opioids, this bill will further provide outlier prescribers with the tools to return to the appropriate prescribing range for their specialty to help reduce overprescribing.

Mr. Speaker, I have to say that we have just been informed that there will be a last-minute change to two of the suspension prints under consideration today in order to accommodate a request from the Appropriations Committee.

The minority only received notice of these changes within the last hour. While they appear to be changes that are technical in nature to address the jurisdictional issues, we want to highlight our concerns with the last-minute changes being made to legislative text that are being considered on the floor with such short notice. It is not the best way to legislate, especially on bipartisan bills on such an important topic.

My colleagues and I have expressed some concern about this process, and this latest issue reinforces those concerns. We urge the Speaker to commit to continuing to work with us on a bipartisan basis to avoid some of these changes in the future.

Mr. Speaker, I support this bill. I hope the House will support it as well, and I yield back the balance of my time.

Mr. WALDEN. Mr. Speaker, I thank my colleagues for their bipartisan support of this legislation.

We also were just notified not long ago about the appropriations flag, and we are working out those matters at a higher pay level. So, we appreciate and understand.

Mr. Speaker, I urge passage of this legislation, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. POE of Texas). 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. 5796, 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 require the Secretary of Health and Human Services to provide grants for eligible entities to provide technical assistance to outlier prescribers of opioids, and for other purposes.''.

A motion to reconsider was laid on the table.

ADVANCING HIGH QUALITY TREATMENT FOR OPIOID USE DISORDERS IN MEDICARE ACT

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5605) to amend title XVIII of the Social Security Act to provide for an opioid use disorder treatment demonstration program, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5605

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 ''Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act''.

SEC. 2. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by inserting after section 1866E (42 U.S.C. 1395cc–5) the following new section:

''SEC. 1866F. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.

''(a) IMPLEMENTATION OF 4-YEAR DEMONSTRATION PROGRAM.—

''(1) IN GENERAL.—Not later than January 1, 2021, the Secretary shall implement a 4-year demonstration program under this title (in this section referred to as the 'Program') to increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce expenditures under this title. Under the Program, the Secretary shall make payments under subsection (e) to participants (as defined in subsection (c)(1)(A)) for furnishing opioid use disorder treatment services delivered through opioid use disorder care teams, or arranging for such service to be furnished, to applicable beneficiaries participating in the Program.

''(2) OPIOID USE DISORDER TREATMENT SERVICES.—For purposes of this section, the term 'opioid use disorder treatment services'—

''(A) means, with respect to an applicable beneficiary, services that are furnished for the treatment of opioid use disorders and that utilize drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act for the treatment of opioid use disorders in an outpatient setting; and

''(B) includes—

''(i) medication assisted treatment;

''(ii) treatment planning;

''(iii) psychiatric, psychological, or counseling services (or any combination of such services), as appropriate;

''(iv) social support services, as appropriate; and

''(v) care management and care coordination services, including coordination with other providers of services and suppliers not on an opioid use disorder care team.

''(b) PROGRAM DESIGN.—

''(1) IN GENERAL.—The Secretary shall design the Program in such a manner to allow for the evaluation of the extent to which the Program accomplishes the following purposes:

''(A) Reduces hospitalizations and emergency department visits.

''(B) Increases use of medication-assisted treatment for opioid use disorders.

''(C) Improves health outcomes of individuals with opioid use disorders, including by reducing the incidence of infectious diseases (such as hepatitis C and HIV).

''(D) Does not increase the total spending on items and services under this title.

''(E) Reduces deaths from opioid overdose.

''(F) Reduces the utilization of inpatient residential treatment.

''(2) CONSULTATION.—In designing the Program, including the criteria under subsection (e)(2)(A), the Secretary shall, not later than 3 months after the date of the enactment of this section, consult with specialists in the field of addiction, clinicians in the primary care community, and beneficiary groups.

