Dora
Department of Regulatory Agencies

Policy for Prescribing and Dispensing Opioids

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

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

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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 rose to the level of constituting a public health epidemic 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 Medical Board, Board of Nursing, State Board of Dental Examiners, and the State Board of Pharmacy collaborated to identify opportunities for improvements in the regulatory framework related to opioid prescribing in Colorado.

The Boards recognize the complexities faced by prescribers in the appropriate management of pain.[1] The Boards recognize that the demands on practitioners considering opioid prescribing differ depending on patient diagnosis, practice settings, and/or conditions. Importantly the approach to long-term therapies addressing cancer-related, palliative and/or hospice care will involve different considerations from the approach to short-term therapies appropriate for acute or chronic non-malignant pain. 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 holding all opioid prescribers to the same minimum standards. **This policy provides guidelines, and may not set out the full requirements necessary to meet the standard of care for each profession.**

Diversion and "doctor shopping" accounts for 40% of drug overdose deaths.[2] To address the dual issues of access to appropriate pain management and opioid-related adverse outcomes, prescribers and dispensers have dual obligations: to manage pain and improve function while reducing problems resulting from misuse and abuse of

[1] "Boards" as used in this policy means the Boards overseeing prescribing and dispensing of Opioids: the Colorado Medical Board, Board of Nursing, State Board of Dental Examiners, and the State Board of Pharmacy. There are other Boards and programs in Colorado that oversee prescribers of controlled substances that are not addressed in this policy

[2] 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

prescription opioids in the patient and community. Dispensers 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 principles regarding opioid prescriptions in Colorado:

Providers prescribing and /or dispensing opioids should:

- be held to the same minimum standards
- register with the Colorado Prescription Drug Monitoring Program
- be informed about best practices for opioid use in healthcare
- educate patients on appropriate use, storage and disposal of opioids, and the potential for diversion
- collaborate within the integrated healthcare team to decrease over-prescribing, misuse and abuse of opioids, and
- conform to the requirements set forth by the respective licensing board.

To this end, we, the Boards regulating the prescribers and dispensers in Colorado, have developed this joint policy incorporating the guidelines above.[3]

[3] 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.

I. Before Prescribing or Dispensing

Comment [CME1]: Formatting to be addressed throughout document for organization and readability after content is finalized.

Develop and maintain competence

Prescribers and dispensers 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.

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

Utilize four 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, risk assessment and pain assessment are conducted, and after relevant PDMP data is reviewed.

1. Diagnose

Prescribers should establish a diagnosis appropriate for opioid therapy legitimate medical purpose through a history, physical exam, and/or laboratory investigation. 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 misuse of opioids such as:

- Family history of substance misuse (including alcohol or drugs)
- Patient history of substance misuse (including alcohol or drugs)
- Patient prescription history (among other reasons, this is taken to avoiding avoid combining opioids with sedative-hypnotics, benzodiazepines, or barbiturates)
- 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 must observe the patient's

behavior and follow-up appropriately when suspicious or drug-seeking behavior is presented. See the Appendix for a detailed description of such behaviors.

See the Appendix for additional resources related to assessment, including "Guidelines for Alcohol and Substance Use Screening, Brief Intervention, Referral to Treatment (SBIRT)" published by HealthTeamWorks.

If the assessment identifies one or more risk factors, prescribers should exercise greater caution before prescribing opioids, consider conducting a drug test or consulting a specialist and put in place strong controls 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

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.

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 decrease over-prescribing, misuse and abuse of opioids. See the Appendix for additional resources.

II. When Prescribing or Dispensing

Verify provider-patient relationship

A bona fide provider-patient relationship must exist. The prescriber or dispenser must 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
- is 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.

Dosage

Factors that have been associated with adverse outcomes include: 1) high opioid doses greater than 120 mg morphine equivalents per day and 2) treatment exceeding 90 days. Additional safeguards have been found to reduce these risks.

High 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 strong controls for the treatment plan (such as utilizing a treatment agreement), consult a specialist or refer the patient, and dispensers should be more cautious.[4]

See the Appendix for additional resources on dose calculators such as the dose calculator recommended by the Colorado School of Public Health.

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.

[4] 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.

- *Tools and Trials* — Prior to prescribing opioids for more than 90 days (for chronic, non-cancer pain), prescribers must conduct a short term opioid trial to determine whether the patient improves functionally on opioids and whether the pain relief improves his/her ability to comply with the overall pain management program.

- *Monitoring* — The prescription and dispensing of opioids for chronic pain must be monitored on an on-going basis. Opioid therapy lasting more than 90 days is another marker requiring renewed monitoring for improved function,
  1. rechecking the PDMP, and
  2. random drug screening at least once a year and more frequently for those at higher risk.

  These monitoring tools and others must 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 (commonly referred to as a plan or contract). Treatment agreements must be reviewed and signed by the patient.

  A treatment agreement often include 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 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 on appropriate storage, use, and disposal of opioids and the potential for diversion.

Comment [CME2]: The next three sections are for patients that exceed the dosage, duration and formulation items above.

Comment [CME3]: Boards may consider recommendation to move "tools and trials," "monitoring" and "Treatment Agreements" to appendix and summarize in bullet points above.

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

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 subsequent aberrant medication use.

The prescriber discontinuing opioid therapy should employ a safe, structured tapering regimen through the prescriber or an addiction or pain specialist. Although most patients tolerate a tapering regimen well, there is certainly a risk of patients turning to street drugs or alcohol abuse if tapering is not done with appropriate supports. 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.

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: \http://www.agencymeddirectors.wa.gov/

Withdrawal Symptoms Assessment --

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

Suspicious behavior

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

Types of suspicious behavior: Prescribers and dispensers should observe, monitor and take precautionary measures when a patient presents suspicious behavior such as:

- Nervousness
- Overly talkative
- Agitated
- Emotionally volatile
- Evasive
- 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.

Drug-seeking behaviors: Prescribers and dispensers should observe, monitor and take precautionary measures when a patient presents drug-seeking behavior such as:

- 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[5]

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, and
- 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,
- To do so with a chemically dependent patient may violate federal or state provisions on maintenance of addiction. The prescriber and/or dispenser could be liable if the patient later injures himself/herself or others.

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

[5] "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

Health and Environment, Colorado School of Public Health.

Functional and Pain Assessments --

"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, University of Colorado School of Public Health. Online at: http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/maperc/online/Pages/Pain-Management-Tool-Kit.aspx

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