History of opioid use through both patient history and the PDMP;
- Overdose history;
- Patient medication history (among other reasons, this is taken to avoid unsafe combinations of opioids with sedative-hypnotics, benzodiazepines, barbiturates, muscle relaxants, other opioids or to determine other drug-drug interactions) through patient history, PDMP, and Urine Drug Screen, as indicated;
- Mental health/psychological conditions and history;

¹² Retrospective cohort study found opioid therapy prescribed for acute pain is associated with increased likelihood of long-term use. Alam A, Gomes T, Zheng H, Mamdani MM, Juurlink DN, Bell CM. *Long-term analgesic use after low-risk surgery; a retrospective cohort study*. Arch Intern Med 2012; 172:425-30. <http://dx.doi.org/10.001/archinternmed.2011.1827>.

- Insomnia or other sleep disorders;
- Abuse history including physical, emotional or sexual¹³;
- Pregnancy or current family planning for women of reproductive age¹⁴;
- Health conditions that could aggravate adverse reactions (including COPD, CHF, sleep disordered breathing, including sleep apnea, obesity, age < 18 years or ≥ 65 years, or history of renal or hepatic dysfunction);¹⁵ and
- Prescribers and dispensers should observe the patient for any aberrant drug-related behavior and follow-up appropriately if such behavior is exhibited. See the Appendix for a description of aberrant drug-related behaviors.

If the assessment identifies risk factors, prescribers should first opt for nonopioid treatment options. If the benefits of opioid therapy outweigh the identified risks, the prescriber should proceed with caution, ensuring safeguards, as detailed below, are in place prior to the initiation of opioid therapy.

See the Appendix for additional resources related to assessment, including resources for alcohol and substance use screening and guidelines for treating patients with risk factors.

3. Assess Pain

Prescriber should assess the patient's pain prior to treatment. This assessment should also be completed periodically during continuation of opioid therapy and before increasing dosage, changing formulation or the addition of other medications in order to document the trajectory of the treatment.

An appropriate pain assessment should include an evaluation of the patient's pain for the:

- Nature and intensity;
- Type;
- Pattern/frequency;
- Duration;
- Past and current treatments;
- Underlying or co-morbid disorders or conditions; and
- Impact on physical and psychological functioning.

4. Assess Function

Functional assessment is critical in the management of pain. Functional ability has been found to be a more reliable measure in the evaluation of treatment and is essential for establishing agreed upon functional goals.

Prescribers should assess the patient's functional ability prior to treatment. This assessment should also be completed periodically during opioid therapy and before increasing dosage, changing formulation or the addition of other medications.

¹³ Individuals suffering childhood trauma, including sexual abuse, physical abuse, and neglect, were three times more likely to misuse prescription pain medication. Quinn, K., Boone, L., Scheidell, J.D., Mateau-Gelabert, P., Mcgorray, S.Sp., Beharie, N., Cottler, L.B, and Kahn, M.R (2016) The relationship of childhood trauma and adult prescription pain reliever misuse and injection drug use. *Drug and Alcohol Dependence*, 169, 190-198.

¹⁴ Providers should consult with an OB/GYN provider prior to initiating opioid therapy in pregnant or breastfeeding patients or those patients currently engaged family planning.

¹⁵ This policy is intended to apply to patient 18 years of age and older. Providers should consult with a pediatric pain specialist prior to initiating opioid therapy in patients under 18 years of age.

See the Appendix for Functional Assessment Tools.

5. Psychological Assessment

In instances where the risk assessment identifies a mental health or psychological condition, the prescriber should consider referring the patient to a mental health provider for a psychological or cognitive behavioral assessment.

6. Review PDMP

Prescribers and dispensers should access the PDMP and review the patient profile prior to making a determination regarding the initiation of opioid therapy. Prescribers and dispensers should also review the patient's PDMP profile prior to each instance in which opioids are prescribed, refilled or dispensed. Prescribers and Dispensers may want to consider reviewing the patient's pet or animal profile if there is a concern for diversion of veterinary prescriptions.

