

Mr. Speaker, I rise in strong support of the Medicaid Reentry Act, and I urge all Members to support its swift passage in the House.

This bill is about saving lives, pure and simple. 64,000 Americans died of a drug overdose in 2016, more than were lost at the peak of the HIV/AIDS crisis. Based on data from the States, we can estimate that as many as 10,000 of those deaths annually are individuals who have had some interaction with the criminal justice system in the previous year. This is a national emergency that demands immediate action.

Individuals who are returning to society after a stay in a corrections facility are particularly vulnerable to overdose deaths. Research has found that formerly incarcerated individuals reentering society are 129 times more likely to die of an overdose during their first 2 weeks back into the community than the general population.

The risk of overdose is elevated during this period due to reduced physiological tolerance for opioids among the incarcerated population, a lack of effective addiction treatment options while incarcerated, and perhaps poor care transitions back into their given community.

According to the Bureau of Justice Statistics, roughly 60 percent of our incarcerated population has a substance use disorder, yet only around one-quarter of those are receiving any type of treatment.

Even for those receiving treatment, out of the roughly 5,000 jails and prisons in our country, fewer than 40 provide medication-assisted addiction treatment using methadone or buprenorphine, which, along with naltrexone, is considered the gold standard in treating opioid use disorder.

□ 1445

Those that do offer full-scale MAT services are seeing results. I have seen firsthand the success of a MAT program called SHARP at the Albany County Correctional Facility in upstate New York where individuals shared anecdotes with me about how access to treatment has transformed their lives for the better.

We have seen even more compelling data from the State of Rhode Island, where a comprehensive addiction treatment program offering access to all FDA-approved forms of medication-assisted treatment in State corrections facilities was able to lower deaths in the first year post-release by a staggering 61 percent.

My legislation would open the door to more of these success stories and is designed to increase State flexibility in the Medicaid program to address the vulnerable population during the 30 days prior to an individual's release.

As amended, the Medicaid Reentry Act would require the Secretary of Health and Human Services to release guidance to State Medicaid Directors on demonstration opportunities that

would allow States to waive the current Medicaid inmate payment restriction during this prerelease period so that individuals could better access mental health and addiction care and have an improved care transition back into the community.

By passing this bill, we can allow States to expand innovative approaches to reentry that are already underway in places such as New York, Ohio, New Mexico, and Rhode Island.

I thank Energy and Commerce Chair GREG WALDEN and Ranking Member PALLONE and their staffs for the constructive collaboration on this bill. I also thank my Republican colleague Representative MIKE TURNER for his efforts to help shine a light on this vulnerable population.

In closing, Mr. Speaker, while I would have liked to have gone even further with this effort, I believe that this smart-on-crime legislation will plant the seeds for meaningful change and will help to give individuals reentering society a fighting chance to live a healthier, drug-free life.

Mr. Speaker, I urge my colleagues to support this legislation.

Mr. WALDEN. Mr. Speaker, I have no other speakers, and I reserve the balance of my time.

Mr. KENNEDY. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, I also endorse H.R. 4005, the Medicaid Reentry Act.

One particularly vulnerable population for overdose is individuals reentering society post-incarceration. Incarcerated individuals, as my colleague, Mr. TONKO, indicated, are far more likely to suffer from substance use disorder. And without proper transition planning and treatment, former inmates are at extremely high risk of dying from an overdose after release. This legislation seeks to get at that problem.

Mr. Speaker, over the course of the hearings we have had on all of these bills, there has not been a more dedicated, poignant, or powerful speaker than Mr. TONKO. This is an issue that he cares passionately about and that he has dedicated much of his time in Congress addressing. He has put that effort into text in this bill.

Mr. Speaker, I urge the House to adopt it, and I yield back the balance of my time.

Mr. WALDEN. Mr. Speaker, I have no further speakers on this bill. I support it and encourage our colleagues to do the same.

Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Oregon (Mr. WALDEN) that the House suspend the rules and pass the bill, H.R. 4005, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: "A bill to promote State in-

novations to ease transitions to the community for individuals who are inmates of a public institution and eligible for medical assistance under the Medicaid program."

A motion to reconsider was laid on the table.

SECURING OPIOIDS AND UNUSED NARCOTICS WITH DELIBERATE DISPOSAL AND PACKAGING ACT OF 2018

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5687) to amend the Federal Food, Drug, and Cosmetic Act to require improved packaging and disposal methods with respect to certain drugs, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5687

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 "Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018" or the "SOUND Disposal and Packaging Act".

