AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE

Submitted electronically via opioidcomments@cdc.gov

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Re: CDC Draft Opioid Prescribing Guidelines – released via webinar on 09-16-15

Dear Dr. Dowell:

On behalf of the nearly 5,000 members of the American Academy of Hospice and Palliative Medicine (AAHPM), thank you for the opportunity to comment on the CDC's recently released draft guidelines for the prescribing of opioid pain relievers to patients 18 and older for chronic, non-end-of-life care in primary care outpatient settings. Below we offer general feedback on the recommendations and process for developing them, along with some specific comments on particular guidelines.

AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses and other health and spiritual care providers deeply committed to improving quality of life for patients facing serious or life-threatening conditions, as well as their families. Our Academy members care for the sickest and most vulnerable patients. The timely and effective management of pain and other distressing symptoms is critical to providing these patients with high-quality palliative care, and opioid analgesics are an important tool in that process.

AAHPM applauds the CDC's commitment to reducing prescription drug abuse and the very good intent behind developing these new prescribing guidelines. We also appreciate that the agency understands the need to except end-of-life care, as many of the draft recommendations would be inappropriate for addressing pain in terminal patients. At the same time, we are concerned that patients with serious illness without a terminal prognosis may require palliation of chronic pain and other distressing symptoms. Because of a shortage of palliative medicine and pain specialists, many of these individuals will receive care solely through a primary care provider. Therefore, **we strongly recommend that the CDC make clear that these guidelines should never preclude an individualized approach to meeting patients' legitimate needs.** Our additional recommendations are provided on the pages that follow.

General Comments

AAHPM is extremely concerned about the process that led to the drafting of these guidelines which we find to include an egregious lack of transparency and woefully inadequate opportunity for review and comment. We would respectfully request that CDC make available the names of its expert panel. We are particularly interested in whether this group included a specialist in palliative medicine. We would also look for clear detail regarding the evidence base for each recommendation. **Any guideline with a "strong recommendation" should be downgraded when there is only "low quality evidence."** To leave those recommendations as they are will ensure the perception that this is a politically motivated document that is not evidence-based. That will, in turn, harm the applicability of the guidelines. Finally, we hope that the agency may re-open the comment period and post the draft recommendations to allow all stakeholders a reasonable opportunity to provide feedback.

In the meantime, **we would encourage the CDC to examine its stated exception for prescribing in the context of end-of-life care and expand it to include prescribing for treatment of chronic pain in patients with serious illness receiving palliative care**. (We would note that it would not be sufficient to specify that the target of these guidelines is a patient with "non-cancer pain" as doing so might result in unequal access to treatment for people with diseases like AIDS, chronic obstructive pulmonary disease, end stage renal disease, heart failure, hemophilia, or sickle cell disease.) Recommendations that aim to limit the duration of prescriptions can inflict terrible suffering in a seriously-ill patient each day that he or she lives past an arbitrary cutoff of their medication. Those that limit allowable daily dosages can result in uncontrollable pain and symptom crises for these patients that could otherwise be managed by an amount of medicine that is arbitrarily discouraged.

There are other vulnerable populations that are also not accounted for in the CDC's draft. The guidelines are written predicated on the assumption that chronic pain only occurs in competent adults. How are cognitively-impaired patients supposed to participate in goal-setting and provide informed consent? Does this apply to long-term care facility patients, who arguably are in the primary care population? We urge the CDC to address these concerns in the final draft and, again, we would recommend a greater emphasis be placed on the importance of an individualized approach to opioid prescribing as well as more patient-focused verbiage within the guidelines themselves.

We urge the CDC to roll-out the final guidelines with caution. We point you to a 2001 joint statement by Drug Enforcement Administration (DEA) Administrator Asa Hutchinson and 21 health organizations – including AAHPM – titled *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. This statement called for a balance in policy between ensuring legitimate patient care and preventing diversion and abuse, warning that focusing only on the abuse potential of a drug could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties. Numerous overlapping policies and guidance for practitioners that aim to stem the crisis of opioid abuse and overdose death have already had a cooling effect on prescribing by primary care providers, with these practitioners confused and in fear of retribution for prescribing opioid analgesics. In fact, we have seen such unintended consequences as physicians trying to get their non-terminal patients into hospice so the hospice can take over prescribing of opioids and overall pain management.