Consider Alternatives to Opioid Therapy

Not all pain conditions require opioid treatment. The first step in reducing the misuse and abuse of opioids is to avoid prescribing opioids when nonpharmacologic or nonopioid pharmacologic treatments are effective in addressing the patient's pain and function. This applies not only to chronic, non-cancer pain, but also, acute pain. Studies have shown that opioid treatment for acute pain has been associated with long-term opioid use¹⁶ and that physical dependence on opioids is an expected physiological response for patients using opioids for more than a few days.¹⁷

The decision to prescribe or dispense opioids should be made only after careful consideration of the benefits and risks of **all** treatment options. Other treatment options may include, but are not limited to, the following:

- **Nonopioid Pharmacologics** such as acetaminophen, alpha-acting agents, anticonvulsants, antidepressants, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, or topical lidocaine; and
- **Nonpharmacologic treatments** such as acupuncture, complementary alternative medicine, cognitive behavioral therapy, dry needling, exercise therapy, massage therapy, physical therapy, occupational therapy, osteopathic manipulation, regenerative therapy, trigger point or interventional/targeted injections, electrical stimulation, biofeedback, radio frequency ablation or interventional pain management procedures.

If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

¹⁶ Retrospective cohort study found opioid therapy prescribed for acute pain is associated with increased likelihood of long-term use. Alam A, Gomes T, Zheng H, Mamdani MM, Juurlink DN, Bell CM. *Long-term analgesic use after low-risk surgery; a retrospective cohort study.* Arch Intern Med 2012; 172:425-30. <http://dx.doi.org/10.001/archinternmed.2011.1827>

¹⁷Dowell D, Haegerich TM, Chou R. *CDC guideline for prescribing opioids for chronic pain – United States, 2016.* MMWR Recomm Rep 2016;65(RR-1):1-49

Collaborate with the Healthcare Team

Prescribers and dispensers should collaborate with members of the healthcare team, including mental and behavioral health providers and addiction and pain management specialists, to prevent under-prescribing, over-prescribing, misuse and abuse of opioids. See the Appendix for additional resources.

Patient Education

A decision to initiate opioid therapy should be a shared decision between the patient and the prescriber. Prescribers should educate patients regarding all treatment options for the management of pain, ensuring the patient is provided with, and understands, the necessary information to make informed decisions. Prescribers should provide this information in a format suited to the particular patient, taking into account the patient's learning style, literacy, culture, language and physiological barriers.

When providing information, prescribers and dispensers should emphasize key points, speak slowly and avoid medical jargon. Prescribers and dispensers should review any handouts or materials with the patient prior to providing them to the patient, using resources as supplement to, rather than substitute for, one-on-one patient education. Prescribers and dispensers should include family members in patient education whenever possible.

Patient education relating to pain management should include the risks and realistic benefits of each therapeutic option. Risks of opioid use may include, but are not limited to, overdose, misuse, diversion, addiction, physical dependence and tolerance, interactions with other medications or substances, and death. When alerted to these risk factors, patients can make more informed decisions about their treatment options. For example, some patients have reduced, discontinued or forgone opioids when alerted to the risk factors.

Prescribers should also ensure patients are provided with information on dose, administration, side effects, effects of opioids on the safe operation of a motor vehicle or heavy machinery, potential medication or substance interactions, risks to family members who may come into contact with the drug, and the safe use, storage, and disposal of opioids. See the Appendix for resources on safe disposal.

Pharmacists should offer to review information with the patient about dose, side effects, medication or substance interactions, risks, disposal, and other applicable topics.

Establish an Exit Strategy

Prior to initiating opioid therapy, prescribers should develop a longitudinal treatment plan for the management of the patient's pain. This plan should be established with the patient, particularly as it relates to how treatment effectiveness will be established and setting realistic goals for pain and function.

This plan should highlight how and when opioid therapy will be discontinued, linking the discontinuation of the therapy to the achievement of functional goals. The

prescriber should further ensure the patient is aware that opioid therapy should be discontinued absent clinically significant improvement in pain and function or when the risks of opioid therapy outweigh the benefits.

This plan is also an opportunity for the prescriber to detail the responsibilities of the patient and the prescriber in the management of the patient's pain.

WHEN PRESCRIBING OR DISPENSING

Verify a provider-patient relationship

A bona fide provider-patient relationship must exist. The prescriber or dispenser should verify the patient's identification prior to prescribing or dispensing opioids to a new or unknown patient.

