

115TH CONGRESS
1ST SESSION

H. R. 4482

To deter opioid abuse and addiction, to establish additional registration requirements for prescribers of opioids, to encourage the development of abuse-deterrent formulations, to require a study and report on policy changes that may have contributed to the opioid epidemic, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 29, 2017

Mr. MEADOWS (for himself and Mr. RENACCI) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To deter opioid abuse and addiction, to establish additional registration requirements for prescribers of opioids, to encourage the development of abuse-deterrent formulations, to require a study and report on policy changes that may have contributed to the opioid epidemic, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Opioid Abuse Deter-
3 rence, Research, and Recovery Act of 2017”.

4 **SEC. 2. REGISTRATION REQUIREMENTS FOR PRESCRIBERS.**

5 Section 303 of the Controlled Substances Act (21
6 U.S.C. 823) is amended by adding at the end the fol-
7 lowing:

8 “(k)(1) The Attorney General shall not register, or
9 renew the registration of, a practitioner under subsection
10 (f) who is licensed under State law to prescribe controlled
11 substances in schedule II or III, unless the practitioner
12 submits to the Attorney General, for each such registra-
13 tion or renewal request, a certification that the practi-
14 tioner, during the applicable registration period, except as
15 provided in paragraph (2), will not prescribe any schedule
16 II or III opioid for the initial treatment of acute pain in
17 an amount in excess of the lesser of—

18 “(A) a 7-day supply (for which no refill is avail-
19 able); or

20 “(B) an opioid prescription limit established
21 under the law of the State where the prescribing oc-
22 curs.

23 “(2) The certification required by paragraph (1) shall
24 not prohibit a practitioner from—

25 “(A) prescribing, for the treatment of an opioid
26 use disorder, a schedule II or III opioid that is ap-

1 proved by the Food and Drug Administration for
2 such treatment;

3 “(B) prescribing, for immediate, post-operative
4 pain relief, a schedule II or III opioid; or

5 “(C) prescribing a schedule II or III opioid in
6 an amount in excess of a 7-day supply if the practi-
7 tioner—

8 “(i) provides a specific reason for exceed-
9 ing the 7-day limit that is in accordance with
10 a clear medical standard of care whose imple-
11 mentation necessarily exceeds such limit;

12 “(ii) documents such reason and medical
13 standard of care in the patient’s medical record;
14 and

15 “(iii) consults the applicable State’s elec-
16 tronic health record system or prescription drug
17 monitoring program.

18 “(3) In this subsection, the term ‘acute pain’—

19 “(A) means pain with abrupt onset and caused
20 by an injury or other process that is diagnostically
21 determined to have minimal risk of escalating in in-
22 tensity; and

23 “(B) does not include—

24 “(i) chronic pain;

1 “(ii) pain being treated as part of cancer
2 care;

3 “(iii) hospice or other end-of-life care; or

4 “(iv) pain being treated as part of pallia-
5 tive care.”.

6 **SEC. 3. ENCOURAGING DEVELOPMENT OF ABUSE-DETER-**
7 **RENT FORMULATIONS.**

8 The Commissioner of Food and Drugs shall continue
9 to work with stakeholders to encourage the development
10 of opioid formulations with abuse-deterrent properties.

11 **SEC. 4. GAO STUDY AND REPORT ON POLICY CHANGES**
12 **THAT MAY HAVE CONTRIBUTED TO THE**
13 **OPIOID EPIDEMIC.**

14 Not later than 2 years after the date of enactment
15 of this Act, the Comptroller General of the United States
16 shall complete a study and submit a report to Congress
17 on health care policy changes that may have contributed
18 to the increase in opioid overdoses and deaths during the
19 10 years preceding the date of enactment of this Act. Such
20 study shall include—

21 (1) a review of health care-related legislative,
22 administrative, and judicial decisions by officers and
23 employees of the Federal Government that have af-
24 fected access to pain management strategies with an
25 emphasis on pharmaceuticals;

1 (2) an analysis of what is known about the
2 costs and benefits, whether financial or non-financial,
3 of reversing or revising such decisions individually
4 or in combination, including whether the reversals
5 or revisions would be expected to achieve a reduction
6 in abuse of, addiction to, overdose on, and
7 death from opioids;

8 (3) an analysis of the differences among State-
9 based prescription drug monitoring programs, including
10 an analysis of what is known about the effects
11 of such differences on monitoring for abuse of,
12 addiction to, overdose on, and death from opioids;

13 (4) an analysis of what is known about positive
14 and negative impacts that prescribing limitations,
15 both State and Federal, have on patient medical
16 outcomes, including for chronic pain patients; and

17 (5) an analysis of what is known about the
18 costs to payers of using abuse-deterrent formulations
19 of opioid pain medications, compared to opioid pain
20 medications without abuse-deterrent features.

21 **SEC. 5. STUDY ON FEASIBILITY OF REPLACING STATUTORY**
22 **LIMITS WITH CLINICAL GUIDELINES ON**
23 **OPIOID PRESCRIBING.**

24 The Commissioner of Food and Drugs shall—

25 (1) conduct a study on the feasibility of—

1 (A) replacing the prescribing limits in sec-
2 tion 303(k)(1) of the Controlled Substances
3 Act, as added by section 2 of this Act, with evi-
4 dence-based clinical guidelines to inform opioid
5 selection, dosage, duration, follow up, and dis-
6 continuation, including guidelines on the first
7 opioid prescription for patients for an acute
8 pain diagnosis to ensure that no greater quan-
9 tity than needed is prescribed for the expected
10 duration of pain severe enough to require
11 opioids; and

12 (B) the incorporation into routine medical
13 visits of evidence-based screening tools for the
14 misuse of opioids and other controlled sub-
15 stances; and

16 (2) not later than the date that is 2 years after
17 the date of enactment of this Act, submit to the
18 Congress, and post on the public website of the Food
19 and Drug Administration, a report on the results of
20 such study.

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