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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.

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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

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# 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.

*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 ''Opioid Abuse Deterrence, Research, and Recovery Act of 2017''.

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

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(k)(1) The Attorney General shall not register, or renew the registration of, a practitioner under subsection (f) who is licensed under State law to prescribe controlled substances in schedule II or III, unless the practitioner submits to the Attorney General, for each such registration or renewal request, a certification that the practitioner, during the applicable registration period, except as provided in paragraph (2), will not prescribe any schedule II or III opioid for the initial treatment of acute pain in an amount in excess of the lesser of—

''(A) a 7-day supply (for which no refill is available); or

''(B) an opioid prescription limit established under the law of the State where the prescribing occurs.

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

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

proved by the Food and Drug Administration for such treatment;

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

"(C) prescribing a schedule II or III opioid in an amount in excess of a 7-day supply if the practitioner—

"(i) provides a specific reason for exceeding the 7-day limit that is in accordance with a clear medical standard of care whose implementation necessarily exceeds such limit;

"(ii) documents such reason and medical standard of care in the patient's medical record; and

"(iii) consults the applicable State's electronic health record system or prescription drug monitoring program.

"(3) In this subsection, the term 'acute pain'—

"(A) means pain with abrupt onset and caused by an injury or other process that is diagnostically determined to have minimal risk of escalating in intensity; and

"(B) does not include—

"(i) chronic pain;

"(ii) pain being treated as part of cancer care;

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

"(iv) pain being treated as part of palliative care.".

**SEC. 3. ENCOURAGING DEVELOPMENT OF ABUSE-DETERRENT FORMULATIONS.**

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

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

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

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

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

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

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

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

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

The Commissioner of Food and Drugs shall—

(1) conduct a study on the feasibility of—

(A) replacing the prescribing limits in section 303(k)(1) of the Controlled Substances Act, as added by section 2 of this Act, with evidence-based clinical guidelines to inform opioid selection, dosage, duration, follow up, and discontinuation, including guidelines on the first opioid prescription for patients for an acute pain diagnosis to ensure that no greater quantity than needed is prescribed for the expected duration of pain severe enough to require opioids; and

(B) the incorporation into routine medical visits of evidence-based screening tools for the misuse of opioids and other controlled substances; and

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

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