



AMERICAN ACADEMY OF  
HOSPICE AND PALLIATIVE MEDICINE

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January 13, 2016

Thomas Frieden, MD, MPH Director  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30329-4027

**Re: Docket No. CDC-2015-0112; Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain**

Dear Dr. Frieden:

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 updated draft guidelines for the prescribing of opioid pain medication by primary care providers to patients 18 and older for chronic pain in outpatient settings outside of active cancer treatment, palliative care, and end-of-life care. 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 with 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 overdose death. It is a goal our Academy shares. At the same time, we well know that patients facing serious illness often require palliation of chronic pain and other distressing symptoms, and AAHPM wants to ensure nothing in the CDC guidance precludes their receiving appropriate treatment. Because of a shortage of palliative medicine and pain specialists, many of these individuals will receive care solely through a primary care provider. We are thus concerned that these recommendations paint patients in chronic pain with broad brush strokes. Though CDC has offered that its guidelines are advisory in nature, there remains a strong likelihood that recommendations from the agency will be appropriated, in whole or in part, by state legislators, professional licensing boards, hospitals, insurers, courts, or others. Therefore, **we strongly recommend that the CDC make clear that these guidelines should never preclude an individualized approach to meeting patients' medically legitimate needs.**

Our additional recommendations are provided on the pages that follow.

## General Comments

### Scope and Audience

AAHPM appreciates that the agency understands the need to except end-of-life care in these prescribing guidelines, as many of the draft recommendations would be inappropriate for addressing pain in terminal patients. Still, we must again point out that patients with serious illness without a terminal prognosis often require palliation of chronic pain and other distressing symptoms, and many of these individuals will receive care solely through a primary care provider.

AAHPM is thus pleased to see that in these updated recommendations CDC recognized the need to expand its stated exception beyond prescribing in the context of end-of-life care to also except prescribing in the context of active cancer treatment as well as palliative care. However, we urge CDC to revisit and slightly modify its definition of palliative care which it states is “consistent with that of the Institute of Medicine.” This IOM definition, drawn the 2014 report “*Dying in America: Honoring Individual Preferences Near the End of Life*,” includes a qualification as it appears in that publication. It begins, “*For the purposes of the report* (emphasis added), the committee defines palliative care as that which provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness and their families.” Because the report focuses on dying, the definition included the qualifier “advanced” illness. However, widely accepted definitions of palliative care do not limit this care to only advanced illness. In fact, as CDC goes on to state, “Palliative care can begin early in the course of treatment for any serious illness that requires excellent management of pain or other distressing symptoms.”

We would further point to the definition of palliative care in the United States used by both the U.S. Department of Health and Human Services Centers for Medicare & Medicaid Services and the National Quality Forum which states: “Palliative care means patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice.” (See The National Consensus Project for Quality Palliative Care’s *Clinical Practice Guidelines for Quality Palliative Care*, 3<sup>rd</sup> edition, 2013.) Again, the definition does not restrict palliative care to those patients who have reached an advanced stage of their illness. **We therefore urge CDC to remove “advanced” from its definition of palliative care when the prescribing guidelines are finalized.**

Along with that, we believe it is imperative that the CDC make clear that none of its recommendations apply to “active cancer treatment, palliative care and end-of-life care.” AAHPM recommends that this language should be included in the top line, bolded section of each recommendation. The chance that the recommendations will be taken out of context is marked and presents a grave danger to the care of these patients.

We also note that CDC specifies survivors of cancer with chronic pain are included under the guidelines. However, this is obviously a population that often requires palliative care, so the scope is contradictory. We suggest clarification and correction in the final guidance.

