Our Response to 2022 CDC Opioid Guidelines

The American Academy of Pain Medicine (AAPM), the nation's preeminent physician-led multispecialty pain management association, is proud of our mission dedicated to advancing multidisciplinary pain care, education, advocacy, and research to improve the quality of life of people suffering with pain.

The AAPM is grateful for the opportunity to provide public comment on the proposed updated CDC Guideline for Prescribing Opioids for Chronic Pain. AAPM leadership was actively involved in three important consensus-based documents that helped to bring to light critical issues related to misapplication of the 2016 guideline (Kroenke K, 2019), harm from forced opioid tapering (Darnall BD, 2019), and appropriate patient-centered safe opioid tapering (Covington E, 2020). Unfortunately, although not the intent of the CDC and its authors, misapplication of the 2016 guideline by outside stakeholders including payers, legislators, medical boards, health care systems, and pharmacy benefit plans (PBMs) continues to negatively impact patients and the ability of pain management physicians to provide evidence-based and humane care. It should be noted that similar concerns about challenges with implementing dose thresholds, hard limits, inflexible tapering, and lack of access to non-opioid pharmacologic and non-pharmacologic therapies, behavioral health, substance use disorder treatment, and interventional therapies, were voiced by the APPM, the American Medical Association (AMA), other medical and patient advocacy groups, prior to the 2016 guideline publication during the formal public comment process. Many of those concerns were relatively ignored by the CDC authors and guideline workgroups, leading to cases of patient harm, unnecessary distress, and suffering, including patient abandonment, as well as stress and confusion by prescribers, including our member pain management specialists who provide compassionate and evidence-based care for our patients.

We applaud the CDC for a shift to a more "whole-person" patient-centered pain medicine approach with recommendations for a more holistic, multimodal treatment paradigm which is evidence-based and risk-stratified in the proposed 2022 updated draft. Many of our initial concerns that were disregarded are now the foundation for an improved draft guidance that more clearly balances the clinical distinction between the careful initiation of opioid therapy for acute, subacute, and chronic pain with understanding of the unique needs of those patients already managed and stable on chronic opioid therapy (legacy patients) as part of their treatment plan.

We respectfully offer the following recommendations for your consideration to further improve the clarity, effectiveness, and dissemination of the proposed 2022 updated CDC opioid guideline:

- **Create an executive summary document to supplement the 211-page source document. • Move from the end of the document the five "guiding principles" and a summary of the twelve recommendations to the beginning of the full 211-page source document (Currently Box 1, pages 207-210) • Communication and dissemination strategies:**

1. **A package of materials to every state public health department in the nation, the issuance of grants to consultants to develop materials related to guideline dissemination, as well as substantial measures targeted at clinicians themselves, such as webinars and easy-to-understand fact sheets.**
2. **An online portal for reporting problems with policymakers who are misapplying the guideline enabling CDC to immediately follow up and respond to misunderstandings and misapplications, ensuring active efforts are being taken to educate policymakers who continue to misapply CDC's Guidelines.**

The proposed guideline is currently 211 pages prior to any forthcoming revisions resulting from public comment. The twelve recommendations do not begin to appear until page 60 of the document and are then scattered over the next 70 pages of the document. The five guiding principles that informed the development of this document are critically important in understanding and interpreting the guidelines, but do not appear until the final paragraphs of the document as well as in Box 1. We recommend that the guiding principles be called out and clearly highlighted at the beginning of the document, followed soon thereafter by a summary of the twelve recommendations. In addition, many non-clinical (payers, legislators) and clinical stakeholders (pharmacists, nurses, physicians, and advanced practice providers) will unlikely thoroughly read hundreds of pages of guidance, especially when the core recommendations are buried within the main text and challenging to locate in the document's current form. In addition to bringing these to the front of the source document, a companion executive summary that includes the five guiding principles, twelve recommendations, and the currently italicized 'implementation considerations' for each recommendation would be very helpful for effective dissemination of the updated guideline.

- **Explicitly highlight factors involved in misapplication of the 2016 guideline by third-party payers, health care organizations, government jurisdictions, medical boards, pharmacy benefit plans (PBMs) and pharmacy chains in wrongly codifying inflexible maximum opioid dosages and days' supply into policy and legislation and publically advocate that those misapplications be revisited and polices and plans appropriately updated. Strongly consider clearly "rescinding" vs "updating" the 2016 guideline to avoid further confusion and help facilitate needed correction of current inaccurate, outdated, and, in some instances, harmful policies.**

