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

impacts of opioids and whether or not they are truly the most effective treatment is still fairly unknown.

FDA Commissioner Gottlieb testified before the Energy and Commerce Committee that many opioids have not been studied for chronic administration and further studying could help address certain questions. This includes the long-term efficacy of opioids and whether opioids may contribute to increased addictive tendencies over time.

This legislation would help us better understand the long-term impacts of opioids and whether opioids truly are the most effective treatment for chronic pain management by allowing the FDA to require manufacturers of controlled substances, such as opioids, to conduct post-market studies to assess the effectiveness of these products and whether or not they pose an increase in serious risk.

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Under current law, the FDA has the authority to request postmarket studies relating to the safety considerations of a drug, but it does not have explicit authority to do so related to the efficacy of a drug. It is our hope that, by granting this authority to the FDA, we will better understand the long-term impacts of opioids that are chronically administered and encourage more responsible prescribing of opioids moving forward.

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

The SPEAKER pro tempore. Without objection, the gentleman from Kentucky (Mr. GUTHRIE) will control the time for the majority.

There was no objection.

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

Ms. JACKSON LEE. Mr. Speaker, I rise in strong support of H.R. 5811, which amends the Federal Food, Drug, and Cosmetic Act with respect to post approval study requirements for certain controlled substances.

H.R. 5811 allows the FDA to require that pharmaceutical manufacturers study certain drugs after they are approved to assess any potential reduction in those drugs' effectiveness for the conditions of use prescribed, recommended, or suggested in labeling.

In recent years, many communities have been devastated by the number of overdoses that have been related to the escalating opioid epidemic.

According to U.S. Department of Health and Human Services, illegal substances, deadly synthetics such as fentanyl, and legally available pain relievers accounted for more than 42,000 deaths across the country in 2016.

Further, in the city of Houston, there were 364 drug-related overdose deaths alone that happened in 2016 according to the Treatment Center, a highly respected drug and alcohol addiction treatment service center.

This is a national emergency that deserves immediate action.

H.R. 5811 would expand an existing mandate that requires drug developers to conduct post-approval studies or clinical trials for certain drugs.

FDA will provide doctors and patients the information they need to use medicines wisely.

This will ensure that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks.

Under current law, in certain instances, the FDA can require studies or clinical trials after a drug has been approved.

H.R. 5811 would permit the FDA to use that authority if the reduction in a drug's effectiveness meant that its benefits no longer outweighed its costs.

I urge my colleagues to join me in voting to pass H.R. 5811.

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. 5811, as amended.

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

A motion to reconsider was laid on the table.

DELAYING REDUCTION IN FEDERAL MEDICAL ASSISTANCE PERCENTAGE FOR CERTAIN MEDICAID PERSONAL CARE SERVICES

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6042) to amend title XIX of the Social Security Act to delay the reduction in Federal medical assistance percentage for Medicaid personal care services furnished without an electronic visit verification system, and for other purposes, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6042

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

SECTION 1. DELAY IN REDUCTION OF FMAP FOR MEDICAID PERSONAL CARE SERVICES FURNISHED WITHOUT AN ELECTRONIC VISIT VERIFICATION SYSTEM.

(a) IN GENERAL.—Section 1903(l) of the Social Security Act (42 U.S.C. 1396b(l)) is amended—

(1) in paragraph (1)—

(A) by striking ''January 1, 2019'' and inserting ''January 1, 2020''; and

(B) in subparagraph (A)(i), by striking ''2019 and''; and

(2) in paragraph (4)(A)(i), by striking ''calendar quarters in 2019'' and inserting ''calendar quarters in 2020''.

(b) SENSE OF CONGRESS ON STAKEHOLDER INPUT REGARDING ELECTRONIC VISIT VERIFICATION SYSTEMS.—It is the sense of Congress that—

(1) the Centers for Medicare & Medicaid Services should—

(A) convene at least one public meeting in 2018 for the purpose of soliciting ongoing feedback from Medicaid stakeholders on guidance issued by the Centers for Medicare & Medicaid Services on May 16, 2018, regarding electronic visit verification; and

(B) communicate with such stakeholders regularly and throughout the implementation process in a clear and transparent manner to monitor beneficiary protections;

(2) such stakeholders should include State Medicaid directors, beneficiaries, family caregivers, individuals and entities who provide personal care services or home health care services, Medicaid managed care organizations, electronic visit verification vendors, and other stakeholders, as determined by the Centers for Medicare & Medicaid Services; and

(3) taking into account stakeholder input on the implementation of the electronic visit verification requirement under the Medicaid program is vital in order to ensure that the Centers for Medicare & Medicaid Services is aware and able to mitigate any adverse outcomes with the implementation of this policy.

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

The Chair recognizes the gentleman from Kentucky.

GENERAL LEAVE

Mr. GUTHRIE. Mr. Speaker, I ask unanimous consent that all Members 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 Kentucky?

There was no objection.

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

Mr. Speaker, I rise today in support of my bill, H.R. 6042, which will ensure the proper implementation of the electronic visit verification system, or EVV, in State Medicaid programs. EVV provides a way to track the delivery of in-home Medicaid personal care services to help prevent instances of fraud and abuse and to protect patients, ensuring they get the services they are entitled to receive.

Many frail, disabled, or otherwise homebound patients benefit from and even rely on Medicaid personal care services and home health services. Yet the Department of Health and Human Services' Office of Inspector General, OIG, found in recent years that the existing program safeguards at the time were often ineffective, despite the fact that they were intended to prevent improper payments and to ensure medical necessity, patient safety, and quality care.

Furthermore, the OIG warned that fraud in this area was on the rise, which endangers vulnerable patients and wastes taxpayer money. EVV systems were developed to protect some of the most vulnerable Medicaid recipients.

Last Congress, in response to the OIG report, I wrote and included a provision in the bipartisan 21st Century Cures Act to require State Medicaid programs to use EVV to track all personal care services conducted in a patient's home. In the time since the implementation of Cures, I have received feedback that more time is needed to implement EVV systems to make sure that they are properly and fully integrating the EVV technology.

This year, I worked with Congresswoman DEGETTE and Congressman