''(c) PARTICIPANTS; OPIOID USE DISORDER CARE TEAMS.—

''(1) PARTICIPANTS.—

''(A) DEFINITION.—In this section, the term 'participant' means an entity or individual—

''(i) that is otherwise enrolled under this title and that is—

''(I) a physician (as defined in section 1861(r)(1));

''(II) a group practice comprised of at least one physician described in subclause (I);

''(III) a hospital outpatient department;

''(IV) a federally qualified health center (as defined in section 1861(aa)(4));

''(V) a rural health clinic (as defined in section 1861(aa)(2));

''(VI) a community mental health center (as defined in section 1861(ff)(3)(B));

''(VII) a clinic certified as a certified community behavioral health clinic pursuant to section 223 of the Protecting Access to Medicare Act of 2014; or

''(VIII) any other individual or entity specified by the Secretary;

''(ii) that applied for and was selected to participate in the Program pursuant to an application and selection process established by the Secretary; and

''(iii) that establishes an opioid use disorder care team (as defined in paragraph (2)) through employing or contracting with health care practitioners described in paragraph (2)(A), and uses such team to furnish or arrange for opioid use disorder treatment services in the outpatient setting under the Program

''(B) PREFERENCE.—In selecting participants for the Program, the Secretary shall give preference to individuals and entities that are located in areas with a prevalence of opioid use disorders that is higher than the national average prevalence.

''(2) OPIOID USE DISORDER CARE TEAMS.—

''(A) IN GENERAL.—For purposes of this section, the term 'opioid use disorder care team' means a team of health care practitioners established by a participant described in paragraph (1)(A) that—

''(i) shall include—

''(I) at least one physician (as defined in section 1861(r)(1)) furnishing primary care services or addiction treatment services to an applicable beneficiary; and

''(II) at least one eligible practitioner (as defined in paragraph (3)(A)), who may be a physician who meets the criterion in subclause (I); and

''(ii) may include other practitioners licensed under State law to furnish psychiatric, psychological, counseling, and social services to applicable beneficiaries.

''(B) REQUIREMENTS FOR RECEIPT OF PAYMENT UNDER PROGRAM.—In order to receive payments under subsection (e), each participant in the Program shall—

''(i) furnish opioid use disorder treatment services through opioid use disorder care teams to applicable beneficiaries who agree to receive the services;

''(ii) meet minimum criteria, as established by the Secretary; and

''(iii) submit to the Secretary, in such form, manner, and frequency as specified by the Secretary, with respect to each applicable beneficiary for whom opioid use disorder treatment services are furnished by the opioid use disorder care team, data and such other information as the Secretary determines appropriate to—

''(I) monitor and evaluate the Program;

''(II) determine if minimum criteria are met under clause (ii); and

''(III) determine the incentive payment under subsection (e).

''(3) ELIGIBLE PRACTITIONERS; OTHER PROVIDER-RELATED DEFINITIONS AND APPLICATION PROVISIONS.—

''(A) ELIGIBLE PRACTITIONERS.—For purposes of this section, the term 'eligible practitioner' means a physician or other health

care practitioner, such as a nurse practitioner, that—

''(i) is enrolled under section 1866(j)(1);

''(ii) is authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment; and

''(iii) has in effect a waiver in accordance with section 303(g) of the Controlled Substances Act for such purpose and is otherwise in compliance with regulations promulgated by the Substance Abuse and Mental Health Services Administration to carry out such section.

''(B) ADDICTION SPECIALISTS.—For purposes of subsection (e)(1)(B)(iv), the term 'addiction specialist' means a physician that possesses expert knowledge and skills in addiction medicine, as evidenced by appropriate certification from a specialty body, a certificate of advanced qualification in addiction medicine, or completion of an accredited residency or fellowship in addiction medicine or addiction psychiatry, as determined by the Secretary.