SEC. 2. IMPROVED TECHNOLOGIES, CONTROLS, OR MEASURES WITH RESPECT TO THE PACKAGING OR DISPOSAL OF CERTAIN DRUGS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505-1 (21 U.S.C. 355-1) the following new section:

"SEC. 505-2. SAFETY-ENHANCING PACKAGING AND DISPOSAL FEATURES.

"(a) ORDERS.—

"(1) IN GENERAL.—The Secretary may issue an order requiring the holder of a covered application to implement or modify one or more technologies, controls, or measures with respect to the packaging or disposal of one or more drugs identified in the covered application, if the Secretary determines such technologies, controls, or measures to be appropriate to help mitigate the risk of abuse or misuse of such drug or drugs, which may include by reducing the availability of unused drugs.

"(2) PRIOR CONSULTATION.—The Secretary may not issue an order under paragraph (1) unless the Secretary has consulted with relevant stakeholders, through a public meeting, workshop, or otherwise, about matters that are relevant to the subject of the order.

"(3) ASSURING ACCESS AND MINIMIZING BURDEN.—Technologies, controls, or measures required under paragraph (1) shall—

"(A) be commensurate with the specific risk of abuse or misuse of the drug listed in the covered application;

"(B) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular any available evidence regarding the expected or demonstrated public health impact of such technologies, controls, or measures; and

"(C) reduce the risk of abuse or misuse of such drug.

"(4) ORDER CONTENTS.—An order issued under paragraph (1) may—

"(A) provide for a range of options for implementing or modifying the technologies, controls, or measures required to be implemented by such order; and

"(B) incorporate by reference standards regarding packaging or disposal set forth in an official compendium, established by a nationally or internationally recognized standard development organization, or described

on the public website of the Food and Drug Administration, so long as the order includes the rationale for incorporation of such standard.

“(5) **ORDERS APPLICABLE TO DRUG CLASS.**—When a concern about the risk of abuse or misuse of a drug relates to a pharmacological class, the Secretary may, after consultation with relevant stakeholders, issue an order under paragraph (1) which applies to the pharmacological class.

“(b) **COMPLIANCE.**—The holder of a covered application shall—

“(1) submit a supplement containing proposed changes to the covered application to comply with an order issued under subsection (a) not later than—

“(A) 180 calendar days after the date on which the order is issued; or

“(B)(i) such longer time period as specified by the Secretary in such order; or

“(ii) if a request for an alternative date is submitted by the holder of such application not later than 60 calendar days after the date on which such order is issued—

“(I) such requested alternative date if agreed to by the Secretary; or

“(II) another date as specified by the Secretary; and

“(2) implement the changes approved pursuant to such supplement not later than the later of—

“(A) 90 calendar days after the date on which the supplement is approved; or

“(B) the end of such longer period as is—

“(i) determined to be appropriate by the Secretary; or

“(ii) approved by the Secretary pursuant to a request by the holder of the covered application that explains why such longer period is needed, including to satisfy any other applicable Federal statutory or regulatory requirements.

“(c) **ALTERNATIVE MEASURES.**—The holder of the covered application may propose, and the Secretary shall approve, technologies, controls, or measures regarding packaging, storage, or disposal other than those specified in the applicable order issued under subsection (a), if such technologies, controls, or measures are supported by data and information demonstrating that such alternative technologies, controls, or measures can be expected to mitigate the risk of abuse or misuse of the drug or drugs involved, including by reducing the availability of unused drugs, to at least the same extent as the technologies, controls, or measures specified in such order.

“(d) **DISPUTE RESOLUTION.**—If a dispute arises in connection with a supplement submitted under subsection (b), the holder of the covered application may appeal a determination made with respect to such supplement using applicable dispute resolution procedures specified by the Secretary in regulations or guidance.

“(e) **DEFINITIONS.**—In this section—

“(1) the term ‘covered application’ means an application submitted under subsection (b) or (j) of section 505 for approval under such section or an application submitted under section 351 of Public Health Service Act for approval under such section, with respect to a drug that is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act; and

“(2) the term ‘relevant stakeholders’ may include scientific experts within the drug manufacturing industry; brand and generic drug manufacturers; standard development organizations; wholesalers and distributors; payers; health care providers; pharmacists; pharmacies; manufacturers; poison centers; and representatives of the National Institute on Drug Abuse, the National Institutes of

Health, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Drug Enforcement Agency, the Consumer Product Safety Commission, individuals who specialize in treating addiction, and patient and caregiver groups.”.

