

To: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, Docket No. CDC-2024-0071

From: Mitchell Berger, (comments made in personal capacity), mazruia@hotmail.com. Nov. 28, 2024

Re: Proposed Data Collection Submitted for Public Comment and Recommendations,
<https://www.federalregister.gov/documents/2024/10/01/2024-22474/proposed-data-collection-submitted-for-public-comment-and-recommendations>

Dear Dr. Zirger: In response to the above notice and request for Comments and Recommendations concerning a “Comprehensive Evaluation of the Implementation and Uptake of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain,” I write to make the following suggestions:

- Consistent with efforts by the Office of Management and Budget and others to “[b]roaden public participation,” if feasible a draft of the evaluation should be posted for public review and comment prior to being finalized.¹ As well, CDC should as part of this evaluation seek input from patients and health care providers, such as through focus groups, workshops and listening sessions, to assess the guidelines’ impacts and continuing needs. (While focus groups are discussed in the *Federal Register* announcement about this study, the numbers of patients involved seems fairly modest). CDC should seek input from patients with a variety of types of pain and medical conditions. Clinicians consulted should include not only specialist and primary care physicians but also nurses, pharmacists and others who support patients in pain.
- Media coverage has impacted development of the opioid epidemic in the United States and how patients in pain and those with opioid use disorder are treated and perceived. CDC should as part of its evaluation of the 2022 guidelines dissemination consider the role of both traditional and non-traditional media (e.g., blogs, social media) and how this has impacted public education and awareness about guideline recommendations.² CDC should consider in its evaluation having one or more focus groups including media representatives and examining the media’s role.
- CDC should seek input about the guidelines from state, local, tribal and territorial public health leaders and policymakers, such as those who have been part of state and other opioid task forces.
- The CDC places strong emphasis in its 2022 guidelines on “nonpharmacologic and nonopioid pharmacologic treatments” for pain, recommending that “Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient.” In evaluating the guidelines’ impact, CDC should assess the extent to which its 2022 guidelines have influenced use of alternatives to opioids for pain treatment.³

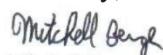
¹ <https://www.performance.gov/blog/2024-public-participation-federal-government/>

² Webster F, Rice K, Sud A. A critical content analysis of media reporting on opioids: The social construction of an epidemic. *Soc Sci Med.* 2020 Jan;244:112642. doi: 10.1016/j.socscimed.2019.112642; McGinty EE, Stone EM, Kennedy-Hendricks A, Sanders K, Beacham A, Barry CL. U.S. news media coverage of solutions to the opioid crisis, 2013-2017. *Prev Med.* 2019 Sep;126:105771. doi: 10.1016/j.ypmed.2019.105771

³ Mazurenko O, O'Brien E, Beug A, Smith SM, McCarthy C. Recommendations for managing adults with chronic non-cancer pain in primary care: A systematic clinical guideline review. *J Eval Clin Pract.* 2024 Aug 5. doi: 10.1111/jep.14118; Pritchard KT, Baillargeon J, Lee W, Raji MA, Kuo Y. Trends in the Use of Opioids vs Nonpharmacologic Treatments in Adults With Pain, 2011-2019. *JAMA Netw Open.* 2022;5(11):e2240612. doi:10.1001/jamanetworkopen.2022.40612

- As work related to opioids is a cross-cutting issue, in addition to CDC, representatives from such agencies as the National Institutes of Health (NIH) and NIH Pain Consortium,⁴ Interagency Pain Research Coordinating Committee (IPRCC),⁵ Substance Abuse and Mental Health Services Administration, Department of Veterans Affairs,⁶ Centers for Medicare and Medicaid Services,⁷ and Food and Drug Administration,⁸ should be able to provide input into the evaluation's planned methodology and drafts.
- Noting that the guidelines have been used (or at times misapplied) by states and payors, CDC emphasizes in its 2022 guidelines that these guidelines are "voluntary and intended to be flexible to support, not supplant, individualized, patient-centered care." CDC should specifically as part of its impact evaluation examine the extent to which its guidelines, which are not binding and do not have the force of law, still may have been adopted as mandates by states, payors, medical boards and others, undermining the 2022 guidelines' express intention to support individualized, patient-centered care.⁹
- The 2022 guidelines were expressly not intended to cover pediatric populations (<18 years old) or to apply to those with such conditions as cancer, palliative care and sickle cell disease treated for pain related to these conditions. CDC noted the availability of other guidance for pain treatment associated with these conditions and since 2022 additional relevant recommendations may have become available.¹⁰ CDC should evaluate the extent to which its guidelines may have been applied to treatment of such patients despite caveats in the 2022 guidelines.
- CDC should in its impact evaluation describe how its current guidelines' recommendations compare to those of other nations.¹¹ Thank you for considering this input.

