Peer Review Plan for the Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

Title: Proposed CDC Clinical Practice Guideline for Prescribing Opioids -- United States, 2022 Subject of Planned Report: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) has developed a proposed clinical practice guideline, CDC Clinical Practice Guideline for Prescribing Opioids - United States, 2022 (the Clinical Practice Guideline). The Clinical Practice Guideline updates and expands the CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016 and provides evidence-based recommendations for clinicians who provide pain care, including those prescribing opioids, for outpatients aged 18 years and older with acute pain (duration less than 1 month), subacute pain (duration of 1-3 months), or chronic pain (duration of 3 months or more), not including sickle cell disease-related pain management, cancer pain treatment, palliative care, and end-of-life care. The Clinical Practice Guideline includes guidance for primary care clinicians (including physicians, nurse practitioners, and physician assistants) as well as for outpatient clinicians in other specialties (including those managing dental and postsurgical pain in outpatient settings and emergency clinicians providing pain management for patients being discharged from emergency departments). This Clinical Practice Guideline provides guidance only and does not require mandatory compliance; and the guideline is intended to be flexible to support, not supplant, clinical judgment and individualized, patient-centered decision-making.

Purpose of Planned Report: In the CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, CDC communicated the intent to evaluate and reassess evidence and recommendations as new evidence became available and to determine when new evidence would prompt an update. To achieve these aims, CDC funded the Evidence-based Practice Centers (EPCs) at the Agency for Healthcare Research and Quality (AHRQ) to conduct systematic reviews of the scientific evidence in the following five areas: noninvasive nonpharmacological treatments for chronic pain; nonopioid pharmacologic treatments for chronic pain; opioid treatments for chronic pain; treatments for acute pain; and acute treatments for episodic migraine. Based upon the new evidence described in these reviews, an update to the CDC's 2016 Guideline was warranted.

CDC evaluated the evidence for the Clinical Practice Guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, which specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. Recommendations were made based on systematic reviews of the available scientific evidence while considering benefits and harms; patients', caregivers', and clinicians' values and preferences for pain treatment; and resource allocation (e.g., costs to patients or health systems, including clinician time). CDC drafted recommendation statements in the Clinical Practice Guideline focused on assisting clinicians in determining whether to initiate opioids for pain; opioid selection and dosage; opioid duration and follow-up; and assessing risk and addressing potential harms of opioid use.

This Clinical Practice Guideline is voluntary and provides guidance only. It is intended to be flexible to support, not supplant, clinical judgment and individualized, patient-centered decision-making. This guideline is not intended to be applied as inflexible standards of care across patient populations by health care professionals, health systems, third-party payers, organizations, or governmental jurisdictions. The Clinical Practice Guideline is intended to achieve the following: improved communication between clinicians and patients about the risks and benefits of pain treatment, including opioid therapy for pain; improved safety and effectiveness for pain treatment, resulting in improved function and quality of life for patients experiencing pain; and a reduction in the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

For more information about the Clinical Practice Guideline or the process of updating it, please visit https://www.cdc.gov/opioids/guideline-update/index.html..

Type of Dissemination: Influential Scientific Information

Timing of Review (including deferrals): February 2022-April 2022

Type of Review (panel, individual or alternative procedure): Individual

Opportunities for the Public to Comment (how and when): To help assure the Clinical Practice Guideline's integrity, credibility, and consideration of patients', caregivers', and providers' values and preferences, CDC obtained input from patients, caregivers, experts, clinicians, the public, a federally chartered advisory committee, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC). In addition, the BSC/NCIPC established an Opioid Workgroup to provide expert input and observations to the BSC/NCIPC on the draft Clinical Practice Guideline. CDC also obtained feedback from a panel of external peer reviewers who are experts in topic areas related to opioid prescribing. Peer reviewers' feedback will be addressed and incorporated into the final Clinical Practice Guideline at the same time that public comments are considered.

In February 2022, CDC posted the following supporting and related materials to help inform public comment:

1) The draft Clinical Practice Guideline; 2) the GRADE tables; 3) the Opioid Workgroup (OWG) Report and CDC's Response to observations outlined in the OWG Report per the BSC/NCIPC's unanimous vote to have CDC adopt and address considerations raised in the OWG Report; 4) and an Overview of Community Engagement and Public Comment Opportunities, which describes key themes that emerged about patients', caregivers', clinicians', and experts' values and preferences regarding pain management, as well as CDC's response to input obtained from these efforts, which is reflected in the Clinical Practice Guideline. The GRADE tables include clinical evidence review ratings of the evidence for the key clinical questions. The OWG Report describes the workgroup's findings and observations about the initial draft Clinical Practice Guideline as presented to the BSC/NCIPC at a public meeting on July 16, 2021. The OWG, comprising a BSC/NCIPC member as the Chair and at least one other BSC member in accordance with federal advisory committee policy, as well as patients with pain, caregivers, and family members of patients with pain, and clinicians and subject matter experts with a variety of relevant pain management expertise, was designed to provide independent, broad, external, input to the BSC/NCIPC on the diverse and complex issues addressed in the