To be clear, our Academy believes there is an indisputable public health imperative to address opioid abuse, misuse and diversion. Toward that end, AAHPM is part of the Collaboration for REMS Education (CO*RE), which is one of several efforts to create an educational curriculum, directed to DEA-registered

prescribers, that covers the basics of opioid prescribing, patient education about opioids, and recommendations for safe storage and disposal. This type of continuing education holds the potential to change clinical behavior in the short and long term and, ultimately, result in optimal pain management and optimal care for all patients. We are also an active member of the American Medical Association's Task Force to Reduce Opioid Abuse, helping to identify strategies and tools that empower physicians to take the lead in combatting opioid abuse, misuse and diversion. AAHPM has also developed our guidelines for effective prescription drug monitoring programs, and encouraged our members to advocate for sound policies.

At the same time, there is also a correlative public health imperative to ensure that our sickest, most vulnerable patients are able to get the medications necessary to treat their pain and suffering. AAHPM stands ready to serve as partner is achieving the balance necessary to ensure both aims are met. As you review our specific recommendations below, please know that we would welcome any further opportunities to provide stakeholder feedback or connect you with our physician leadership as your guideline development progresses or as you undertake future initiatives. Please address questions to Jacqueline M. Kocinski, MPP, AAHPM Director of Health Policy and Government Relations, at jkocinski@aahpm.org or 847-375-4841.

Sincerely,

Joseph Rotella, MD MBA HMDC FAAHPM
Chief Medical Officer

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Feedback on Specific Recommendations

Determining When to Initiate or Continue Opioids for Chronic Pain Outside of End-of-Life Care

1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.

- *Inappropriately endorses all non-opioid analgesics over opioids. For example, you would not recommend prescribing an NSAID to a patient with renal insufficiency, and hemophiliacs should never receive aspirin or NSAIDs because of bleeding risk. At a minimum, verbiage should be changed to "generally preferred." However, this might be better stated as: "Opioid analgesia may be a consideration for patients in whom non-opioid analgesics are clinically contraindicated."*

2. Before starting long-term opioid therapy, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

- *Does not account for vulnerable populations. Patients with impaired cognition would have difficulty doing this.*

3. Before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.

- *Does not account for vulnerable populations. Patients with impaired cognition would have difficulty doing this.*

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy, providers should prescribe short-acting opioids instead of extended release/long-acting (ER/LA) opioids.

5. When opioids are started, providers should prescribe the lowest possible effective dosage. Providers should implement additional precautions when increasing dosage to > 50 MME/day and should avoid increasing dosages to > 90 MME/ day.

- *The verbiage "should avoid" implies that there is inherent danger with no likelihood of benefit. Better language would be "should use caution."*

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.

- *A three-day limit seems very arbitrary. What is the evidence for this recommendation?*

7. Providers should evaluate patients within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation to assess benefits and harms of continued opioid therapy. Providers should evaluate patients receiving long-term opioid therapy every 3 months or more frequently for benefits and harms of continued opioid therapy. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids when possible.

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid-related harms are present.

- *Could include recommendation to use one of the standardized screening tools to assess risk for opioid abuse.*

9. Providers should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving excessive opioid dosages or dangerous combinations that put him/her at high risk for overdose. Providers should review PDMP data when starting opioid therapy and periodically during long-term opioid therapy, ranging from every prescription to every 3 months.

10. Providers should use urine drug testing before starting opioids for chronic pain and consider urine-drug testing at least annually for all patients on long-term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs.

11. Providers should avoid prescribing of opioid pain medication and benzodiazepines concurrently whenever possible.

12. Providers should offer or arrange evidence-based treatment (usually opioid agonist treatment in combination with behavioral therapies) for patients with opioid use disorder.

- *Needs clarification. As written, this guideline does not convey its meaning to someone who is not already familiar with the language of pain management and addiction therapy specialists. As such, those prescribers to whom it is targeted will not easily understand or benefit from the recommendation*.