



July 31, 2023

Sarah Werner Colorado Department of Regulatory Agencies 1560 Broadway #1545 Denver, CO 80202

Subject: Written Stakeholder Comments for the Opioid Guideline Stakeholder Meeting

Dear Ms. Werner:

On behalf of the American Medical Association (AMA) and Colorado Medical Society (CMS) and our respective physician and medical student members, we are writing to encourage the Division of Regulatory Agencies (DORA) to take further action to support patients with pain. DORA's actions have the benefit of Senate Bill (SB) 23-144—a bill strongly supported by the AMA and CMS to help ensure individualized care for patients with pain. DORA also has the benefit of being able to follow the recommendations from the U.S. Centers for Disease Control and Prevention (CDC), which were updated in 2022 to remove arbitrary numeric thresholds for prescribing opioids when clinically indicated.

First, we urge that DORA revise and update all its policies and protocols, including investigative and disciplinary guidelines used by its boards, to be consistent with SB 23-144's emphasis on individualized patient care decisions. Specifically, we urge DORA to remove all policies inconsistent with the following provisions of SB 23-144, which are taken directly from the enacted bill:

- "A health-care provider acting in good faith and based on the needs of the patient with a diagnosed condition causing chronic pain is not subject to discipline from the regulator solely for prescribing a dosage that equates to an upward deviation from morphine milligram equivalent dosage recommendations or from thresholds specified in state or federal opioid prescribing guidelines or policies."
- "A health-care provider treating a patient with chronic pain by prescribing, dispensing, or administering one or more Schedule II, III, IV or V controlled substances that include, but are not limited to, opioid analgesics shall not be required to taper a patient's medication dosage solely to meet a predetermined morphine milligram equivalent dosage recommendation or threshold if the patient is stable and compliant with the treatment plan and is not experiencing serious harm from the level of medication currently being prescribed or previously prescribed. A decision to taper or maintain medication must include an individualized assessment of the patient's current medical condition and treatment plan, the risks, and benefits of maintaining or tapering the patient's medication, and a discussion with the patient."

Second, we urge DORA to make clear to pharmacies, health insurance companies, and pharmacy benefit managers operating in Colorado that they must rescind or nullify one-size-fits-all policies relating to denials of an opioid prescription based on predetermined Milligram Morphine Equivalent (MME) recommendations or thresholds. Whether by official guidance, rule, or other communication, we urge DORA to inform and oversee compliance with the following provision of SB 23-144:

• "A pharmacy, carrier, or pharmacy benefit manager shall not have a policy in place that requires the pharmacist to refuse to fill a prescription for an opiate issued by a health-care provider with the authority to prescribe opiates solely because the prescription is for an opiate or because the

prescription order exceeds a predetermined morphine milligram equivalent dosage recommendation or threshold."

We further urge that DORA request that all pharmacies, health insurance companies, and pharmacy benefit managers attest to not only receiving the communication but affirm that they have removed all policies inconsistent or in conflict with this provision of SB 23-144.

Finally, we urge DORA to issue guidance to its licensees that hospitals, health systems, or other practice settings also may not have policies prohibiting prescribing or dispensing of opioid analgesics, "solely because the prescription exceeds a predetermined morphine milligram equivalent dosage recommendation or threshold."

Collectively, these actions will help restore balance and compassion for patients with pain. One of the primary reasons the Colorado Legislature enacted SB 23-144 was to address the harms experienced by patients with pain due to the CDC's 2016 Opioid Prescribing Guidelines. Nowhere in the 2016 CDC Guidelines was the encouragement for states to implement these guidelines as hardline policy. In fact, in 2022, the CDC finally made that point clear:

This clinical practice guideline provides voluntary clinical practice recommendations for clinicians that should not be used as inflexible standards of care. The recommendations are not intended to be implemented as absolute limits for policy or practice across populations by organizations, health care systems, or government entities. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?scid=rr7103a1 w

In summary, the AMA and CMS want to emphasize the following: DORA taking the recommended courses of action above will ensure that it is following the clear intent of SB 24-133 and the revised CDC 2022 Opioid Prescribing Guidelines. Taking this bold and decisive action will provide clarity to licensees that patients with pain deserve individualized care that is free from arbitrary, predetermined thresholds that have been rebuked by the CDC itself.

The AMA and CMS strongly urge DORA to act on behalf of patients with pain. We would be happy to help communicate DORA's efforts, consistent with our recommendations, to our members in Colorado. Please contact Daniel Blaney-Koen, JD, Senior Attorney, American Medical Association, at daniel.blaney-koen@ama-assn.org or Chet Seward, Chief Strategy Officer, Colorado Medical Society, at chet_seward@cms.org if you have any questions. We look forward to working with you and thank you for your consideration.

Sincerely,

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