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115TH CONGRESS
2D SESSION

H. R. 6133

To deter opioid abuse and addiction through the development of high-quality, evidence-based opioid analgesic prescribing guidelines, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 19, 2018

Mr. MEADOWS introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To deter opioid abuse and addiction through the development of high-quality, evidence-based opioid analgesic prescribing guidelines, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Informing Opioid Prescribing Through Evidence-Based Guidelines Act of 2018''.

SEC. 2. STUDY AND REPORT.

(a) STUDY.—The Commissioner of Food and Drugs shall develop high-quality, evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment

of acute pain in the relevant therapeutic areas where such high-quality, evidence-based opioid analgesic prescribing guidelines—

(1) do not exist; and

(2) are not redundant of existing guidelines.

(b) PUBLIC INPUT.—In conducting the study under subsection (a), the Commissioner of Food and Drugs shall—

(1) conduct a public workshop, open to representatives of State medical societies and medical boards, various medical specialties including pain medicine specialty societies, patient groups, universities, and others; and

(2) provide a period for the submission of comments by the public.

(c) REPORT.—Not later than the date that is 2 years after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit to the Congress, and post on the public website of the Food and Drug Administration, a report on the results of the study under subsection (a).

(d) UPDATES.—On a biennial basis after submission of the report required by subsection (c), the Commissioner of Food and Drugs shall—

(1) update the study under subsection (a), informed by public input described in subsection (b); and

(2) submit to the Congress and post on the public website of the Food and Drug Administration an updated report under subsection (c).

SEC. 3. EVIDENCE-BASED REGULATIONS, GUIDANCE, AND POLICIES TO INFORM CLINICAL OPIOID PRACTICES.

(a) IN GENERAL.—To the maximum extent possible, the Commissioner of Food and Drugs shall ensure that regulations, guidance, and polices that are related to opioid prescribing practices and issued after the date of enactment of this Act are based on opioid prescribing practices that are evidence-based.

(b) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS.—The Commissioner of Food and Drugs shall ensure that any opioid analgesic prescribing guidelines and other recommendations developed under this Act are accompanied by a clear statement that such guidelines or recommendations, as applicable—

(1) are intended to help inform clinical decision-making by prescribers and patients; and

(2) should not be used by other parties, including pharmacy benefit management companies, retail

or community pharmacies, or public and private payors, for the purposes of restricting, limiting, delaying, or denying coverage for or access to a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

(c) DEFINITION.—In this section, the term ''evidence-based'' means informed by a robust and systemic review of treatment efficacy and clinical evidence, including a review of the study and reports under section 2.

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