Sincerely,



**Mitchell
Berger**

Digitally signed by Mitchell Berger
DN: cn=Mitchell Berger, c=US,
email=mazruia@hotmail.com
Date: 2024.11.28 10:56:28 -05'00'

Mitchell Berger Note: I am submitting these suggestions in my personal/private capacity. The views expressed are mine only and should not be imputed to other individuals nor to any public or private entity.

⁴ NIH Pain Consortium, <https://www.painconsortium.nih.gov/about/about-nih-pain-consortium>

⁵ <https://www.iprcc.nih.gov/>

⁶ <https://www.va.gov/PAINMANAGEMENT/index.asp>

⁷ <https://www.cms.gov/priorities/key-initiatives/opioids>

⁸ <https://www.fda.gov/drugs/information-drug-class/opioid-medications>

⁹ <https://www.cato.org/blog/cdc-replaces-flawed-2016-opioid-prescribing-guideline-flawed-2022-opioid-prescribing-guideline>;

<https://www.cdc.gov/overdose-prevention/hcp/clinical-guidance/healthcare-admin-applying-guidelines.html>;

https://archive.cdc.gov/www_cdc_gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html;

<https://kffhealthnews.org/news/article/cdc-new-opioid-guidelines-chronic-pain-patients/>; <https://www.astho.org/topic/population-health-prevention/social-behavioral-health/overdose-prevention/cdc-clinical-practice-guideline-for-prescribing-opioids-resources-for-decision-makers/>

¹⁰ Hadland SE, Agarwal R, Raman SR, Smith MJ, Bryl A, Michel J, Kelley-Quon LI, Raval MV, Renny MH, Larson-Steckler B, Wexelblatt S, Wilder RT, Flinn SK. Opioid Prescribing for Acute Pain Management in Children and Adolescents in Outpatient Settings: Clinical Practice Guideline. Pediatrics. 2024 Sep 30:e2024068752. doi: 10.1542/peds.2024-068752

¹¹ See e.g., Furlan AD, Williamson OD. New Canadian guidance on opioid use for chronic pain: necessary but not sufficient.

CMAJ. 2017 May 8;189(18):E650-E651. doi: 10.1503/cmaj.170431; <https://www.sydne.edu.au/news-opinion/news/2023/06/26/guidelines-to-help-clinicians-on-safer-opioid-deprescribing-.html>; Häuser W, Schug S, Furlan AD. The

opioid epidemic and national guidelines for opioid therapy for chronic noncancer pain: a perspective from different continents. Pain Rep. 2017 May 12;2(3):e599. doi: 10.1097/PR9.0000000000000599; Humphreys K, et al. Responding to the opioid crisis in

North America and beyond: recommendations of the Stanford-Lancet Commission. Lancet. 2022 Feb 5;399(10324):555-604. doi:

10.1016/S0140-6736(21)02252-2; Petzke F, Bock F, Hüppe M, Nothacker M, Norda H, Radbruch L, Schiltenswolf M, Schuler M,

Tölle T, Viniol A, Häuser W. Long-term opioid therapy for chronic noncancer pain: second update of the German guidelines.

Pain Rep. 2020 Aug 20;5(5):e840. doi: 10.1097/PR9.0000000000000840



December 2, 2024

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Atlanta, GA, 30341-3717

RE: **Docket No. CDC-2024-0071**; Proposed Data Collection Submitted for Public Comment and Recommendations

Dear Dr. Cohen:

On behalf of the more than 59,000 members of the American Society of Anesthesiologists (ASA), I wish to provide comments to the Centers for Disease Control and Prevention (CDC) on the agency's project titled "Comprehensive Evaluation of the Implementation and Uptake of the CDC Clinical Practice Guideline for Prescribing Opioids for Pain." Thank you for the opportunity to provide insight into the impact of the CDC guideline.

In 2016, the CDC established guidelines for prescribing opioids for chronic pain, later revising them in 2022. The 2016 recommendation to minimize opioid prescriptions exceeding 90 morphine milligram equivalents (MME) per day was met with controversy, particularly among patients. Many patients and physicians expressed concerns that this threshold could not be reliably applied to individual cases and considered it somewhat arbitrary by clinical standards. Over time, the 2016 guidelines led to a variety of restrictive policies, including limitations on opioid dosages. These measures created significant barriers for patients trying to access pain care and made it more challenging for physicians to prescribe necessary medications.