For pharmacists, this includes exercising judgment and conducting research (such as use of the PDMP or communication with the prescriber or relevant pharmacies) when the prescription order is:

- For a new or unknown patient;
- For a weekend or late day prescription;
- Issued far from the location of the pharmacy or patient's residential address; or,
- Denied by another pharmacist.

Prescribing Safeguards

Prescribers should ensure the dose, quantity, and refills for prescription opioids are appropriate to improve the function and condition of the patient, at the lowest effective dose and quantity, in order to avoid over-prescribing opioids.

Factors that have been associated with adverse outcomes include: 1) opioid doses greater than 50 morphine milligram equivalents per day; 2) long-acting or extended relief formulations; and, 3) treatment exceeding 3 to 7 days for acute pain and 90 days for chronic, non-cancer pain. Risk Mitigation strategies have been found to reduce these risks.

Dosage

When initiating and throughout continuing opioid therapy, prescribers should prescribe the lowest effective dosage. Opioid doses greater than 50 morphine milligram equivalents (MME) per day is a dosage that the Boards and the Centers for Disease Control¹⁸ agree is more likely dangerous for the average adult (chances for unintended death are higher) over which prescribers should use clinical judgment, invoke additional risk mitigation strategies, consult a specialist or refer the patient to a specialist. Pharmacists and dispensers should exercise greater caution in such instances.

When determining dosage, prescribers should consider patient medications including, but not limited to, benzodiazepines, that are known to potentiate the effects of

¹⁸ Dowell D, Haegerich TM, Chou R. *CDC guideline for prescribing opioids for chronic pain – United States, 2016*. MMWR Recomm Rep 2016;65(RR-1):23.

opioids and health conditions that may affect that patient's ability to process and excrete the drug. In addition, prescribers should exercise caution when determining dosage using dose calculators, particularly when prescribing methadone.¹⁹ See the Appendix for additional resources regarding dose calculators.

Formulation

Long-acting or extended relief opioids increase the risk of overdose in opioid naïve patients.²⁰ In addition, patients who begin opioid therapy with long-acting opioids are over 4 times more likely to use opioids long term than patients who begin opioid therapy with immediate release formulations.²¹ Prescribers should not prescribe long-acting or extended relief opioid formulations for the treatment of acute pain, subacute pain or when initiating opioid therapy for chronic, non-cancer pain.

Long-acting or extended relief opioids should be reserved for severe, continuous pain and should be considered for only those patients who have received immediate release opioids for at least one week.²² When prescribing long-acting or extended relief opioids, the prescriber should consider patient medications, including concurrent use of immediate relief opioids, which may potentiate the effects of the opioid and health conditions that may affect that patient's ability to process and excrete the drug.

- Providers should exercise caution when prescribing or dispensing transdermal fentanyl, or methadone. See Appendix for information regarding methadone.

Duration

Long-term opioid use often begins with treatment of acute pain. When treating acute pain, prescribers should prescribe only the amount of medication needed for the expected duration of the pain. In most instances of non-traumatic or non-surgical pain, three days or less is sufficient, while more than seven days is rarely necessary.²³

For longer-term opioid therapy for subacute pain²⁴ and the treatment of chronic, non-cancer pain, prescribers should note that contextual evidence suggests that patients who do not experience pain relief from opioids at 30 days are unlikely to experience relief at six months.²⁵ Prescribers should reassess pain and function within 30 days of initiating therapy to minimize the risks of long-term opioid use for those patients receiving no clear benefit from opioid therapy.

Continuing opioid therapy for over 90 days substantially increases the risk for opioid

¹⁹ The equianalgesic dose ratio of methadone is non-linear, becoming more potent as the methadone dose increases. National Vital Statistics System 1999-2009; Drug Enforcement Administration Automation of Reports and Consolidated Order Systems (ARCOS), 1999-2010.

²⁰ Chou R, Clark E, Helfand, M. *Comparative efficacy and safety of long-acting oral opioids for chronic non-cancer pain: a systematic review.* J. Pain Symptom Manage, 2003;26:1026-1048.

