

April 11, 2022

Via Electronic Mail

Deborah Dowell, MD, MPH
Chief Medical Officer
National Center for Injury Prevention and Control
Centers for Disease Control and Prevention
Attn: CDC-2022-0024
4470 Buford Highway NE
Mail Stop S106-9
Atlanta, GA 30341

Re: Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

Dear Dr. Dowell,

On behalf of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments for consideration by the Centers for Disease Control and Prevention (CDC) regarding the proposed updates to the *CDC Guideline for Prescribing Opioids for Chronic Pain*. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests that treat, manage, and monitor pain.

We thank the CDC's National Center for Injury Prevention and Control (NCIPC) for its continued efforts to promote the safe pain management needs of our citizens during the ongoing opioid epidemic. However, we remain concerned this draft update fails to recognize the critical role evidence-based and FDA-approved/cleared devices can and should play in improving pain management and reducing opioid-related harms.



Addressing Interventional Approaches to Pain Management

We appreciate that the proposed 2022 guidelines include reference to “Interventional Approaches to Subacute and Chronic Pain”. However, we remain concerned regarding the characterization of and lack of detail regarding interventional approaches for the treatment of pain, including medical devices. In the proposed guideline update, CDC states its goal that the updated guidelines be used “to assist clinicians in weighing benefits and risks of prescribing opioid pain medication for painful acute conditions . . . and pain related to procedures.”¹ This vision appears to be borne out in other sections of the guidance, such as noninvasive nonpharmacologic treatments for chronic pain, where CDC provides a detailed evaluation of the available evidence regarding the use of these varied treatments for different types of chronic pain.² By contrast, the draft guidance groups all interventional approaches under a single broad category and evaluation indicating evidence is “limited”,³ without meaningful discussion of individual treatments or their associated evidence.

Unlike many non-opioid treatments profiled by CDC, medical devices must meet stringent safety and effectiveness as well as reasonable and necessary standards. The Food and Drug Administration (FDA) has approved/cleared more than 200 medical device alternatives to opioids that help treat or manage various types of pain. The manufacturers of many of these products have developed evidence which shows a correlation between use of the devices and a reduction in the need to use and/or prescribe opioids. By omitting available evidence regarding the range of interventional approaches available to treat both acute and chronic pain, we believe the updated guidelines may inadvertently disincentivize the use of these technologies through lack of sufficient detail to meaningfully inform clinician decision-making. We therefore recommend CDC provide additional detail on the types of interventional approaches available for the treatment of pain and the most up-to-date evidence available to support each treatment.

We are further concerned that, based on the unintended negative effects observed following release of the 2016 guidelines,⁴ failure to provide meaningful discussion of interventional approaches to pain management in the updated guidance may exacerbate existing coverage and reimbursement barriers for these technologies. Problems related to the deployment of opioid alternative devices and the inability of patients to access these innovations at the appropriate time persist. These access concerns are the result of various payment and insurance coverage issues, including delays (such as prior authorization or “step-therapy”) which may require patients to undergo and/or fail drug therapy for chronic pain relief (posing possible addiction risk) prior to being able to utilize a non-opioid device-based intervention. In some instances, patients are required to undergo additional medical evaluation

¹ See lines 352-355 of the draft guidance

² See lines 989-1055 of the draft guidance

³ See lines 2110-2113 of the draft guidance

⁴ See lines 246-263 of the draft guidance



prior to receiving device-based non-opioid interventions for chronic pain. These additional requirements pose barriers to access and treatment delays for beneficiaries, especially those in areas with limited or no qualified providers to conduct the evaluation, prolonging their exposure to opioids and increasing their risk of addiction. We therefore urge CDC to update the “Interventional Approaches to Subacute and Chronic Pain” section of the updated guidelines to better reflect the standard of care, consistent with the recommendations of the HHS Pain Management Best Practices Task Force, which has been endorsed by the American Medical Association, American Hospital Association, specialty societies, and 160 other stakeholder organizations.

Improving Clinician Education on Alternative Pain Treatment Options

Clinician education and sensitivity to the risk of opioid dependence is critical. As CDC expands the scope of these guidelines beyond primary care physicians, education regarding the epidemic, appropriate screening, and treatment options (device, drug, combinations, and restorative therapy alternatives) must be made known to all care providers. Clinicians and other care providers must be better informed of the treatment impacts that can be gained by using non-opioid devices, and be prepared to discuss alternative treatment options available with their patients. This will require more education regarding the range of devices/device-based treatments and the appropriate time for their incorporation into patient treatment plans. This education should extend to the full range of providers who are treating patients with acute and chronic pain, especially those at risk for developing an opioid dependency. AdvaMed agrees with findings were included in the 2019 Pain Management Best Practices Inter-Agency Taskforce Report⁵ that this could be addressed through the integration of additional information into the medical school curriculum, including pain training in CME courses, and the dissemination and adoption of protocols, clinical practice guidelines, and information across sites of care. We also believe that CDC could engage with public health entities and agencies, HHS, and physician and nursing specialty societies to collaboratively develop strategies for addressing training and education shortfalls and could incorporate this information into its guidelines.

Improving Patient Education and Engagement in Decision-Making

Sound patient education and preventative consultation earlier in the care continuum plays a meaningful role in preventing opioid misuse and addiction while ensuring patients have their pain and painful conditions addressed. However, discussion of patient education in the proposed update is limited and focused on the benefits and risks of opioid therapy.⁶ We urge CDC to increase the guideline’s discussion on early, proactive patient education regarding non-opioid alternatives to pain management, including medical devices. We believe improved patient education

⁵ <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>

⁶ See lines 2038-2097 of the draft guidance



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and presentation of alternatives to opioids could reduce the rate of initial opioid prescription and, in turn, reduce the risk of opioid misuse.

AdvaMed appreciates the opportunity to provide these comments and urges the CDC to strongly consider them while finalizing updates to its Clinical Practice Guideline for Prescribing Opioids. We, along with our members, look forward to continuing to work with the CDC on solutions that will help to alleviate and control the acute and chronic pain that is contributing to the nationwide opioid epidemic. Please feel free to contact me should you have any questions at (202)257-5659 or ktullia@advamed.org.

Sincerely,



Kirsten Tullia, J.D., MPH

Vice President, Payment & Healthcare Delivery Policy