The 2022 guideline aims to improve patient care and safety by providing evidence-based recommendations for clinicians who provide pain care, including those prescribing opioids, for outpatients aged 18 years and older with acute pain. The updated guidelines address four key areas of pain management:

1. The guidelines provide clear recommendations to help clinicians decide when it is appropriate to start opioid treatment for patients experiencing acute (less than 1 month), subacute (1-3 months), or chronic pain (more than 3 months).
2. The guidelines offer guidance on choosing the right type of opioid and establishing the appropriate dosage to ensure effective pain management while minimizing risks.
3. The guidelines emphasize the importance of determining the proper length of the initial prescription and the necessity of regular follow-up appointments to monitor patient progress and adjust treatment as needed.
4. The guidelines provide strategies for evaluating the risks associated with opioid use and implementing measures to address potential harms, ensuring a balanced approach to pain management.

The ASA Committee on Pain Medicine conducted an internal survey of its chronic pain physicians to evaluate the impact of the 2022 CDC guidelines on opioid prescribing among respondents. The survey suggested that the primary sources of information about the guidelines were professional society announcements (64%) and online/medical news sources (44%), with other sources including word of mouth, social media, hospital/clinical updates, and CME programs. 56% of respondents stated that dissemination of these CDC guidelines was somewhat effective, while 40% found it ineffective.

The survey also evaluated the impact of the guidelines on clinical practice and decision-making. Approximately 70% of physicians reported making changes to their clinical practice due to the guidelines, highlighting the crucial impact these had in decision-making while prescribing opioids. The guidelines have influenced clinical decision-making by enhancing documentation practices and improving patient communication about risks and benefits of opioid use.

The 2022 Clinical Practice Guideline for Prescribing Opioids for Pain was generally well-received by the medical community for its comprehensive and evidence-based recommendations. They were seen as a significant improvement over the 2016 guidelines, providing more nuanced guidance on opioid prescribing. However, there were also criticisms, particularly from patients who felt the guidelines might lead to reduced access to necessary pain medications.^{1,2}

The primary method for the CDC's evaluation and data collection appears to be a web-based survey. However, details on the identification process for clinicians, dentists, professional societies, and patients are limited. While these surveys could support Aim 1 (assessing the effectiveness of guideline dissemination) and Aim 3 (evaluating guideline implementation from both patient and clinician perspectives), they do not seem to adequately address Aim 2, which focuses on population-wide changes in prescribing practices for opioids and medications used in opioid use disorder treatment.

By following these updated guidelines, clinicians can improve patient outcomes and ensure a safer and more effective approach to pain management. ASA appreciates the opportunity to comment on this project and looks forward to working with the CDC to ensure both the safe prescribing by physicians and that the needs of patients are met. If you have any questions, please feel free to contact Emily Olearczyk at e.olearczyk@asahq.org or 202-330-4888.

Sincerely,

A handwritten signature in black ink, appearing to read 'DEA', followed by the printed text 'MD FASA'.

Donald E. Arnold, MD, FACHE, FASA
President
American Society of Anesthesiologists

¹ <https://www.cdc.gov/overdose-prevention/hcp/clinical-guidance/index.html>

² <https://www.cdc.gov/media/releases/2022/p1103-Prescribing-Opioids.html>

From: NCIPC OMB (CDC)
Sent: Friday, December 6, 2024 8:24 AM
To: mazruia@hotmail.com
Cc: NCIPC OMB (CDC)
Subject: Docket No. CDC-2024-0071 - Information Collection Review Office, Centers for Disease Control and Prevention.

Re: Proposed Data Collection Submitted for Public Comment and Recommendations,
<https://www.federalregister.gov/documents/2024/10/01/2024-22474/proposed-data-collection-submitted-for-public-comment-and-recommendations>

Mr. Berger,

Thank you for taking the time to provide a comment on this Federal Register Notice (FRN). CDC highly values insights gained from public comment opportunities.

