



COLORADO
Department of
Regulatory Agencies

Policy for Prescribing and Dispensing Opioids

**Colorado Dental Board, Colorado Medical Board, State Board of Nursing,
and State Board of Pharmacy**

**In collaboration with the Nurse-Physician Advisory Task Force for
Colorado Healthcare**

PREAMBLE

Prescribing and dispensing medication for the appropriate treatment of pain is a priority for Colorado healthcare providers. However, in 2013 the misuse and abuse of prescription opioids became a public health epidemic in the United States in general, and Colorado in particular, leading to drug addiction, death from overdose, and increased costs to society.

In order to address this 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 identify opportunities and provide meaningful guidance to prescribers and dispensers in Colorado.

The Boards recognize that reversing the trend of opioid misuse and abuse requires coordinated efforts to increase public awareness, take-back events for safe disposal, addiction treatment and recovery options, and enforcement, among others. The Boards and the practitioners they license are one part of a multi-pronged solution.

The Boards recognize the complexities faced by prescribers in the appropriate management of pain.¹ The demands on practitioners considering opioid prescribing differ depending on patient diagnosis, practice settings, and/or conditions. Importantly, long-term therapies addressing cancer-related treatment, palliative and/or hospice care involve different considerations from short-term therapies appropriate for acute or chronic non-cancer pain.

Pain and addiction specialists play an important role in healthcare and the communities they serve to compassionately and safely care for patients. Many of the tools and practices referenced in this policy were developed by such specialists. The need for therapeutic care of pain in Colorado patients exceeds the supply of specialists in the state. However, 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 prescribers and dispensers broadly by providing useful tools that may be utilized at the point-of-care to support clinical decision making.

The Boards further recognize that decreasing opioid misuse and abuse in Colorado should be addressed by collaborative and constructive policies aimed at improving prescriber education and practice, decreasing diversion, and establishing the same guidelines for all opioid prescribers and dispensers. This includes opioid therapies for both acute and chronic non-cancer pain,² because the Boards find that treatment for pain often does not fall clearly into one category or another.

¹ "Boards" as used in this policy means the Boards overseeing prescribing and dispensing of opioids and involved in the drafting of this policy: the Colorado Medical Board, State Board of Nursing, Colorado Dental Board, and the State Board of Pharmacy.

² Pain is categorized by a number of descriptors ranging from duration, impact, or physiological response, among others. For the purpose of this policy, the term "chronic, non-cancer pain" is utilized to refer to pain that lasts longer than 90 days and is non-terminal. It does not include conditions such as cancer, scleroderma, multiple sclerosis, muscular dystrophy, or rheumatoid arthritis.

Diversion and “doctor shopping” accounts for 40% of drug overdose deaths.³ To address the dual issues of access to appropriate pain management and opioid-related adverse outcomes, prescribers have dual obligations: to manage pain and improve function while reducing problems resulting from misuse and abuse of prescription opioids in the patient and community. 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 being treated.

Therefore, the Boards have agreed to the following guidelines regarding opioid prescriptions in Colorado. Providers prescribing and/or dispensing opioids should:

- Follow the same guidelines
- Use the Colorado Prescription Drug Monitoring Program (PDMP)
- Be informed about evidence-based practices for opioid use in healthcare and risk mitigation
- Educate patients on appropriate use, storage and disposal of opioids, risks and the potential for diversion
- Collaborate within the integrated healthcare team to decrease over-prescribing, misuse and abuse of opioids.

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

To this end, we, the Boards regulating the prescribers and dispensers in Colorado, have developed this joint policy incorporating the guidelines above.