(b) **PROHIBITED ACTS.**—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after paragraph (j) the following:

“(k) If it is a drug approved under a covered application (as defined in section 505-2(e)), the holder of which does not meet the requirements of paragraphs (1) and (2) of subsection (b) of such section.”.

(c) **REQUIRED CONTENT OF AN ABBREVIATED NEW DRUG APPLICATION.**—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vii)(IV), by striking “and” at the end;

(2) in clause (viii), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following:

“(ix) if the drug is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act, information to show that the applicant has proposed technologies, controls, or measures related to the packaging or disposal of the drug that provide protections comparable to those provided by the technologies, controls, or measures required for the applicable listed drug under section 505-2, if applicable.”.

(d) **GROUND FOR REFUSING TO APPROVE AN ABBREVIATED NEW DRUG APPLICATION.**—Section 505(j)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(4)), is amended—

(1) in subparagraph (J), by striking “or” at the end;

(2) in subparagraph (K), by striking the period at the end and inserting “; or”; and

(3) by adding at the end the following:

“(L) if the drug is a drug described in paragraph (2)(A)(ix) and the applicant has not proposed technologies, controls, or measures related to the packaging or disposal of such drug that the Secretary determines provide protections comparable to those provided by the technologies, controls, or measures required for the applicable listed drug under section 505-2.”.

(e) **RULES OF CONSTRUCTION.**—

(1) Any labeling describing technologies, controls, or measures related to packaging or disposal intended to mitigate the risk of abuse or misuse of a drug product that is subject to an abbreviated new drug application, including labeling describing differences from the reference listed drug resulting from the application of section 505-2 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall not be construed—

(A) as changes to labeling not permissible under clause (v) of section 505(j)(2)(A) of such Act (21 U.S.C. 355(j)(2)(A)), or a change in the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug under clause (i) of such section; or

(B) to preclude approval of an abbreviated new drug application under subparagraph (B) or (G) of section 505(j)(4) of such Act (21 U.S.C. 355(j)(4)).

(2) For a covered application that is an application submitted under subsection (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), subsection (j)(2)(A) of such section 505 shall not be construed to limit the type of data or information the Secretary of Health and Human Services may request or consider in connection with making any determination under section 505-2.

(f) **GAO REPORT.**—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to the Congress a report containing—

(1) a description of available evidence, if any, on the effectiveness of site-of-use, in-home controlled substance disposal products and packaging technologies;

(2) identification of ways in which such disposal products intended for use by patients, consumers, and other end users that are not registrants under the Controlled Substances Act, are made available to the public and barriers to the use of such disposal products;

(3) identification of ways in which packaging technologies are made available to the public and barriers to the use of such technologies;

(4) a description of Federal oversight, if any, of site-of-use, in-home controlled substance disposal products, including—

(A) identification of the Federal agencies that oversee such products;

(B) identification of the methods of disposal of controlled substances recommended by these agencies for site-of-use, in-home disposal; and

(C) a description of the effectiveness of such recommendations at preventing the diversion of legally prescribed controlled substances;

(5) a description of Federal oversight, if any, of controlled substance packaging technologies, including—

(A) identification of the Federal agencies that oversee such technologies;

(B) identification of the technologies recommended by these agencies, including unit dose packaging, packaging that provides a set duration, or other packaging systems that may mitigate abuse or misuse; and

(C) a description of the effectiveness of such recommendations at preventing the diversion of legally prescribed controlled substances; and

(6) recommendations on—

(A) whether site-of-use, in-home controlled substance disposal products and packaging technologies require Federal oversight and, if so, which agencies should be responsible for such oversight and, as applicable, approval of such products or technologies; and

(B) the potential role of the Federal Government in evaluating such products to ensure product efficacy.

The **SPEAKER** pro tempore. Pursuant to the rule, the gentleman from Oregon (Mr. WALDEN) and the gentleman from Massachusetts (Mr. KENNEDY) each will control 20 minutes.

The Chair recognizes the gentleman from Oregon.

GENERAL LEAVE

Mr. WALDEN. Mr. Speaker, I ask unanimous consent that Members may have 5 legislative days to revise and extend their remarks and insert extraneous materials in the **RECORD** on the bill.

The **SPEAKER** pro tempore. Is there objection to the request of the gentleman from Oregon?

There was no objection.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in strong support of this bipartisan legislation, and I want to thank Representatives HUDSON and BUTTERFIELD, both of North Carolina, for their hard work on it.

