



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

April 10, 2019

Sally Satel, MD
Yale University School of Medicine
300 George Street, Suite 901
New Haven Connecticut 06511

Dear Dr. Satel:

Thank you for your letter regarding the need to address the potential unintentional harms to patients with pain that may result from misinterpretation of the *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016* (the Guideline, www.cdc.gov/media/modules/dpk/2016/dpk-pod/rr6501e1er-ebook.pdf). The Centers for Disease Control and Prevention (CDC) appreciates your sharing personal testimonies from patients across the country. We agree that patients suffering from chronic pain deserve safe and effective pain management. CDC is committed to addressing the needs of patients living with chronic pain while reducing the risk of opioid-related misuse, overdose, and death.

CDC is working diligently to evaluate the impact of the Guideline and clarify its recommendations to help reduce unintended harms. We provide details of that work in the enclosure that accompanies this response.

The Guideline does not endorse mandated or abrupt dose reduction or discontinuation, as these actions can result in patient harm. The Guideline includes recommendations for clinicians to work with patients to taper or reduce dosage **only** when patient harm outweighs patient benefit of opioid therapy. The recommendation on high-dose prescribing focuses on initiation. The Guideline offers different recommendations for patients already on opioid dosages greater than or equal to 90 morphine milligram equivalents per day. The recommendations include reviewing the risks and benefits of continuing high-dosage therapy, and if a patient would like to taper, collaborating with the patient on an individualized plan. The Guideline also recommends that the plan be based on the patient's goals and concerns and that tapering be slow enough to minimize opioid withdrawal, e.g., 10 percent a week or 10 percent a month for patients who have been on high-dose opioids for years.

Thank you, again, for your letter and your interest in this important public health issue. Chronic pain is multidimensional. CDC is committed to using the best available research to support providers in relieving patients' pain, preventing suffering, and improving quality of life. This

response is being sent to the co-signers of your letter. Please share it with other interested parties.
Thank you.

Sincerely,

A handwritten signature in black ink that reads "Robert R. Redfield MD". The signature is written in a cursive, slightly slanted style.

Robert R. Redfield, MD
Director, CDC

Enclosure

Details on the Centers for Disease Control and Prevention's (CDC) Efforts to Evaluate the Impact of the *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, and Clarify Its Recommendations

The Centers for Disease Control and Prevention (CDC) is working diligently to evaluate the impact of the Guideline and clarify its recommendations. Specifically:

- CDC supports four extramural research projects that are examining unintended consequences of tapering and discontinuation, particularly as it relates to health systems guidelines and policies, including use of heroin and other illicit opioids. The four extramural sites are Oregon State University, University of Michigan, Kaiser Foundation Research Institute, and Public Health Foundation Enterprises.
- CDC is sponsoring a clinical Quality Improvement Collaborative to help health systems integrate Guideline recommendations into practice. This collaborative encourages care coordination, which should lead to safer prescribing for patients already on long-term opioid therapy, and underscores the importance of clinician decision making. Five healthcare systems across eight states are piloting and evaluating these activities—Atrius Health in Massachusetts; the Indian Health Service in Oregon, Minnesota, North Dakota, and New Mexico; Montefiore Medical Center in New York; St. Mary's/Clearwater Valley Hospital and Clinics in Idaho; and Stormont Vail Health in Kansas—are piloting and evaluating these activities.
- CDC is collaborating with the Agency for Healthcare Research and Quality to conduct systematic reviews of the scientific literature that has been published since the Guideline was released in March 2016. The reviews will be completed in early 2020 and will evaluate the evidence on the effectiveness and comparative effectiveness of opioids, non-opioid pharmacologic therapy, and non-pharmacologic therapy for chronic and acute pain by considering function, quality of life, and adverse events. Results of these reviews will assist CDC in identifying whether evidence gaps have been sufficiently filled to warrant a Guideline update or expansion.