The greatest failure of the 2016 guideline was its misapplication leading to codification of evidence-based guidelines that had been intended to inform safe opioid prescribing within the unique circumstances and clinical care needs of an individual patient into an inflexible algorithm in which one size fits all. Unfortunately, its legacy endures in legislation and policy and those policies will hinder adoption of the proposed 2022 CDC opioid guidelines. We commend the CDC in its open discussion of this in the text of the 2022 proposed guidelines. However, we believe it will be lost to most readers and policymakers who will be focused on the guideline summary rather than the extensive supporting document. We recommend a summary statement advocating that in situations in which maximum opioid dosages or days' supply have been incorporated into policy or legislation based on the 2016 CDC opioid guidelines that those misapplications should be revisited and corrected. Failure to highlight and address these now widespread unintended legacy policies from the 2016 guidelines as a summary recommendation (included in the executive summary document) in the 2022 iteration will make it impossible to accomplish the CDC's stated goal in the new guideline to shift the focus back towards the appropriate, evidence-based, safe treatment of pain, flexibility to meet the care needs and clinical circumstances of each patient through a multi-modal and multidisciplinary approach to pain management, and avoiding misapplying the practice guidelines beyond its intended use.

This could be done in one of two ways. The 2016 guideline recommendations could be 'rescinded' and 'replaced' with the current 2022 guidelines rather than 'updating' them as the current verbiage states. We recognize the practical challenges of rescinding prior guidance, but a clear plan needs to be in place that the current guidelines update and replace the prior recommendations so that providers and stakeholders are not picking and choosing elements from the two versions. As such an alternative, a softer approach would be to expand on guiding principle number four which calls for avoidance of the misapplication of the current 2022 guidelines. Two additional sentences could state:

"The 2016 CDC opioid practice guideline was misapplied when maximum opioid dosages and days' prescription were codified into policy and legislation. Situations in which this has occurred should be revisited and corrected to allow for individualized care guided by the 2022 CDC evidence-based guidelines."

- **Clarify confusion within the "scope and guidance" section regarding applicability of the guideline to pain management specialists and clarify in the recommendation section that the guideline does not apply to pain management specialist who follows principles of evidence-based safe opioid prescribing. The text document appreciates a pain management specialists' training and "expertise in applying pain management modalities" and that many pain specialist "see patients with clinical situations that are more complex, less prevalent, and not well-addressed by the available evidence, and thus balance benefits and risks to patients that may differ." Page 17 (line 380) states "use [of the guideline] by pain management specialists is not the focus of this clinical practice guideline". Unfortunately, this distinction has not been evident in the current practice environment and application of the guideline. Pharmacy plans, payers, prescriber databases, and medical board oversight tools more often cannot distinguish or fail to consider these important provider distinctions. Many pain specialists have been wrongly subjected to guideline-influenced opioid prescribing policies including unnecessary step-therapy, prior authorization, and, in rare instances, sanctions, that prohibit and disincentivize providing comprehensive pain management care plans for complex patients with unique biopsychosocially-based needs.**

This is acknowledged in the text on page 17 but should be highlighted earlier with the exception groups for the guidelines (cancer, palliative care, end of life care, and sickle cell care) and included in the executive summary.

- **Incorporate an acknowledgement that all the non-opioid therapies proposed as opioid sparing have a similar literature limitation as opioids, in that there are no long-term efficacy data (greater than 12 months).**

One of the recurring and appropriate, criticisms of opioid therapy in the document is the lack of long-term treatment-controlled trials demonstrating sustained efficacy and safety. This is used to suggest that these alternative treatments are preferred. They certainly have a better safety profile, but the document reads as though providers are simply deferring proven non-opioid therapies. In situations in which the efficacy of these modalities and non-opioid pharmacologic adjuvants (including mixed opioid agonist/antagonist like buprenorphine), are supported in the literature, like opioids, the clinical outcomes should be interpreted with caution. For example, randomized controlled trials (RCTs) of non-opioid therapies are constrained by eligibility criteria and the expertise of the clinical investigators. This maximizes internal validity, but it can limit the generalization of the findings beyond a carefully controlled study environment. As a result, data from RCTs are often insufficient as it is impossible to rigorously address how unique patient differences and variations in clinical application impact the clinical effectiveness of the intervention in daily clinical practice.

- **Expand and acknowledge the role of interventional pain management strategies for the management of acute, subacute, and chronic pain, including neuropathic, spine-related, musculoskeletal, myofascial, and headache pain types.**

