Board Discussion and Action
CMS Comments and Recommendations
Draft Quad-Regulator Policy for Prescribing and Dispensing Opioids
(April 3, 2014 draft)

The question before the BOD is approval of Executive Committee April 24 recommendations that originated with the new Committee on Prescription Drug Abuse authorizing CMS to advocate on draft Quad-Regulator Policy for Prescribing and Dispensing Opioids (attached) as outlined below

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Issue: There is great concern that the policy does not differentiate between (1) chronic, non-malignant pain, (2) cancer related pain, palliative/hospice care, and (3) short-term acute care situations. There is also great concern that this policy does not address problems of underuse, which continues to be a significant barrier to proper healthcare for patients with pain.

Recommendation: We urge one of the following two options: (1) Limit the policy and guidance to prescribing for chronic non-malignant pain; or, (2) clearly delineate between guidelines for chronic non-malignant pain, acute pain or cancer related pain, and palliative/hospice care in the proposed policy.

Issue: The physicians are very concerned about the use of the word "must" throughout the draft policy. The feeling is that "must" is setting a hard standard and removes clinical judgment based on the uniqueness of the patient. We make reference to these provisions later.

Recommendation: Remove the word "must" throughout the document and replace it as appropriate with "should".

Issue: We are very sensitive to the growing heroin problem in our communities and want to be sure that these rules are consistent with the CMS goal of assuring compassionate, evidenced-based care for patients who suffer acute and chronic pain while also significantly reducing the potential for medically inappropriate use.

Recommendation: The final policy should provide guidance in the form of guidelines and once adopted be used as a springboard for an aggressive physician educational campaign. A letter to all physicians in Colorado signed by Governor Hickenlooper and physician leaders in organized medicine should be considered.

The Preamble:

We applaud the following important points in the preamble that recognize:

a. Prescribing and dispensing medication for the appropriate treatment of pain is a priority for Colorado healthcare providers;
b. The misuse and abuse of prescription opioids has risen to the level of constituting a public health epidemic in the United States and in Colorado specifically;
c. Prescribers face many complexities in the appropriate management of pain;

d. The demands on practitioners considering opioid prescribing differ depending on patient diagnosis, practice settings, and/or conditions;
e. 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;
f. That decreasing opioid misuse and abuse in Colorado should be addressed by collaborative and constructive policies aimed at improving prescriber education and practice and decreasing diversion;
g. Prescribers and dispensers have a dual obligation to manage pain and improve function while at the same time, reduce problems resulting from misuse and abuse of prescription opioids in the patient and community; and,
h. The reference to the agreement among the boards that the draft policy reflects "principles regarding opioid prescriptions in Colorado" and "guidelines."

Issue: The preamble is inconsistent, confusing and not clearly articulated. The following language is the cause of the confusion: "The policy provides guidelines, and may not set out the full requirements necessary to meet the standard of care for each profession." Some of the physicians felt strongly that this language can allow an attorney or the board to later come back and claim the guideline is actually a standard of care.

Recommendation: We suggest clarifying this language to state that this policy does not set a standard of care for the professional practice of medicine.

Issue: The preamble also states that the boards agreed on "principles", and then refers to the document as a "joint policy incorporating guidelines," yet the "principles" state that prescribers should be held "to the same minimum standards" and "conform to the requirements set forth by the respective licensing boards". The physicians felt strongly that the preamble needs to be clear and that it should state that the policy is setting forth "guidelines" and not setting a standard of care.

Recommendation: We strongly recommend language consistent with the agreement among the four boards that the policy represents "principles" and "guidelines" and remove any reference to mandatory minimum standard requirements (see additional example on page 3, "providers prescribing and/or dispensing opioids should be held to the same minimum standard").

Recommendation: The preamble should include language as follows: "The Board will refer to current clinical practice guidelines and expert review in approaching cases involving the management of pain. The medical management of pain should consider current clinical knowledge and evidence-based research according to the judgment of the physician. No disciplinary action will be taken for not following the policy when contemporaneous medical records document a reasonable cause for deviation. These guidelines are not intended to serve as a standard of care."

