

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Informing Opioid Pre-
5 scribing Through Evidence-Based Guidelines Act of
6 2018”.

7 **SEC. 2. STUDY AND REPORT.**

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

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

4 (1) do not exist; and

5 (2) are not redundant of existing guidelines.

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

9 (1) conduct a public workshop, open to rep-
10 resentatives of State medical societies and medical
11 boards, various medical specialties including pain
12 medicine specialty societies, patient groups, univer-
13 sities, and others; and

14 (2) provide a period for the submission of com-
15 ments by the public.

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

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

1 (1) update the study under subsection (a), in-
2 formed by public input described in subsection (b);
3 and

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

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

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

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

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

24 (2) should not be used by other parties, includ-
25 ing pharmacy benefit management companies, retail

1 or community pharmacies, or public and private
2 payors, for the purposes of restricting, limiting, de-
3 laying, or denying coverage for or access to a pre-
4 scription issued for a legitimate medical purpose by
5 an individual practitioner acting in the usual course
6 of professional practice.

7 (c) DEFINITION.—In this section, the term “evi-
8 dence-based” means informed by a robust and systemic
9 review of treatment efficacy and clinical evidence, includ-
10 ing a review of the study and reports under section 2.

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