While CDC currently offers evidence-based tools, recommendations, and guidance for decision-making to providers and health systems (www.cdc.gov/drugoverdose/prescribing/resources.html), we are also working with these partners and insurers to:

- Clarify the content of these resources to improve opioid prescribing and pain management;
- Highlight recommendations within the Guideline, including tapering guidance, options for non-opioid treatments for chronic pain, and communicating with patients; and
- Emphasize the importance of developing policies consistent with the Guideline's intent.

These efforts will provide further clarity on issues like opioid tapering and discontinuation.

CDC also worked with the Centers for Medicare & Medicaid Services (CMS) on their annual Medicare Call Letter for 2019, an announcement to Medicare Advantage organizations and prescription drug plan sponsors on Medicare Advantage capitation rates and Medicare Advantage and Part D payment policies. Specifically, we provided content on interpreting the Guideline's recommendation on increasing opioid dosages. CDC emphasized that this

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recommendation applied to preventing dose escalation among patients not already receiving long-term, high-dose opioid therapy, and that different guidance was provided for patients already receiving high-dose opioid therapy. You can find this information on pages 246 to 247 of the letter at www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.

In addition, when CDC learned of cases in which insurers denied coverage for buprenorphine treatment for opioid use disorder based on a misinterpretation of dosage guidance in the Guideline, we developed messages and worked with the American Society of Addiction Medicine (ASAM) to clarify that the dosage thresholds for caution are not intended to apply to medication-assisted treatment for opioid use disorder. You can find a copy of our letter to ASAM and the public policy statement ASAM issued following receipt of our letter at [www.asam.org/docs/default-source/advocacy/letters-and-comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-\(002\).pdf?sfvrsn=7fa840c2_2](http://www.asam.org/docs/default-source/advocacy/letters-and-comments/2018-1-4-letter-on-buprenorphine-and-cdcs-guideline-(002).pdf?sfvrsn=7fa840c2_2) and www.asam.org/docs/default-source/public-policy-statements/2016-statement-on-morphine-equivalent-units-morphine-milligram-equivalents.pdf?sfvrsn=3bc177c2_6, respectively.

CDC has also been contacted by health systems and insurers that are developing quality measures aimed at improving safe prescribing at the provider, health system, and health plan levels. During these conversations, CDC encouraged the organizations to consider guideline-concordant quality measures. For example, the Guideline encourages assessing opioid treatment before increasing dosage to 50 morphine milligram equivalents (MME) or more per day and avoiding or carefully justifying opioid titration to 90 MME or more per day. In addition the Guideline recommends providing multimodal care for chronic pain, collaborating with patients, and tapering slowly when tapering is needed.

CDC has also communicated with medical professionals about patient safety when tapering and discontinuing opioids and emphasized Guideline recommendations related to tapering. For example, in *Changing the Conversation about Opioid Tapering*, a commentary in the *Annals of Internal Medicine* (<http://annals.org/aim/fullarticle/2643843/changing-conversation-about-opioid-tapering>), we emphasized that the Guideline does not support involuntary or precipitous tapering. We further emphasized that that practice can be associated with withdrawal symptoms, can damage the clinician-patient relationship, and can cause patients to obtain opioids from other sources. Moreover, we emphasized that clinicians have a responsibility to carefully manage opioid therapy and not abandon patients in chronic pain, and that obtaining patient buy-in before tapering is critical. In addition, CDC developed a pocket guide to tapering for clinicians (www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf) that includes information on when and how to taper and considerations for dosage adjustments.

CDC will continue supporting providers through education, training, and provision of resources. This work includes materials to help providers communicate with patients about tapering and new resources on acute pain, coordinated care, training health care professionals, and best practices for prescribing opioids. CDC encourages clinicians to continue to use their clinical judgment and base treatment on what they know about their patients, including the use of opioids if that is determined to be the best course of treatment. Providers should communicate frequently

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with their patients to discuss both the benefits and risks of opioid therapy and revisit treatment plans for pain regularly to achieve the most positive outcomes.