Opioids are often prescribed in higher volumes than necessary and not properly disposed of after patients no

longer need them. That leads to an oversupply of unneeded drugs that can be subject to abuse by family members and others.

In order to reduce the volume of unused opioids in the market, this bill will direct the Food and Drug Administration to work with manufacturers to establish programs for the efficient return or destruction of unused schedule II or III opioid analgesics.

In addition, this bill will facilitate utilization of packaging that may reduce overprescribing, diversion, or abuse of opioids.

Finally, the bill will require the GAO to study new and innovative technologies that claim to be able to dispose of opioids and other unused medications safely.

This bill takes several targeted steps to minimize the amount of unused opioids on the market, and I encourage my colleagues to support its passage.

Mr. Speaker, I yield such time as he may consume to gentleman from North Carolina (Mr. HUDSON), one of the authors of this important legislation.

Mr. HUDSON. Mr. Speaker, in 2018, more than 2 million Americans will suffer from addiction to prescription opioids.

As I have traveled across my district, I have seen firsthand the devastating effects these drugs can have on families, friends, and loved ones. There is no barrier for these drugs. They strike at every level of society and across every geographic region. It touches all of us.

In North Carolina, we have 4 of the top 25 worst cities for opioid abuse in the country. This truly is the crisis next door, and I am proud of the collective effort the House of Representatives has undertaken in a bipartisan way to address this epidemic.

One important piece of this effort is a bipartisan bill I worked on with my colleague G.K. BUTTERFIELD, the SOUND Disposal and Packaging Act, which will direct the FDA to work with manufacturers to help reduce diversion, overprescribing, and abuse of schedule II or III opioids.

I focused on packaging and disposal because it seemed everyone I talked to had sort of a lightbulb go off. So many of us have unused opioids in our medicine cabinets from surgeries, accidents, or hospital visits.

With 70 percent of heroin addictions beginning in the medicine cabinet, attacking this oversupply with packaging on the front end and disposal on the back end was a logical place to start. We need to reduce the supply of opioids that find their way out of the medicine cabinet, and this legislation is the first step.

I appreciate the leadership of my friend, G.K. BUTTERFIELD, for working with me in a bipartisan manner in authoring this bill. I want to thank the leadership of the Energy and Commerce Committee and Health Subcommittee, Chairman WALDEN and Chairman BURGESS, and Ranking Mem-

bers PALLONE and GREEN for their partnership and help to ensure this could be a reality today.

Mr. Speaker, I include in the RECORD a letter from DisposeRx in support of H.R. 5687, the SOUND Disposal and Packaging Act.

DISPOSERX,
June 18, 2018.

Hon. RICHARD HUDSON,
House of Representatives,
Washington, DC.

DEAR REPRESENTATIVE HUDSON: As our country continues to combat the opioid epidemic, we commend the United States House of Representative for voting on your legislation, H.R. 5687, the "the 'SOUND' Disposal and Packaging Act." Opioid overdoses kill tens of thousands of people each year, and this landmark legislation is pivotal to saving lives and overcoming the opioid crisis.

Our mission at DisposeRx is to empower the consumer to safely and permanently dispose of unused medications, including opioids and drugs with abuse liabilities, with at-home solutions that render drugs non-retrievable. Research has shown that take-back and kiosk strategies are inconvenient and encourage diversion, whereas at-home solutions that empower consumers to destroy their drugs in an environmentally friendly manner are a better solution to preventing opioid abuse, overdoses and deaths that begin in the medicine cabinet.

For years, the federal government has recommended substandard methods of disposal for controlled substances, such as placing them in coffee grounds or kitty litter, and even flushing them down the toilet for eventual transport to our nation's waterways. With the passage of H.R. 5687, Congress will be taking a crucial leap to change how we deal with drug disposal. In particular, section 2(f) of H.R. 5687 will require the General Accounting Office (GAO) to provide an independent report to Congress on the benefits of in-home disposal of controlled substances. We believe that the bill represents a clear recognition that immediate disposal of prescription medications within the home will reduce the number of new addictions and deaths.

We are grateful for your leadership, and that of your cosponsors, including Representative G.K. Butterfield, in this critical area and we congratulate you on this pioneering legislation. We thank your staff and that of the House Energy and Commerce Committee, especially Preston Bell, who has tirelessly championed deterrent solutions to prevent abuse before it begins.

We are passionate about providing a solution to our country's epidemic of overdose and death brought about by the misuse and abuse of opioids. Thank you for your consideration, and we look forward to working with you and your colleagues to confront and reverse this crisis.