''(d) PARTICIPATION OF APPLICABLE BENEFICIARIES.—

''(1) APPLICABLE BENEFICIARY DEFINED.—In this section, the term 'applicable beneficiary' means an individual who—

''(A) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B;

''(B) is not enrolled in a Medicare Advantage plan under part C;

''(C) has a current diagnosis for an opioid use disorder; and

''(D) meets such other criteria as the Secretary determines appropriate.

Such term shall include an individual who is dually eligible for benefits under this title and title XIX if such individual satisfies the criteria described in subparagraphs (A) through (D).

''(2) VOLUNTARY PARTICIPATION; LIMITATION ON NUMBER OF PARTICIPANTS.—An applicable beneficiary may participate in the Program on a voluntary basis and may terminate participation in the Program at any time. Not more than 20,000 applicable beneficiaries may participate in the Program at any time.

''(3) SERVICES.—In order to participate in the Program, an applicable beneficiary shall agree to receive opioid use disorder treatment services from a participant. Participation under the Program shall not affect coverage of or payment for any other item or service under this title for the applicable beneficiary.

''(4) BENEFICIARY ACCESS TO SERVICES.—Nothing in this section shall be construed as encouraging providers to limit applicable beneficiary access to services covered under this title and applicable beneficiaries shall not be required to relinquish access to any benefit under this title as a condition of receiving services from a participant in the Program.

''(e) PAYMENTS.—

''(1) PER APPLICABLE BENEFICIARY PER MONTH CARE MANAGEMENT FEE.—

''(A) IN GENERAL.—The Secretary shall establish a schedule of per applicable beneficiary per month care management fees. Such a per applicable beneficiary per month care management fee shall be paid to a participant in addition to any other amount otherwise payable under this title to the health care practitioners in the participant's opioid use disorder care team or, if applicable, to the participant. A participant may use such per applicable beneficiary per month care management fee to deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under this title.

''(B) PAYMENT AMOUNTS.—In carrying out subparagraph (A), the Secretary shall—

''(i) consider payments otherwise payable under this title for opioid use disorder treatment services and the needs of applicable beneficiaries;

''(ii) pay a higher per applicable beneficiary per month care management fee for an applicable beneficiary who receives more intensive treatment services from a participant and for whom those services are appropriate based on clinical guidelines for opioid use disorder care;

''(iii) pay a higher per applicable beneficiary per month care management fee for the month in which the applicable beneficiary begins treatment with a participant than in subsequent months, to reflect the greater time and costs required for the planning and initiation of treatment, as compared to maintenance of treatment;

''(iv) pay higher per applicable beneficiary per month care management fees for participants that have established opioid use disorder care teams that include an addiction specialist (as defined in subsection (c)(3)(B)); and

''(v) take into account whether a participant's opioid use disorder care team refers applicable beneficiaries to other suppliers or providers for any opioid use disorder treatment services.

''(C) NO DUPLICATE PAYMENT.—The Secretary shall make payments under this paragraph to only one participant for services furnished to an applicable beneficiary during a calendar month.

''(2) INCENTIVE PAYMENTS.—

''(A) IN GENERAL.—Under the Program, the Secretary shall establish a performance-based incentive payment, which shall be paid (using a methodology established and at a time determined appropriate by the Secretary) to participants based on the performance of participants with respect to criteria, as determined appropriate by the Secretary, in accordance with subparagraph (B).

''(B) CRITERIA.—

''(i) IN GENERAL.—Criteria described in subparagraph (A) may include consideration of the following:

''(I) Patient engagement and retention in treatment.

''(II) Evidence-based medication-assisted treatment.

''(III) Other criteria established by the Secretary.

''(ii) REQUIRED CONSULTATION AND CONSIDERATION.—In determining criteria described in subparagraph (A), the Secretary shall—

''(I) consult with stakeholders, including clinicians in the primary care community and in the field of addiction medicine; and

''(II) consider existing clinical guidelines for the treatment of opioid use disorders.