Finally, there are other vulnerable populations that are 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? We urge the CDC to address such 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.**

### Evidence

In our earlier comments, AAHPM expressed concerns about the process that led to the drafting of these guidelines which we found to lack transparency and an adequate opportunity for review and comment. We appreciate that CDC has re-opened the guidance for additional public comment and since provided greater detail regarding the expert panel used to craft its recommendations and the evidence behind them. However, even with the additional information, AAHPM remains concerned about the evidence base for each recommendation. Moreover, we echo the AMA's comments that "the change in terminology from 'low quality' or 'very low quality' evidence to category 3 or 4 evidence is not helpful to the reader and primarily serves to camouflage the criticism derived from issuing 'strong' recommendations based on low quality evidence." We therefore agree with the AMA's recommendation to identify the quality of the evidence used by returning to the easily understandable and common sense language used in the original draft. Whatever terminology is used, **any guideline with a strong recommendation should be downgraded when there is only low quality evidence.**

Overall, we urge the CDC to roll-out the final guidelines with caution. We point you to a 2001 joint statement by Drug Enforcement Administration 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 PDMP 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 in achieving the balance necessary to ensure both aims are met. As you

review our feedback and recommendations, please know that we would welcome any further opportunities to provide stakeholder input 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@aaahpm.org](mailto:jkocinski@aaahpm.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

- 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 to the patient.**
  - *This recommendation 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."*
  - *AAHPM echoes AMA's cautions that insurer practices do not currently support broad access to non-pharmacologic and multi-disciplinary care treatments.*
- 2. Before starting long-term opioid therapy, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should not initiate opioid therapy without consideration of how therapy will be discontinued. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.**
  - *This recommendation does not account for vulnerable populations. Patients with impaired cognition would have difficulty doing this.*
  - *There is no consensus definition of "clinically meaningful improvement in pain."*

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.

- *This recommendations does not account for vulnerable populations. Patients with impaired cognition would have difficulty doing this.*
- *The bulleted list of recommended discussion points bears additional review by clinicians with expertise in pain/palliative medicine. For example, the reference to possible need for stool softeners or laxatives, if medically accurate, should indicate that "routine promotility laxative agents must be used in concert with all opioids."*

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

4. When starting opioid therapy, providers should prescribe immediate-release 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 use caution when prescribing opioids at any dosage, should implement additional precautions when increasing dosage to > 50 morphine milligram equivalents (MME)/day and should generally avoid increasing dosages to > 90 MME/day.

- *AAHPM supports the notion of using the lowest effective dosage, but opposes any limits on clinical decision-making tied to MME.*
- *AAHPM finds evidence for this recommendation severely lacking and reiterates AMA's concerns that this recommendation as currently stated has the potential to cause confusion, uncertainty, and conflicting institutional or state policies that may have unintended consequences, particularly if insurers and other payers use it to deny or impose new coverage limits. In particular, limiting allowable daily dosages can result in uncontrollable pain and symptom crises for patients with serious illness that could otherwise be managed by an amount of medicine that is arbitrarily discouraged.*

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 is very arbitrary.*

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, such as history of overdose, history of substance use disorder, or higher opioid dosages ( $\geq 50$  MME), including considering offering naloxone when factors that increase risk for opioid-related harms are present.

- *This explanatory detail suggests "additional caution and increased monitoring" for every situation under this recommendation without clearly defining what this means. More clarity is necessary.*
- *Evidence is lacking for the rationale. For example, "moderate to severe sleep disordered breathing" is suggested as a relative contraindication to opioids. There is no quality evidence to support this finding.*

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.

- *CDC notes its experts disagreed as to whether a PDMP should be checked either with "every prescription" or "every three months." The lack of expert consensus should be indicated by a lower category of recommendation.*
- *AAHPM echoes AMA's recommendation that the statement on frequency end with "periodically during long-term opioid therapy." Guidance for PDMP checks must recognize the varying potential for abuse and diversion among different practice types and patients.*
- *This list prescribing what providers "should" do with aberrance on the PDMP is entirely too prescriptive and the language should be loosened to "may" at the most.*

10. When prescribing opioids for chronic pain, providers should use urine drug testing before starting opioids therapy 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 medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.