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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2015-0112]

Proposed 2016 Guideline for Prescribing Opioids for Chronic Pain

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment on the draft CDC Guideline for Prescribing Opioids for Chronic Pain (Guideline). The Guideline provides recommendations regarding initiation or continuation of opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessment of risk and addressing harms of opioid use. The Guideline is

intended to be used by primary care providers (e.g., family physicians or internists) who are treating patients with chronic pain (i.e., pain lasting longer than 3 months or past the time of normal tissue healing) in outpatient settings. The draft Guideline is intended to apply to patients aged 18 years of age or older with chronic pain outside of palliative and end-of-life care. The Guideline is not intended to apply to patients in treatment for active cancer. The Guideline is not a federal regulation; adherence to the Guideline will be voluntary.

DATES: Written comments must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0112 by any of the following methods:

- Federal eRulemaking Portal:
<http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway N.E., Mailstop F-63, Atlanta, GA, 30341, Attn: Docket CDC-2015-0112.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Arlene I. Greenspan, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway N.E., Mailstop F-63, Atlanta, GA, 30341; Telephone: 770-488-4696.

SUPPLEMENTARY INFORMATION:

Background

CDC developed the draft Guideline to provide recommendations about opioid prescribing for primary care providers who are treating adult patients with chronic pain in outpatient settings, outside of active cancer treatment, palliative care, and end-of-life care. The draft Guideline summarizes scientific knowledge about the effectiveness and risks of long-term opioid therapy, and provides recommendations for when to initiate or continue opioids

for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. The draft Guideline identifies important gaps in the literature where further research is needed.

To develop the recommendations, CDC conducted a systematic review on benefits and harms of opioids and developed the draft Guideline using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. CDC drafted recommendations and consulted with experts on the evidence to inform the recommendations. CDC hosted webinars in September 2015 and also provided opportunities for stakeholder and peer review of the draft Guideline. The Guideline is not a federal regulation; adherence to the Guideline will be voluntary. For additional information on prescription drug overdose, please visit

<http://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

Supporting and Related Material in the Docket

The docket contains the following supporting and related materials to help inform public comment: the Guideline; the Clinical Evidence Review Appendix; the Contextual Evidence Review Appendix; and three documents

that comprise the Comment Summaries and CDC Responses (Constituent Comment Summary, Peer Review Summary, and Stakeholder Review Group Summary). The Clinical Evidence Review Appendix and the Contextual Evidence Review Appendix include primary evidence, studies, and data tables that were used by CDC to develop the recommendations in the Guideline. The Constituent Comment Summary reflects input obtained in response to webinars hosted on September 16 and September 17, 2015, during which CDC shared an overview of the development process and draft recommendation statements. The Stakeholder Review Group Summary also reflects input obtained from stakeholders (comprised of professional and community organizations) following their review of a prior draft of the Guideline. Finally, the Peer Review Summary reflects input obtained from three scientific peer reviewers following their review of a draft of the full Guideline, along with a summary of comments received and CDC responses.

Dated: December 9, 2015

Veronica Kennedy, M.P.H.

Acting Executive Secretary,

Centers for Disease Control and Prevention

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