''(C) NO DUPLICATE PAYMENT.—The Secretary shall ensure that no duplicate payments under this paragraph are made with respect to an applicable beneficiary.

''(f) MULTIPAYER STRATEGY.—In carrying out the Program, the Secretary shall encourage other payers to provide similar payments and to use similar criteria as applied under the Program under subsection (e)(2)(C). The Secretary may enter into a memorandum of understanding with other payers to align the methodology for payment provided by such a payer related to opioid use disorder treatment services with such methodology for payment under the Program.

''(g) EVALUATION.—

''(1) IN GENERAL.—The Secretary shall conduct an intermediate and final evaluation of the program. Each such evaluation shall determine the extent to which each of the purposes described in subsection (b) have been accomplished under the Program.

''(2) REPORTS.—The Secretary shall submit to the Secretary and Congress—

''(A) a report with respect to the intermediate evaluation under paragraph (1) not later than 3 years after the date of the implementation of the Program; and

''(B) a report with respect to the final evaluation under paragraph (1) not later than 6 years after such date.

''(h) FUNDING.—

''(1) ADMINISTRATIVE FUNDING.—For the purposes of implementing, administering, and carrying out the Program (other than for purposes described in paragraph (2)), $5,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''(2) CARE MANAGEMENT FEES AND INCENTIVES.—For the purposes of making payments under subsection (e), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 for each of fiscal years 2021 through 2024.

''(3) AVAILABILITY.—Amounts transferred under this subsection for a fiscal year shall be available until expended.

''(i) WAIVERS.—The Secretary may waive any provision of this title as may be necessary to carry out the Program under this section.''.

SEC. 3. REQUIRING E-PRESCRIBING FOR COVERAGE OF COVERED PART D CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e)) is amended by adding at the end the following:

''(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

''(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

''(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, pursuant to rulemaking, specify circumstances with respect to which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

''(i) a prescription issued when the practitioner and dispenser are the same entity;

''(ii) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

''(iii) a prescription issued by a practitioner who has received a waiver or a renewal thereof for a specified period determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established by regulation by the Secretary, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

''(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

''(v) a prescription issued by a practitioner allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy,

collaborative drug management, or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a non-patient specific prescription;

''(vi) a prescription issued by a practitioner prescribing a drug under a research protocol;

''(vii) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use; and

''(viii) a prescription issued by a practitioner for an individual who—

''(I) receives hospice care under this title; or

''(II) is a resident of a skilled nursing facility (as defined in section 1819(a)), or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B), for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, as determined by the Secretary in accordance with this paragraph.

''(C) DISPENSING.—Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A). Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral or fax prescriptions that are consistent with laws and regulations. Nothing in this paragraph shall be construed as affecting the ability of the beneficiary involved to designate a particular pharmacy to dispense a prescribed drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

''(D) ENFORCEMENT.—The Secretary shall, pursuant to rulemaking, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage of drugs prescribed on or after January 1, 2021.

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 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 want to commend Representative RUIZ, Representative CLARK, and Representative MULLIN; they all worked together to make this bipartisan bill a success.

This bill would authorize a 4-year demonstration project to test new ways to treat opioid use disorder among the Medicare population.

In addition, this bill will help secure the prescribing of controlled substances in Medicare by requiring the use of e-prescribing. Pretty important work.

We have heard from providers that have not only cut down on the abuse of fraudulent prescriptions by switching to e-prescribing but also have saved time for themselves and their nurses, all while saving millions of dollars in the process. So these are really important, substantive steps forward, another piece of the puzzle in addressing the opioid crisis.

Mr. Speaker, I urge passage of the legislation, and I reserve the balance of my time.

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 bills to address the opioid epidemic facing communities across our nation. Several of the bills were also referred to the Committee on Ways and Means.