This policy provides guidelines, and does not set a standard of care for prescribers and dispensers. This policy represents the Boards’ current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind Boards or the public. Prescribers may use an alternative approach if the approach satisfies the requirements of the applicable statutes, regulations, and standard of care. The Boards will refer to current clinical practice guidelines and expert review in approaching cases involving the management of pain.⁴

³ Paulozzi, L., Baldwin, G., Franklin, G., Ghiya, N., & Popovic, T. (2012). CDC Grand Rounds: Prescription drug overdoses — a U.S. epidemic. *Center for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR)*, 61(01), 10-13. Retrieved from <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>

⁴ A “policy” is adopted by a board to provide guidance to licensees regarding the board’s position on various subjects. Policies are unlike statutes or rules in that they are not law. Conversely, “board rules” have the force of law and set forth requirements to which licensees must adhere.

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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. In some clinical situations consultation with a specialist is appropriate. Pharmacists must maintain competence in the appropriateness of therapy. See the Appendix for a list of resources and tools for developing and maintaining competence.

Utilize safeguards for the initiation of pain management

The decision to prescribe or dispense opioid medication for outpatient use may be made only after a proper diagnosis and complete evaluation which should include a risk assessment, pain assessment, and review of relevant PDMP data. These safeguards apply to acute and chronic, non-cancer pain but not to palliative end-of-life care.

Not all pain requires opioid treatment. Prescribers should not prescribe opioids when non-opioid medication is both effective and appropriate for the level of pain.

1. Diagnose

Prescribers should establish a diagnosis and legitimate medical purpose appropriate for 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 for outpatient use and again before increasing dosage or duration. Risk assessment is defined as identification of factors that may lead to adverse outcomes and may include:

- Patient and family history of substance use (drugs including alcohol and marijuana)
- Patient medication history (among other reasons, this is taken to avoid unsafe combinations of opioids with sedative-hypnotics, benzodiazepines, barbiturates, muscle relaxants or to determine other drug-drug interactions)
- Mental health/psychological conditions and history
- Abuse history including physical, emotional or sexual
- Health conditions that could aggravate adverse reactions (including COPD, CHF, sleep apnea, elderly, or history of renal or hepatic dysfunction)
- Prescribers and dispensers should observe the patient for any aberrant drug-related behavior and follow-up appropriately when aberrant drug-related behavior is presented. See the Appendix for a description of such behaviors.

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.

If the assessment identifies risk factors, prescribers should exercise greater caution before prescribing opioids as detailed in subsequent sections, consider conducting a drug test or consulting a specialist and put in place additional safeguards as part of the treatment plan.

3. Assess Pain

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
- Impact on physical and psychological functioning

4. Review PDMP

Prescribers and dispensers should utilize the Prescription Drug Monitoring Program (PDMP) prior to prescribing or dispensing opioids.

Collaborate with the healthcare team

Prescribers and dispensers should collaborate within the healthcare team to prevent under-prescribing, over-prescribing, misuse and abuse of opioids. See the Appendix for additional resources.

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 if appropriate (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
- Denied by another pharmacist.

Additional Safeguards

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 120 mg morphine equivalents per day 2) certain formulations and 3) treatment exceeding 90 days. Additional safeguards have been found to reduce these risks.

Dosage

Opioid doses >120 mg morphine equivalents per day is a dosage that the Boards agree is more likely dangerous for the average adult (chances for unintended death are higher) over which prescribers should use clinical judgment, put in place additional safeguards for the treatment plan (such as utilizing a treatment agreement), consult a specialist or refer the patient; and dispensers should be more cautious.⁵ Benzodiazepines are known to potentiate the effects of opioids and may increase the risk of adverse outcomes. See the Appendix for additional resources on dose calculators

Formulation

In addition to noting and responding to this dosage marker, prescribers and dispensers must use clinical judgment regardless of dose, especially when:

- The prescription is considered an outlier to what is normally prescribed, or
- Transdermal, extended relief or long-acting preparation is prescribed.

Duration

Treatment **exceeding 90 days** should be re-evaluated as opioids may no longer be as effective.