²¹ Shah A, Hayes CJ, Martin BC, *Characteristics of Initial Prescription Episodes and Likelihood of Long Term Opioid Use-United States.* 2006-2015, *MMWR*, 2017;66:265-269.

²² Dowell D, Haegerich TM, Chou R. *CDC guideline for prescribing opioids for chronic pain – United States, 2016.* *MMWR Recomm Rep* 2016;65(RR-1):22.

²³ Dowell D, Haegerich TM, Chou R. *CDC guideline for prescribing opioids for chronic pain – United States, 2016.* *MMWR Recomm Rep* 2016;65(RR-1):24.

²⁴ For the purpose of this policy, “subacute” pain is defined as pain that exceeds 30 days but is limited to less than 90 days.

²⁵ Dowell D, Haegerich TM, Chou R. *CDC guideline for prescribing opioids for chronic pain – United States, 2016.* *MMWR Recomm Rep* 2016;65(RR-1):25.

use disorder.²⁶ As such, treatment for chronic non-cancer pain exceeding 90 days should be re-evaluated, assessing both the effectiveness of the therapy as measured by attainment of functional goals and weighing the benefits of the therapy against the risks to the patient.

In those instances in which the benefits continue to outweigh the risks and the patient continues to show clinical improvement after 90 days of opioid therapy, prescribers and dispensers should implement additional risk mitigation strategies, if not already in place, as detailed below.

RISK MITIGATION STRATEGIES

Tools and Trials

Prior to issuing prescriptions that are outliers to the dosage, formulation and duration guidelines, described herein, for chronic, non-cancer pain, prescribers should determine whether the opioid therapy has resulted in clinically significant improvement in pain and function and that the benefits of the therapy outweigh the risks to the patient. Opioid trials may assist in this determination.

Referral to Pain Management Specialist

Prior to issuing prescriptions that are outliers to the dosage, formulation or duration guidelines, as described herein, for chronic, non-cancer pain, prescribers should consult with, or consider referral of the patient to, a pain management specialist. Such consultation or referral should also be considered for those patients at risk for respiratory depression, suicide or overdose and any patient concurrently prescribed medications such as benzodiazepines that are known to potentiate the effects of opioids.

Monitoring

Opioid therapy for chronic, non-cancer pain requires regular monitoring by the prescriber. Monitoring should include:

- Reassessment of the patient's pain, function, and risk;
- Rebalancing of the risks and benefits of continued opioid therapy;
- Rechecking the PDMP, and,
- Conducting random and/or routine pill counts or drug screening according to the prescriber's clinical assessment.

These monitoring tools and others should be documented in a treatment agreement signed by the patient, described more below. Prescribers should not increase an initial opioid dosage without reassessing the patient's pain, function and risk, rechecking the PDMP and rebalancing the risks and benefits of continued opioid therapy.

Treatment Agreements

Prescribers should utilize treatment agreements (also commonly referred to as a plan or contract). Treatment agreements should incorporate information from the patient's

²⁶Dowell D, Haegerich TM, Chou R. *CDC guideline for prescribing opioids for chronic pain – United States, 2016*. MMWR Recomm Rep 2016;65(RR-1):25

longitudinal treatment plan including, the agreed upon pain and function goals, the responsibilities of the patient and the prescriber in the management of the patient's pain and the discontinuation plan. The agreement should also address the risks and benefits of opioid therapy and address alternative treatment options. Treatment agreements should address risk mitigation strategies that may include, but are not limited to:

- Prescribing and Dispensing Controls (single prescriber, single pharmacy for refills);
- Random or routine drug testing;
- Restrictions on alcohol and/or illicit drug use;
- Random or routine pill counts;
- Storage, disposal, and diversion precautions (including detailed precautions related to adolescents and/or children and visitors to the home); and,
- Disclosure of alternative therapies.

Treatment agreements should also address the process and reasons for changing or discontinuing the treatment plan, the reassessment schedule and referral to a specialist for pain management or suspected opioid use disorder.

Prescribers should ensure the patient has a clear understanding of the treatment agreement using the patient education techniques previously discussed and by documenting the patient's understanding in the medical record or through the patient's signature on the treatment plan.

See the Appendix for resources on sample agreements.