I ask that the Committee on Ways and Means not insist on its referral of the following bills so that they may be scheduled for consideration by the Majority Leader:

H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017;

H.R. 3331, To amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology;

H.R. 3528, Every Prescription Conveyed Securely Act;

H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018;

H.R. 5582, Abuse Deterrent Access Act of 2018;

H.R. 5590, Opioid Addiction Action Plan Act;

H.R. 5603, Access to Telehealth Services for Opioid Use Disorder;

H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act;

H.R. 5675, To amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries;

H.R. 5684, Protecting Seniors from Opioid Abuse Act;

H.R. 5685, Medicare Opioid Safety Education Act;

H.R. 5686, Medicare Clear Health Options in Care for Enrollees (CHOICE) Act;

H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act;

H.R. 5716, Commit to Opioid Medical Prescriber Accountability and Safety for Seniors (COMPASS) Act;

H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment (REACH OUT) Act of 2018;

H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act;

H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act; and

H.R. 5809, Postoperative Opioid Prevention Act of 2018.

This concession in no way affects your jurisdiction over the subject matter of these bills, and it will not serve as precedent for future referrals. In addition, should a conference on the bills be necessary, I would support your request to have the Committee on Ways and Means on the conference committee. Finally, I would be pleased to include this letter and your response in the bill reports and the Congressional Record.

Thank you for your consideration of my request and for the extraordinary cooperation shown by you and your staff over matters of shared jurisdiction. I look forward to further opportunities to work with you this Congress.

Sincerely,

GREG WALDEN,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
Washington, DC, June 8, 2018.

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce, Washington, DC.

DEAR CHAIRMAN WALDEN: Thank you for your letter concerning several bills favorably reported out of the Committee on Energy and Commerce to address the opioid epidemic and which the Committee on Ways and Means was granted an additional referral.

As a result of your having consulted with us on provisions within these bills that fall within the Rule X jurisdiction of the Committee on Ways and Means, I agree to waive formal consideration of the following bills so that they may move expeditiously to the floor:

H.R. 1925, At-Risk Youth Medicaid Protection Act of 2017;

H.R. 3331, To amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology;

H.R. 3528, Every Prescription Conveyed Securely Act;

H.R. 4841, Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018;

H.R. 5582, Abuse Deterrent Access Act of 2018;

H.R. 5590, Opioid Addiction Action Plan Act;

H.R. 5603, Access to Telehealth Services for Opioid Use Disorder;

H.R. 5605, Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act;

H.R. 5675, To amend title XVIII of the Social Security Act to require prescription drug plan sponsors under the Medicare program to establish drug management programs for at-risk beneficiaries;

H.R. 5684, Protecting Seniors from Opioid Abuse Act;

H.R. 5685, Medicare Opioid Safety Education Act;

H.R. 5686, Medicare Clear Health Options in Care for Enrollees (CHOICE) Act; fl H.R. 5715, Strengthening Partnerships to Prevent Opioid Abuse Act;

H.R. 5716, Commit to Opioid Medical Prescriber Accountability and Safety for Seniors (COMPASS) Act;

H.R. 5796, Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment (REACH OUT) Act of 2018;

H.R. 5798, Opioid Screening and Chronic Pain Management Alternatives for Seniors Act;

H.R. 5804, Post-Surgical Injections as an Opioid Alternative Act; and

H.R. 5809, Postoperative Opioid Prevention Act of 2018.

The Committee on Ways and Means takes this action with the mutual understanding that we do not waive any jurisdiction over the subject matter contained in this or similar legislation, and the Committee will be appropriately consulted and involved as the bill or similar legislation moves forward so that we may address any remaining issues that fall within our jurisdiction. The Committee also reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation and requests your support for such a request.

Finally, I would appreciate your commitment to include this exchange of letters in the bill reports and the Congressional Record.

Sincerely,

KEVIN BRADY,
Chairman.

Mr. KENNEDY. Mr. Speaker, I yield such time as he may consume to the gentleman from California (Mr. RUIZ), my colleague.