The development of the 2022 Clinical Practice Guideline included multiple opportunities for public comment and feedback to ensure that the public had a voice in the process. CDC also worked closely with federal partners to garner crucial feedback and input, which is reflected in the final released 2022 Clinical Practice Guideline. This evaluation assesses the implementation and uptake of the final 2022 Clinical Practice Guideline, which incorporates these perspectives. For more information on the development of the 2022 Clinical Practice Guideline, please visit our website: [Process for the Development of the 2022 Clinical Practice Guideline for Prescribing Opioids for Pain | Opioids | CDC](#)

As stated in the FRN, this evaluation will include systematic collection and analysis of a range of primary and secondary data sources. To answer the research questions, we will employ qualitative synthesis and analytic approaches, quantitative analyses, and various mixed-methods approaches. Primary data collection efforts include a web-based survey conducted among a national sample of clinicians, virtual interviews with clinicians, virtual interviews with dentists, virtual interviews with leaders from professional organizations, payers, medical boards, and health systems, and virtual focus groups with patients and caregivers.

This evaluation seeks to include a variety of clinicians who support patients with pain and are the intended audience of the 2022 Clinical Practice Guideline. Inclusion criteria for practicing clinicians include that the clinicians: 1) practice in an ambulatory, outpatient and/or emergency department at least once a week; 2) primarily treat adults; 3) treat patients with acute, subacute, or chronic pain other than pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and/or end of life care; and 4) practice in the following care areas: family medicine, internal medicine, emergency medicine, surgery, occupational medicine, physical medicine and rehabilitation medicine, neurology, obstetrics and gynecology. To ensure that patients and caregivers with a variety of experiences (e.g., types of pain, medical conditions) are included, patient and caregiver advocacy groups will help identify potential focus group participants.

Interviews with key informants from professional associations, payers, health systems, and medical boards will be conducted to focus on the awareness and implementation of the 2022 Clinical Practice Guideline, including unintended consequences of the 2022 Clinical Practice Guideline. To ensure a variety of perspectives and experiences, key informants will be identified through comprehensive searches and organizations (e.g., Association of State and Territorial Health Officials, state health departments that have engaged in previous opioid management work). In addition, an analysis of changes in payer policies after the 2022 Clinical Practice Guideline was released and an environmental scan of federal guidance documents are included in the overall evaluation protocol. Targeted literature searches in the gray and published literature (e.g., traditional and non-traditional media) will be used to investigate how the 2022 Clinical Practice Guideline was received.

The goal of Aim 2 is to evaluate the impact of the 2022 Clinical Practice Guideline through population-wide changes on expected outcomes. We will estimate the impact of the 2022 Clinical Practice Guideline using commercial claims data. Through this secondary data analysis, outcomes such as prescription rates for opioids and non-opioid medications to treat acute, subacute, and chronic pain will be assessed.

Thank you again for taking the time to provide a thorough public comment.

OMB/PRA Office

Office of Science

National Center for Injury Prevention and Control

Centers for Disease Control and Prevention

From: NCIPC OMB (CDC)
Sent: Friday, December 6, 2024 8:27 AM
To: e.olearczyk@asahq.org
Cc: NCIPC OMB (CDC)
Subject: Docket No. CDC-2024-0071 - Information Collection Review Office, Centers for Disease Control and Prevention.

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<https://www.federalregister.gov/documents/2024/10/01/2024-22474/proposed-data-collection-submitted-for-public-comment-and-recommendations>

Dr. Arnold,

Thank you for taking the time to provide a comment on this Federal Register Notice (FRN). CDC highly values insights gained from public comment opportunities, and we appreciate you providing results from the ASA Committee on Pain Medicine's internal survey of its chronic pain physicians.

The development of the 2022 Clinical Practice Guideline included several opportunities for community and partner engagement to ensure that multiple perspectives were represented in the final released 2022 Clinical Practice Guideline. This evaluation assesses the implementation and uptake of the final 2022 Clinical Practice Guideline, which incorporates these perspectives. For more information on the development of the 2022 Clinical Practice Guideline, please visit our website: [Process for the Development of the 2022 Clinical Practice Guideline for Prescribing Opioids for Pain | Opioids | CDC](#).

As stated in the FRN, this evaluation will include systematic collection and analysis of a range of primary and secondary data sources. To answer the research questions, we will employ qualitative synthesis and analytic approaches, quantitative analyses, and various mixed-methods approaches. Primary data collection efforts include a web-based survey conducted among a national sample of clinicians, virtual interviews with clinicians, virtual interviews with dentists, virtual interviews with leaders from professional organizations, payers, medical boards, and health systems, and virtual focus groups with patients and caregivers.

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We hope the information we've shared about the evaluation is helpful for you and your constituents. Thank you again for taking the time to provide a thorough public comment.

OMB/PRA Office

Office of Science

National Center for Injury Prevention and Control

Centers for Disease Control and Prevention