Concurrent Naloxone Prescriptions

Opioid overdose deaths may be preventable by the timely administration of naloxone. Several studies indicate that home naloxone programs are effective in decreasing overdose mortality and have a low rate of adverse events.²⁷ Prescribers and dispensers should consider concurrent naloxone prescriptions for those patients at risk for respiratory depression, suicide or overdose and any patient concurrently prescribed medications such as benzodiazepines that are known to potentiate the effects of opioids. In addition, concurrent naloxone prescriptions should be considered for patients receiving any prescription outlier for dosage, formulation or duration.

Naloxone rescue prescriptions should be accompanied by patient and family member education regarding signs of overdose, administration of naloxone and activation of emergency medical services.

Patient Education

In addition to educating the patient prior to initiating opioid therapy, prescribers should incorporate patient education into each patient's evaluation during opioid treatment. Education is particularly important prior to increasing dosage, extending treatment, changing formulations, upon learning of new factors that may lead to adverse outcomes and any change in the risk/benefit balance.

Prescribers should regularly re-educate patients regarding risks, benefits, side effects, alternative treatments, diversion and the safe use, and the storage and disposal of opioids.

²⁷ McDonald R, Strang J. *Are take-home naloxone programmes effective? Systematic review utilizing application of the Bradford Hill criteria.* *Addiction.* Jul 2016;111(7):1177-1187.

Pharmacists should offer to re-review information with the patient about risks, disposal, and other applicable topics with each refill.

DISCONTINUING OPIOID THERAPY

The prescriber should consider discontinuing opioid therapy when:

- The underlying painful condition is resolved;
- Intolerable side effects emerge;
- The analgesic effect is inadequate;
- The patient’s quality of life fails to improve;
- Functioning fails to improve or deteriorates;
- The risks of treatment outweigh the benefits;
- The patient overdoses;
- The patient demonstrates suicidality;
- Non-compliance with the treatment plan;
- The prescriber suspects diversion; or
- The prescriber suspects opioid misuse or abuse.

The prescriber discontinuing opioid therapy should employ a safe, structured tapering regimen through the prescriber or an addiction or pain specialist. There is a risk of patients turning to street drugs or alcohol abuse if tapering is too rapid or is completed without appropriate support. See the Appendix for resources addressing tapering.

TREATMENT FOR OPIOID USE DISORDER

Opioid use disorder is defined as a problematic pattern of opioid use leading to clinically significant impairment or distress, manifested by at least two defined criteria occurring within one year.²⁸ Studies estimate that 2.1 million people in the United States suffer from substance abuse disorders related to prescription opioids.²⁹ Medically Assisted Treatment (“MAT”) in combination with cognitive behavioral therapy has been shown to reduce relapse in patients with opioid use disorder.³⁰

The identification of an opioid use disorder is an opportunity for the prescriber to collaborate with the patient to improve their safety and increase the likelihood of successful opioid use disorder treatment. Prescribers suspecting opioid use disorder should discuss their concerns with the patient and identify treatment resources for the patient.

Because treatment need is often not met with sufficient MAT resources, prescribers should consider undergoing training and obtaining a waiver from the Substance Abuse and Mental Health Services Administration (“SAMHSA”) to provide buprenorphine to treat opioid use disorder in an office setting. (See the Appendix for resources related to MAT and obtaining a waiver from SAMHSA).

²⁸Diagnostic and Statistical Manual of Mental Disorders: *DSM-5*. 5th ed. Arlington: American Psychiatric Association, 2013.

²⁹ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H-46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

³⁰ Dowell D, Haegerich TM, Chou R. *CDC guideline for prescribing opioids for chronic pain – United States, 2016*. *MMWR Recomm Rep* 2016;65(RR-1):32.

APPENDIX

PDMP

Colorado Prescription Drug Monitoring Program (PDMP):

<https://www.colorado.gov/dora-pdmp>

Please note, pursuant to [SB-1746, Access to Prescription Drug Monitoring Program](#), authorized use of the PDMP was expanded effective April 6, 2017, to include the following:

- Prescribers are authorized to query the PDMP about a current patient, regardless of intent to prescribe controlled substance, thus making the PDMP an even more useful tool for health professionals in their clinical decision-making for patients;
- Veterinarians are authorized to query the PDMP about a current client if the veterinarian has a reasonable basis to suspect the client has committed drug abuse or has mistreated an animal; and
- Pharmacists are authorized to query the PDMP about a current patient for whom the pharmacist is dispensing any prescription drug, rather than only patients receiving controlled substances.