Mr. RUIZ. Mr. Speaker, I rise to support H.R. 5605, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act.

I introduced the bill to give older Americans across our Nation more access to comprehensive addiction treatment services through Medicare. Seniors are frequently prescribed opioids to treat chronic illnesses with constant, lasting pain issues, such as arthritis and other issues related to their musculoskeletal system.

The frequency and chronicity of this prescribing puts them at risk of developing a dependency, as seniors are more physiologically vulnerable to experiencing dependency and overdose effects. That is because as you get older your physiology changes, which makes seniors less able to deal with the side effects of opioids and more prone to respiratory depression, the leading cause of opioid-related death.

When you consider that roughly one-third of Medicare beneficiaries received an opioid prescription in 2016, with over half a million receiving a high dose, it makes sense that the hospitalization rate related to opioid misuse in patients over 65 has increased by 500 percent in the past two decades.

Despite these heightened risk factors, many seniors still do not have access to comprehensive, evidence-based treatment under traditional Medicare, and we cannot leave our seniors behind as we work to address this national crisis. Our seniors deserve access to the gold standard of care for treating opioid addiction. It is that simple.

My bill, H.R. 5605, the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act, will open doors for older Americans to get that gold standard of care by strengthening Medicare for our seniors. My bill does this by creating an alternative payment model demonstration program through Medicare for comprehensive treatment and care programs for opioid misuse disorder and will establish quality measures that reward comprehensive treatment programs that actually produce the best patient outcomes.

It works by giving providers and institutions that choose to participate a case management payment, which they would use to provide wraparound services for Medicare beneficiaries. Teams with an addiction specialist would also receive a higher incentive. Seniors participating in this program will receive medication-assisted treatment alongside psychosocial support, such as psychotherapy, treatment planning, and appropriate social services.

This coordinated care approach is considered the gold standard of care, and if we want to successfully address this crisis, we need to ensure that individuals have access to treatments that will result in successful outcomes. I have seen firsthand the importance of this with my own patients in the emergency department. Getting medication-assisted treatment is important, and the success of that treatment is enhanced if that patient is also participating in psychotherapy and receiving the appropriate social services.

That is why this demo is supported by the American Society of Addiction Medicine and the California Medical Association, among others. It is critical that all Americans, regardless of their age or how much money they make, have access to high quality, comprehensive treatment. My bill will strengthen Medicare so we can help seniors address opioid dependence by ensuring they get the care they need.

I also want to thank Ranking Member PALLONE and Chairman WALDEN for their support of this legislation and of our seniors.

Also included in my bill is H.R. 3528, the Every Prescription Conveyed Securely Act, introduced by Representative KATHERINE CLARK from Massachusetts, with the assistance of Representative MULLIN.

I want to thank Representative CLARK for her hard work to address this crisis by expanding the use of technology to reduce fraudulent prescribing.

Her legislation will direct providers to use electronic prescribing for controlled substances technology for Medicare part D by 2021 to cut down on fraud and overprescribing. Already, seven States have implemented this system in an effort to combat this crisis and keep illicit opioids off the streets.

According to the Department of Justice, most fraudulent opioid prescriptions are obtained either through doctor shopping, forged prescriptions, or theft, all of which can be addressed by an effective electronic prescribing for controlled substances system.

As amended, my bill, H.R. 5605, will improve care for our seniors and help get illegally obtained opioids off the streets.

Mr. KENNEDY. Mr. Speaker, I think Dr. RUIZ has done an extraordinary job on this legislation. I would urge the House to support it, and I yield back the balance of my time.

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

Ms. JACKSON LEE. Mr. Speaker, I support H.R. 5605, the "Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act."

This important bill provides applicable beneficiaries increased access to opioid use disorder treatment services and will improve physical and mental health outcomes for such beneficiaries.