The review of non-interventional modalities and non-opioid pharmacologic therapies to limit the need for opioids is extensive in the proposed 2022 CDC opioid guideline. However, in 211 pages of the document, pain medicine interventions for all pain types are lumped into a single dismissive paragraph, despite strong literature, utilization, and 3rd party payer coverage for numerous pain interventions used for the diagnostic work-up and therapeutic short and long-term management of distinct pain types and acting through several mechanisms of action. Pain medicine interventions have a proven role for the treatment of spine-related pain (epidural steroid injections, medial branch radiofrequency ablation, sacroiliac joint injections and ablation, neuromodulation, vertebral augmentation, acupuncture), musculoskeletal pain (joint injections, capsular ablations), myofascial pain (trigger point injections), and neuropathic pain and headache pain (nerve blocks and neuromodulation). Neuromodulation (spinal cord stimulation, dorsal root ganglion stimulation, peripheral nerve stimulation) is supported for a variety of spine, neuropathic, and vascular pain disorders, and intrathecal drug delivery systems are applicable for several refractory pain conditions, spasticity, as well as cancer, palliative, and end of life pain management. Interventional procedures have an important role in the diagnosis and treatment of pain. The guidelines require a more balanced view and acknowledgment of the role of interventional therapies as one of the primary components of a potentially opioid-sparing, pain-reducing, and function improving multi-modal pain management regiment. As with the discussion of non-opioid pharmacologic and non-interventional therapies, there is also a need to highlight advocacy for access and third-party coverage of all the components of an opioid-sparing multimodal treatment program, including pain medicine interventions.

- **Expansion and added clarity of telehealth recommendations for opioid management.**

Telehealth has exploded through the pandemic and will remain a core component of medical care moving forward. This should be balanced with the guiding principles and need for frequent assessments and monitoring of patients receiving opioid therapy. The text of the current guideline notes that telehealth options are acceptable for monitoring of opioid therapy (p 120). We would advocate for the following guardrail additions relative to the use of telehealth for the initiation and monitoring of opioid management.

  - An in-person evaluation (not telemedicine) is recommended for assessment (including physical examination), diagnosis, discussion of the risk, benefits, and alternatives of opioid therapy, signing of informed consent, review of provider and patient expectations regarding opioid management, and consideration of urine toxicology testing prior to prescribing opioids for a patient deemed likely to continue on a long-term basis.
  - Patients at high-risk for opioid use disorder or opioid-associated adverse events (e.g., prior history of substance misuse, high opioid dosage, polypharmacy) should primarily be monitored with in-person evaluations. Telehealth may supplement the monitoring of these patients but should not be the primary monitoring method.
  - For low-risk patients, telehealth is acceptable for some of the monitoring visits for the opioid therapy. However, the provider should have a low threshold for bringing the patient back for an in-person visit if there is suspected aberrant use, misuse, or diversion. Additionally, it is recommended that all patients have an in-person reassessment at least annually.

- **Clarification and more guidance need to be integrated into the recommendations relating to post-operative pain control. Specifically, post-operative pain control needs to be distinguished from the acute pain guideline recommendations, particularly considering the confusion regarding this distinction with the 2016 guidelines.**

Implementation of the 2016 guideline has led to significant reduction in postoperative pain management that primarily focuses on reduced opioid doses or pill counts. We applaud the reduction of widespread inadvertent over-prescribing of opioids, many times wrongly due to provider convenience, in the postoperative setting. The AAPM supports and has led educational initiatives to help prescribers better educate patients about safe disposal of unused medication and increased access to take-back programs (i.e., pharmacy and community take-back receptacles). All these strategies have helped to contribute to a reduction in unnecessary unused opioids in our communities and have likely reduced diversion. Unfortunately, the CDC's "acute" pain guidance has often been misapplied to the post-operative setting and led to a "one-size fits all approach" in the postoperative setting. Commonly, patients have been prescribed a maximum of 2-3 days of opioid medication regardless of the complexity of the surgical intervention. We recognize that this may be appropriate for less invasive surgical and dental procedures that require 1-2 days of opioid therapy, but it clearly has led to harm and needless suffering for those patients with more invasive surgical procedures (i.e., joint replacement, spinal fusions, complex fractures), as well as patients already managed on chronic opioid therapy and undergoing elective surgeries, who frequently receive inadequate post-operative medical management.

The American Academy of Pain Medicine appreciates the opportunity to provide feedback and for your consideration of our comments on the proposed 2022 Guideline and will be pleased to serve as an ongoing resource as the CDC continues to consider the role of opioid and non-opioid therapies in the management of pain.

Respectfully submitted,

Kayode A. Williams, MD, MBA, FFARCSI

President

And, Steven Stanos, DO, FAAPM&R, DABPM; James C Watson, MD; Michael Hooten, MD; Farshad M Ahadian, MD; Charles E Argoff; Rany T Abdallah MBA, MD, PhD; Randall Brewer, MD; Nancy Bratanow, MD; Hui-Ming Chang MD,MPH; David A Edwards, MD; R Norman Harden, MD; Joseph Hendrix MD; Beth Minzter MD, MS; Michael Osborne MD; Michael Schatman MA; To-Nhu Vu, M.D; Ajay D Wasan MD Msc; Robert W. Hurley, MD PhD

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