Preventing diversion through appropriate disposal

In order to prevent diversion, providers should provide information regarding appropriate disposal, including the following:

- Secure unused prescription opioids until such time they can be safely disposed. Specifically, ensure that prescription opioids are not readily accessible to other family members (including adolescents and/or children) or visitors to the home.
- **Take-back events are preferable to flushing prescriptions down the toilet or throwing them in the trash.** Only some medications may be flushed down the toilet. See the FDA's guidelines for a list of medications that may be flushed: www.fda.gov
- **Utilize take-back events and permanent drop box locations** www.colorado.gov/pacific/cdphe/colorado-medication-take-back-program
- Utilize DEA disposal guidelines if take-back or drop boxes are unavailable. Those guidelines include:
 - **Take the drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter; then put them in a sealable bag, empty can, or other container to prevent the medication from leaking out of a garbage bag;**
 - Before throwing out a medicine container, tell the patient to scratch out all identifying information on the prescription label to protect their identity and personal health information; and
- Educate patients that prescriptions are patient specific. Patients may not share prescription opioids with friends, family or others and may pose serious health risks, including death.
- Use activated charcoal absorption technologies to inactivate unused medications or used fentanyl patches.

Record keeping

Prescribers who treat patients with opioids should maintain accurate and complete medical records according to the requirements set forth by their licensing board. The medical record should include, but is not limited to, 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;
- 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. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers; and,
- Authorization for release of information to other treatment providers.

Discontinuing/tapering opioid therapy

Weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account several factors related to risk, symptom, and alternatives.

Opioid Taper Plan and Calculator:

- “Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain” State of Washington Agency Medical Directors Group. 2010 Online: www.agencymeddirectors.wa.gov
- Pocket Guide: Tapering Opioids for Chronic Pain www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf
- Tapering Long-Term opioid Therapy in Chronic Noncancer Pain [www.mayoclinicproceedings.org/article/S0025-6196\(15\)00303-1/fulltext](http://www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext)

Withdrawal Symptoms Assessment:

“Clinical Opiate Withdrawal Scale” The National Alliance for Advocates for Buprenorphine Treatment. Online at: www.naabt.org

Aberrant drug-related behavior

Prescribers and dispensers should use clinical judgment when aberrant drug-related behaviors are observed. Such behavior should be reported to the proper authorities and/or healthcare team as appropriate.

Aberrant drug-related behaviors broadly range from hoarding medications to have an extra dose during times of more severe pain to felonious acts such as selling

medication. These are any medication-related behaviors that depart from strict adherence to a prescribed therapeutic plan of care.

Prescribers and dispensers should observe, monitor and take enhanced precautionary measures when a patient presents aberrant drug-related behaviors such as:

- Requesting early and/or repeated refills;
- Presents at or from an emergency department seeking high quantities of a prescription;
- Denied by other prescribers or dispensers;
- Presents what is suspected to be a forged, altered or counterfeit prescription;
- Forging prescriptions;
- Stealing or borrowing drugs;
- Frequently losing prescriptions;
- Aggressive demand for opioids;
- Injecting oral/topical opioids;
- Unsanctioned use of opioids;
- Unsanctioned dose escalation;
- Concurrent use of illicit drugs;
- Positive drug screen;
- Obtaining opioids from multiple prescribers;
- Obtaining multiple veterinary prescriptions for opioids for the patient's animal(s); or,
- Recurring emergency department visits for chronic pain management³¹

Prescribers and dispensers should be alert for subjective behaviors such as being nervous, overly talkative, agitated, emotionally volatile, and evasive, as these may be signs of a psychological condition that may be considered in a treatment plan or could suggest drug misuse.³²

Practitioner Considerations

Healthcare team:

Consider that the patient may be receiving opioids from another prescriber. Contact the patient's healthcare team when appropriate which may include the following:

- Physician;
- Specialist (pain, addiction, etc.);
- Dentist;
- Optometrist;
- Advanced Practice Nurse (APN);
- Podiatrist;
- Physician assistant;
- Mental and Behavioral Health Providers;
- Pharmacists;
- Area emergency rooms and urgent care clinics;
- Surrounding (within 5 miles) or historical pharmacies; and
- Veterinarian³³.