Clinical Practice Guideline. OWG meetings were coordinated by an NCIPC subject matter expert who served as the Designated Federal Official. CDC's Response to the OWG Report reflects and describes how CDC incorporated OWG observations and comments in the revised draft of the Clinical Practice Guideline. The Overview of Community Engagement and Public Comment Opportunities document provides a summary of efforts implemented throughout the guideline update process to better understand the lived experiences and perspectives of community members that we serve and to ensure additional input from patients, caregivers, clinicians, and the public. CDC's response to the themes and findings that emerged throughout the initial community engagement and public comment opportunities describes how CDC carefully considered and incorporated diverse perspectives and input from multiple sources and stakeholders into the Clinical Practice Guideline.

Peer Reviewers Provided with Public Comments before the Review: Comments from peer reviewers were obtained simultaneously with comments from the public. Concurrent review is required to allow for rapid publication of the guidelines to address an urgent public health need.

Anticipated Number of Reviewers: 4

Primary Disciplines or Expertise: Peer reviewers were selected based on expertise and diversity of scientific viewpoints, while addressing conflict of interest concerns and ensuring independence from the guideline development process. The selection of peer reviewers involved specific effort to identify appropriate academic training and relevant experience, proven scientific excellence, publication records, and subject matter expertise in topics such as: chronic, surgical, and acute pain management; clinical practice; health equity; mental health and well-being; opioids and opioid therapies; opioid tapering; opioid use disorder treatment; and pharmacological and non-pharmacological pain management.

Reviewers Selected by (agency or designated outside organization): Centers for Disease Control and Prevention (CDC)

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: CDC identified four peer reviewers, who were notified that CDC was in the process of seeking independent peer review of the draft Clinical Practice Guideline by subject matter experts. They were informed that CDC sought clinicians and researchers based on scientific and subject-matter expertise, racial/ethnic diversity, diversity of experiences and perspectives, independence from the guideline development process, and consideration of conflicts of interest. Reviewers were invited to serve as a peer reviewer of the proposed Clinical Practice Guideline, indicating that their extensive expertise and the research to which they have contributed made them well qualified to serve as a reviewer of this important product designed to improve communication between clinicians and patients to help them make informed, patient-centered decisions related to safely and effectively treating pain. Specifically, they were asked to provide their critical insight as a peer reviewer to ensure the Clinical Practice Guideline is balanced, grounded in scientific evidence, and can be reasonably translated into clinical practice. Reviewers were informed that CDC's peer review panel requirements also require that the names of peer reviewers be publicly disclosed in the Office of Management and Budget (OMB) Peer Review Bulletin. CDC's charge to

peer reviewers explicitly requested that they "provide a thorough review of the draft Guideline, evaluating its scientific merit and practical implementation considerations, with the goal of maintaining high quality science and providing evidence-based recommendations to guide clinical practice and decision-making to help prevent opioid related-harms."

Peer Reviewers:

Ajay D. Wasan, MD, MSc, Vice Chair for Pain Medicine, University of Pittsburgh Medical Center; Professor of Anesthesiology and Perioperative Medicine and Psychiatry, University of Pittsburgh School of Medicine; Director, Chronic Pain Research Program; Director, Center for Innovation in Pain Care

Expertise: pharmacological and non-pharmacological pain management; chronic, surgical, and acute pain management; opioids and opioid treatment; clinical practice; opioid use disorder treatment; mental health and opioid use; racial/ethnic minority researcher perspective

Anika Alvanzo, MD, MS, FACP, DFASAM, Eastern Region Medical Director for Pyramid Healthcare, Inc.; Chair of the American Society of Addiction Medicine Annual Conference Program Planning Committee and Region V Director for the ASAM Board of Directors

Expertise: pharmacological and non-pharmacological pain management; opioids and opioid treatment; opioid tapering; clinical practice; opioid use disorder treatment; health equity; opioid use during pregnancy; mental health and opioid use; racial/ethnic minority researcher perspective

Michael Englesbe, MD, Cyrenus G. Darling Sr., MD and Cyrenus G Darling Jr., MD Professor of Surgery, University of Michigan

Expertise: pharmacological and non-pharmacological pain management; chronic, surgical, and acute pain management; opioids and opioid treatment; opioid tapering; clinical practice

Joseph Frank, MD, Associate Professor, Medicine-Internal Medicine, University of Colorado Hospital Expertise: pharmacological and non-pharmacological pain management; chronic, surgical, and acute pain management; opioids and opioid treatment; opioid tapering; clinical practice; opioid use disorder treatment

Additional elements to be added to the public posting as they become available:

• CDC's response to peer review and public comments