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114TH CONGRESS
*2d Session*
HOUSE OF REPRESENTATIVES
REPORT
114–556

# REDUCING UNUSED MEDICATIONS ACT OF 2016

MAY 10, 2016.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

# R E P O R T

[To accompany H.R. 4599]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4599) to amend the Controlled Substances Act to permit certain partial fillings of prescriptions, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "Reducing Unused Medications Act of 2016".

**SEC. 2. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.**

(a) IN GENERAL.—Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

"(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

"(1) PARTIAL FILLS.—

"(A) IN GENERAL.—A prescription for a controlled substance in schedule II may be partially filled if—

"(i) it is not prohibited by State law;

"(ii) the prescription is written and filled in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), regulations prescribed by the Attorney General, and State law;

"(iii) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

"(iv) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

"(B) OTHER CIRCUMSTANCES.—A prescription for a controlled substance in schedule II may be partially filled in accordance with section 1306.13 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Reducing Unused Medications Act of 2016).

"(2) REMAINING PORTIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 30 days after the date on which the prescription is written.

"(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 72 hours after the prescription is issued.".

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

## PURPOSE AND SUMMARY

H.R. 4599 would amend the Controlled Substances Act (CSA) to clarify the circumstances under which a controlled substance in Schedule II may be partially filled.

## BACKGROUND AND NEED FOR LEGISLATION

The number of prescriptions for opioid pain medications has significantly increased in recent years. While opioids can benefit patients with acute and chronic pain, when their pain is sufficiently addressed, there may be unused pills that could be misused and diverted. In fact, the National Institute on Drug Abuse estimates that over 70 percent of adults who misuse prescription opioids get them from friends or relatives. Several states have considered enabling pharmacies to partially fill such prescriptions to minimize the number of pills in circulation in a manner that continues to address patient need. However, current regulations are not entirely clear about whether and under what circumstances this is permitted for drugs listed in Schedule II of the CSA. H.R. 4599 amends the CSA to clarify the extent of permissible partial fills for Schedule II controlled substances, including prescription opioids.

## HEARINGS

The Committee on Energy and Commerce did not hold a hearing on H.R. 4599.

## COMMITTEE CONSIDERATION

On April 20, 2016, the Subcommittee on Health met in open markup session and forwarded H.R. 4599, as amended, to the full Committee by a voice vote. On April 26, 27, and 28, 2016, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 4599, as amended, favorably reported to the House by a voice vote.

## COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4599 reported.

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee did not hold a hearing on this legislation.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of this act is to to increase the flexibility in filling opioid prescriptions, to reduce the number of unused pills in circulation, and to help prevent opioid misuse, diversion, and medical emergencies.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4599 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 4599 contains no earmarks, limited tax benefits, or limited tariff benefits.

## COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

At the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

## FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

## DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4599 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

## DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4599 does not direct any specific rule making within the meaning of 5 U.S.C. 551.

## ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

## APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Short title*

The section provides the short title of "Reducing Unused Medications Act of 2016."

*Section 2. Partial fills of Schedule II Controlled Substances*

Section 309 of the Controlled Substances Act is amended to clarify that a prescription for a controlled substance listed in Schedule II may be partially filled if it is not prohibited by state law, the prescription is written and filled in accordance with the CSA regulations and state law, the partial fill is requested by the patient or the practitioner that wrote the prescription, and the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed. A prescription for a controlled substance listed in Schedule II may also be filled in accordance with current Drug Enforcement Administration (DEA) regulations, which allow for partial fills of prescriptions for terminally ill or Long Term Care Facility Patients and in instances when a pharmacy is unable to supply the full quantity, provided that the remaining portion may not be supplied beyond 72 hours without a new prescription. In emergency situations, the remaining portions of such a partially filled prescription may be filled if done so not later than 72 hours after the prescription is issued. Remaining portions of such a partially filled prescription may only be filled within 30 days after the date on which the prescription is written. Further, this bill clarifies that

current DEA regulations permitting partial fills in other circumstances are not affected.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

## CONTROLLED SUBSTANCES ACT

### TITLE II—CONTROL AND ENFORCEMENT

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### PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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#### PRESCRIPTIONS

SEC. 309. (a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 307 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or

(ii) a covering practitioner.

(B)(i) The term "in-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) The term "covering practitioner" means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—

(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

(ii) is temporarily unavailable to conduct the evaluation of the patient.

(3) Nothing in this subsection shall apply to—

(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.

*(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—*

*(1) PARTIAL FILLS.—*

*(A) IN GENERAL.—A prescription for a controlled substance in schedule II may be partially filled if—*

*(i) it is not prohibited by State law;*

*(ii) the prescription is written and filled in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), regulations prescribed by the Attorney General, and State law;*

*(iii) the partial fill is requested by the patient or the practitioner that wrote the prescription; and*

*(iv) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.*

*(B) OTHER CIRCUMSTANCES.—A prescription for a controlled substance in schedule II may be partially filled in accordance with section 1306.13 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Reducing Unused Medications Act of 2016).*

*(2) REMAINING PORTIONS.—*

*(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—*

*(i) may be filled; and*

*(ii) shall be filled not later than 30 days after the date on which the prescription is written.*

*(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled prescription for a controlled substance in schedule II—*

*(i) may be filled; and*

*(ii) shall be filled not later than 72 hours after the prescription is issued.*

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