Authorities:

- If the prescriber or dispenser suspects illegal activity, the matter should be

³¹ **"Interagency Guidelines on Opioid Dosing for Chronic Non-Cancer Pain" State of Washington Agency Medical Directors Group. 2010 Online: <http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf>.

³² Webster LR, Dove B. *Avoiding Opioid Abuse While Managing Pain*. Sunrise River Press, North Branch, MN 2007.

³³ Patients may be obtaining opioids through the diversion of a veterinary prescription for an animal.

referred to the Drug Enforcement Agency (DEA) and local law enforcement.

- If a prescriber or dispenser suspect illegal activity on behalf of another prescriber or dispenser, at a minimum, the matter should be reported to the appropriate licensing board.

Prescribers and dispensers should be aware that:

- There is no legal obligation to prescribe or dispense a prescription; and,
- Colorado law strongly encourages prescribers and dispensers of opiate antagonists “to educate persons receiving the opiate antagonist on the use of an opiate antagonist for overdose, including but not limited to instructions concerning risk factors for overdose, recognition of overdose, calling emergency medical services, rescue breathing and administration of an opiate antagonist.” (Section 18-1-712(3)(b), C.R.S.)

Additional Resources and Tools

Establishing and maintaining competence:

- Tenney, Lili and Lee Newman. “The Opioid Crisis: Guidelines and Tools for Improving Pain Management” Center for Worker Health and Environment, Colorado School of Public Health.
www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/CHWE/training/Online/Pages/PainCME.aspx
- SAMHSA- Opioid Prescribing Courses for Healthcare Providers
www.samhsa.gov/medication-assisted-treatment/training-resources/opioid-courses
- Opioid and Pain Management CMEs
www.drugabuse.gov/opioid-pain-management-cmesces
- American College of Physicians- Safe Opioid Prescribing: Strategies, Assessment. Fundamentals. Education.
www.acponline.org/meetings-courses/focused-topics/safe-opioid-prescribing-strategies-assessment-fundamentals-education
- Accreditation Council for Continuing Medical Education-Opioids
www.accme.org/tags/opioids
- American Medical Association Opioid CME
cme.ama-assn.org/Activity/4896593/Detail.aspx

Functional and pain assessment:

- Colorado Division of Workers Compensation “Functional Assessment” Tools
- Functional Assessment for Chronic Pain:
 - English-
www.colorado.gov/pacific/sites/default/files/Functional_Assessment_Chronic_Pain.pdf

- Spanish-
 - www.colorado.gov/pacific/sites/default/files/Functional_Assessment_Chronic_Pain_Spanish.pdf
 - Functional Capacity Evaluation Explanation and Consent Form
www.colorado.gov/pacific/sites/default/files/Functional_Capacity_Evaluation_Consent.pdf
 - Colorado Division of Workers Compensation “Pain Diagram”
www.colorado.gov/pacific/sites/default/files/Pain_Diagram.pdf
 - Colorado Division of Workers Compensation “Psychological Tests Commonly Used in the Assessment of Chronic Pain”
www.colorado.gov/pacific/sites/default/files/Psychological_Tests_Chronic_Pain_1.pdf

Substance Use Screening/Counseling

- Screening, Brief Intervention and Referral to Treatment (SBIRT)- is an evidence-based prevention practice that aims to identify, reduce, and prevent misuse and severe problems with alcohol, marijuana, prescription, and illicit drugs. www.SBIRTColorado.org
- www.integration.samhsa.gov/clinical-practice/screening-tools#drugs

Mental Health, Behavioral Health and Trauma Screening Tools

- Screening tools and sample screening forms
 - www.integration.samhsa.gov/clinical-practice/screening-tools
- www.ncbi.nlm.nih.gov/books/NBK207188/
- https://www.ptsd.va.gov/professional/assessment/te-measures/brief_trauma_questionnaire_btq.asp

Patient Education

- The Risk Evaluation and Mitigation Strategy (REMS) Patient counseling documents in English and Spanish.
www.er-la-opioidrems.com/lwgUI/remspcd.action

Calculator:

- www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

Methadone Treatment:

Methadone has a complex pharmacokinetic profile that may lead to increased morbidity and mortality due to its non-linear equianalgesic dose ratio. Methadone becomes more potent as the dose increases. It is critical to understand that conversions to and from Methadone are not bi-directional.