Recommendation: The preamble should include a glossary or definition of terms utilized throughout the document.

<u>Before Prescribing or Dispensing</u>

Issue: Page 4, Title 2, Paragraph 1-"Utilize four safeguards for the initiation of pain management"

"The decision to prescribe or dispense opioids 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."

Recommendation: Delete the word "four" and substitute the following edits or replacement language:

> "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 should include risk assessment (such as psychological conditions, drug-to-drug interactions, general health conditions, and the likelihood of aberrant drug-related behavior), ~~and~~ pain assessment, ~~are conducted~~ and ~~after~~ review of relevant PDMP data. ~~is reviewed.~~"

Physicians may not use all or any of the four referenced assessments in acute clinical cases, chronic non-malignant pain or in palliative/hospice cases. Physicians may use other factors/assessments in conducting their history and physical examination of the patient when treating pain. A risk assessment, pain assessment and required PDMP access in every situation is not always in the best interests of patients and will be burdensome to workflow and therefore should not be mandated in all cases.

Issue: Page 4, Subtitle 2. Assess Risk, provides: "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."

Recommendation:

1. Change the opening paragraph as follows: "Prescribers should conduct a risk assessment (such as psychological conditions, drug-to-drug interactions, general health conditions, and the likelihood of aberrant drug-related behavior) prior to prescribing opioids and again before increasing dosage or duration. Risk assessment is defined as identification of factors that may lead to adverse outcomes."
2. All Bullet Points under "Assess risk" should be moved to the Appendix.
3. Bullet Point 3 should be revised as follows:

"Patient prescription history (among other reasons, this is taken to avoid unnecessary combination of opioids with sedative-hypnotics, benzodiazepines, or barbiturates or to determine other drug-to-drug interactions)"

There are other drugs that could have interactions with opioids' therefore the more general language is appropriate.

4. Bullet Point 7, should be revised as follows:
"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."

Aberrant drug-related behavior is the correct clinical term for this type of behavior. The phrase "suspicious and drug-seeking behavior" should be replaced with **aberrant drug-related behavior** throughout the entire document and should be defined in the Appendix.

Issue: Page 5, Subtitle 2. Assess Risk, Paragraph 3, provides: "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."

Recommendation: Please consider the following edits:

"If the chronic pain 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 chronic treatment plan."

This paragraph does not apply to acute or palliative care and only applies to chronic non-malignant pain and there is no definition for the term "strong."

Issue: Page 5, Subtitle 3. Assess pain, Paragraph 1, provides: "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"

Recommendation: We recommend removal of the last three (3) bullet points for this section of pain assessment. The first four bullet points are common to any assessment of pain, whether it is acute or chronic. Additional assessment should be done on patients who are being treated for chronic pain with chronic opioid therapy. Those additional bullet points can be placed under the subtitle – Tools and trials.

When Prescribing or Dispensing

Issue: Page 5, paragraph 1 provides as follows: "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."

Recommendation: Revise as follows: "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."

Issue: Page 6, Dosage, Paragraphs 1 & 2 provides: "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 greater than 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."

Recommendation: The references to "high opioid doses greater than 120 mg morphine equivalents per day" should be deleted. There was concern that by including this level of medication that the policy has now become a medical treatment guideline for prescribers. The committee also recommends language that separates the prescribing of opioids (methadone and buprenorphine) for addiction.

Issue: Page 6, Duration, Paragraphs 1 provides: "Treatment exceeding 90 days should be re-evaluated as opioids may no longer be as effective."

Recommendation: Change sentence to read, "Treatment exceeding 90 days should be re-evaluated. If the prescriber anticipates sooner than 90 days that opioid treatment will likely go beyond 90 days, controls for chronic management and monitoring should be put into place."

Issue: Page 6, Paragraph 2 that provides: "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."

Recommendation: Delete this paragraph in its entirety.

