



November 4, 2016

Mr. Nicholas Strata
Executive Director
Ohio State Chiropractic Association
172 East Street, Suite 502
Columbus, Ohio 43215

Dear Mr. Strata:

Thank you for your letter to Ms. Sylvia Burwell, Secretary of the U.S. Department of Health and Human Services, regarding a petition to amend the *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016* (the Guideline). Your message was forwarded to the National Center for Injury Prevention and Control (NCIPC) at the Centers for Disease Control and Prevention (CDC) for a response.

We have received your petition for the amendment of the Guideline as published in the *Morbidity and Mortality Weekly Report*, Early Release/Vol. 65 March 15, 2016. Your petition cites two authorities, one in the petition header and one in the petition body: 5 USC § 555(e) and 5 USC § 553(e). The latter authority is not applicable because the Guideline is not a rule and was not promulgated under the rulemaking requirements of 5 USC § 553. Therefore, CDC considers the petition to be invalid on that basis. The other provision you cited, 5 USC §555(e), provides as follows:

(e) Prompt notice shall be given of the denial in whole or in part of a written application, petition, or other request of an interested person made in connection with any agency proceeding. Except in affirming a prior denial or when the denial is self-explanatory, the notice shall be accompanied by a brief statement of the grounds for denial.

Because the Guideline is final and has already been published, there is no ongoing “agency proceeding.” However, CDC would like to respond to the points made in your petition.

The Guideline is a set of *voluntary* recommendations intended to guide primary care providers as they work in consultation with their patients and specialists to address chronic pain. It is not intended to take away physician discretion and decision-making. The Guideline is designed to help physicians assess how to more safely maintain or discontinue opioid use in patients who are currently on an opioid treatment plan or start opioids more safely if the benefits are likely to outweigh the harms of these drugs.

In developing the Guideline, CDC followed a rigorous scientific process, which included a review of the best available scientific evidence, consultation with experts, and careful consideration of more than 4,350 public comments. To obtain public comments on the full

Guideline, CDC published a notice in the *Federal Register* (80 FR 77351) announcing the availability of the Guideline and the supporting clinical and contextual evidence reviews for public comment. CDC received comments from the general public, including patients with chronic pain, clinicians, families who have lost loved ones to overdose, medical associations, professional organizations, academic institutions, state and local governments, and industry. CDC reviewed each of the comments and carefully considered them when finalizing the Guideline.

Patients with chronic pain should receive treatment that provides the greatest benefit. Non-opioid treatments are preferred for chronic pain, and opioids should not be first-line therapy for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The Guideline recognizes that non-opioid treatments, including non-opioid medications and nonpharmacological therapies, can provide relief to those suffering from chronic pain and are safer. Further, the Guideline encourages providers and patients to consider all treatment options, particularly non-opioid therapies that can be used alone or in combination with opioids. The Guideline helps providers and patients—together—assess the benefits and risks of opioid use and address potential harms. CDC encourages physicians to continue to use their clinical judgment and base their treatment on what they know about their patients to determine the best course of treatment.

Recommendations highlighting specific non-opioid therapies were informed by systematic reviews and clinical guidelines published before April 2015, in addition to expert consultation, peer review, and public comment. CDC plans to revisit this Guideline as new evidence becomes available to determine when evidence gaps have been sufficiently closed to warrant an update of the Guideline. Until this research is conducted, clinical practice guidelines will be based on the best available evidence and expert opinion. CDC is committed to evaluating the Guideline to identify the impact of the recommendations on clinician and patient outcomes, both intended and unintended, and revising the recommendations in future updates when warranted.

Thank you for sharing your interest in this important public health issue. We hope this information is helpful to you.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Debra Houry', with a long horizontal flourish extending to the right.

Debra Houry, MD, MPH
Director
NCIPC, CDC