In 2016, approximately one-third of Medicare beneficiaries received an opioid prescription, 500,000 of which received high doses of opioids yet many lack access to quality treatment for substance abuse.

This legislation would create an Alternative Payment Model (APM) demonstration program to incentivize the delivery of high quality, evidence-based substance use disorder treatment services.

The voluntary program would enroll eligible beneficiaries who agree to receive Substance Use Disorder (SUD) treatment services through providers and institutions participating in the Program.

To support those who are suffering from opioid use disorders, we must employ a multifaceted approach that actually achieves results.

The purpose of the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act is to assist states in the implementation of a variety of strategies, including:

Reducing hospitalizations and emergency department visits;

Increasing the use of medication-assisted treatment for opioid use disorders;

Improving health outcomes of individuals with opioid use disorders, including by reducing the incidence of infectious diseases (such as hepatitis C and HIV);

Reducing deaths from opioid overdose; and

Reducing the utilization of inpatient residential treatment.

Under the Program, the Secretary of the Health and Human Services shall make payments to participants for:

Furnishing opioid use disorder treatment services delivered through opioid use disorder care teams; or

Arranging for such service to be furnished, to applicable beneficiaries participating in the Program.

The current surge of opioid usage requires a strong, national response, and with passage of the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act, we are addressing this issue.

Opioid use disorder leads to physical and functional changes to parts of the brain affecting impulse, reward, and motivation.

In recent years, it is estimated that 2.1 million individuals in the United States have an opioid use disorder.

This legislation would require APM demonstration program participants to provide both medication as well as psychosocial supports, such as care management, psychotherapy, treatment planning and appropriate social services to treat substance use disorder, which is considered the gold standard of care.

Voluntary APM demonstration program participation would be prioritized in regions with high prevalence of opioid use disorders.

Care teams would require inclusion of health care providers who are licensed to dispense opioid medications for the purpose of detoxification or maintenance treatment for opioid use disorder, as well as appropriate providers of psychosocial treatment.

In addition, in conjunction with stakeholders, the Health and Human Services Secretary would develop quality and outcome measures to assess the care beneficiaries receive through the Program.

Participating providers or institutes will receive a monthly case management fee for all beneficiaries receiving opioid treatment services.

Program participants will receive a higher case management fee if their care team includes an addiction specialist, and for the initiation of treatment period, which is treatment and resource intensive.

Participants would be eligible to receive an additional incentive payment for providing quality substance use disorder treatment care.

The demonstration program is authorized for four years and capped at 20,000 participants.

I am confident that the comprehensive approach we are taking to address those suffering from Opioid Use Disorder will help address the nation's growing epidemic.

For these reasons, I support the Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act and the goal of ensuring the best possible response to treat opioid use disorder in America.

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. 5605, 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 amend title XVIII of the Social Security Act to provide for an opioid use disorder treatment demonstration program, and for other purposes.''.

A motion to reconsider was laid on the table.

POSTAPPROVAL STUDY REQUIREMENTS FOR CERTAIN CONTROLLED SUBSTANCES

Mr. WALDEN. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5811) to amend the Federal Food, Drug, and Cosmetic Act with respect to postapproval study requirements for certain controlled substances, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5811

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. POSTAPPROVAL STUDY REQUIREMENTS.

(a) PURPOSES OF STUDY.—Section 505(o)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(B)) is amended by adding at the end the following:

''(iv) To assess a potential reduction in effectiveness of the drug for the conditions of use prescribed, recommended, or suggested in the labeling thereof if—

''(I) the drug involved—

''(aa) is or contains a substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act; or

''(bb) is a drug that has not been approved under this section or licensed under section 351 of the Public Health Service Act, for which an application for such approval or licensure is pending or anticipated, and for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act; and

''(II) the potential reduction in effectiveness could result in the benefits of the drug no longer outweighing the risks.''.