Issue: Page 7, Tools and Trials, provides: "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"

Recommendation: Revise to read as follows: "Prior to prescribing opioids for more than 90 days (for chronic, non-malignant pain), prescribers **should** ~~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. If the prescriber anticipates sooner than 90 days that opioid treatment will likely go beyond 90 days, controls for chronic management and monitoring should be put into place**."**

The physicians were very concerned about the use of the word "must" within the document. The feeling is that "must" is setting a hard standard and removing clinical judgment based on the uniqueness of the patient.

Appendix

Page 10, Subtitle Suspicious behavior – Delete the terms "suspicious" or "drug-seeking behavior" throughout this subtitle and replace them with the proper clinical term "aberrant drug-related behavior."

Recommendation: The committee recommends removal of the term "suspicious behavior" and drug-seeking behavior" since they are judgmental and a nonmedical term. We suggest substitution of "aberrant drug-related behavior" as the recommended wording.
Aberrant drug-related behavior definition - this term describes behaviors broadly ranging from mildly problematic *(such as hoarding medications to have extra doses during times of more severe pain)*, **to** felonious acts *(such as selling medications)*. Simply, these are any medication-related behaviors that depart from strict adherence to the prescribed therapeutic plan of care.

Page 10, Subtitle Suspicious behavior, Paragraph 2 – "Types of suspicious behavior" –

Recommendation – delete the first five (5) bullet points in this paragraph as they are subjective, not necessarily clinical indicators of aberrant drug-related behavior, and show no interrater reliability.

Background:
CMS strongly supports Colorado Medical Board (CMB) guidance to physicians for prescribing opioids for the treatment of chronic non-malignant pain and to provide the basis for additional prescriber educational initiatives in Colorado. This undertaking is a critical part of Colorado's overall effort to reduce the medically inappropriate use of opioids and CMS brings a collaborative philosophy and a multi-specialty perspective to the challenge. Of extreme importance is for this policy to provide evidence-based, meaningful guidance to physicians in the course of their professional practice. CMS wants a policy that is meaningful and helpful to physicians and one that is broadly supported. Should more time be needed to craft this important policy, CMS urges a delay in the final approval until the four boards meet later this summer.

Colorado Medical Society strongly supports Governor John Hickenlooper's efforts to reverse the escalating trend of opioid abuse and misuse and its often tragic consequences in Colorado. CMS appointed a special Committee on Prescription Drug Abuse earlier this year and actively participates in the Colorado Consortium to Reduce Prescription Drug Abuse. The Society has been educating its members about the crisis over the past 15 months. The 2013 CMS Annual Meeting featured a special presentation on Colorado's opioid crisis and the Colorado Consortium to Reduce Prescription Drug Abuse will be making a CME-certified presentation at the CMS Spring Conference next month.

A multi-specialty work group was appointed and charged with reviewing the draft policy and to craft a proposed set of CMS recommendations. The work group proposals were then reviewed, discussed

and approved by the full Committee on Prescription Drug Abuse. The comments and recommendations below are a product of these discussions.

A new policy should be consistent with the Society's long-term goals for addressing the opioid abuse and misuse crisis in Colorado. These long-term goals include:

1. To assure access to compassionate, evidence-based care for patients who suffer from acute and chronic pain.
2. To significantly reduce the potential for medically inappropriate use and diversion of prescribed medications – that is, to help prevent the medical, psychological and social consequences, including addiction, overdose and death.
3. The prescription drug diversion and abuse crisis requires a multi-pronged, coordinated strategy that includes a public-health focus, positive incentives to promote physician education and public awareness, useful tools that physicians can use at the point-of-care to support medical decision making, concerted attention to increase access to addiction treatment and recovery, and appropriate enforcement.

In summary, CMS is eager to embrace a new policy that is beneficial for physicians and the patients and communities they serve. As currently written, the draft policy lacks focus and fails to take into account the wide variation of presentations confronted in prescribing opioids including, for example, addiction, acute pain, malignant, terminal pain and under prescribing. Although there are some principles that are generally applicable to several settings like the ones on misuse and diversion, the vast majority of the policy appears to focus on chronic, non-malignant pain. CMS believes that the Preamble should reflect the agreement between the four boards that the policy represents guidelines and that it should focus on non-malignant chronic pain or that the policy be restructured to reflect the different considerations in the different presentations of patients.