One way to distinguish pain is as either acute (that lasting less than 90 days) or chronic (that lasting 90 days or greater). Management of each presents its own unique challenges. The overwhelming majority of prescribers treat patients with acute pain; in fact the pain for these patients lasts considerably less than 90 days.

⁵ Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: a cohort study. *Ann Intern Med* 2010;152(2):85-92.

If a prescriber extends short-term treatment, and results in exceeding 90 days, prescribers should re-conduct the risk and pain assessments, review the PDMP and undertake the additional safeguards.

PRESCRIBING AND DISPENSING FOR ADVANCED DOSAGE, FORMULATION OR DURATION

Tools and Trials

Prior to issuing prescriptions that are outliers to the dosage, formulation and duration guidelines described above (for chronic, non-cancer pain), prescribers should determine whether the patient improves functionally on opioids, which could include an opioid trial, and whether the pain relief improves his/her ability to comply with the overall pain management program.

Monitoring

The prescribing and dispensing of opioids for chronic pain must be monitored on an ongoing basis, such as:

- assessing for improved function
- rechecking the PDMP, and
- random 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 rechecking the PDMP.

Treatment Agreements

Prescribers should utilize treatment agreements (also commonly referred to as a plan or contract) and should ensure the patient understands the terms of the agreement. This may be accomplished by having the patient review and sign the treatment agreement.

A treatment agreement often includes information about proper:

- Goals of treatment
- Patient education (proper use, risks of addiction, alternatives)
- Controls (single prescriber, single pharmacy for refills)
- Random drug testing and restrictions on alcohol use
- Storage, disposal, and diversion precautions (including detailed precautions related to adolescents and/or children and visitors to the home).
- Process and reasons for changing/discontinuing the treatment plan; communicating reduction or increase of symptoms; and referring to a specialist.

See the Appendix for resources on sample agreements.

PATIENT EDUCATION

Prescribers should educate patients regardless of the dosage, formulation and duration of opioid therapy on proper use, risks of addiction, alternatives, storage, and disposal of opioids and the potential for diversion (see the Appendix for resources on disposal). Risks may include but are not limited to: overdose, misuse, diversion, addiction, physical dependence and tolerance, interactions with other medications or substances, and death.

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

Providers should educate patients about the risks and benefits of medications that exceed the dosage, formulation and duration guidelines indicated above which may place them at increased risk for long-term dependence and unintended adverse drug effects. Patients who have a previous history of substance use disorder (including alcohol) are at elevated risk.

When alerted to these risk factors, patients can make more informed decisions about their healthcare treatment. For example, some patients have reduced or forgone opioids when alerted to the risk factors. If a decision is made to continue with opioid therapy, a satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function and/or improved quality of life. The use of an interdisciplinary team and family members may be considered as a part of the treatment plan and ongoing monitoring.

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 deteriorates; or
- There is aberrant medication use.

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 not done with appropriate supports. Prescribers of opioids should be familiar with treatment options for opioid addiction. See the Appendix for tips on tapering.

APPENDIX

PDMP

Colorado Prescription Drug Monitoring Program (PDMP):

<http://www.hidinc.com/copdmp>

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**
- 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.

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

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 mildly problematic (such as 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 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
- Failing a drug screen
- Getting opioids from multiple prescribers
- Recurring emergency department visits for chronic pain management*

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.**

*“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>

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

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
- Advanced Practice Nurse (APN)
- Physician assistant
- Pharmacists
- Area emergency rooms
- Surrounding (within 5 miles) or historical pharmacies

Authorities:

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

Functional and pain assessment:

"Functional Assessment" Colorado Division of Workers Compensation

Patient agreements:

"Screener and Opioid Assessment for Patients with Pain - Revised (SOAPP - R)" PainEDU.org Online at: www.painedu.org

Pain tool kit:

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. Online at:

<http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Pages/Pain-Management-CME.aspx>

Substance use screening and brief counseling:

SBIRT Colorado

www.ImprovingHealthColorado.org

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