(b) ESTABLISHMENT OF REQUIREMENT.—Section 505(o)(3)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(C)) is amended by striking ''such requirement'' and all that follows through ''safety information.'' and inserting the following: ''such requirement—

''(i) in the case of a purpose described in clause (i), (ii), or (iii) of subparagraph (B), only if the Secretary becomes aware of new safety information; and

''(ii) in the case of a purpose described in clause (iv) of such subparagraph, if the Secretary determines that new effectiveness information exists.''.

(c) APPLICABILITY.—Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)) is amended by adding at the end the following new subparagraph:

''(G) APPLICABILITY.—The conduct of a study or clinical trial required pursuant to this paragraph for the purpose specified in subparagraph (B)(iv) shall not be considered a new clinical investigation for the purpose of a period of exclusivity under clause (iii) or (iv) of subsection (c)(3)(E) or clause (iii) or (iv) of subsection (j)(5)(F).''.

(d) NEW EFFECTIVENESS INFORMATION DEFINED.—Section 505(o)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(2)) is amended by adding at the end the following new subparagraph:

''(D) NEW EFFECTIVENESS INFORMATION.—The term 'new effectiveness information', with respect to a drug that is or contains a controlled substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act, means new information about the effectiveness of the drug, including a new analysis of existing information, derived from—

''(i) a clinical trial; an adverse event report; a postapproval study or clinical trial (including a study or clinical trial under paragraph (3));

''(ii) peer-reviewed biomedical literature;

''(iii) data derived from the postmarket risk identification and analysis system under subsection (k); or

''(iv) other scientific data determined to be appropriate by the Secretary.''.

(e) CONFORMING AMENDMENTS WITH RESPECT TO LABELING CHANGES.—Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(4)) is amended—

(1) in subparagraph (A)—

(A) in the heading, by inserting ''OR NEW EFFECTIVENESS'' after ''SAFETY'';

(B) by striking ''safety information'' and inserting ''new safety information or new effectiveness information such''; and

(C) by striking ''believes should be'' and inserting ''believes changes should be made to'';

(2) in subparagraph (B)(i)—

(A) by striking ''new safety information'' and by inserting ''new safety information or new effectiveness information''; and

(B) by inserting ''indications,'' after ''boxed warnings,'';

(3) in subparagraph (C), by inserting ''or new effectiveness information'' after ''safety information''; and

(4) in subparagraph (E), by inserting ''or new effectiveness information'' after ''safety information''.

(f) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed to alter, in any manner, the meaning or application of the provisions of paragraph (3) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)) with respect to the authority of the Secretary of Health and Human Services to require a postapproval study or clinical trial for a purpose specified in clauses (i) through (iii) of subparagraph (B) of such paragraph (3) or paragraph (4) of such section 505(o) with respect to the Secretary's authority to require safety labeling changes.

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 into 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 want to speak in favor of this bipartisan bill and thank Representative MCNERNEY and Representative GRIFFITH for working so hard to advance this important policy.

Currently, there are limited data on the long-term efficacy of opioids, their increased addictive tendencies over time, and their overall place in the treatment of pain. This legislation will enhance the Food and Drug Administration's authorities and enforcement tools to ensure timely post-marketing studies for chronically administered opioids.

Collecting and analyzing data is the best way to ensure that patients and physicians have access to evidence-based treatments. This bill will advance our understanding of the science underlying long-term use of opioids, and I encourage my colleagues to support its passage.

Mr. Speaker, I especially appreciate the work of the sponsors of this bill, including Representative GRIFFITH, who would be here with us to speak in favor of this legislation but for traffic congestion on his way back from his district that has detained him from getting here as he had previously scheduled.

Mr. Speaker, I encourage my colleagues to support the bill, and I reserve the balance of my time.

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

Mr. Speaker, I rise in support of H.R. 5811, the Long-Term Opioid Efficacy Act of 2018, authored by Representatives MCNERNEY and GRIFFITH.

Despite the prevalent use of opioids today in combating pain, the long-term