Sincerely,

WM. SIMPSON,
President.

Mr. HUDSON. Mr. Speaker, I urge all my colleagues to please support this legislation.

Mr. KENNEDY. Mr. Speaker, I yield myself such time as I may consume.

I rise to voice my support for H.R. 5687, legislation authored by my colleagues, Mr. HUDSON and Mr. BUTTERFIELD, to provide the FDA with authority to employ the use of packaging and disposal technologies to help mitigate the risk of abuse and misuse of opioids.

As a part of FDA's efforts to help prevent misuse of opioids, Commis-

sioner Gottlieb has been actively exploring how packaging and disposal innovations can deter abuse and reduce the supply of opioids in the market.

This included hosting a public workshop in December to explore how we can harness these technologies in the fight against opioid addiction and how to improve the safety of these products for those patients who rely on them to manage chronic pain every day.

Commissioner Gottlieb also noted, Mr. Speaker, that the use of these technologies, such as packaging, merits consideration through a careful, science-based process, one that I hope will continue.

The legislation we are considering today builds on this work and grants FDA authority to require packaging and disposal technologies for schedule II and schedule III controlled substances that reflect a level of risk associated with that substance.

FDA is provided with the flexibility to permit a range of options for packaging or disposal technologies, as long as such technologies demonstrate comparable effectiveness. This flexibility will be crucial to reduce barriers to generic entry, one of the concerns that was raised during our committee consideration, and to maintain appropriate patient access to these substances.

H.R. 5687 also clarifies that labeling related to the inclusion of packaging or disposal technologies cannot be used as a blocking strategy by brand manufacturers.

If enacted, it is my hope that the FDA will continue to work with stakeholders, including manufacturers, to ensure that generic entry is not impeded by the requirement of packaging or disposal technologies. Both brand and generic manufacturers should be held to the same performance outcome of mitigating risk and abuse; however, at a time of rising drug costs, I believe manufacturers should be afforded enough flexibility to pursue cost-effective technologies that will also meet the shared goals of the FDA and patient community.

I also hope that any costs associated with the adoption of packaging or disposal technologies will not be borne by the patients who rely on these medications to manage their diseases or conditions.

Mr. Speaker, I want to thank Mr. HUDSON and Mr. BUTTERFIELD for their work on this issue as well as the FDA for their guidance through the process.

Mr. Speaker, I urge my colleagues to support H.R. 5687, and I yield back the balance of my time.

Mr. WALDEN. Mr. Speaker, I have no other speakers on this legislation. I encourage my colleagues to support the bill, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Oregon (Mr. WALDEN) that the House suspend the rules and pass the bill, H.R. 5687, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the yeas have it.

Mr. WALDEN. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, further proceedings on this motion will be postponed.

RESPONSIBLE EDUCATION ACHIEVES CARE AND HEALTHY OUTCOMES FOR USERS' TREAT- MENT ACT OF 2018

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5796) to require the Secretary of Health and Human Services to provide grants for eligible entities to provide technical assistance to outlier prescribers of opioids, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5796

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 "Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018" or the "REACH OUT Act of 2018".

SEC. 2. GRANTS TO PROVIDE TECHNICAL ASSISTANCE TO OUTLIER PRESCRIBERS OF OPIOIDS.

(a) GRANTS AUTHORIZED.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall, through the Centers for Medicare & Medicaid Services, award grants, contracts, or cooperative agreements to eligible entities for the purposes described in subsection (b).

(b) USE OF FUNDS.—Grants, contracts, and cooperative agreements awarded under subsection (a) shall be used to support eligible entities through technical assistance—

(1) to educate and provide outreach to outlier prescribers of opioids about best practices for prescribing opioids;

(2) to educate and provide outreach to outlier prescribers of opioids about non-opioid pain management therapies; and

(3) to reduce the amount of opioid prescriptions prescribed by outlier prescribers of opioids.

(c) APPLICATION.—Each eligible entity seeking to receive a grant, contract, or cooperative agreement under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(d) GEOGRAPHIC DISTRIBUTION.—In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall prioritize establishing technical assistance resources in each State.

(e) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means—

(A) an organization—

(i) that has demonstrated experience providing technical assistance to health care professionals on a State or regional basis; and

(ii) that has at least—

(I) one individual who is a representative of consumers on its governing body; and

(II) one individual who is a representative of health care providers on its governing body; or

(B) an entity that is a quality improvement entity with a contract under part B of title XI of the Social Security Act (42 U.S.C. 1320c et seq.).

(2) OUTLIER PRESCRIBER OF OPIOIDS.—The term "outlier prescriber of opioids" means a prescriber, identified by the Secretary of Health and Human Services (through use of prescriber information provided by prescriber National Provider Identifiers included pursuant to section 1860D-4(c)(4)(A) of the Social Security Act (42 U.S.C. 1395w-104(c)(4)(A)) on claims for covered part D drugs for part D eligible individuals enrolled in prescription drug plans under part D of title XVIII of such Act (42 U.S.C. 1395w-101 et seq.) and MA-PD plans under part C of such title (42 U.S.C. 1395w-21 et seq.)) as prescribing, as compared to other prescribers in the specialty of the prescriber and geographic area, amounts of opioids in excess of a threshold (and other criteria) specified by the Secretary, after consultation with stakeholders.

(3) PRESCRIBERS.—The term "prescriber" means any health care professional, including a nurse practitioner or physician assistant, who is licensed to prescribe opioids by the State or territory in which such professional practices.

(f) FUNDING.—For purposes of implementing this section, \$75,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t), to remain available until expended.

SEC. 3. PROMOTING VALUE IN MEDICAID MANAGED CARE.

Section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)) is amended by adding at the end the following new paragraph:

"(7)(A) With respect to expenditures described in subparagraph (B) that are incurred by a State for any fiscal year after fiscal year 2025 (and before fiscal year 2029), in determining the pro rata share to which the United States is equitably entitled under subsection (d)(3), the Secretary shall substitute the Federal medical assistance percentage that applies for such fiscal year to the State under section 1905(b) (without regard to any adjustments to such percentage applicable under such section or any other provision of law) for the percentage that applies to such expenditures under section 1905(y).

"(B) Expenditures described in this subparagraph, with respect to a fiscal year to which subparagraph (A) applies, are expenditures incurred by a State for payment for medical assistance provided to individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) by a managed care entity, or other specified entity (as defined in subparagraph (D)(iii)), that are treated as remittances because the State—

"(i) has satisfied the requirement of section 438.8 of title 42, Code of Federal Regulations (or any successor regulation), by electing—

"(I) in the case of a State described in subparagraph (C), to apply a minimum medical loss ratio (as defined in subparagraph (D)(ii)) that is at least 85 percent but not greater than the minimum medical loss ratio (as so defined) that such State applied as of May 31, 2018; or

"(II) in the case of a State not described in subparagraph (C), to apply a minimum medical loss ratio that is equal to 85 percent; and

"(ii) recovered all or a portion of the expenditures as a result of the entity's failure to meet such ratio.

"(C) For purposes of subparagraph (B), a State described in this subparagraph is a State that as of May 31, 2018, applied a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code

of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in such subparagraph under the State plan under this title (or a waiver of the plan) that is equal to or greater than 85 percent.

"(D) For purposes of this paragraph:

"(i) The term 'managed care entity' means a medicare managed care organization described in section 1932(a)(1)(B)(i).

"(ii) The term 'minimum medical loss ratio' means, with respect to a State, a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in subparagraph (B) under the State plan under this title (or a waiver of the plan).

"(iii) The term 'other specified entity' means—

"(I) a prepaid inpatient health plan, as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation); and

"(II) a prepaid ambulatory health plan, as defined in such section (or any successor regulation)."

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Oregon (Mr. WALDEN) and the gentleman from Massachusetts (Mr. KENNEDY) each will control 20 minutes.

The Chair recognizes the gentleman from Oregon.

GENERAL LEAVE

Mr. WALDEN. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials on the bill under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Oregon?

There was no objection.

Mr. WALDEN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I want to commend my colleague Representative FITZPATRICK, who is here on the floor with us today, as well as Representative CURBELO and Representative THOMPSON. They all worked very hard to make this bipartisan legislation a success.

H.R. 5796 would establish technical assistance grants to make best practices available to those providers who are identified as opioid-prescribing outliers. This bill would establish a means of identifying statistical outliers and then notifying providers if they are an outlier.

In addition, the bill authorizes quality improvement organizations and other grant recipients to review prescribing patterns and to share educational materials and best practices. This legislation will ensure that best prescribing practices are clinically appropriate for patients and are implemented throughout the Medicare program.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,

Washington, DC, June 7, 2018.

Hon. KEVIN BRADY,
Chairman, Committee on Ways and Means,
Washington, DC.

DEAR CHAIRMAN BRADY: On May 9 and 17, 2018, the Committee on Energy and Commerce ordered favorably reported over 50