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

LANGEVIN to introduce H.R. 6042, which gives States an extra year to put in place their EVV systems and ensure stakeholder input. Home visits are a critical part of providing quality care to patients, many of whom have disabilities and rely on extra care in their homes.

H.R. 6042 will make sure that EVV can be implemented effectively. Thanks to hard work, the bill has changed a little bit working with Congresswoman DEGETTE, who came to me and said we want to make sure that we have stakeholder input. That is included in this version of the bill that is before us now. Her diligence in doing that has been very helpful, and I appreciate her efforts in that.

Mr. Speaker, I urge my colleagues to support this bipartisan bill to provide a simple fix for the benefit of improved accountability and patient care in State Medicaid programs.

Mr. Speaker, I reserve the balance of my time.

Mr. KENNEDY. Mr. Speaker, I yield such time as he may consume to the gentleman from Rhode Island (Mr. LANGEVIN).

Mr. LANGEVIN. Mr. Speaker, I thank the gentleman from Massachusetts for yielding.

Mr. Speaker, I rise in support of H.R. 6042, which will delay implementation of the Medicaid electronic visit verification system requirement by 1 year and promote stakeholder feedback as part of its implementation.

The Medicaid EVV system requirement under the landmark 21st Century Cures Act was established to ensure accurate billing and delivery of personal care services in the homes of Medicaid beneficiaries. We want to make sure that Medicaid patients are accurately getting the care that they received, that Medicaid is properly billed for those services, and that we do everything possible to wring fraud out of the system.

Unfortunately, the short implementation period, compounded by a delay in CMS guidance and a lack of stakeholder input, has presented significant challenges for affected populations, especially seniors and people with disabilities.

I am pleased to join my colleagues, Representative GUTHRIE and Representative DEGETTE, in supporting this important piece of legislation. I am glad to see that Representative GUTHRIE's bill largely mirrors the bipartisan, bicameral legislation I introduced to address this issue last month.

The collaboration and the inclusive approach it took to bring this bill to the floor is the same dynamic Medicaid beneficiaries, family caregivers, personal care and home health providers, and other stakeholders are hoping to see from CMS when the agency defines EVV system requirements so that States can design effective and thoughtful EVV programs.

Delaying implementation by 1 year and encouraging input from relevant stakeholders will be paramount to the success of the EVV programs and is a part of our enduring promise to protect vulnerable populations, people who would otherwise suffer from adverse outcomes should the policy be hastily implemented.

Mr. Speaker, I thank Mr. GUTHRIE, Congresswoman DEGETTE, Chairman WALDEN, Ranking Member PALLONE, and all those who had a hand in bringing this bill to the floor today for the opportunity to join in leading this important effort.

Mr. KENNEDY. Mr. Speaker, I want to commend the gentleman from Rhode Island for all of his work and dedication on this issue.

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

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

Mr. Speaker, I didn't see my friend from Rhode Island on the floor when I was speaking earlier on Ms. DEGETTE and her work in this. He has been working really hard. I appreciate my friend from Rhode Island leading on this issue and us being able to work together and our staffs working together to make something very important like this. His input was very important on the stakeholder issue, as was Ms. DEGETTE's.

Mr. Speaker, I urge my colleagues to vote for the bill, and I yield back the balance of my time.

Ms. DEGETTE. Mr. Speaker, I would like to thank Representatives GUTHRIE and LANGEVIN for working with me on this very important bill, which addresses a national health care issue involving safety, efficiency and privacy affecting many of our constituents.

As most people who have been engaged in this matter know, the mental health portion of the 21st Century Cures Act—the overwhelmingly bipartisan biomedical reform bill that was signed into law in December 2016—included what is called electronic visit verification (EVV) provisions. These provisions require states to verify the provider, date, time and site of personal care and home health services.

They were meant to give patients the power to hold their providers accountable for delivering services when and where they are supposed to do so.

But given the delay by the Centers for Medicare and Medicaid Services (CMS) in getting guidance for implementation of the provisions to the states, and the way the agency ignored Congressional intent to involve stakeholders in the regulatory process, House members had to step in to try and right what the Executive Branch has done poorly in the past year and a half.

The bill before you today grants a one-year delay in implementation of the EVV requirements. It also requires CMS to involve stakeholders both in the planning and throughout the implementation of the EVV requirements to ensure that the privacy and civil rights of consumers are protected.

This bill ensures that administrative and financial burdens on service providers are neither onerous nor duplicative and that states are able to design and implement their EVV programs in a thoughtful, deliberative manner. It also affords CMS the opportunity to hear from beneficiaries enrolled in self-directed plans about the challenges EVV could present for them.

This legislation will also help foster a comprehensive and transparent process that carefully balances the serious privacy concerns of consumers and caregivers, the administrative and financial concerns of providers and states, and EVV's goals of patient control and fraud prevention.

Mr. Speaker, if properly implemented EVV has potential to ensure that high-quality services are delivered when and where needed, while also reducing the potential for waste and fraud. This legislation will require CMS to follow a proper stakeholder engagement process, in order to ensure that the policy is implemented correctly. It will also allow each state greater opportunity to ensure that its EVV programs are best suited to individuals' specific needs.

I strongly urge all members to support this bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Kentucky (Mr. GUTHRIE) that the House suspend the rules and pass the bill, H.R. 6042, 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.

MEDICAID PROVIDERS ARE REQUIRED TO NOTE EXPERIENCES IN RECORD SYSTEMS TO HELP IN-NEED PATIENTS ACT

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5801) to amend title XIX of the Social Security Act to provide for requirements under the Medicaid program relating to the use of qualified prescription drug monitoring programs and prescribing certain controlled substances, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5801

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 ''Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-need Patients Act'' or the ''Medicaid PARTNERSHIP Act''.

SEC. 2. MEDICAID PROVIDERS ARE REQUIRED TO NOTE EXPERIENCES IN RECORD SYSTEMS TO HELP IN-NEED PATIENTS.

(a) REQUIREMENTS UNDER THE MEDICAID PROGRAM RELATING TO QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAMS AND PRESCRIBING CERTAIN CONTROLLED SUBSTANCES.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1943 the following new section:

''SEC. 1944. REQUIREMENTS RELATING TO QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAMS AND PRESCRIBING CERTAIN CONTROLLED SUBSTANCES.

''(a) IN GENERAL.—Beginning October 1, 2021, a State shall, subject to subsection (d),