Methadone is lipophilic with a large Vd and long elimination half-life. Rapid dose escalation may cause methadone to accumulate and cause an overdose. In addition, when discontinuing Methadone it can take up to 3 weeks for Methadone to fully clear the body. This is particularly important if converting from Methadone to another opioid as the patient can have overlapping exposure to two opioids and potentially overdose.

Methadone is subject to drug-drug interactions that can increase or decrease blood concentrations.³⁴

[www.jpain.org/article/S1526-5900\(14\)00522-7/fulltext](http://www.jpain.org/article/S1526-5900(14)00522-7/fulltext)

Patient agreements:

“Screeener and Opioid Assessment for Patients with Pain - Revised (SOAPP - R)”

www.painedu.org

Drug testing

Prescribers and dispensers should utilize drug testing laboratories that meet high standards using state of the art technologies. Laboratories should be chosen based on their ability to provide solutions for clinicians and agencies involved with addiction and pain management. When evaluating laboratories consider the following certifications:

- College of American Pathologists
www.cap.org/web/home/lab?_adf.ctrlstate=d89ksjwe5_4&_afLoop=147570914427507#!
- Department of Health and Human Services
www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/

Drug abuse resources:

- Substance Abuse and Mental Health Services Administration:
www.samhsa.gov
- NIH National Institute on Drug Abuse:
www.drugabuse.gov or www.nida.nih.gov

Opioid Overdose Response

- Recognize signs & symptoms of opioid overdose, instructions for administration of Naloxone, join a network of responders, report reversals- Available for Android and iPhone in English and Spanish
Opirescue.com
- Prescribe Naloxone, Save a Life
<http://prescribetoprevent.org/>

Pain tool kits:

Various resources for assessing and managing pain including risk assessments, patient agreements, dose and conversion calculators among others.

- Center for Worker Health and Environment, Colorado School of Public Health.
www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Pages/Pain-Management-CME.aspx
- Colorado Consortium for Prescription Drug Abuse Prevention
www.corxconsortium.org/#
- Colorado Department of Health Care Policy and Finance

³⁴ Fudin J, Raouf M, Wegrzyn EL. *Opioid Dosing Policy: Pharmacological Considerations Regarding Equianalgesic Dosing*. American Academy of Integrative Pain Management. Lenexa, KS 2017.

www.colorado.gov/pacific/hcpf/pain-management-resources-and-opioid-use

Other Opioid Prescribing Policies and Guidelines

- Colorado Division of Worker’s Compensation “Chronic Pain Disorder Medical Treatment Guideline”
www.colorado.gov/pacific/sites/default/files/Rule_17_Exhibit_9_Chronic_Pain_Disorder.pdf
- Colorado Department of Health Care Policy and Finance
www.colorado.gov/pacific/hcpf/pain-management-resources-and-opioid-use
- CDC Guidelines for Prescribing Opioids for Chronic Pain
www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
- Colorado Academy of Emergency Physicians (ACEP) 2017 Opioid Prescribing & Treatment Guidelines
coacep.org/docs/COACEP_Opioid_Guidelines-Final.pdf
- North Colorado Health Alliance Opioid Best Practice Checklist
northcoloradohealthalliance.org/opioid-best-practice-checklist/
- Federation of State Medical Boards Guidelines for the Chronic Use of Opioid Analgesics
www.fsmb.org/Media/Default/PDF/Advocacy/Opioid%20Guidelines%20As%20Adopted%20April%202017_FINAL.pdf
- Colorado Medicaid Program- Prior Authorization Procedures and Criteria and Quantity Limits For Physicians and Pharmacists (Page A-20, Opioids)
www.colorado.gov/pacific/sites/default/files/Appendix%20P%20effective%201-01-18.pdf
- VA/DoD Clinical Practice Guideline For Opioid Therapy For Chronic Pain
www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf