



United States
of America

Congressional Record

PROCEEDINGS AND DEBATES OF THE 114th CONGRESS, SECOND SESSION

Vol. 162

WASHINGTON, WEDNESDAY, NOVEMBER 30, 2016

No. 171—Book II

House of Representatives

PROVIDING FOR CONSIDERATION OF SENATE AMENDMENT TO H.R. 34, TSUNAMI WARNING, EDUCATION, AND RESEARCH ACT OF 2015, AND PROVIDING FOR CONSIDERATION OF H.R. 6392, SYSTEMIC RISK DESIGNATION IMPROVEMENT ACT OF 2016

Mr. BURGESS. Mr. Speaker, by the direction of the Committee on Rules, I call up House Resolution 934 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

H. RES. 934

Resolved, That upon adoption of this resolution it shall be in order to take from the Speaker's table the bill (H.R. 34) to authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and Atmospheric Administration, and for other purposes, with the Senate amendment thereto, and to consider in the House, without intervention of any point of order, a motion offered by the chair of the Committee on Energy and Commerce or his designee that the House concur in the Senate amendment with an amendment consisting of the text of Rules Committee Print 114-67 modified by the amendment printed in part A of the report of the Committee on Rules accompanying this resolution. The Senate amendment and the motion shall be considered as read. The motion shall be debatable for 80 minutes, with 60 minutes equally divided and controlled by the chair and ranking minority member of the Committee on Energy and Commerce and 20 minutes equally divided and controlled by the chair and ranking minority member of the Committee on Ways and Means. The previous question shall be considered as ordered on the motion to its adoption without intervening motion.

SEC. 2. Upon adoption of this resolution it shall be in order to consider in the House the bill (H.R. 6392) to amend the Dodd-Frank Wall Street Reform and Consumer Protection Act to specify when bank holding companies may be subject to certain enhanced supervision, and for other purposes. All points of order against consideration of the bill are waived. The bill shall be considered as read. All points of order against provisions in the bill are waived. The previous

question shall be considered as ordered on the bill and on any amendment thereto to final passage without intervening motion except: (1) one hour of debate equally divided and controlled by the chair and ranking minority member of the Committee on Financial Services; (2) the amendment printed in part B of the report of the Committee on Rules accompanying this resolution, if offered by the Member designated in the report, which shall be in order without intervention of any point of order, shall be considered as read, shall be separately debatable for the time specified in the report equally divided and controlled by the proponent and an opponent, and shall not be subject to a demand for a division of the question; and (3) one motion to recommit with or without instructions.

The SPEAKER pro tempore. The gentleman from Texas (Mr. BURGESS) is recognized for 1 hour.

Mr. BURGESS. Mr. Speaker, for the purpose of debate only, I yield the customary 30 minutes to the gentleman from Colorado (Mr. POLIS), pending which I yield myself such time as I may consume. During consideration of this resolution, all time yielded is for the purpose of debate only.

GENERAL LEAVE

Mr. BURGESS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks.

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

There was no objection.

Mr. BURGESS. Mr. Speaker, House Resolution 934 provides for a rule to consider a critical bill that will help millions of Americans and their families who are suffering from diseases. The rule provides 80 minutes of debate, with 1 hour being provided to the Energy and Commerce Committee, and 20 minutes given to the Committee on Ways and Means. The rule provides for a motion to concur with the Senate amendment to H.R. 34, placing the base text of the 21st Century Cures into the bill. The rule further incorporates the

manager's amendment into the base text of the Cures bill, reflecting the bipartisan and bicameral negotiations which took place to get us to where we are today with the legislation.

Second, the resolution before us today provides for a rule to consider H.R. 6392, the Systemic Risk Designation Improvement Act of 2016, an important bill to remove onerous Federal regulations imposed on small and community banks by the ill-conceived Dodd-Frank Act by replacing current and arbitrary SIFI designation standards with a more effective activity-based standard. The rule provides for 1 hour of debate, equally divided between the majority and minority of the Committee on Financial Services. Further, the rule makes one amendment in order and provides the minority with the standard motion to recommit.

I am pleased that the House is considering both of these pieces of legislation today.

The Energy and Commerce Committee has spent 4 years working to bring our healthcare innovation infrastructure into the 21st century.

Today, there are 10,000 known diseases or conditions, but the bad news is we have cures and treatments for only 500.

There is a gap between innovation and therapy. There are problems with how we regulate our therapies. It is not unheard of to have a company take over 14 years and \$2 billion to bring a new drug to market.

□ 1230

Members held 20 roundtables, discussions, hearings, field hearings, and events around the country to ensure that we involved our patients, their advocates, researchers, innovators, financiers—all who have firsthand experience and who understand the gaps in our current system.

The House amendment to H.R. 34 includes two bipartisan bills that have

□ This symbol represents the time of day during the House proceedings, e.g., □ 1407 is 2:07 p.m.

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been developed over the course of several years by the Committee on Energy and Commerce and its members to meet some of our country's most pressing healthcare needs. The mental health reforms that are based on the Helping Families in Mental Health Crisis Act, authored by Representative TIM MURPHY, passed the House in July by a vote of 422-2. This legislative effort represents the most significant reforms in the mental health system in over a decade.

The 21st Century Cures Act title in the bill is the result of a unified Energy and Commerce Committee effort, championed by Chairman FRED UPTON of Michigan and Representative DIANA DEGETTE of Colorado over the course of multiple Congresses, to bring our laws into a modern era of medicine. The House passed the 21st Century Cures Act in July of 2015 by a vote of 344-77. Our commitment to this transformational bill has not and must not waver until it is across the finish line and signed into law. We owe it to the patients, their families, medical providers, advocates, scientists, and researchers to see this through.

Our country is a global leader in medical innovation, but even in recognizing that, there is progress that we can make. With 10,000 known diseases and with 10,000 known conditions, and with cures and treatments for only 500, we must do more to alleviate that gap which is causing so much human suffering. Advances in science and technology over the past decade have the potential to revolutionize medical innovation; yet the way drugs and devices are approved is back in the horse-and-buggy days. It is largely unchanged.

In recognizing the growing divide between innovation and regulation, the House Committee on Energy and Commerce launched the 21st Century Cures Initiative in the 113th Congress—that was a Congress ago—to examine the state of discovery, development, and delivery of medical therapies in America. The ensuing process by which the Cures legislation was developed should serve as a model for policy development long into the future.

Members of the committee convened hearings, forums, and roundtables in Washington, DC, and in centers and locations around the Nation. These forums brought together the leading scientists, the medical experts, patient and disease group advocates, and researchers and innovators across multiple sectors. The objective of these events was to uncover opportunities and to strengthen and streamline the process by which cures are discovered and made available to patients.

Based on what we have learned, Representatives worked across the aisle—across the dais—on comprehensive legislation that would make the government an ally rather than an obstacle in the cycle of medical innovation. The 21st Century Cures Act touches each step of the process through which new

treatments and cures come to market: the discovery, the development, the delivery.

To accelerate discovery, the House amendment to H.R. 34 includes provisions that facilitate collaboration and increase access to health data. It invests billions of dollars in research through the National Institutes of Health, and it incentivizes the exploration of the most rare and challenging conditions. To modernize the development, among other things, the 21st Century Cures Act establishes a review pathway at the Food and Drug Administration for biomarkers and other drug development tools that can be used to help shorten drug development time while, at the same time, maintaining the safety standard that the public demands and that we have all come to expect from the agency.

The very confused regulation of combination products by the very different centers at the Food and Drug Administration will be improved to cut down on inefficiencies and to reduce the cost of development. The Food and Drug Administration will be required to work with stakeholders and the National Institute of Standards and Technology to establish a regulatory framework for the development, evaluation, and review of drugs that are classified as regenerative medicine and advanced therapies.

A number of provisions seek to empower patients to engage in their health care and to engage in their treatment decisions with their doctors, to contribute health information to scientific research, and to participate in the drug and device approval process. The Food and Drug Administration is required to engage in a range of activities that will establish a framework for the consideration of patient experience data when weighing the benefits of a new treatment. Individuals will have the opportunity to share health data with the global research community through platforms, such as the Precision Medicine Initiative and a new National Neurological Diseases Surveillance System. Multiple measures ensure patients will have better access to secure, up-to-date information through their electronic health records, and they ensure that this health information technology will continue to be developed with patient needs and patient safety and privacy as a priority.

I am grateful to have had the opportunity to work directly on several provisions in the bill. This includes the creation of a national surveillance system for neurologic diseases and conditions which may then be used to help us further understand these devastating diseases. Thousands of Americans are affected—multiple sclerosis, Parkinson's, Alzheimer's, other neurologic diseases—but there is very little accurate information that exists today to assist those who research, treat, and provide care for individuals who suffer from these diseases.

I have also worked on a provision that will improve patient access to pharmaceutical companies' compassionate use policies for drugs that treat serious or life-threatening conditions. To increase the efficiency and foster robust data collection analysis, the Food and Drug Administration will be required to evaluate the use of real-world evidence and summary-level review where an application is submitted for a new indication for an already approved drug. To help insurers and formulary committees make informed coverage decisions, a provision in the 21st Century Cures Act clarifies how medical product manufacturers can communicate economic information about therapies and technologies.

I am particularly happy that the House amendment to H.R. 34 includes multiple provisions that will make meaningful progress toward achieving an interoperable health system. Increasingly, electronic health system interoperability is critical to achieving the promises of the 21st Century Cures and to scaling up the benefits of health reform more broadly. While we have seen the widespread adoption of electronic health records, our Nation continues to maintain a fragmented system, which makes it difficult to ensure the continuity of evidence-based care for patients.

The 21st Century Cures Act would finally set us on a path towards achieving a nationwide interoperable health system that puts the needs of patients and that puts the needs of providers first. Federal advisory committees are streamlined and directed to prioritize interoperability. Preference is directed to utilizing the existing standards of implementation rather than of recreating them.

In addition to increasing the transparency and accountability for providers and patients, enforcement mechanisms will arm the Office of Inspector General with the authority necessary to punish bad actors for improperly impeding the flow of information. Data blocking will stop. The provisions in this bill will expedite the interoperability of electronic health record systems to make good on the \$30 billion taxpayer investment in order to benefit patients, doctors, and researchers.

As I have referenced, developing the 21st Century Cures Act was a process that brought everyone to the table. No one is getting everything that he wanted. I would note my disappointment that this bill does not include an important clarification to the Physician Payments Sunshine Act that was part of the House-passed version of this bill and was supported by over 200 supporting organizations.

Certified continuing medical education, peer-reviewed medical textbooks, and journal reprints play a vital role in improving patient outcomes. They play a role in facilitating medical innovation, keeping our Nation's medical professionals up to date with the rapid pace of scientific discoveries.

These materials and activities should not be confused with improper payments from pharmaceutical manufacturers to physicians. These materials were always intended to be excluded from the reporting requirements in the physician sunshine law, but, unfortunately, the Centers for Medicare & Medicaid Services' interpretation of the exemption has been inconsistent and unreliable. The narrowly constructed language in the 21st Century Cures Act was carefully drafted to maintain the transparency originally intended in the sunshine law while it ensured robust access to medical education.

Mr. Speaker, I think it goes without saying that we all want our doctors to be smart, that we want them to be informed, and that we want them to be up to date. Certainly, that is a priority that I will continue to pursue going forward.

Groundbreaking discoveries rely on a robust and reliable investment in basic research. The House amendment to H.R. 34 provides the National Institutes of Health with almost \$5 billion in funding, including almost \$2 billion for the Cancer Moonshot and \$1.5 billion for the BRAIN Initiative. It also includes \$500 million for the Food and Drug Administration and \$1 billion in grants to four States in order to address the growing and burgeoning opioid crisis that continues to claim so many lives across our country. This approach provides dedicated funding through 2026 while it ensures spending is subject to review and oversight in the annual appropriations process. In addition to fully offsetting all of the authorized funds, H.R. 34 will actually reduce the deficit by almost \$6 billion over the next 10 years.

Federal regulation, Federal policy, and Federal investment have been outpaced by science, medicine, and technology. The bipartisan 21st Century Cures Act will make needed changes to bring our laws into a modern era of medicine and to keep the Nation at the forefront of healthcare innovation. The 21st Century Cures Act not only delivers hope to millions of patients who are living with untreatable diseases, but it also helps modernize and helps streamline the regulation in America's healthcare system.

I encourage all of my colleagues to vote "yes" on the rule and "yes" on the two underlying bills. The 21st Century Cures Act will not only deliver hope to millions of people who are living with untreatable disease, but it will also help modernize and streamline America's healthcare system.

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

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

I thank the gentleman for yielding me the customary time, but I have to say that I think that this somewhat breaks with the custom of this body not to delay floor proceedings during the reorganization of the Democratic

Caucus. I know that, when the Democrats were in the majority, we routinely gave deference to the Republican Conference's plan for retreats and for caucus reorganizations. We have before us several contested races. Of course, the Nation's business comes first, which is why we are here making the case on these bills.

I would like to add that I hope that this is not the tone we are going to be setting for the next Congress. I think it is very important that, despite our differences on policies, both conferences are respectful of the responsibilities that Members have not only within the institution of Congress but within their respective conferences and caucuses. On our side, we will be brief because we do have additional responsibilities, as I mentioned.

Mr. Speaker, I yield 2½ minutes to the gentlewoman from Oregon (Ms. BONAMICI).

Ms. BONAMICI. I thank the gentleman for yielding.

Mr. Speaker, I rise in opposition to the rule on H.R. 34, which is now the vehicle for the 21st Century Cures Act.

Although I understand the detailed rules of our Chamber, I am deeply disappointed that the underlying bill, the Tsunami Warning, Education, and Research Act, was completely stripped out and replaced with unrelated language. The Tsunami Warning, Education, and Research Act is bipartisan. It was passed by a voice vote on January 7 of 2015, and a similar version has passed the Senate. We have worked out our differences, and this legislation is ready to be signed into law, and it is vital for our West Coast communities.

My constituents on the Oregon coast know that it is a matter of when, not if, our community will face a Cascadia subduction zone earthquake and tsunami. Most of the city of Seaside, including all of its public schools, is located in the tsunami inundation zone. It is some of my youngest constituents—the students of Seaside—who have been the most vocal about keeping their communities safe. Recently, I met with the students there at the high school. They have spoken all over the State about the dangers they face from tsunami. Their presentation was very strong. They made a case for moving their schools out of the tsunami zone.

□ 1245

It helped the community pass a bond measure earlier this month to move the schools. That is a positive step for Seaside, but there is so much more to be done.

I have an app on my phone. Almost every day, there is an earthquake off the coast of Alaska or Hawaii. Two days ago there were two earthquakes off the coast of Oregon. When there is a near-shore tsunami, the warning time is about 15 minutes. That is all.

The Tsunami Warning, Education, and Research Act would help communities up and down the entire coast by strengthening the warning system, pro-

viding more assistance to local communities like Seaside to prepare for that disaster, coordinating government agencies to make sure they're sharing information and working together, and supporting community outreach and education programs.

This is not just about Oregonians. Millions of people in Alaska, Hawaii, Washington State, California also face significant risk. We are overdue for the really big one.

Now, I understand that the Cures Act may save lives, but I am very disappointed that the provisions of the tsunami bill, which is also lifesaving policy, was not retained in the underlying bill.

Mr. Speaker, again, I urge my colleagues to oppose this rule so we can immediately consider swift passage of the Tsunami Warning, Education, and Research Act. Our West Coast communities are counting on us to keep them safe.

Mr. BURGESS. Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania (Mr. MURPHY), the author of the mental health portion of this bill.

Mr. MURPHY of Pennsylvania. Mr. Speaker, this bill includes in it elements of H.R. 2646, the Helping Families in Mental Health Crisis Act, which is the most revolutionary change to mental health since the Community Mental Health Act of 1963.

It includes fundamental changes in how we think about, talk about, and treat serious mental illness. It establishes an assistant secretary for mental health and substance use to disseminate evidence-based practices, ensure grants meet objective outcome measures, conduct ongoing oversight of grantees, and collaborates with other Federal departments on mental health.

It creates an interagency coordinating committee to evaluate Federal programs related to mental illness and provide recommendations to better coordinate those programs. It authorizes a national mental health and substance use policy laboratory to promote evidence-based models of care and further develop, expand, replicate, or scale those programs. It provides funding for treatment and recovery for homeless individuals with mental health and substance use disorder services.

It authorizes for the first time in law the National Suicide Prevention Lifeline program and the Minority Fellowship Program. It awards grants to develop, maintain, and enhance online psychiatric bed registries.

It funds programs for telehealth so that people in rural communities and primary care physicians can have ready access to mental health services so sorely needed for their patients. It reauthorizes the Garrett Lee Smith Suicide Prevention program, increases funding for assisted outpatient treatment and, for the first time, provides Federal grants for assertive community treatment.

It increases access to medical residencies and fellowships in psychiatry and addiction medicine in underserved, community-based settings for nurse practitioners, physician assistants, health service psychologists, and social workers. It removes barriers for providing volunteering at community health centers.

It updates the National Child Traumatic Stress Initiative, which supports a national network of child trauma centers, including university, hospital, and community-based centers.

It requires the Secretary of HHS to clarify how healthcare providers can communicate with the caregiver of an adult with a mental health or substance use disorder. It clarifies the coverage of eating disorder benefits, including residential treatment under existing mental parity requirements.

It allows Federal grants to local law enforcement to be used for crisis intervention teams to roll back the tragedies of violence that occur when a mentally ill person encounters a policeman. It provides funding to develop school-based mental health crisis intervention teams. And this list goes on.

I am pleased that this has all been merged into one bill here so that we can move forward on this. This truly will provide many lifesaving measures and bring mental health treatment out of the shadows.

I encourage my colleagues to support this bill as we move forward and provide help because where there is help, there is hope.

Mr. POLIS. Mr. Speaker, I just want to note that this rule contains two completely different bills. The first is the 21st Century Cures Act, which would help address many of the health crises that we face. The other bill is H.R. 6392, the Systemic Risk Designation Improvement Act, that would weaken many of the protections that were put in place in the Dodd-Frank Wall Street reform bill. So there are two very different bills here under one rule, a very closed process which the Democrats will be opposing.

Mr. Speaker, I yield 3 minutes to the gentleman from Oregon (Mr. BLUMENAUER).

Mr. BLUMENAUER. Mr. Speaker, it is a pleasure to follow my friend from Pennsylvania, acknowledging his hard work in the mental health sphere. I do think that this is setting the platform for the most significant initiative in the next half century. There are some good things in this bill, but I hope it is just the beginning. I know the gentleman has a number of other initiatives that he is working on in a bipartisan way, and I am hopeful that this Bill serves as a springboard.

On a personal note, the Garrett Smith Suicide Prevention Act, was created by our former colleague, Senator Gordon Smith from Oregon, who took a personal tragedy in his family and moved forward with important legislation that other families may be spared by that effort.

There are a number of things here that matter in another context. In terms of what happens dealing with the opioid crisis that we have now, America has been too slow to respond. I am hopeful that these resources will help us move in the right direction. Again, I must, I suppose, note with a certain amount of irony that there are other alternatives available to deal with the epidemic of opioid overdose deaths.

I would note that it is interesting that States that actually utilize medical marijuana prescribe fewer pills. There is an opportunity here for us to do something that is less expensive, less addictive, and not deadly. But the provisions in this bill, I think, are a step in the right direction.

It also is important to note the investments in neuroscience. We have created a Neuroscience Caucus in Congress because this is an area that has stubbornly resisted being able to have the progress that we have seen in other areas, like cancer and cardiac health, and building on an initiative that the administration has, developed the BRAIN Initiative, which is modest but potentially very significant to accelerate the understanding of the human brain, leading to new ways to treat and cure neurological disorders.

Everybody in this Chamber knows a variety of people who suffer—everything from Alzheimer's, multiple sclerosis, addiction problem—and being able to double down those investments in a more systematic way will pay dividends that are incalculable.

Already, mental and behavioral disorders are among the leading causes of disability around the world. The impact is greater than heart disease and cancer combined. As I mentioned, where we have actually made some progress.

Last but not least, there is a technical fix that matters in my community and others around the country, which is bringing fairness to hospitals. When Congress changed the hospital payment rules last November, there were hospitals like Oregon Health & Science University that were caught unfairly in the middle of payment changes. We did not provide any exceptions for hospital outpatient departments that were under development at that time.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. POLIS. Mr. Speaker, I yield an additional 1 minute to the gentleman from Oregon.

Mr. BLUMENAUER. Mr. Speaker, this means that hospitals like Oregon Health & Science University, who made significant investments in building off-site departments under one set of Medicare rules, suddenly faced a new set of rules that were changed by Congress midstream. I am pleased that this will prevent pulling the rug out from underneath them.

So, in sum, Mr. Speaker, this technical fix, which is important, support for the BRAIN Initiative, the impor-

tant work in mental health, and dealing with the opioid crisis are reasons that I think this bill is worthy of support, although I share the concerns of the gentlewoman from Oregon (Ms. BONAMICI), whose underlying, bipartisan, very important bill somehow is a casualty of this legislation. That is unfortunate.

I hope the rule is defeated so we can fix that and get on with business.

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from Oklahoma (Mr. COLE).

Mr. COLE. Mr. Speaker, I rise for the purpose of supporting the rule and the underlying legislation.

I want to begin by congratulating Chairman UPTON and the members of the Energy and Commerce Committee on both sides of the aisle for crafting what is genuinely a bipartisan piece of legislation in a very divisive era and working it for years and bringing it to a successful conclusion. They have given all of us an opportunity to vote for something really, really important to every single American.

Now, a lot of focus will be put on the money aspect of this bill. Certainly, \$6-plus billion is a nice chunk of change and will be very, very gratefully received. But in that same multiple-year period, in 5 years, if we didn't increase appropriations by a dime, we would spend \$160 billion dollars at NIH. And over a 10-year period, if we didn't increase annual appropriations by a dime, we would spend \$320 billion.

So the real genius of the bill is not the money. It is actually the three things that have been mentioned by multiple speakers before me. First is the regulatory reform that, at the FDA and at the NIH, will literally save billions of dollars and thousands of lives over the next decade.

Second is the opioid initiative. We all know the crisis. It touches all of our districts. To direct money there and then to build on that through the appropriations process is extraordinarily important, and I congratulate the Energy and Commerce Committee for taking a lead here.

Finally, the mental health legislation that is wound up in this that the gentleman from Pennsylvania (Mr. MURPHY) provided is just absolutely spectacular in terms of its long-term importance.

We can all disagree about this or that or some technicality in the rule. The reality is this is important legislation. If it doesn't pass now, it won't pass and we will be missing an opportunity.

So I want to urge my friends on both sides of the aisle—I don't expect my friends to vote for the rule. They shouldn't. They never do. I wouldn't if I were in the minority. But I hope they will vote for the underlying legislation because that legislation is worthy of passage. It is a bipartisan compromise, and it will improve the life of every single American.

Mr. POLIS. Mr. Speaker, there is a lot of bipartisan support for the 21st

Century Cures Act. I commend Chairman UPTON, Ranking Member PALONE, Ranking Member DEGETTE, Ranking Member GREEN, and so many others who worked hard on this legislation that will save lives by improving the access that Americans have to potentially lifesaving drugs and devices, helping to keep people healthy and independent and out of the hospital.

I plan to support this legislation. I think we also all know that it is a starting point. We have additional work to do to make prescription drugs more affordable, to make the approval process more streamlined for both prescription drugs and medical devices, regenerative medicines safe, and, of course, funding levels for research.

Mr. Speaker, I would like to inquire if there are any speakers remaining on the other side?

Mr. BURGESS. Mr. Speaker, I have two additional speakers and myself to close.

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

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from Pennsylvania (Mr. PITTS), the chairman of the Subcommittee on Health that played a vital role in getting the 21st Century Cures bill across the finish line.

Mr. PITTS. Mr. Speaker, I rise in strong support of the rule for the 21st Century Cures Act, a momentous innovation package which will help advance the discovery, development, and delivery of new treatments and cures for patients and will foster private-sector innovation here in the United States.

Additionally, the package includes provisions of H.R. 2646, the Helping Families in Mental Health Crisis Act, as well as provisions to increase choice, access, and quality health care for Americans.

Arriving here today has been a long journey full of lots of steps and twists and turns along the way. I especially want to thank legislative counsel for their tireless efforts in helping translate our legislative aims into legislative language. Together with our health team staff, they worked nights and weekends and were consummate professionals throughout the process.

Additionally, I want to thank the healthcare staff of the Congressional Budget Office for all of their help in recent months. In addition to their role in estimating the budgetary effects of numerous policies in the bill, they were instrumental in helping us shape a number of proposals the committee considered.

I would be remiss if I did not thank again the outstanding team on Energy and Commerce and most especially the health team led by Chief Health Counsel Paul Edattell, supported by Josh Trent, John Stone, Carly McWilliams, J.P. Paluskiewicz, Adrianna Simonelli, Adam Buckalew, Sophie Trainor, and Jay Gulshen; and Heidi Stirrup and

Monica Valenti on my staff, without whose expertise, wisdom, and counsel this legislative work would not be possible.

□ 1300

This landmark medical innovation package includes provisions designed to help almost every American family, whether it is leading to the discovery, development, and delivery of new treatments and cures, or advancing the President's Precision Medicine Initiative or the Vice President's Cancer Moonshot, or the BRAIN Initiative to advance Alzheimer's research. This package is an innovation game changer and will truly bring our health innovation into the 21st century. I urge support for this bipartisan effort.

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

Mr. BURGESS. Mr. Speaker, I yield 2 minutes to the gentleman from Michigan (Mr. WALBERG).

Mr. WALBERG. Mr. Speaker, I stand in support of the rule and the underlying bill. Why? Well, the 21st Century Cures Act is a transformational piece of legislation that will allow us to discover and develop new lifesaving cures and treatments for some of the worst diseases.

This act will offer hope to millions of patients and families, including Gale, a constituent of mine from Newport, who has been affected and afflicted with pancreatic cancer. Or Brandon, a boy from Rives Junction, who has been on a clinical trial for 8 years as he battles Duchenne muscular dystrophy.

In addition to streamlining the FDA approval process and boosting NIH funding, the Cures Act includes significant provisions to update our mental health system and help States fight opioid addiction.

I congratulate my good friend and colleague Chairman FRED UPTON for his vision in tackling this challenge and for his tireless efforts to get this bill to the floor. The Cures Act is innovative; it is bipartisan; it is fully paid for and life changing for my constituents in Michigan and many others around this great country.

I ask my colleagues to vote in support of the rule and the underlying bill.

Mr. POLIS. Is the gentleman prepared to close?

Mr. BURGESS. I am prepared to close.

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

Again, I do want to point out, in breaking with custom, there were many other Democrats who wanted to discuss this bill; but, as we speak, the Democratic Caucus is having elections for the vice chair position. While we were on the floor, we had elections for the whip position and the assistant leader position, both of which I was unable to participate in because, of course, I had to conduct the business of the Nation.

But, again, I would hope that both parties are respectful of the scheduling

requirements that are incumbent upon being a member of one of the two major parties of this body. In the past, we have always been able to work in when Republican Conference has a retreat or a reorganization meeting. I think that is important to this body because, while, of course, as Americans and Representatives we have responsibilities to the institution of Congress, as elected officials of the Democratic or Republican Party, we do have a responsibility to select our leaders and establish our rules.

I don't think that the amount of time that either party spends doing that is unreasonable, but I think that it is very important that both parties and leadership of this body, the Speaker and the majority leader, are respectful of that while, of course, understanding we have important people's business to conduct. There were, of course, many other options. This House could have come to order and gotten this work done at 8 in the morning or they could do it later in the afternoon. There are a number of different ways we could have worked around the previously scheduled reorganization of the Democratic Caucus.

Frankly, I am disappointed not just for myself having been unable to participate in those party functions, but also on behalf of other members of the Democratic Caucus who were unable to come and speak on these very important issues because of playing active roles in running for or supporting or speaking on behalf of various candidates for party positions, which is occurring as I speak.

This bill has two completely unrelated bills that are in it. Again, the 21st Century Cures Act has strong bipartisan support. I add my voice to those who have praised this legislation, and hopefully it will challenge the next Congress to continue to move forward with facilitating the approval process.

I have often heard the approval process, for instance, for a new drug for inception to market can often be in excess of \$1 billion or \$2 billion. We hear a number of different figures tossed around. I think sometimes it is in the high hundreds of millions. Sometimes it is as high as 1.5 or 2 billion. Regardless, that is one of the reasons that there is an upward pressure on prices for proprietary prescription drugs. It is also one of the reasons that lifesaving prescription drugs are often unavailable here even while they are on the market in Europe and other areas. Of course, without compromising safety—and Democrats and Republicans agree on that—there needs to be a way that we can facilitate, particularly in the realm of personalized medicine, bringing new lifesaving products to market in an affordable way.

An excellent model for that that has saved hundreds of thousands of lives was put in place during the first administration of the first George Bush, which provided an expedited route for HIV drugs. Thanks to that route that

was used for many of the HIV drugs, some of which are still in use today, hundreds of thousands of people affected by HIV, including many LGBT Americans, are still alive today because of that effort. I am also confident, because of today's effort with the 21st Century Cures Act, it will save the lives of many more Americans. Again, it is a starting point. We have room to go.

The other bill would, for some reason—it is not something I hear from constituents, but apparently it is something Republicans want to do—exempt some of the very biggest banks from some of the requirements under Dodd-Frank regarding ensuring their stability and preventing them from failing. It is my understanding it only affects a few dozen banks, the very largest banks, banks that are worth tens or hundreds of billions of dollars. I am sure they like it. It probably reduces their ability to have to comply.

But there is a reason those requirements were put in place for those very big banks. We are worried that the failure of any one or certainly multiple banks could create a systemic risk and lead to future bailouts. So I strongly believe that this bill before us today on the banking regulations, if it were to become the law, it would increase the likelihood of future bailouts, which surprises me because many of us have been traditionally opposed to those very kinds of bailouts.

It is my understanding there is one remaining speaker on the other side, so I reserve the balance of my time to allow that speaker to speak.

Mr. BURGESS. Mr. Speaker, I thank the gentleman for the accommodation. I am pleased to yield 2 minutes to the gentleman from Oregon (Mr. WALDEN).

Mr. WALDEN. Mr. Speaker, I want to thank my colleagues on both sides of the aisle and especially for the courtesy to spend a minute or two talking about not only this rule, but also the legislation that will be coming to the floor soon. I want to thank especially Chairman FRED UPTON, who has put his whole heart and soul into the 21st Century Cures Act, joined by DIANA DEGETTE, certainly Dr. BURGESS, Congressman MURPHY, and others who have really played a key role in trying to find cures to diseases that don't exist today, find treatments for those in order to bring better health to all Americans, both physical health and, certainly in the case of Dr. Murphy, mental health as well.

This really means a lot. This will make a difference in real people's lives back home in our communities. I have heard from those people, like Carol Fulkerson in Bend, who has MS. She is ecstatic about this. She said it is a great step toward making it possible to find a cure to MS. Can you imagine what that means in a person's life?

There are critical reforms and improvements on mental health and substance abuse programs, as we have heard. These changes will help people

all across America, and certainly in Oregon. A Medford resident, Justin, overcame his own battle with addiction through a dual diagnosis treatment program that dealt with the underlying issues fueling addiction instead of just sort of a Band-Aid approach to his symptoms. These are the kinds of ideas coming from our folks back home that are now incorporated in legislation.

I heard from a clinical lab owner in rural Oregon, Judy Kennedy, who voiced her support for the provisions in Cures that provide precise diagnostic testing services to rural and other underserved communities across the country. We are going to do so much to improve the health, both mental and physical, in the lives of people we represent when this legislation becomes law.

Mr. Speaker, I am just delighted to support this bill. I think it is an enormous step forward in so many ways, and I commend Chairman UPTON and all those who have been involved in this in its writing. I urge passage of the rule so we can get on to this legislation.

Mr. POLIS. Is the gentleman prepared to close?

Mr. BURGESS. Once again.

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

So, again, I think there is some good and some bad in this. The 21st Century Cures Act is very important, and I hope that this body sees it as a starting point, not an ending point. There are some important reforms in there that will save lives and also help remove some of the upward pressure on prescription drug prices, something we hear about very often from constituents.

There is another bill in there which most Democrats will be voting against with regard to making it potentially more likely that larger banks can fail us or need bailouts, and that is not something that most of us have an appetite for. Of course, the closed nature of the bill is not consistent with the expressed desire of the Speaker to have an open process. The Committee on Rules yesterday shut down a number of excellent ideas and amendments that were offered, and they are not allowed to be debated here on the floor.

Of course the timing of this bill, particularly for a bipartisan bill, to bring it up in a way, in a manner and a time that conflicts with the previously noticed meeting that happens to include all of the members of one of the two political parties is not the best way to foster the type of bipartisan cooperation that is important to get things done around here.

So Democrats will not be supporting the rule. Many of us will, thanks to the work of Chairman UPTON, Ranking Member PALLONE, Ranking Member DEGETTE, Ranking Member GENE GREEN, and others, be proud to hopefully send to the President's desk the 21st Century Cures Act as an excellent starting point in helping to save lives.

I urge a "no" vote on the rule.

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

Mr. BURGESS. I yield myself the balance of my time.

Mr. Speaker, today's rule provides for the consideration of two important bills: a bill that will transform and advance the discovery, the development, the delivery of treatments and cures; and a bill that will help our small and community banks, institutions that, in turn, can further assist small and local businesses and help our communities grow.

I want to thank all of the Members who did put a lot of effort into the final package on the Cures bill, as well as the staff on both sides of the aisle, all members of the Committee on Energy and Commerce, and the House as a whole, who were asked to bring their ideas to the table, and we worked to include as many of those as we could.

I would also like to express my thanks to the great attorneys at the Legislative Counsel who sometimes worked around the clock to get this bill ready for both the committee and floor activity. I want to thank Chairman UPTON, Representative DEGETTE, as well as Chairman PITTS and Ranking Member PALLONE and Ranking Member GENE GREEN for their leadership throughout.

It has already been mentioned, but I also want to thank the staff, both in our personal offices and at the committee staff, who have worked so hard on this over the past 4 years. This was truly all hands on deck. There is not one staffer on the Subcommittee on Health of the Committee on Energy and Commerce who does not have their fingerprints all over this bill.

Mr. Speaker, I yield back the balance of my time, and I move the previous question on the resolution.

The previous question was ordered.

The SPEAKER pro tempore. The question is on the resolution.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. POLIS. 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, this 15-minute vote on adopting House Resolution 934 will be followed by a 5-minute vote on suspending the rules and passing H.R. 5047.

The vote was taken by electronic device, and there were—yeas 230, nays 180, not voting 24, as follows:

[Roll No. 590]

YEAS—230

Abraham	Bishop (UT)	Buchanan
Aderholt	Black	Buck
Allen	Blackburn	Bucshon
Amash	Blum	Burgess
Amodei	Bost	Byrne
Babin	Boustany	Calvert
Barr	Brady (TX)	Carter (GA)
Barton	Brat	Carter (TX)
Benishek	Bridenstine	Chabot
Bilirakis	Brooks (AL)	Chaffetz
Bishop (MI)	Brooks (IN)	Coffman

Cole	Issa	Reed	Kind	Neal	Scott, David	Boyle, Brendan	Foster	LoBiondo
Collins (GA)	Jenkins (KS)	Reichert	Kuster	Nolan	Serrano	F.	Fox	Loeb
Collins (NY)	Jenkins (WV)	Ribble	Langevin	Norcross	Sewell (AL)	Brady (PA)	Frankel (FL)	Loftgren
Comer	Johnson (OH)	Rice (SC)	Larsen (WA)	O'Rourke	Sherman	Brady (TX)	Franks (AZ)	Long
Comstock	Johnson, Sam	Rigell	Larson (CT)	Pallone	Sires	Brat	Frelinghuysen	Loudermilk
Conaway	Jordan	Roby	Lawrence	Pascrell	Slaughter	Bridenstine	Fudge	Love
Cook	Joyce	Roe (TN)	Lee	Payne	Smith (WA)	Gabbard	Gabbard	Lowenthal
Costello (PA)	Katko	Rogers (AL)	Levin	Pelosi	Speier	Brooks (IN)	Gallego	Lowey
Cramer	Kelly (MS)	Rogers (KY)	Lewis	Perlmutter	Swalwell (CA)	Brownley (CA)	Garamendi	Lucas
Crawford	Kelly (PA)	Rohrabacher	Lieu, Ted	Peters	Takano	Buchanan	Garrett	Luetkemeyer
Culberson	King (IA)	Rokita	Lipinski	Peterson	Thompson (CA)	Buck	Gibbs	Lujan Grisham
Curbelo (FL)	King (NY)	Rooney (FL)	Loeb	Pingree	Thompson (MS)	Bucshon	Gibson	(NM)
Davidson	Kinzing (IL)	Ros-Lehtinen	Lofgren	Pocan	Titus	Burgess	Gohmert	Lujan, Ben Ray
Davis, Rodney	Kline	Roskam	Lowenthal	Polis	Tonko	Bustos	Goodlatte	(NM)
Denham	Knight	Ross	Lowey	Price (NC)	Torres	Butterfield	Gosar	Lummis
Dent	Labrador	Rothfus	Lujan Grisham	Quigley	Tsongas	Byrne	Gowdy	Lynch
DeSantis	LaHood	Rouzer	(NM)	Rangel	Van Hollen	Calvert	Graham	MacArthur
DesJarlais	LaMalfa	Royce	Lujan, Ben Ray	Rice (NY)	Vargas	Capps	Granger	Maloney,
Diaz-Balart	Lamborn	Russell	(NM)	Richmond	Veasey	Capuano	Graves (GA)	Carolyn
Dold	Lance	Salmon	Lynch	Roybal-Allard	Ruiz	Cárdenas	Graves (LA)	Maloney, Sean
Donovan	Latta	Sanford	Maloney,	Ruiz	Velazquez	Carney	Graves (MO)	Marchant
Duffy	LoBiondo	Scalise	Carolyn	Ruppersberger	Walz	Carson (IN)	Grayson	Marino
Duncan (SC)	Long	Schweikert	Maloney, Sean	Rush	Wasserman	Carter (GA)	Green, Al	Massie
Duncan (TN)	Loudermilk	Scott, Austin	Matsui	Ryan (OH)	Schultz	Carter (TX)	Green, Gene	Matsui
Emmer (MN)	Lucas	Sensenbrenner	McCollum	Sánchez, Linda	Sanchez, Loretta	Cartwright	Griffith	McCarthy
Farenthold	Luetkemeyer	Sessions	McGovern	T.	Sarbanes	Castor (FL)	Grijalva	McClintock
Fitzpatrick	Lummis	Shimkus	McNeerney	Waters, Maxine	Schakowsky	Castro (TX)	Grothman	McCollum
Fleischmann	MacArthur	Simpson	Meeks	Watson Coleman	Schiff	Chabot	Guinta	McGovern
Fleming	Marchant	Sinema	Meng	Welch	Schradler	Chaffetz	Guthrie	McHenry
Flores	Marino	Smith (MO)	Moulton	Wilson (FL)	Scott (VA)	Chu, Judy	Gutiérrez	McKinley
Forbes	Massie	Smith (NE)	Nadler	Yarmuth		Cicilline	Hanabusa	McMorris
Fortenberry	McCarthy	Smith (NJ)	Napolitano			Clark (MA)	Hanna	Rodgers
Fox	McClintock	Smith (TX)				Clarke (NY)	Hardy	McNeerney
Franks (AZ)	McHenry	Stefanik				Clay	Harper	McSally
Frelinghuysen	McKinley	Stewart	Barletta	Hensarling	Moore	Cleaver	Harris	Meadows
Garrett	McMorris	Stivers	Brown (FL)	Hurt (VA)	Murphy (FL)	Clyburn	Hartzler	Meehan
Gibbs	Rodgers	Stutzman	Clawson (FL)	Jolly	Nugent	Coffman	Hastings	Meeks
Gibson	McSally	Thompson (PA)	Crenshaw	Jones	Poe (TX)	Cohen	Heck (NV)	Meng
Gohmert	Meadows	Thornberry	Ellmers (NC)	Kirkpatrick	Renacci	Cole	Heck (WA)	Messer
Goodlatte	Meehan	Tiberi	Farr	Love	Shuster	Collins (GA)	Hensarling	Mica
Gosar	Messer	Tipton	Fincher	McCauley	Westmoreland	Collins (NY)	Herrera Beutler	Miller (FL)
Gowdy	Mica	Trott	Hahn	McDermott	Williams	Comer	Hice, Jody B.	Miller (MI)
Granger	Miller (FL)	Turner				Comstock	Higgins	Moolenaar
Graves (GA)	Miller (MI)	Upton				Conaway	Hill	Mooney (WV)
Graves (LA)	Moolenaar	Valadao				Connolly	Himes	Moore
Graves (MO)	Mooney (WV)	Wagner				Conyers	Hinojosa	Moulton
Griffith	Mullin	Walberg				Cook	Holding	Mullin
Grothman	Mulvaney	Walden				Cooper	Honda	Mulvaney
Guinta	Murphy (PA)	Walker				Costa	Hoyer	Murphy (FL)
Guthrie	Neugebauer	Walorski				Costello (PA)	Hudson	Murphy (PA)
Hanna	Newhouse	Walters, Mimi				Courtney	Huelskamp	Nadler
Hardy	Noem	Weber (TX)				Cramer	Huffman	Napolitano
Harper	Nunes	Webster (FL)				Crawford	Huizenga (MI)	Neal
Harris	Olson	Wenstrup				Crowley	Hultgren	Neugebauer
Hartzler	Palazzo	Westerman				Cuellar	Hunter	Newhouse
Heck (NV)	Palmer	Wilson (SC)				Culberson	Hurd (TX)	Noem
Herrera Beutler	Paulsen	Wittman				Cummings	Israel	Norcross
Hice, Jody B.	Pearce	Womack				Curbelo (FL)	Issa	Nunes
Hill	Perry	Woodall				Davidson	Jackson Lee	O'Rourke
Holding	Pittenger	Yoder				Davis (CA)	Jeffries	Olson
Hudson	Pitts	Yoho				Davis, Danny	Jenkins (KS)	Palazzo
Huelskamp	Poliquin	Young (AK)				Davis, Rodney	Jenkins (WV)	Pallone
Huizenga (MI)	Pompeo	Young (IA)				DeFazio	Johnson (GA)	Palmer
Hultgren	Posey	Young (IN)				DeGette	Johnson (OH)	Pascrell
Hunter	Price, Tom	Zeldin				Delaney	Johnson, E. B.	Paulsen
Hurd (TX)	Ratcliffe	Zinke				DeLauro	Johnson, Sam	Payne

NAYS—180

Adams	Clyburn	Frankel (FL)
Aguilar	Cohen	Fudge
Ashford	Connolly	Gabbard
Bass	Conyers	Gallego
Beatty	Cooper	Garamendi
Becerra	Costa	Graham
Bera	Courtney	Grayson
Beyer	Crowley	Green, Al
Bishop (GA)	Cuellar	Green, Gene
Blumenauer	Cummings	Grijalva
Bonamici	Davis (CA)	Gutiérrez
Boyle, Brendan	Davis, Danny	Hanabusa
F.	DeFazio	Hastings
Brady (PA)	DeGette	Heck (WA)
Brownley (CA)	Delaney	Higgins
Bustos	DeLauro	Himes
Butterfield	DelBene	Hinojosa
Capps	DeSaulnier	Honda
Capuano	Deutch	Hoyer
Cárdenas	Dingell	Huffman
Carney	Doggett	Israel
Carson (IN)	Doyle, Michael	Jackson Lee
Cartwright	F.	Jeffries
Castor (FL)	Duckworth	Johnson (GA)
Castro (TX)	Edwards	Johnson, E. B.
Chu, Judy	Ellison	Kaptur
Cicilline	Engel	Keating
Clark (MA)	Eshoo	Kelly (IL)
Clarke (NY)	Esty	Kennedy
Clay	Evans	Kildee
Cleaver	Foster	Kilmer

NOT VOTING—24

Brown (FL)	Hensarling
Clawson (FL)	Hurt (VA)
Crenshaw	Jolly
Ellmers (NC)	Jones
Farr	Kirkpatrick
Fincher	Love
Hahn	McCauley
	McDermott

□ 1333

Mr. HONDA changed his vote from "yea" to "nay."

So the resolution was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

PROTECTING VETERANS' EDUCATIONAL CHOICE ACT OF 2016

The SPEAKER pro tempore (Mr. HULTGREN). The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 5047) to direct the Secretary of Veterans Affairs and the Secretary of Labor to provide information to veterans and members of the Armed Forces about articulation agreements between institutions of higher learning, and for other purposes, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Florida (Mr. MILLER) that the House suspend the rules and pass the bill.

This is a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 411, nays 3, not voting 20, as follows:

[Roll No. 591]

YEAS—411

Abraham	Barr	Bishop (MI)
Adams	Barton	Bishop (UT)
Aderholt	Beatty	Black
Aguilar	Becerra	Blackburn
Allen	Benishek	Blum
Amash	Bera	Blumenauer
Amodei	Beyer	Bonamici
Ashford	Bilirakis	Bost
Babin	Bishop (GA)	Boustany

Roskam	Simpson	Velázquez
Ross	Sinema	Visclosky
Rothfus	Sires	Wagner
Rouzer	Slaughter	Walberg
Roybal-Allard	Smith (MO)	Walden
Royce	Smith (NE)	Walker
Ruiz	Smith (NJ)	Walorski
Ruppersberger	Smith (TX)	Walters, Mimi
Rush	Speler	Walz
Russell	Stefanik	Wasserman
Ryan (OH)	Stewart	Schultz
Salmon	Stivers	Waters, Maxine
Sánchez, Linda T.	Stutzman	Watson Coleman
Sánchez, Loretta	Swalwell (CA)	Weber (TX)
Sanford	Takano	Webster (FL)
Sarbanes	Thompson (CA)	Welch
Scalise	Thompson (MS)	Wenstrup
Schakowsky	Thompson (PA)	Westerman
Schiff	Thornberry	Wilson (FL)
Schrader	Tiberi	Wilson (SC)
Schweikert	Tipton	Wittman
Scott (VA)	Titus	Womack
Scott, Austin	Tonko	Woodall
Scott, David	Torres	Yarmuth
Sensenbrenner	Trott	Yoder
Serrano	Tsongas	Yoho
Sessions	Turner	Young (AK)
Sewell (AL)	Upton	Young (IA)
Sherman	Valadao	Young (IN)
Shimkus	Vargas	Zeldin
Shuster	Veasey	Zinke
	Vela	

NAYS—3

Bass	Perlmutter	Smith (WA)
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NOT VOTING—20

Barletta	Hurt (VA)	Nugent
Brown (FL)	Jolly	Poe (TX)
Clawson (FL)	Jones	Renacci
Crenshaw	Kirkpatrick	Van Hollen
Farr	McCaul	Westmoreland
Fincher	McDermott	Williams
Hahn	Nolan	

□ 1340

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

PERSONAL EXPLANATION

Mr. RENACCI. Mr. Speaker, I was unavoidably detained on rollcalls 590 and 591. Had I been present, I would have voted "yea" on rollcall No. 590 and "yea" on rollcall No. 591.

PERMISSION TO POSTPONE PROCEEDINGS ON MOTION TO CONCUR ON SENATE AMENDMENT TO H.R. 34, TSUNAMI WARNING, EDUCATION, AND RESEARCH ACT OF 2015

Mr. UPTON. Mr. Speaker, I ask unanimous consent that the question of adopting a motion to concur in the Senate amendment to H.R. 34 with an amendment may be subject to postponement as though under clause 8 of rule XX.

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

There was no objection.

TSUNAMI WARNING, EDUCATION, AND RESEARCH ACT OF 2015

Mr. UPTON. Mr. Speaker, pursuant to House Resolution 934, I call up the bill (H.R. 34) to authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and At-

mospheric Administration, and for other purposes, with the Senate amendment thereto, and ask for its immediate consideration.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The Clerk will designate the Senate amendment.

Senate amendment:

In lieu of the matter proposed to be inserted, add the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Tsunami Warning, Education, and Research Act of 2015".

SEC. 2. REFERENCES TO THE TSUNAMI WARNING AND EDUCATION ACT.

Except as otherwise expressly provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Tsunami Warning and Education Act (Public Law 109-424; 33 U.S.C. 3201 et seq.).

SEC. 3. EXPANSION OF PURPOSES OF TSUNAMI WARNING AND EDUCATION ACT.

Section 3 (33 U.S.C. 3202) is amended—

(1) in paragraph (1), by inserting "research," after "warnings,";

(2) by amending paragraph (2) to read as follows:

"(2) to enhance and modernize the existing United States Tsunami Warning System to increase the accuracy of forecasts and warnings, to ensure full coverage of tsunami threats to the United States with a network of detection assets, and to reduce false alarms;"

(3) by amending paragraph (3) to read as follows:

"(3) to improve and develop standards and guidelines for mapping, modeling, and assessment efforts to improve tsunami detection, forecasting, warnings, notification, mitigation, resiliency, response, outreach, and recovery;"

(4) by redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (8), respectively;

(5) by inserting after paragraph (3) the following:

"(4) to improve research efforts related to improving tsunami detection, forecasting, warnings, notification, mitigation, resiliency, response, outreach, and recovery;"

(6) in paragraph (5), as redesignated—

(A) by striking "and increase" and inserting "increase, and develop uniform standards and guidelines for"; and

(B) by inserting "including the warning signs of locally generated tsunami" after "approaching";

(7) in paragraph (6), as redesignated, by striking "including the Indian Ocean; and" and inserting a semicolon; and

(8) by inserting after paragraph (6), as redesignated, the following:

"(7) to foster resilient communities in the face of tsunami and other similar coastal hazards; and"

SEC. 4. MODIFICATION OF TSUNAMI FORECASTING AND WARNING PROGRAM.

(a) IN GENERAL.—Subsection (a) of section 4 (33 U.S.C. 3203(a)) is amended by striking "Atlantic Ocean, Caribbean Sea, and Gulf of Mexico region" and inserting "Atlantic Ocean region, including the Caribbean Sea and the Gulf of Mexico".

(b) COMPONENTS.—Subsection (b) of section 4 (33 U.S.C. 3203(b)) is amended—

(1) in paragraph (1), by striking "established" and inserting "supported or maintained";

(2) by redesignating paragraphs (7) through (9) as paragraphs (8) through (10), respectively;

(3) by redesignating paragraphs (2) through (6) as paragraphs (3) through (7), respectively;

(4) by inserting after paragraph (1) the following:

"(2) to the degree practicable, maintain not less than 80 percent of the Deep-ocean Assessment and Reporting of Tsunamis buoy array at operational capacity to optimize data reliability;"

(5) by amending paragraph (5), as redesignated by paragraph (3), to read as follows:

"(5) provide tsunami forecasting capability based on models and measurements, including tsunami inundation models and maps for use in increasing the preparedness of communities and safeguarding port and harbor operations, that incorporate inputs, including—

"(A) the United States and global ocean and coastal observing system;

"(B) the global Earth observing system;

"(C) the global seismic network;

"(D) the Advanced National Seismic system;

"(E) tsunami model validation using historical and paleotsunami data;

"(F) digital elevation models and bathymetry;

"(G) newly developing tsunami detection methodologies using satellites and airborne remote sensing; and

"(H) any other data the Administrator determines is necessary;"

(6) by amending paragraph (7), as redesignated by paragraph (3), to read as follows:

"(7) include a cooperative effort among the Administration, the United States Geological Survey, and the National Science Foundation under which the Director of the United States Geological Survey and the Director of the National Science Foundation shall—

"(A) provide rapid and reliable seismic information to the Administrator from international and domestic seismic networks; and

"(B) support seismic stations installed before the date of the enactment of the Tsunami Warning, Education, and Research Act of 2015 to supplement coverage in areas of sparse instrumentation;"

(7) in paragraph (8), as redesignated by paragraph (2)—

(A) by inserting "including graphical warning products," after "warnings";

(B) by inserting "territories," after "States"; and

(C) by inserting "and Wireless Emergency Alerts" after "Hazards Program"; and

(8) in paragraph (9), as redesignated by paragraph (2)—

(A) by inserting "provide and" before "allow"; and

(B) by inserting "and commercial and Federal undersea communications cables" after "observing technologies".

(c) TSUNAMI WARNING SYSTEM.—Subsection (c) of section 4 (33 U.S.C. 3203(c)) is amended to read as follows:

"(c) TSUNAMI WARNING SYSTEM.—The program under this section shall operate a tsunami warning system that—

"(1) is capable of forecasting tsunami, including forecasting tsunami arrival time and inundation estimates, anywhere in the Pacific and Arctic Ocean regions and providing adequate warnings;

"(2) is capable of forecasting and providing adequate warnings, including tsunami arrival time and inundation models where applicable, in areas of the Atlantic Ocean, including the Caribbean Sea and Gulf of Mexico, that are determined—

"(A) to be geologically active, or to have significant potential for geological activity; and

"(B) to pose significant risks of tsunami for States along the coastal areas of the Atlantic Ocean, Caribbean Sea, or Gulf of Mexico; and

"(3) supports other international tsunami forecasting and warning efforts."

(d) TSUNAMI WARNING CENTERS.—Subsection (d) of section 4 (33 U.S.C. 3203(d)) is amended to read as follows:

"(d) TSUNAMI WARNING CENTERS.—

"(1) IN GENERAL.—The Administrator shall support or maintain centers to support the tsunami warning system required by subsection (c). The Centers shall include—

“(A) the National Tsunami Warning Center, located in Alaska, which is primarily responsible for Alaska and the continental United States;

“(B) the Pacific Tsunami Warning Center, located in Hawaii, which is primarily responsible for Hawaii, the Caribbean, and other areas of the Pacific not covered by the National Center; and

“(C) any additional forecast and warning centers determined by the National Weather Service to be necessary.

“(2) RESPONSIBILITIES.—The responsibilities of the centers supported or maintained under paragraph (1) shall include the following:

“(A) Continuously monitoring data from seismological, deep ocean, coastal sea level, and tidal monitoring stations and other data sources as may be developed and deployed.

“(B) Evaluating earthquakes, landslides, and volcanic eruptions that have the potential to generate tsunami.

“(C) Evaluating deep ocean buoy data and tidal monitoring stations for indications of tsunamis resulting from earthquakes and other sources.

“(D) To the extent practicable, utilizing a range of models, including ensemble models, to predict tsunami, including arrival times, flooding estimates, coastal and harbor currents, and duration.

“(E) Using data from the Integrated Ocean Observing System of the Administration in coordination with regional associations to calculate new inundation estimates and periodically update existing inundation estimates.

“(F) Disseminating forecasts and tsunami warning bulletins to Federal, State, tribal, and local government officials and the public.

“(G) Coordinating with the tsunami hazard mitigation program conducted under section 5 to ensure ongoing sharing of information between forecasters and emergency management officials.

“(H) In coordination with the Coast Guard, evaluating and recommending procedures for ports and harbors at risk of tsunami inundation, including review of readiness, response, and communication strategies, and data sharing policies.

“(I) Making data gathered under this Act and post-warning analyses conducted by the National Weather Service or other relevant Administration offices available to the public.

“(J) Integrating and modernizing the program operated under this section with advances in tsunami science to improve performance without compromising service.

“(3) FAIL-SAFE WARNING CAPABILITY.—The tsunami warning centers supported or maintained under paragraph (1) shall maintain a fail-safe warning capability and perform back-up duties for each other.

“(4) COORDINATION WITH NATIONAL WEATHER SERVICE.—The Administrator shall coordinate with the forecast offices of the National Weather Service, the centers supported or maintained under paragraph (1), and such program offices of the Administration as the Administrator or the coordinating committee, as established in section 5(d), consider appropriate to ensure that regional and local forecast offices—

“(A) have the technical knowledge and capability to disseminate tsunami warnings for the communities they serve;

“(B) leverage connections with local emergency management officials for optimally disseminating tsunami warnings and forecasts; and

“(C) implement mass communication tools in effect on the day before the date of the enactment of the Tsunami Warning, Education, and Research Act of 2015 used by the National Weather Service on such date and newer mass communication technologies as they are developed as a part of the Weather-Ready Nation program of the Administration, or otherwise, for the purpose of timely and effective delivery of tsunami warnings.

“(5) UNIFORM OPERATING PROCEDURES.—The Administrator shall—

“(A) develop uniform operational procedures for the centers supported or maintained under paragraph (1), including the use of software applications, checklists, decision support tools, and tsunami warning products that have been standardized across the program supported under this section;

“(B) ensure that processes and products of the warning system operated under subsection (c)—

“(i) reflect industry best practices when practicable;

“(ii) conform to the maximum extent practicable with internationally recognized standards for information technology; and

“(iii) conform to the maximum extent practicable with other warning products and practices of the National Weather Service;

“(C) ensure that future adjustments to operational protocols, processes, and warning products—

“(i) are made consistently across the warning system operated under subsection (c); and

“(ii) are applied in a uniform manner across such warning system;

“(D) establish a systematic method for information technology product development to improve long-term technology planning efforts; and

“(E) disseminate guidelines and metrics for evaluating and improving tsunami forecast models.

“(6) AVAILABLE RESOURCES.—The Administrator, through the National Weather Service, shall ensure that resources are available to fulfill the obligations of this Act. This includes ensuring supercomputing resources are available to run, as rapidly as possible, such computer models as are needed for purposes of the tsunami warning system operated under subsection (c).”

(e) TRANSFER OF TECHNOLOGY; MAINTENANCE AND UPGRADES.—Subsection (e) of section 4 (33 U.S.C. 3203(e)) is amended to read as follows:

“(e) TRANSFER OF TECHNOLOGY; MAINTENANCE AND UPGRADES.—In carrying out this section, the Administrator shall—

“(1) develop requirements for the equipment used to forecast tsunami, including—

“(A) provisions for multipurpose detection platforms;

“(B) reliability and performance metrics; and

“(C) to the maximum extent practicable, requirements for the integration of equipment with other United States and global ocean and coastal observation systems, the global Earth observing system of systems, the global seismic networks, and the Advanced National Seismic System;

“(2) develop and execute a plan for the transfer of technology from ongoing research conducted as part of the program supported or maintained under section 6 into the program under this section; and

“(3) ensure that the Administration’s operational tsunami detection equipment is properly maintained.”

(f) FEDERAL COOPERATION.—Subsection (f) of section 4 (33 U.S.C. 3203(f)) is amended to read as follows:

“(f) FEDERAL COOPERATION.—When deploying and maintaining tsunami detection technologies under the program under this section, the Administrator shall—

“(1) identify which assets of other Federal agencies are necessary to support such program; and

“(2) work with each agency identified under paragraph (1)—

“(A) to acquire the agency’s assistance; and

“(B) to prioritize the necessary assets in support of the tsunami forecast and warning program.”

(g) UNNECESSARY PROVISIONS.—Section 4 (33 U.S.C. 3203) is further amended—

(1) by striking subsection (g);

(2) by striking subsections (i) through (k); and

(3) by redesignating subsection (h) as subsection (g).

(h) CONGRESSIONAL NOTIFICATIONS.—Subsection (g) of section 4 (33 U.S.C. 3203(g)), as redesignated by subsection (g)(3), is amended—

(1) in the matter before paragraph (1), by striking “30” and inserting “90”;

(2) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and moving such subparagraphs 2 ems to the right;

(3) in the matter before subparagraph (A), as redesignated by paragraph (2), by striking “The Administrator” and inserting the following:

“(1) IN GENERAL.—The Administrator”;

(4) in paragraph (1), as redesignated by paragraph (3)—

(A) in subparagraph (A), as redesignated by paragraph (2), by striking “and” at the end;

(B) in subparagraph (B), as redesignated by paragraph (2), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following:

“(C) the occurrence of a significant tsunami warning.”; and

(5) by adding at the end the following:

“(2) CONTENTS.—In a case in which notice is submitted under paragraph (1) within 90 days of a significant tsunami warning described in subparagraph (C) of such paragraph, such notice shall include, as appropriate, brief information and analysis of—

“(A) the accuracy of the tsunami model used;

“(B) the specific deep ocean or other monitoring equipment that detected the incident, as well as the deep ocean or other monitoring equipment that did not detect the incident due to malfunction or other reasons;

“(C) the effectiveness of the warning communication, including the dissemination of warnings with State, territory, local, and tribal partners in the affected area under the jurisdiction of the National Weather Service; and

“(D) such other findings as the Administrator considers appropriate.”

SEC. 5. MODIFICATION OF NATIONAL TSUNAMI HAZARD MITIGATION PROGRAM.

(a) IN GENERAL.—Section 5 (33 U.S.C. 3204) is amended by striking subsections (a) through (d) and inserting the following:

“(a) PROGRAM REQUIRED.—The Administrator, in coordination with the Administrator of the Federal Emergency Management Agency and the heads of such other agencies as the Administrator considers relevant, shall conduct a community-based tsunami hazard mitigation program to improve tsunami preparedness and resiliency of at-risk areas in the United States and the territories of the United States.

“(b) PROGRAM COMPONENTS.—The Program conducted under subsection (a) shall include the following:

“(1) Technical and financial assistance to coastal States, territories, tribes, and local governments to develop and implement activities under this section.

“(2) Integration of tsunami preparedness and mitigation programs into ongoing State-based hazard warning, resilience planning, and risk management activities, including predisaster planning, emergency response, evacuation planning, disaster recovery, hazard mitigation, and community development and redevelopment planning programs in affected areas.

“(3) Activities to promote the adoption of tsunami resilience, preparedness, warning, and mitigation measures by Federal, State, territorial, tribal, and local governments and non-governmental entities, including educational and risk communication programs to discourage development in high-risk areas.

“(4) Activities to support the development of regional tsunami hazard and risk assessments. Such regional risk assessments may include the following:

“(A) The sources, sizes, and other relevant historical data of tsunami in the region, including paleotsunami data.

“(B) Inundation models and maps of critical infrastructure and socioeconomic vulnerability in areas subject to tsunami inundation.

“(C) Maps of evacuation areas and evacuation routes, including, when appropriate, traffic studies that evaluate the viability of evacuation routes.

“(D) Evaluations of the size of populations that will require evacuation, including populations with special evacuation needs.

“(E) Evaluations and technical assistance for vertical evacuation structure planning for communities where models indicate limited or no ability for timely evacuation, especially in areas at risk of near shore generated tsunami.

“(F) Evaluation of at-risk ports and harbors.

“(G) Evaluation of the effect of tsunami currents on the foundations of closely-spaced, coastal high-rise structures.

“(5) Activities to promote preparedness in at-risk ports and harbors, including the following:

“(A) Evaluation and recommendation of procedures for ports and harbors in the event of a distant or near-field tsunami.

“(B) A review of readiness, response, and communication strategies to ensure coordination and data sharing with the Coast Guard.

“(6) Activities to support the development of community-based outreach and education programs to ensure community readiness and resilience, including the following:

“(A) The development, implementation, and assessment of technical training and public education programs, including education programs that address unique characteristics of distant and near-field tsunami.

“(B) The development of decision support tools.

“(C) The incorporation of social science research into community readiness and resilience efforts.

“(D) The development of evidence-based education guidelines.

“(7) Dissemination of guidelines and standards for community planning, education, and training products, programs, and tools, including—

“(A) standards for—

“(i) mapping products;

“(ii) inundation models; and

“(iii) effective emergency exercises; and

“(B) recommended guidance for at-risk port and harbor tsunami warning, evacuation, and response procedures in coordination with the Coast Guard.

“(c) AUTHORIZED ACTIVITIES.—In addition to activities conducted under subsection (b), the program conducted under subsection (a) may include the following:

“(1) Multidisciplinary vulnerability assessment research, education, and training to help integrate risk management and resilience objectives with community development planning and policies.

“(2) Risk management training for local officials and community organizations to enhance understanding and preparedness.

“(3) Interagency, Federal, State, tribal, and territorial intergovernmental tsunami response exercise planning and implementation in high risk areas.

“(4) Development of practical applications for existing or emerging technologies, such as modeling, remote sensing, geospatial technology, engineering, and observing systems, including the integration of tsunami sensors into Federal and commercial submarine telecommunication cables if practicable.

“(5) Risk management, risk assessment, and resilience data and information services, including—

“(A) access to data and products derived from observing and detection systems; and

“(B) development and maintenance of new integrated data products to support risk management, risk assessment, and resilience programs.

“(6) Risk notification systems that coordinate with and build upon existing systems and actively engage decisionmakers, State, local, tribal, and territorial governments and agencies, business communities, nongovernmental organizations, and the media.

“(d) COORDINATING COMMITTEE.—

“(1) IN GENERAL.—The Administrator shall maintain a coordinating committee to assist the Administrator in the conduct of the program required by subsection (a).

“(2) COMPOSITION.—The coordinating committee shall be composed of members as follows:

“(A) Representatives from each of the States and territories most at risk from tsunami, including Alaska, Washington, Oregon, California, Hawaii, Puerto Rico, Guam, American Samoa, and the Northern Marianas Islands.

“(B) Such other members as the Administrator considers appropriate to represent Federal, State, tribal, territorial, and local governments.

“(3) SUBCOMMITTEES.—The Administrator may approve the formation of subcommittees to address specific program components or regional issues.

“(4) RESPONSIBILITIES.—The coordinating committee shall—

“(A) provide feedback on how funds should be prioritized to carry out the program required by subsection (a);

“(B) ensure that areas described in section 4(c) in the United States and its territories have the opportunity to participate in the program;

“(C) provide recommendations to the Administrator on how to improve and continuously advance the TsunamiReady program of the National Weather Service, particularly on ways to make communities more tsunami resilient through the use of inundation maps and models and other hazard mitigation practices;

“(D) ensure that all components of the program required by subsection (a) are integrated with ongoing State based hazard warning, risk management, and resilience activities, including—

“(i) integrating activities with emergency response plans, disaster recovery, hazard mitigation, and community development programs in affected areas; and

“(ii) integrating information to assist in tsunami evacuation route planning.

“(5) EXEMPTION FROM FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the committee established and maintained under paragraph (1).

“(e) NO PREEMPTION WITH RESPECT TO DESIGNATION OF AT-RISK AREAS.—The establishment of national standards for inundation models under this section shall not prevent States, territories, tribes, and local governments from designating additional areas as being at risk based on knowledge of local conditions.

“(f) NO NEW REGULATORY AUTHORITY.—Nothing in this Act may be construed as establishing new regulatory authority for any Federal agency.”.

(b) REPORT ON ACCREDITATION OF TSUNAMIREADY PROGRAM.—Not later than 180 days after the date of enactment of this Act, the Administrator of the National Oceanic and Atmospheric Administration shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Science, Space, and Technology of the House of Representatives a report on which authorities and activities would be needed to have the TsunamiReady program of the National Weather Service accredited by the Emergency Management Accreditation Program.

SEC. 6. MODIFICATION OF TSUNAMI RESEARCH PROGRAM.

Section 6 (33 U.S.C. 3205) is amended—

(1) in the matter before paragraph (1), by striking “The Administrator shall” and all that follows through “establish or maintain” and inserting the following:

“(a) IN GENERAL.—The Administrator shall, in consultation with such other Federal agencies, State, tribal, and territorial governments, and academic institutions as the Administrator considers appropriate, the coordinating committee under section 5(d), and the panel under section 8(a), support or maintain”;

(2) in subsection (a), as designated by paragraph (1), by striking “and assessment for tsu-

nami tracking and numerical forecast modeling. Such research program shall—” and inserting the following: “assessment for tsunami tracking and numerical forecast modeling, and standards development.

“(b) RESPONSIBILITIES.—The research program supported or maintained under subsection (a) shall—”; and

(3) in subsection (b), as designated by paragraph (2)—

(A) by amending paragraph (1) to read as follows:

“(1) consider other appropriate and cost effective solutions to mitigate the impact of tsunami, including the improvement of near-field and distant tsunami detection and forecasting capabilities, which may include use of a new generation of the Deep-ocean Assessment and Reporting of Tsunamis array, integration of tsunami sensors into commercial and Federal telecommunications cables, and other real-time tsunami monitoring systems and supercomputer capacity of the Administration to develop a rapid tsunami forecast for all United States coastlines;”;

(B) in paragraph (3)—

(i) by striking “include” and inserting “conduct”; and

(ii) by striking “and” at the end;

(C) by redesignating paragraph (4) as paragraph (5);

(D) by inserting after paragraph (3) the following:

“(4) develop the technical basis for validation of tsunami maps, numerical tsunami models, digital elevation models, and forecasts; and”;

(E) in paragraph (5), as redesignated by subparagraph (C), by striking “to the scientific community” and inserting “to the public and the scientific community”.

SEC. 7. GLOBAL TSUNAMI WARNING AND MITIGATION NETWORK.

Section 7 (33 U.S.C. 3206) is amended—

(1) by amending subsection (a) to read as follows:

“(a) SUPPORT FOR DEVELOPMENT OF AN INTERNATIONAL TSUNAMI WARNING SYSTEM.—The Administrator shall, in coordination with the Secretary of State and in consultation with such other agencies as the Administrator considers relevant, provide technical assistance, operational support, and training to the Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific, and Cultural Organization, the World Meteorological Organization of the United Nations, and such other international entities as the Administrator considers appropriate, as part of the international efforts to develop a fully functional global tsunami forecast and warning system comprised of regional tsunami warning networks.”;

(2) in subsection (b), by striking “shall” each place it appears and inserting “may”; and

(3) in subsection (c)—

(A) in paragraph (1), by striking “establishing” and inserting “supporting”; and

(B) in paragraph (2)—

(i) by striking “establish” and inserting “support”; and

(ii) by striking “establishing” and inserting “supporting”.

SEC. 8. TSUNAMI SCIENCE AND TECHNOLOGY ADVISORY PANEL.

(a) IN GENERAL.—The Act is further amended—

(1) by redesignating section 8 (33 U.S.C. 3207) as section 9; and

(2) by inserting after section 7 (33 U.S.C. 3206) the following:

“SEC. 8. TSUNAMI SCIENCE AND TECHNOLOGY ADVISORY PANEL.

“(a) DESIGNATION.—The Administrator shall designate an existing working group within the Science Advisory Board of the Administration to manage the Tsunami Science and Technology Advisory Panel to provide advice to the Administrator on matters regarding tsunami science, technology, and regional preparedness.

“(b) MEMBERSHIP.—

“(1) COMPOSITION.—The Panel shall be composed of no fewer than 7 members selected by the Administrator from among individuals from academia or State agencies who have academic or practical expertise in physical sciences, social sciences, information technology, coastal resilience, emergency management, or such other disciplines as the Administrator considers appropriate.

“(2) FEDERAL EMPLOYMENT.—No member of the Panel may be a Federal employee.

“(c) RESPONSIBILITIES.—Not less frequently than once every 4 years, the Panel shall—

“(1) review the activities of the Administration, and other Federal activities as appropriate, relating to tsunami research, detection, forecasting, warning, mitigation, resiliency, and preparation; and

“(2) submit to the Administrator and such others as the Administrator considers appropriate—

“(A) the findings of the working group with respect to the most recent review conducted under paragraph (1); and

“(B) such recommendations for legislative or administrative action as the working group considers appropriate to improve Federal tsunami research, detection, forecasting, warning, mitigation, resiliency, and preparation.

“(d) REPORTS TO CONGRESS.—Not less frequently than once every 4 years, the Administrator shall submit to the Committee on Commerce, Science, and Transportation of the Senate, and the Committee on Science, Space, and Technology of the House of Representatives a report on the findings and recommendations received by the Administrator under subsection (c)(2).”.

SEC. 9. REPORTS.

(a) REPORT ON IMPLEMENTATION OF TSUNAMI WARNING AND EDUCATION ACT.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Administrator of the National Oceanic and Atmospheric Administration shall submit to Congress a report on the implementation of the Tsunami Warning and Education Act (33 U.S.C. 3201 et seq.).

(2) ELEMENTS.—The report required by paragraph (1) shall include the following:

(A) A detailed description of the progress made in implementing sections 4(d)(6), 5(b)(6), and 6(b)(4) of the Tsunami Warning and Education Act.

(B) A description of the ways that tsunami warnings and warning products issued by the Tsunami Forecasting and Warning Program established under section 4 of the Tsunami Warning and Education Act (33 U.S.C. 3203) can be standardized and streamlined with warnings and warning products for hurricanes, coastal storms, and other coastal flooding events.

(b) REPORT ON NATIONAL EFFORTS THAT SUPPORT RAPID RESPONSE FOLLOWING NEAR-SHORE TSUNAMI EVENTS.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Administrator and the Secretary of Homeland Security shall jointly, in coordination with the Director of the United States Geological Survey, Administrator of the Federal Emergency Management Agency, the Chief of the National Guard Bureau, and the heads of such other Federal agencies as the Administrator considers appropriate, submit to the appropriate committees of Congress a report on the national efforts in effect on the day before the date of the enactment of this Act that support and facilitate rapid emergency response following a domestic near-shore tsunami event to better understand domestic effects of earthquake derived tsunami on people, infrastructure, and communities in the United States.

(2) ELEMENTS.—The report required by paragraph (1) shall include the following:

(A) A description of scientific or other measurements collected on the day before the date of

the enactment of this Act to quickly identify and quantify lost or degraded infrastructure or terrestrial formations.

(B) A description of scientific or other measurements that would be necessary to collect to quickly identify and quantify lost or degraded infrastructure or terrestrial formations.

(C) Identification and evaluation of Federal, State, local, tribal, territorial, and military first responder and search and rescue operation centers, bases, and other facilities as well as other critical response assets and infrastructure, including search and rescue aircraft, located within near-shore and distant tsunami inundation areas on the day before the date of the enactment of this Act.

(D) An evaluation of near-shore tsunami response plans in areas described in subparagraph (C) in effect on the day before the date of the enactment of this Act, and how those response plans would be affected by the loss of search and rescue and first responder infrastructure described in such subparagraph.

(E) A description of redevelopment plans and reports in effect on the day before the date of the enactment of this Act for communities in areas that are at high-risk for near-shore tsunami, as well identification of States or communities that do not have redevelopment plans.

(F) Recommendations to enhance near-shore tsunami preparedness and response plans, including recommended responder exercises, predisaster planning, and mitigation needs.

(G) Such other data and analysis information as the Administrator and the Secretary of Homeland Security consider appropriate.

(3) APPROPRIATE COMMITTEES OF CONGRESS.—In this subsection, the term “appropriate committees of Congress” means—

(A) the Committee on Commerce, Science, and Transportation and the Committee on Homeland Security and Governmental Affairs of the Senate; and

(B) the Committee on Science, Space, and Technology and the Committee on Homeland Security of the House of Representatives.

SEC. 10. AUTHORIZATION OF APPROPRIATIONS.

Section 9 of the Act, as redesignated by section 8(a)(1) of this Act, is amended—

(1) in paragraph (4)(B), by striking “and” at the end;

(2) in paragraph (5)(B), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following:

“(6) \$27,000,000 for each of fiscal years 2016 through 2021, of which—

“(A) not less than 27 percent of the amount appropriated for each fiscal year shall be for activities conducted at the State level under the tsunami hazard mitigation program under section 5; and

“(B) not less than 8 percent of the amount appropriated shall be for the tsunami research program under section 6.”.

SEC. 11. OUTREACH RESPONSIBILITIES.

The Administrator of the National Oceanic and Atmospheric Administration, in coordination with State and local emergency managers, shall develop and carry out formal outreach activities to improve tsunami education and awareness and foster the development of resilient communities. Outreach activities may include—

(1) the development of outreach plans to ensure the close integration of tsunami warning centers supported or maintained under section 4(d) of the Tsunami Warning and Education Act (33 U.S.C. 3203(d)) with local Weather Forecast Offices of the National Weather Service and emergency managers;

(2) working with appropriate local Weather Forecast Offices to ensure they have the technical knowledge and capability to disseminate tsunami warnings to the communities they serve; and

(3) evaluating the effectiveness of warnings and of coordination with local Weather Forecast Offices after significant tsunami events.

SEC. 12. MODIFICATION OF COASTAL OCEAN PROGRAM.

Section 201(c) of the National Oceanic and Atmospheric Administration Authorization Act of 1992 (Public Law 102-567; 106 Stat. 4280) is amended—

(1) by inserting “(1) IN GENERAL.—” before “Of the sums” and indenting appropriately; and

(2) by adding at the end the following:

“(2) REGIONAL COASTAL RISK MANAGEMENT COALITIONS.—The Administrator of the National Oceanic and Atmospheric Administration may form regional coastal risk management coalitions comprised of representatives of Federal, State, local, and tribal governments, community groups, academic institutions, and nongovernmental groups to advance the goals of this section for communities facing common coastal hazards and risks. Such coalitions may enter into an agreement with an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to establish a nonprofit foundation in order to accept gifts and donations to support the goals of this subsection.”.

SEC. 13. REPEAL OF DUPLICATE PROVISIONS OF LAW.

(a) REPEAL.—The Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 (Public Law 109-479) is amended by striking title VIII (relating to tsunami warning and education).

(b) CONSTRUCTION.—Nothing in this section shall be construed to repeal, or affect in any way, Public Law 109-424.

MOTION OFFERED BY MR. UPTON

Mr. UPTON. Mr. Speaker, I have a motion at the desk.

The SPEAKER pro tempore. The Clerk will designate the motion.

The text of the motion is as follows:

Mr. Upton moves that the House concur in the Senate amendment to H.R. 34 with an amendment inserting the text of Rules Committee Print 114-67, modified by the amendment printed in part A of House Report 114-839, in lieu of the matter proposed to be added by the Senate.

The text of the House amendment to the Senate amendment to the text is as follows:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “21st Century Cures Act”.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.

DIVISION A—21ST CENTURY CURES

Sec. 1000. Short title.

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

Sec. 1001. NIH innovation projects.

Sec. 1002. FDA innovation projects.

Sec. 1003. Account for the state response to the opioid abuse crisis.

Sec. 1004. Budgetary treatment.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

Sec. 2001. National Institutes of Health Reauthorization.

Sec. 2002. EUREKA prize competitions.

Subtitle B—Advancing Precision Medicine

Sec. 2011. Precision Medicine Initiative.

Sec. 2012. Privacy protection for human research subjects.

Sec. 2013. Protection of identifiable and sensitive information.

Sec. 2014. Data sharing.

Subtitle C—Supporting Young Emerging Scientists

Sec. 2021. Investing in the next generation of researchers.

- Sec. 2022. *Improvement of loan repayment program.*
- Subtitle D—National Institutes of Health Planning and Administration
- Sec. 2031. *National Institutes of Health strategic plan.*
- Sec. 2032. *Triennial reports.*
- Sec. 2033. *Increasing accountability at the National Institutes of Health.*
- Sec. 2034. *Reducing administrative burden for researchers.*
- Sec. 2035. *Exemption for the National Institutes of Health from the Paperwork Reduction Act requirements.*
- Sec. 2036. *High-risk, high-reward research.*
- Sec. 2037. *National Center for Advancing Translational Sciences.*
- Sec. 2038. *Collaboration and coordination to enhance research.*
- Sec. 2039. *Enhancing the rigor and reproducibility of scientific research.*
- Sec. 2040. *Improving medical rehabilitation research at the National Institutes of Health.*
- Sec. 2041. *Task force on research specific to pregnant women and lactating women.*
- Sec. 2042. *Streamlining National Institutes of Health reporting requirements.*
- Sec. 2043. *Reimbursement for research substances and living organisms.*
- Sec. 2044. *Sense of Congress on increased inclusion of underrepresented populations in clinical trials.*
- Subtitle E—Advancement of the National Institutes of Health Research and Data Access
- Sec. 2051. *Technical updates to clinical trials database.*
- Sec. 2052. *Compliance activities reports.*
- Sec. 2053. *Updates to policies to improve data.*
- Sec. 2054. *Consultation.*
- Subtitle F—Facilitating Collaborative Research
- Sec. 2061. *National neurological conditions surveillance system.*
- Sec. 2062. *Tick-borne diseases.*
- Sec. 2063. *Accessing, sharing, and using health data for research purposes.*
- Subtitle G—Promoting Pediatric Research
- Sec. 2071. *National pediatric research network.*
- Sec. 2072. *Global pediatric clinical study network.*
- TITLE III—DEVELOPMENT
- Subtitle A—Patient-Focused Drug Development
- Sec. 3001. *Patient experience data.*
- Sec. 3002. *Patient-focused drug development guidance.*
- Sec. 3003. *Streamlining patient input.*
- Sec. 3004. *Report on patient experience drug development.*
- Subtitle B—Advancing New Drug Therapies
- Sec. 3011. *Qualification of drug development tools.*
- Sec. 3012. *Targeted drugs for rare diseases.*
- Sec. 3013. *Reauthorization of program to encourage treatments for rare pediatric diseases.*
- Sec. 3014. *GAO study of priority review voucher programs.*
- Sec. 3015. *Amendments to the Orphan Drug grants.*
- Sec. 3016. *Grants for studying continuous drug manufacturing.*
- Subtitle C—Modern Trial Design and Evidence Development
- Sec. 3021. *Novel clinical trial designs.*
- Sec. 3022. *Real world evidence.*
- Sec. 3023. *Protection of human research subjects.*
- Sec. 3024. *Informed consent waiver or alteration for clinical investigations.*
- Subtitle D—Patient Access to Therapies and Information
- Sec. 3031. *Summary level review.*
- Sec. 3032. *Expanded access policy.*
- Sec. 3033. *Accelerated approval for regenerative advanced therapies.*
- Sec. 3034. *Guidance regarding devices used in the recovery, isolation, or delivery of regenerative advanced therapies.*
- Sec. 3035. *Report on regenerative advanced therapies.*
- Sec. 3036. *Standards for regenerative medicine and regenerative advanced therapies.*
- Sec. 3037. *Health care economic information.*
- Sec. 3038. *Combination product innovation.*
- Subtitle E—Antimicrobial Innovation and Stewardship
- Sec. 3041. *Antimicrobial resistance monitoring.*
- Sec. 3042. *Limited population pathway.*
- Sec. 3043. *Prescribing authority.*
- Sec. 3044. *Susceptibility test interpretive criteria for microorganisms; antimicrobial susceptibility testing devices.*
- Subtitle F—Medical Device Innovations
- Sec. 3051. *Breakthrough devices.*
- Sec. 3052. *Humanitarian device exemption.*
- Sec. 3053. *Recognition of standards.*
- Sec. 3054. *Certain class I and class II devices.*
- Sec. 3055. *Classification panels.*
- Sec. 3056. *Institutional review board flexibility.*
- Sec. 3057. *CLIA waiver improvements.*
- Sec. 3058. *Least burdensome device review.*
- Sec. 3059. *Cleaning instructions and validation data requirement.*
- Sec. 3060. *Clarifying medical software regulation.*
- Subtitle G—Improving Scientific Expertise and Outreach at FDA
- Sec. 3071. *Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service.*
- Sec. 3072. *Hiring authority for scientific, technical, and professional personnel.*
- Sec. 3073. *Establishment of Food and Drug Administration Intercenter Institutes.*
- Sec. 3074. *Scientific engagement.*
- Sec. 3075. *Drug surveillance.*
- Sec. 3076. *Reagan-Udall Foundation for the Food and Drug Administration.*
- Subtitle H—Medical Countermeasures Innovation
- Sec. 3081. *Medical countermeasure guidelines.*
- Sec. 3082. *Clarifying BARDA contracting authority.*
- Sec. 3083. *Countermeasure budget plan.*
- Sec. 3084. *Medical countermeasures innovation.*
- Sec. 3085. *Streamlining Project BioShield procurement.*
- Sec. 3086. *Encouraging treatments for agents that present a national security threat.*
- Sec. 3087. *Paperwork Reduction Act waiver during a public health emergency.*
- Sec. 3088. *Clarifying Food and Drug Administration emergency use authorization.*
- Subtitle I—Vaccine Access, Certainty, and Innovation
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- Sec. 9006. Connecting individuals and families with care.
- Sec. 9007. Strengthening community crisis response systems.
- Sec. 9008. Garrett Lee Smith Memorial Act reauthorization.
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- Sec. 9011. Sense of Congress on prioritizing American Indians and Alaska Native youth within suicide prevention programs.
- Sec. 9012. Evidence-based practices for older adults.
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- Subtitle B—Strengthening the Health Care Workforce
- Sec. 9021. Mental and behavioral health education and training grants.
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- Sec. 9031. Mental health and substance use disorder services on campus.

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- Sec. 10001. Programs for children with a serious emotional disturbance.
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TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

- Sec. 11001. Sense of Congress.
- Sec. 11002. Confidentiality of records.
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TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

- Sec. 12001. Rule of construction related to Medicaid coverage of mental health services and primary care services furnished on the same day.
- Sec. 12002. Study and report related to Medicaid managed care regulation.
- Sec. 12003. Guidance on opportunities for innovation.
- Sec. 12004. Study and report on Medicaid emergency psychiatric demonstration project.
- Sec. 12005. Providing EPSDT services to children in IMDs.
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TITLE XIII—MENTAL HEALTH PARITY

- Sec. 13001. Enhanced compliance with mental health and substance use disorder coverage requirements.
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- Sec. 13003. Report on investigations regarding parity in mental health and substance use disorder benefits.
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- Sec. 14001. Law enforcement grants for crisis intervention teams, mental health purposes.
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- Sec. 14005. Forensic assertive community treatment initiatives.
- Sec. 14006. Assistance for individuals transitioning out of systems.
- Sec. 14007. Co-occurring substance abuse and mental health challenges in drug courts.

Sec. 14008. Mental health training for Federal uniformed services.

Sec. 14009. Advancing mental health as part of offender reentry.

Sec. 14010. School mental health crisis intervention teams.

Sec. 14011. Active-shooter training for law enforcement.

Sec. 14012. Co-occurring substance abuse and mental health challenges in residential substance abuse treatment programs.

Sec. 14013. Mental health and drug treatment alternatives to incarceration programs.

Sec. 14014. National criminal justice and mental health training and technical assistance.

Sec. 14015. Improving Department of Justice data collection on mental illness involved in crime.

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- Sec. 14021. Sequential intercept model.
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- Sec. 14023. Allowable uses.
- Sec. 14024. Law enforcement training.
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Sec. 15000. Short title.

TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

- Sec. 15001. Development of Medicare HCPCS version of MS-DRG codes for similar hospital services.
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- Sec. 15003. Five-year extension of the rural community hospital demonstration program.
- Sec. 15004. Regulatory relief for LTCHs.
- Sec. 15005. Savings from IPPS MACRA pay-for-through not applying documentation and coding adjustments.
- Sec. 15006. Extension of certain LTCH Medicare payment rules.
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- Sec. 16001. Continuing Medicare payment under HOPD prospective payment system for services furnished by mid-build off-campus outpatient departments of providers.
- Sec. 16002. Treatment of cancer hospitals in off-campus outpatient department of a provider policy.
- Sec. 16003. Treatment of eligible professionals in ambulatory surgical centers for meaningful use and MIPS.

- Sec. 16004. Continuing Access to Hospitals Act of 2016.
- Sec. 16005. Delay of implementation of Medicare fee schedule adjustments for wheelchair accessories and seating systems when used in conjunction with complex rehabilitation technology (CRT) wheelchairs.
- Sec. 16006. Allowing physical therapists to utilize locum tenens arrangements under Medicare.
- Sec. 16007. Extension of the transition to new payment rates for durable medical equipment under the Medicare program.
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- Sec. 17001. Delay in authority to terminate contracts for Medicare Advantage plans failing to achieve minimum quality ratings.
- Sec. 17002. Requirement for enrollment data reporting for Medicare.
- Sec. 17003. Updating the Welcome to Medicare package.
- Sec. 17004. No payment for items and services furnished by newly enrolled providers or suppliers within a temporary moratorium area.
- Sec. 17005. Preservation of Medicare beneficiary choice under Medicare Advantage.
- Sec. 17006. Allowing end-stage renal disease beneficiaries to choose a Medicare Advantage plan.
- Sec. 17007. Improvements to the assignment of beneficiaries under the Medicare Shared Savings Program.

TITLE XVIII—OTHER PROVISIONS

- Sec. 18001. Exception from group health plan requirements for qualified small employer health reimbursement arrangements.

DIVISION D—CHILD AND FAMILY SERVICES AND SUPPORT

- Sec. 19000. Short title.
- TITLE XIX—INVESTING IN PREVENTION AND FAMILY SERVICES**

- Sec. 19001. Purpose.
Subtitle A—Prevention Activities Under Title IV-E
- Sec. 19011. Foster care prevention services and programs.
- Sec. 19012. Foster care maintenance payments for children with parents in a licensed residential family-based treatment facility for substance abuse.
- Sec. 19013. Title IV-E payments for evidence-based kinship navigator programs.

Subtitle B—Enhanced Support Under Title IV-B

- Sec. 19021. Elimination of time limit for family reunification services while in foster care and permitting time-limited family reunification services when a child returns home from foster care.
- Sec. 19022. Reducing bureaucracy and unnecessary delays when placing children in homes across State lines.
- Sec. 19023. Enhancements to grants to improve well-being of families affected by substance abuse.

Subtitle C—Miscellaneous

- Sec. 19031. Reviewing and improving licensing standards for placement in a relative foster family home.
- Sec. 19032. Development of a statewide plan to prevent child abuse and neglect fatalities.

- Sec. 19033. Modernizing the title and purpose of title IV-E.
- Sec. 19034. Effective dates.

TITLE XX—ENSURING THE NECESSITY OF A PLACEMENT THAT IS NOT IN A FOSTER FAMILY HOME

- Sec. 20001. Limitation on Federal financial participation for placements that are not in foster family homes.
- Sec. 20002. Assessment and documentation of the need for placement in a qualified residential treatment program.
- Sec. 20003. Protocols to prevent inappropriate diagnoses.
- Sec. 20004. Additional data and reports regarding children placed in a setting that is not a foster family home.
- Sec. 20005. Effective dates; application to waivers.

TITLE XXI—CONTINUING SUPPORT FOR CHILD AND FAMILY SERVICES

- Sec. 21001. Supporting and retaining foster families for children.
- Sec. 21002. Extension of child and family services programs.
- Sec. 21003. Improvements to the John H. Chafee foster care independence program and related provisions.

TITLE XXII—CONTINUING INCENTIVES TO STATES TO PROMOTE ADOPTION AND LEGAL GUARDIANSHIP

- Sec. 22001. Reauthorizing adoption and legal guardianship incentive programs.

TITLE XXIII—TECHNICAL CORRECTIONS

- Sec. 23001. Technical corrections to data exchange standards to improve program coordination.
- Sec. 23002. Technical corrections to State requirement to address the developmental needs of young children.

TITLE XXIV—ENSURING STATES REINVEST SAVINGS RESULTING FROM INCREASE IN ADOPTION ASSISTANCE

- Sec. 24001. Delay of adoption assistance phase-in.
- Sec. 24002. GAO study and report on State reinvestment of savings resulting from increase in adoption assistance.

TITLE XXV—SOCIAL IMPACT PARTNERSHIPS TO PAY FOR RESULTS

- Sec. 25001. Short title.
- Sec. 25002. Social Impact Partnerships to Pay for Results.
- Sec. 25003. Extension of TANF program.
- Sec. 25004. Strengthening welfare research and evaluation and development of a What Works Clearinghouse.
- Sec. 25005. Technical corrections to data exchange standards to improve program coordination.

DIVISION A—21ST CENTURY CURES

SEC. 1000. SHORT TITLE.

This Division may be cited as the “21st Century Cures Act”.

TITLE I—INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE

SEC. 1001. NIH INNOVATION PROJECTS.

(a) IN GENERAL.—The Director of the National Institutes of Health (referred to in this section as the “Director of NIH”) shall use any funds appropriated pursuant to the authorization of appropriations in subsection (b)(3) to carry out the National Institutes of Health innovation projects described in subsection (b)(4) (referred to in this section as the “NIH Innovation Projects”).

(b) NATIONAL INSTITUTES OF HEALTH INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF NIH INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the “NIH Innovation Account” (referred to in this subsection as the

“Account”), for purposes of carrying out the NIH Innovation Projects described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—(A) IN GENERAL.—The following amounts shall be transferred to the Account from the general fund of the Treasury:

- (i) For fiscal year 2017, \$352,000,000.
- (ii) For fiscal year 2018, \$496,000,000.
- (iii) For fiscal year 2019, \$711,000,000.
- (iv) For fiscal year 2020, \$492,000,000.
- (v) For fiscal year 2021, \$404,000,000.
- (vi) For fiscal year 2022, \$496,000,000.
- (vii) For fiscal year 2023, \$1,085,000,000.
- (viii) For fiscal year 2024, \$407,000,000.
- (ix) For fiscal year 2025, \$127,000,000.
- (x) For fiscal year 2026, \$226,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2026, there is authorized to be appropriated from the Account to the Director of NIH, for the purpose of carrying out the NIH Innovation Projects, an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2026, for any discretionary appropriation under the heading “NIH Innovation Account” provided to the Director of NIH pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the NIH Innovation Projects, the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) NIH INNOVATION PROJECTS.—NIH Innovation Projects authorized to be funded under this section shall consist of the following and, of the total amounts authorized to be appropriated under paragraph (3), there are authorized to be appropriated to each such project a total amount not to exceed the following, over the period of fiscal years 2017 through 2026:

(A) For the Precision Medicine Initiative, including for the advancement of a cohort of individuals to support the goals of the Precision Medicine Initiative, not to exceed a total of \$1,455,000,000, as follows:

- (i) For fiscal year 2017, \$40,000,000.
- (ii) For fiscal year 2018, \$100,000,000.
- (iii) For fiscal year 2019, \$186,000,000.
- (iv) For fiscal year 2020, \$149,000,000.
- (v) For fiscal year 2021, \$109,000,000.
- (vi) For fiscal year 2022, \$150,000,000.
- (vii) For fiscal year 2023, \$419,000,000.
- (viii) For fiscal year 2024, \$235,000,000.
- (ix) For fiscal year 2025, \$36,000,000.
- (x) For fiscal year 2026, \$31,000,000.

(B) For the Brain Research through Advancing Innovative Neurotechnologies Initiative (known as the “BRAIN Initiative”), not to exceed a total of \$1,511,000,000, as follows:

- (i) For fiscal year 2017, \$10,000,000.
- (ii) For fiscal year 2018, \$86,000,000.
- (iii) For fiscal year 2019, \$115,000,000.
- (iv) For fiscal year 2020, \$140,000,000.
- (v) For fiscal year 2021, \$100,000,000.
- (vi) For fiscal year 2022, \$152,000,000.
- (vii) For fiscal year 2023, \$450,000,000.
- (viii) For fiscal year 2024, \$172,000,000.
- (ix) For fiscal year 2025, \$91,000,000.
- (x) For fiscal year 2026, \$195,000,000.

(C) To support cancer research, such as the development of cancer vaccines, the development of more sensitive diagnostic tests for cancer, immunotherapy and the development of

combination therapies, and research that has the potential to transform the scientific field, that has inherently higher risk, and that seeks to address major challenges related to cancer, not to exceed a total of \$1,800,000,000, as follows:

- (i) For fiscal year 2017, \$300,000,000.
- (ii) For fiscal year 2018, \$300,000,000.
- (iii) For fiscal year 2019, \$400,000,000.
- (iv) For fiscal year 2020, \$195,000,000.
- (v) For fiscal year 2021, \$195,000,000.
- (vi) For fiscal year 2022, \$194,000,000.
- (vii) For fiscal year 2023, \$216,000,000.

(D) For the National Institutes of Health, in coordination with the Food and Drug Administration, to award grants and contracts for clinical research to further the field of regenerative medicine using adult stem cells, including autologous stem cells, for which grants and contracts shall be contingent upon the recipient making available non-Federal contributions toward the costs of such research in an amount not less than \$1 for each \$1 of Federal funds provided in the award, not to exceed a total of \$30,000,000, as follows:

- (i) For fiscal year 2017, \$2,000,000.
- (ii) For each of fiscal years 2018 and 2019, \$10,000,000.
- (iii) For fiscal year 2020, \$8,000,000.
- (iv) For each of fiscal years 2021 through 2026, \$0.

(C) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds authorized to be appropriated pursuant to subsection (b)(3) for each of fiscal years 2017 through 2026 for the NIH Innovation Projects and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

- (i) recommendations from the Advisory Committee described in subparagraph (C);
- (ii) the amount of money to be obligated or expended in each fiscal year for each NIH Innovation Project;
- (iii) a description and justification of each such project; and
- (iv) a description of how each such project supports the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Director of NIH shall seek recommendations from the Advisory Committee to the Director of NIH appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a) on—

- (i) the allocations of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2026; and
- (ii) on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2027, the Director of NIH shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

- (i) the amount of money obligated or expended in the prior fiscal year for each NIH Innovation Project;
- (ii) a description of any such project using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and
- (iii) whether such projects are advancing the strategic research priorities identified in the NIH Strategic Plan under subsection (m) of sec-

tion 402 of the Public Health Service Act (42 U.S.C. 282), as added by section 2031.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Director of NIH shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the NIH Innovation Projects.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (b)(3) may not be used for any purpose other than a NIH Innovation Project.

(e) SUNSET.—This section shall expire on September 30, 2026.

SEC. 1002. FDA INNOVATION PROJECTS.

(a) IN GENERAL.—The Commissioner of Food and Drugs (referred to in this section as the “Commissioner”) shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) to carry out the activities described in subsection (b)(4).

(b) FDA INNOVATION ACCOUNT.—

(1) ESTABLISHMENT OF FDA INNOVATION ACCOUNT.—There is established in the Treasury an account, to be known as the “FDA Innovation Account” (referred to in this subsection as the “Account”), for purposes of carrying out the activities described in paragraph (4).

(2) TRANSFER OF DIRECT SPENDING SAVINGS.—(A) IN GENERAL.—For each of fiscal years 2017 through 2025, the following amounts shall be transferred to the Account from the general fund of the Treasury:

- (i) For fiscal year 2017, \$20,000,000.
- (ii) For fiscal year 2018, \$60,000,000.
- (iii) For fiscal year 2019, \$70,000,000.
- (iv) For fiscal year 2020, \$75,000,000.
- (v) For fiscal year 2021, \$70,000,000.
- (vi) For fiscal year 2022, \$50,000,000.
- (vii) For fiscal year 2023, \$50,000,000.
- (viii) For fiscal year 2024, \$50,000,000.
- (ix) For fiscal year 2025, \$55,000,000.

(B) AMOUNTS DEPOSITED.—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) APPROPRIATIONS.—

(A) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2017 through 2025, there is authorized to be appropriated from the Account to the Commissioner, for the purpose of carrying out the activities described in paragraph (5), an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2017 through 2025, for any discretionary appropriation under the heading “FDA Innovation Account” provided to the Commissioner pursuant to the authorization of appropriations under subparagraph (A) for the purpose of carrying out the projects activities described in paragraph (4), the total amount of such appropriations in the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(4) FDA ACTIVITIES.—The activities authorized to be funded under this section are the activities under subtitles A through F (including the amendments made by such subtitles) of title III of this Act and section 1014 of the Federal

Food, Drug, and Cosmetic Act, as added by section 3073 of this Act.

(c) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and the contents described in subparagraph (B).

(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

- (i) recommendations from the Advisory Committee described in subparagraph (C);
- (ii) the amount of money to be obligated or expended in each fiscal year for each activity described in subsection (b)(4); and
- (iii) a description and justification of each such project activity.

(C) RECOMMENDATIONS.—Prior to submitting the work plan under this paragraph, the Commissioner shall seek recommendations from the Science Board to the Food and Drug Administration, on the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (b)(3) for each of fiscal years 2017 through 2025 and on the contents of the proposed work plan.

(2) REPORTS.—

(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2018 through 2026, the Commissioner shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report including—

- (i) the amount of money obligated or expended in the prior fiscal year for each activity described in subsection (b)(4);
- (ii) a description of all such activities using funds provided pursuant to the authorization of appropriations under subsection (b)(3); and
- (iii) how the activities are advancing public health.

(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor, and Pensions or the Committee on Appropriations of the Senate, or the Committee on Energy and Commerce or the Committee on Appropriations of the House of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the activities undertaken with such funding.

(d) LIMITATIONS.—Notwithstanding any transfer authority authorized by this Act or any appropriations Act, any funds made available pursuant to the authorization of appropriations in subsection (b)(3) shall not be used for any purpose other than an activity described in subsection (b)(4).

(e) SUNSET.—This section shall expire on September 30, 2025.

SEC. 1003. ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall use any funds appropriated pursuant to the authorization of appropriations under subsection (b) to carry out the grant program described in subsection (c) for purposes of addressing the opioid abuse crisis within the States.

(b) ACCOUNT FOR THE STATE RESPONSE TO THE OPIOID ABUSE CRISIS.—

(1) ESTABLISHMENT.—There is established in the Treasury an account, to be known as the “Account For the State Response to the Opioid

Abuse Crisis” (referred to in this subsection as the “Account”), to carry out the opioid grant program described in subsection (c).

(2) **TRANSFER OF DIRECT SPENDING SAVINGS.**—(A) **IN GENERAL.**—The following amounts shall be transferred to the Account from the general fund of the Treasury:

(i) For fiscal year 2017, \$500,000,000.

(ii) For fiscal year 2018, \$500,000,000.

(B) **AMOUNTS DEPOSITED.**—Any amounts transferred under subparagraph (A) shall remain unavailable in the Account until such amounts are appropriated pursuant to paragraph (3).

(3) **APPROPRIATIONS.**—

(A) **AUTHORIZATION OF APPROPRIATIONS.**—In each of the fiscal years 2017 and 2018, there is authorized to be appropriated from the Account to the Secretary, for the grant program described in subsection (c), an amount not to exceed the total amount transferred to the Account under paragraph (2)(A), to remain available until expended.

(B) **OFFSETTING FUTURE APPROPRIATIONS.**—In each of fiscal years 2017 and 2018, for any discretionary appropriation under the heading “Account For the State Response to the Opioid Abuse Crisis” for the grant program described in subsection (c), the total amount of such appropriations in the applicable fiscal year (not to exceed the total amount remaining in the Account) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Account shall be reduced by the same amount.

(C) **OPIOID GRANT PROGRAM.**—

(1) **STATE RESPONSE TO THE OPIOID ABUSE CRISIS.**—Subject to the availability of appropriations, the Secretary shall award grants to States for the purpose of addressing the opioid abuse crisis within such States, in accordance with subparagraph (B). In awarding such grants, the Secretary shall give preference to States with an incidence or prevalence of opioid use disorders that is substantially higher relative to other States.

(2) **OPIOID GRANTS.**—Grants awarded to a State under this subsection shall be used for carrying out activities that supplement activities pertaining to opioids undertaken by the State agency responsible for administering the substance abuse prevention and treatment block grant under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.), which may include public health-related activities such as the following:

(A) Improving State prescription drug monitoring programs.

(B) Implementing prevention activities, and evaluating such activities to identify effective strategies to prevent opioid abuse.

(C) Training for health care practitioners, such as best practices for prescribing opioids, pain management, recognizing potential cases of substance abuse, referral of patients to treatment programs, and overdose prevention.

(D) Supporting access to health care services, including those services provided by Federally certified opioid treatment programs or other appropriate health care providers to treat substance use disorders.

(E) Other public health-related activities, as the State determines appropriate, related to addressing the opioid abuse crisis within the State.

(d) **ACCOUNTABILITY AND OVERSIGHT.**—A State receiving a grant under subsection (c) shall include in a report related to substance abuse submitted to the Secretary pursuant to section 1942 of the Public Health Service Act (42 U.S.C. 300x–52), a description of—

(1) the purposes for which the grant funds received by the State under such subsection for the preceding fiscal year were expended and a description of the activities of the State under the program; and

(2) the ultimate recipients of amounts provided to the State in the grant.

(e) **LIMITATIONS.**—Any funds made available pursuant to the authorization of appropriations under subsection (b)—

(1) notwithstanding any transfer authority in any appropriations Act, shall not be used for any purpose other than the grant program in subsection (c); and

(2) shall be subject to the same requirements as substance abuse prevention and treatment programs under titles V and XIX of the Public Health Service Act (42 U.S.C. 290aa et seq., 300w et seq.).

(f) **SUNSET.**—This section shall expire on September 30, 2026.

SEC. 1004. BUDGETARY TREATMENT.

(a) **STATUTORY PAYGO SCORECARDS.**—The budgetary effects of division A of this Act shall not be entered on either PAYGO scorecard maintained pursuant to section 4(d) of the Statutory Pay-As-You-Go Act of 2010.

(b) **SENATE PAYGO SCORECARDS.**—The budgetary effects of division A of this Act shall not be entered on any PAYGO scorecard maintained for purposes of section 201 of S. Con. Res. 21 (110th Congress).

(c) **RESERVATION OF SAVINGS.**—None of the funds in the NIH Innovation Account, the FDA Innovation Account, or the Account For the State Response to the Opioid Abuse Crisis established by this title shall be made available except to the extent provided in advance in appropriations Acts, and legislation or an Act that rescinds or reduces amounts in such accounts shall not be estimated as a reduction in direct spending under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985.

TITLE II—DISCOVERY

Subtitle A—National Institutes of Health Reauthorization

SEC. 2001. NATIONAL INSTITUTES OF HEALTH RE-AUTHORIZATION.

Section 402A(a)(1) of the Public Health Service Act (42 U.S.C. 282a(a)(1)) is amended—

(1) in subparagraph (B), by striking “and” at the end;

(2) in subparagraph (C), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following new subparagraphs:

“(D) \$34,851,000,000 for fiscal year 2018;

“(E) \$35,585,871,000 for fiscal year 2019; and

“(F) \$36,472,442,775 for fiscal year 2020.”

SEC. 2002. EUREKA-PRIZE COMPETITIONS.

(a) **IN GENERAL.**—Pursuant to the authorities and processes established under section 24 of the Stevenson-Wylder Technology Innovation Act of 1980 (15 U.S.C. 3719), the Director of the National Institutes of Health shall support prize competitions for one or both of the following goals:

(1) Identifying and funding areas of biomedical science that could realize significant advancements through a prize competition.

(2) Improving health outcomes, particularly with respect to human diseases and conditions—

(A) for which public and private investment in research is disproportionately small relative to Federal Government expenditures on prevention and treatment activities with respect to such diseases and conditions, such that Federal expenditures on health programs would be reduced;

(B) that are serious and represent a significant disease burden in the United States; or

(C) for which there is potential for significant return on investment to the United States.

(b) **TRACKING; REPORTING.**—The Director of the National Institutes of Health shall—

(1) collect information on—

(A) the effect of innovations funded through the prize competitions under this section in advancing biomedical science or improving health outcomes pursuant to subsection (a); and

(B) the effect of the innovations on Federal expenditures; and

(2) include the information collected under paragraph (1) in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032).

Subtitle B—Advancing Precision Medicine

SEC. 2011. PRECISION MEDICINE INITIATIVE.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end the following:

“SEC. 498E. PRECISION MEDICINE INITIATIVE.

“(a) **IN GENERAL.**—The Secretary is encouraged to establish and carry out an initiative, to be known as the ‘Precision Medicine Initiative’ (in this section referred to as the ‘Initiative’), to augment efforts to address disease prevention, diagnosis, and treatment.

“(b) **COMPONENTS.**—The Initiative described under subsection (a) may include—

“(1) developing a network of scientists to assist in carrying out the purposes of the Initiative;

“(2) developing new approaches for addressing scientific, medical, public health, and regulatory science issues;

“(3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;

“(4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and

“(5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

“(c) **AUTHORITY OF THE SECRETARY.**—In carrying out this section, the Secretary may—

“(1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;

“(2) develop and utilize public-private partnerships; and

“(3) leverage existing data sources.

“(d) **REQUIREMENTS.**—In the implementation of the Initiative under subsection (a), the Secretary shall—

“(1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;

“(2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;

“(3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;

“(4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;

“(5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and

“(6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.

“(e) **REPORT.**—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on the relevant data access policies and procedures to the Committee on Health, Education, Labor, and

Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such report shall include steps the Secretary has taken to consult with experts or other heads of departments or agencies of the Federal Government in the development of such policies.”.

SEC. 2012. PRIVACY PROTECTION FOR HUMAN RESEARCH SUBJECTS.

(a) *IN GENERAL.*—Subsection (d) of section 301 of the Public Health Service Act (42 U.S.C. 241) is amended to read as follows:

“(d)(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

“(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

“(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

“(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

“(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

“(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

“(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

“(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

“(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

“(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

“(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

“(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

“(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

“(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to

ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

“(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual’s participation in the research.

“(4) For purposes of this subsection, the term ‘identifiable, sensitive information’ means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

“(A) through which an individual is identified; or

“(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.”.

(b) *APPLICABILITY.*—Beginning 180 days after the date of enactment of this Act, all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act).

SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

“(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

“(A) an individual is identified; or

“(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

“(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

“(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

“(3) Nothing in this subsection shall be construed to limit a research participant’s access to information about such participant collected during the participant’s participation in the research.”.

SEC. 2014. DATA SHARING.

(a) *IN GENERAL.*—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (23), by striking “and” at the end;

(2) in paragraph (24), by striking the period and inserting “; and”; and

(3) by inserting after paragraph (24) the following:

“(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

“(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

“(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient.”.

(b) *CONFIDENTIALITY.*—Nothing in the amendments made by subsection (a) authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or be construed to require recipients of grants or cooperative agreements through the National Institutes of Health to share such information.

Subtitle C—Supporting Young Emerging Scientists

SEC. 2021. INVESTING IN THE NEXT GENERATION OF RESEARCHERS.

(a) *IN GENERAL.*—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following:

“SEC. 404M. NEXT GENERATION OF RESEARCHERS.

“(a) *NEXT GENERATION OF RESEARCHERS INITIATIVE.*—There shall be established within the Office of the Director of the National Institutes of Health, the Next Generation of Researchers Initiative (referred to in this section as the ‘Initiative’), through which the Director shall coordinate all policies and programs within the National Institutes of Health that are focused on promoting and providing opportunities for new researchers and earlier research independence.

“(b) *ACTIVITIES.*—The Director of the National Institutes of Health, through the Initiative shall—

“(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

“(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity;

“(3) coordinate, as appropriate, with relevant agencies, professional and academic associations, academic institutions, and others, to improve and update existing information on the biomedical research workforce in order to inform programs related to the training, recruitment, and retention of biomedical researchers; and

“(4) carry out other activities, including evaluation and oversight of existing programs, as appropriate, to promote the development of the next generation of researchers and earlier research independence.”.

(b) *CONSIDERATION OF RECOMMENDATIONS.*—In carrying out activities under section 404M(b) of the Public Health Service Act, the Director of the National Institutes of Health shall take into consideration the recommendations made by the National Academies of Sciences, Engineering, and Medicine as part of the comprehensive study on policies affecting the next generation of researchers under the Department of Health and Human Services Appropriations Act, 2016 (Public Law 114–113), and submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, with respect to any actions taken by the National Institutes of Health based on the recommendations not later than 2 years after the completion of the study required pursuant to the Department of Health and Human Services Appropriations Act, 2016.

SEC. 2022. IMPROVEMENT OF LOAN REPAYMENT PROGRAM.

(a) *INTRAMURAL LOAN REPAYMENT PROGRAM.*—Section 487A of the Public Health Service Act (42 U.S.C. 288–1) is amended—

(1) by amending the section heading to read as follows: “INTRAMURAL LOAN REPAYMENT PROGRAM”;

(2) in subsection (a)—

(A) by striking “The Secretary shall carry out a program” and inserting “The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))”;

(B) by striking “conduct” and inserting “conduct research”;

(C) by striking “research with respect to acquired immune deficiency syndrome”;

(D) by striking “\$35,000” and inserting “\$50,000”;

(3) by redesignating subsection (b) as subsection (d);

(4) by inserting after subsection (a), the following:

“(b) SUBCATEGORIES OF RESEARCH.—

“(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

“(A) shall continue to focus on—

“(i) general research;

“(ii) research on acquired immune deficiency syndrome; and

“(iii) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

“(B) may focus on an area of emerging scientific or workforce need.

“(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

“(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).”;

(5) by adding at the end the following:

“(e) AVAILABILITY OF APPROPRIATIONS.—Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts are made available.”.

(b) EXTRAMURAL LOAN REPAYMENT PROGRAM.—Section 487B of the Public Health Service Act (42 U.S.C. 288-2) is amended—

(1) by amending the section heading to read as follows: “EXTRAMURAL LOAN REPAYMENT PROGRAM”;

(2) in subsection (a)—

(A) by striking “The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program” and inserting “IN GENERAL.—The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))”;

(B) by striking “(including graduate students)”;

(C) by striking “with respect to contraception, or with respect to infertility,”;

(D) by striking “service, not more than \$35,000” and inserting “research, not more than \$50,000”;

(3) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively;

(4) by inserting after subsection (a), the following:

“(b) SUBCATEGORIES OF RESEARCH.—

“(1) IN GENERAL.—In carrying out the program under subsection (a), the Director of the National Institutes of Health—

“(A) shall continue to focus on—

“(i) contraception or infertility research;

“(ii) pediatric research, including pediatric pharmacological research;

“(iii) minority health disparities research;

“(iv) clinical research; and

“(v) clinical research conducted by appropriately qualified health professional who are from disadvantaged backgrounds; and

“(B) may focus on an area of emerging scientific or workforce need.

“(2) ELIMINATION OR ESTABLISHMENT OF SUBCATEGORIES.—The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

“(c) LIMITATION.—The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).”;

(5) in subsection (d) (as so redesignated), by striking “The provisions” and inserting “APPLICABILITY OF CERTAIN PROVISIONS REGARDING OBLIGATED SERVICE.—The provisions”;

(6) in subsection (e) (as so redesignated), by striking “Amounts” and inserting “AVAILABILITY OF APPROPRIATIONS.—Amounts”.

(c) TECHNICAL AND CONFORMING AMENDMENTS.—Title IV of the Public Health Service Act is amended—

(1) by striking section 464a-5 (42 U.S.C. 285t-2);

(2) by striking section 487C (42 U.S.C. 288-3);

(3) by striking section 487E (42 U.S.C. 288-5);

(4) by striking section 487F (42 U.S.C. 288-5a), as added by section 205 of Public Law 106-505, relating to loan repayment for clinical researchers; and

(5) by striking section 487F (42 U.S.C. 288-6), as added by section 1002(b) of Public Law 106-310 relating to pediatric research loan repayment.

(d) GAO REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the efforts of the National Institutes of Health to attract, retain, and develop emerging scientists, including underrepresented individuals in the sciences, such as women, racial and ethnic minorities, and other groups. Such report shall include an analysis of the impact of the additional authority provided to the Secretary of Health and Human Services under this Act to address workforce shortages and gaps in priority research areas, including which centers and research areas offered loan repayment program participants the increased award amount.

Subtitle D—National Institutes of Health Planning and Administration

SEC. 2031. NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.

(a) STRATEGIC PLAN.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) in subsection (b)(5), by inserting before the semicolon the following: “, and through the development, implementation, and updating of the strategic plan developed under subsection (m)”;

(2) by adding at the end the following:

“(m) NATIONAL INSTITUTES OF HEALTH STRATEGIC PLAN.—

“(1) IN GENERAL.—Not later than 2 years after the date of enactment of the 21st Century Cures

Act, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the ‘National Institutes of Health Strategic Plan’) to provide direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

“(2) REQUIREMENTS.—The strategy under paragraph (1) shall—

“(A) identify strategic research priorities and objectives across biomedical research, including—

“(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

“(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

“(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

“(iv) the identification of near-, mid-, and long-term scientific needs;

“(B) consider, in carrying out subparagraph (A)—

“(i) disease burden in the United States and the potential for return on investment to the United States;

“(ii) rare diseases and conditions;

“(iii) biological, social, and other determinants of health that contribute to health disparities; and

“(iv) other factors the Director of National Institutes of Health determines appropriate;

“(C) include multi-institute priorities, including coordination of research among institutes and centers;

“(D) include strategic priorities for funding research through the Common Fund, in accordance with section 402A(c)(1)(C);

“(E) address the National Institutes of Health’s proposed and ongoing activities related to training and the biomedical workforce; and

“(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

“(3) USE OF PLANS.—Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

“(4) CONSULTATION.—The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.”.

(b) CONFORMING AMENDMENT.—Section 402A(c)(1)(C) of the Public Health Service Act (42 U.S.C. 282a(c)(1)(C)) is amended by striking “Not later than June 1, 2007, and every 2 years thereafter,” and inserting “As part of the National Institutes of Health Strategic Plan required under section 402(m).”.

(c) STRATEGIC PLAN.—Section 492B(a) of the Public Health Service Act (42 U.S.C. 289a-2(a)) is amended by adding at the end the following:

“(3) STRATEGIC PLANNING.—

“(A) IN GENERAL.—The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women’s Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women

and minorities and are focused on reducing health disparities.

“(B) STRATEGIC PLANS.—Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).”

SEC. 2032. TRIENNIAL REPORTS.

Section 403 of the Public Health Service Act (42 U.S.C. 283) is amended—

(1) in the section heading, by striking “BIENNIAL” and inserting “TRIENNIAL”; and

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “biennial” and inserting “triennial”;

(B) by amending paragraph (3) to read as follows:

“(3) A description of intra-National Institutes of Health activities, including—

“(A) identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

“(B) recommendations for promoting coordination of information among the centers of excellence.”;

(C) in paragraph (4)—

(i) in subparagraph (B), by striking “demographic variables and other variables” and inserting “demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health.”; and

(ii) in subparagraph (C)(v)—

(I) by striking “demographic variables and such” and inserting “demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 492B(f), and such”; and

(II) by striking “(regarding inclusion of women and minorities in clinical research)” and inserting “and other applicable requirements regarding inclusion of demographic groups”; and

(D) in paragraph (6)—

(i) in the matter preceding subparagraph (A), by striking “the following:” and inserting “the following—”;

(ii) in subparagraph (A)—

(I) by striking “An evaluation” and inserting “an evaluation”; and

(II) by striking the period and inserting “; and”;

(iii) by striking subparagraphs (B) and (D);

(iv) by redesignating subparagraph (C) as subparagraph (B); and

(v) in subparagraph (B), as redesignated by clause (iv), by striking “Recommendations” and inserting “recommendations”.

SEC. 2033. INCREASING ACCOUNTABILITY AT THE NATIONAL INSTITUTES OF HEALTH.

(a) APPOINTMENT AND TERMS OF DIRECTORS OF NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—Subsection (a) of section 405 of the Public Health Service Act (42 U.S.C. 284) is amended to read as follows:

“(a) APPOINTMENT.—

“(1) IN GENERAL.—The Director of the National Cancer Institute shall be appointed by the President, and the Directors of the other national research institutes and national centers shall be appointed by the Secretary, acting through the Director of National Institutes of Health. Each Director of a national research institute or national center shall report directly to the Director of National Institutes of Health.

“(2) APPOINTMENT.—

“(A) TERM.—A Director of a national research institute or national center who is appointed by the Secretary, acting through the Director of National Institutes of Health, shall be appointed for 5 years.

“(B) REAPPOINTMENT.—At the end of the term of a Director of a national research institute or

national center, the Director may be reappointed in accordance with standards applicable to the relevant appointment mechanism. There shall be no limit on the number of terms that a Director may serve.

“(C) VACANCIES.—If the office of a Director of a national research institute or national center becomes vacant before the end of such Director’s term, the Director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

“(D) CURRENT DIRECTORS.—Each Director of a national research institute or national center who is serving on the date of enactment of the 21st Century Cures Act shall be deemed to be appointed for a 5-year term under this subsection beginning on such date of enactment.

“(E) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director of National Institutes of Health to terminate the appointment of a director referred to in subparagraph (A) before the expiration of such director’s 5-year term.

“(F) NATURE OF APPOINTMENT.—Appointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the Secretary or Director of National Institutes of Health determines relevant.

“(3) NONAPPLICATION OF CERTAIN PROVISION.—The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102-394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.”

(b) REVIEW OF CERTAIN AWARDS BY DIRECTORS.—Section 405(b) of the Public Health Service Act (42 U.S.C. 284(b)) is amended by adding at the end the following:

“(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an ‘R-series grant’), other than an award constituting a noncompetitive renewal of such a grant, or a noncompetitive administrative supplement to such a grant, the Director of such national research institute or national center shall, consistent with the peer review process—

“(A) review and make the final decision with respect to making the award; and

“(B) take into consideration, as appropriate—

“(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 402(m);

“(ii) programs or projects funded by other agencies on similar research topics; and

“(iii) advice by staff and the advisory council or board of such national research institute or national center.”.

(c) REPORT ON DUPLICATION IN FEDERAL BIOMEDICAL RESEARCH.—The Secretary of Health and Human Services (referred to in this subsection as the “Secretary”), shall, not later than 2 years after the date of enactment of this Act, submit a report to Congress on efforts to prevent and eliminate duplicative biomedical research that is not necessary for scientific purposes. Such report shall—

(1) describe the procedures in place to identify such duplicative research, including procedures for monitoring research applications and funded research awards to prevent unnecessary duplication;

(2) describe the steps taken to improve the procedures described in paragraph (1), in response to relevant recommendations made by the Comptroller General of the United States;

(3) describe how the Secretary operationally distinguishes necessary and appropriate scientific replication from unnecessary duplication; and

(4) provide examples of instances where the Secretary has identified unnecessarily duplicative research and the steps taken to eliminate the unnecessary duplication.

SEC. 2034. REDUCING ADMINISTRATIVE BURDEN FOR RESEARCHERS.

(a) PLAN PREPARATION AND IMPLEMENTATION OF MEASURES TO REDUCE ADMINISTRATIVE BURDENS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall—

(A) lead a review by research funding agencies of all regulations and policies related to the disclosure of financial conflicts of interest, including the minimum threshold for reporting financial conflicts of interest;

(B) make revisions, as appropriate, to harmonize existing policies and reduce administrative burden on researchers while maintaining the integrity and credibility of research findings and protections of human participants; and

(C) confer with the Office of the Inspector General about the activities of such office related to financial conflicts of interest involving research funding agencies.

(2) CONSIDERATIONS.—In updating policies under paragraph (1)(B), the Secretary shall consider—

(A) modifying the timelines for the reporting of financial conflicts of interest to just-in-time information by institutions receiving grant or cooperative agreement funding from the National Institutes of Health;

(B) ensuring that financial interest disclosure reporting requirements are appropriate for, and relevant to, awards that will directly fund research, which may include modification of the definition of the term “investigator” for purposes of the regulations and policies described in subparagraphs (A) and (B) of paragraph (1); and

(C) updating any applicable training modules of the National Institutes of Health related to Federal financial interest disclosure.

(b) MONITORING OF SUBRECIPIENTS OF FUNDING FROM THE NATIONAL INSTITUTES OF HEALTH.—The Director of the National Institutes of Health (referred to in this section as the “Director of National Institutes of Health”) shall implement measures to reduce the administrative burdens related to monitoring of subrecipients of grants by primary awardees of funding from the National Institutes of Health, which may incorporate findings and recommendations from existing and ongoing activities. Such measures may include, as appropriate—

(1) an exemption from subrecipient monitoring requirements, upon request from the primary awardees, provided that—

(A) the subrecipient is subject to Federal audit requirements pursuant to the Uniform Guidance of the Office of Management and Budget;

(B) the primary awardee conducts, pursuant to guidance of the National Institutes of Health, a pre-award evaluation of each subrecipient’s risk of noncompliance with Federal statutes and regulations, the conditions of the subaward, and any recurring audit findings; and

(C) such exemption does not absolve the primary awardee of liability for misconduct by subrecipients; and

(2) the implementation of alternative grant structures that obviate the need for subrecipient monitoring, which may include collaborative grant models allowing for multiple primary awardees.

(c) REPORTING OF FINANCIAL EXPENDITURES.—The Secretary, in consultation with the Director of National Institutes of Health, shall evaluate financial expenditure reporting procedures and requirements for recipients of funding from the National Institutes of Health and take action, as appropriate, to avoid duplication between department and agency procedures and requirements and minimize burden to funding recipients.

(d) **ANIMAL CARE AND USE IN RESEARCH.**—Not later than 2 years after the date of enactment of this Act, the Director of National Institutes of Health, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs, shall complete a review of applicable regulations and policies for the care and use of laboratory animals and make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. In carrying out this effort, the Director of the National Institutes of Health shall seek the input of experts, as appropriate. The Director of the National Institutes of Health shall—

(1) identify ways to ensure such regulations and policies are not inconsistent, overlapping, or unnecessarily duplicative, including with respect to inspection and review requirements by Federal agencies and accrediting associations;

(2) take steps to eliminate or reduce identified inconsistencies, overlap, or duplication among such regulations and policies; and

(3) take other actions, as appropriate, to improve the coordination of regulations and policies with respect to research with laboratory animals.

(e) **DOCUMENTATION OF PERSONNEL EXPENSES.**—The Secretary shall clarify the applicability of the requirements under the Office of Management and Budget Uniform Guidance for management and certification systems adopted by entities receiving Federal research grants through the Department of Health and Human Services regarding documentation of personnel expenses, including clarification of the extent to which any flexibility to such requirements specified in such Uniform Guidance applies to entities receiving grants through the Department of Health and Human Services.

(f) **RESEARCH POLICY BOARD.**—

(1) **ESTABLISHMENT.**—Not later than 1 year after the date of enactment of this Act, the Director of the Office of Management and Budget shall establish an advisory committee, to be known as the “Research Policy Board” (referred to in this subsection as the “Board”), to provide Federal Government officials with information on the effects of regulations related to Federal research requirements.

(2) **MEMBERSHIP.**—

(A) **IN GENERAL.**—The Board shall include not more than 10 Federal members, including each of the following Federal members or their designees:

(i) The Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.

(ii) The Director of the Office of Science and Technology Policy.

(iii) The Secretary of Health and Human Services.

(iv) The Director of the National Science Foundation.

(v) The secretaries and directors of other departments and agencies that support or regulate scientific research, as determined by the Director of the Office of Management and Budget.

(B) **NON-FEDERAL MEMBERS.**—The Board shall be comprised of not less than 9 and not more than 12 representatives of academic research institutions, other private, nonprofit research institutions, or other nonprofit organizations with relevant expertise. Such members shall be appointed by a formal process, to be established by the Director of the Office of Management and Budget, in consultation with the Federal membership, and that incorporates—

(i) nomination by members of the nonprofit scientific research community, including academic research institutions; and

(ii) procedures to fill membership positions vacated before the end of a member’s term.

(3) **PURPOSE AND RESPONSIBILITIES.**—The Board shall make recommendations regarding the modification and harmonization of regulations and policies having similar purposes across

research funding agencies to ensure that the administrative burden of such research policy and regulation is minimized to the greatest extent possible and consistent with maintaining responsible oversight of federally funded research. Activities of the Board may include—

(A) providing thorough and informed analysis of regulations and policies;

(B) identifying negative or adverse consequences of existing policies and making actionable recommendations regarding possible improvement of such policies;

(C) making recommendations with respect to efforts within the Federal Government to improve coordination of regulation and policy related to research;

(D) creating a forum for the discussion of research policy or regulatory gaps, challenges, clarification, or harmonization of such policies or regulation, and best practices; and

(E) conducting ongoing assessment and evaluation of regulatory burden, including development of metrics, periodic measurement, and identification of process improvements and policy changes.

(4) **EXPERT SUBCOMMITTEES.**—The Board may form temporary expert subcommittees, as appropriate, to develop timely analysis on pressing issues and assist the Board in anticipating future regulatory challenges, including challenges emerging from new scientific advances.

(5) **REPORTING REQUIREMENTS.**—Not later than 2 years after the date of enactment of this Act, and once thereafter, the Board shall submit a report to the Director of the Office of Management and Budget, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, the Director of the Office of Science and Technology Policy, the heads of relevant Federal departments and agencies, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives containing formal recommendations on the conceptualization, development, harmonization, and reconsideration of scientific research policy, including the regulatory benefits and burdens.

(6) **SUNSET.**—The Board shall terminate on September 30, 2021.

(7) **GAO REPORT.**—Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out by the Board pursuant to this subsection and submit to the appropriate committees of Congress a report regarding the results of the independent evaluation. Such report shall review and assess the Board’s activities with respect to the responsibilities described in paragraph (3).

SEC. 2035. EXEMPTION FOR THE NATIONAL INSTITUTES OF HEALTH FROM THE PAPERWORK REDUCTION ACT REQUIREMENTS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2013, is further amended by adding at the end the following:

“(g) Subchapter I of chapter 35 of title 44, United States Code, shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.”.

SEC. 2036. HIGH-RISK, HIGH-REWARD RESEARCH.

(a) **IN GENERAL.**—Section 402 of the Public Health Service Act (42 U.S.C. 282), as amended by section 2031, is further amended by adding at the end the following:

“(n) **UNIQUE RESEARCH INITIATIVES.**—

“(1) **IN GENERAL.**—The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

“(A) the Precision Medicine Initiative under section 498E; or

“(B) section 402(b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 402A(c)(1) for purposes of carrying out such section 402(b)(7) may be used to engage in such other transactions.

“(2) **REQUIREMENTS.**—The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

“(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

“(B) receives approval for the use of such authority from the Director of NIH; and

“(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.”.

(b) **REPORT TO CONGRESS.**—Not later than September 30, 2020, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct an evaluation of the activities under subsection (n) of section 402 of the Public Health Service Act (42 U.S.C. 282), as added by subsection (a), and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the results of such evaluation.

(c) **DUTIES OF DIRECTORS OF INSTITUTES.**—Section 405(b)(1) of the Public Health Service Act (42 U.S.C. 284(b)(1)) is amended—

(1) by redesignating subparagraphs (C) through (L) as subparagraphs (D) through (M), respectively; and

(2) by inserting after subparagraph (B), the following:

“(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges.”.

SEC. 2037. NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.

(a) **IN GENERAL.**—Section 479(b) of the Public Health Service Act (42 U.S.C. 287(b)) is amended—

(1) in paragraph (1), by striking “phase IIA” and inserting “phase IIB”; and

(2) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by striking “phase IIB” and inserting “phase III”;

(B) in subparagraph (A), by striking “phase IIB” and inserting “phase III”;

(C) in subparagraph (B), by striking “phase IIA” and inserting “phase IIB”; and

(D) in subparagraph (C), by striking “phase IIB” and inserting “phase III”.

(b) **INCREASED TRANSPARENCY.**—Section 479 of the Public Health Service Act (42 U.S.C. 287) is amended—

(1) in subsection (c)—

(A) in paragraph (4)(D), by striking “and” at the end;

(B) in paragraph (5), by striking the period and inserting a semicolon; and

(C) by adding at the end the following:

“(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

“(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews.”; and

(2) by adding at the end the following:

“(d) **INCLUSION OF LIST.**—The first biennial report submitted under this section after the

date of enactment of the 21st Century Cures Act shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

“(e) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.”

SEC. 2038. COLLABORATION AND COORDINATION TO ENHANCE RESEARCH.

(a) **RESEARCH PRIORITIES; COLLABORATIVE RESEARCH PROJECTS.**—Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) by amending paragraph (4) to read as follows:

“(4) shall assemble accurate data to be used to assess research priorities, including—

“(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

“(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

“(i) specifies the inclusion of—

“(I) women;

“(II) members of minority groups;

“(III) relevant age categories, including pediatric subgroups; and

“(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

“(ii) is disaggregated by research area, condition, and disease categories; and

“(iii) is to be made publicly available on the Internet website of the National Institutes of Health;”;

(2) in paragraph (8)—

(A) in subparagraph (A), by striking “and” at the end; and

(B) by adding at the end the following:

“(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

“(i) conduct research involving human subjects; and

“(ii) collect similar data; and

“(D) encourage the collaboration described in subparagraph (C) to—

“(i) allow for an increase in the number of subjects studied; and

“(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;”.

(b) **REPORTING.**—Section 492B(f) of the Public Health Service Act (42 U.S.C. 289a-2(f)) is amended—

(1) by striking “biennial” each place such term appears and inserting “triennial”;

(2) by striking “The advisory council” and inserting the following:

“(1) **IN GENERAL.**—The advisory council”;

(3) by adding at the end the following:

“(2) **CONTENTS.**—Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

“(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

“(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

“(C) For the applicable reporting period, the number of projects of clinical research that in-

clude women and members of minority groups and that—

“(i) have been completed during such reporting period; and

“(ii) are being carried out during such reporting period and have not been completed.

“(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).”.

(c) **COORDINATION.**—Section 486(c)(2) of the Public Health Service Act (42 U.S.C. 287d(c)(2)) is amended by striking “designees” and inserting “senior-level staff designees”.

(d) **IN GENERAL.**—Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.), as amended by section 2021, is further amended by adding at the end the following:

“SEC. 404N. POPULATION FOCUSED RESEARCH.

“The Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

“(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable;

“(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

“(3) addressing methodological challenges.”.

(e) **REPORTING.**—

(1) **IN GENERAL.**—The Secretary, in collaboration with the Director of the National Institutes of Health, shall as appropriate—

(A) continue to support research for the development of appropriate measures related to reporting health information about sexual and gender minority populations; and

(B) not later than 2 years after the date of enactment of this Act, disseminate and make public such measures.

(2) **NATIONAL ACADEMY OF MEDICINE RECOMMENDATIONS.**—In developing the measures described in paragraph (1)(A), the Secretary shall take into account recommendations made by the National Academy of Medicine.

(f) **IMPROVING COORDINATION RELATED TO MINORITY HEALTH AND HEALTH DISPARITIES.**—Section 464a-3 of the Public Health Service Act (42 U.S.C. 285t) is amended—

(1) by redesignating subsection (h), relating to interagency coordination, that follows subsection (j) as subsection (k); and

(2) in subsection (k) (as so redesignated)—

(A) in the subsection heading, by striking “INTERAGENCY” and inserting “INTRA-NATIONAL INSTITUTES OF HEALTH”;

(B) by striking “as the primary Federal officials” and inserting “as the primary Federal official”;

(C) by inserting a comma after “review”;

(D) by striking “Institutes and Centers of the National Institutes of Health” and inserting “national research institutes and national centers”;

(E) by adding at the end the following: “The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.”.

(g) **BASIC RESEARCH.**—

(1) **DEVELOPING POLICIES.**—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health (referred to in this section as the “Director of the National Institutes of Health”), taking into consideration the recommendations developed under section 2039, shall develop policies for projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) **REVISING POLICIES.**—The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

(3) **CONSULTATION AND OUTREACH.**—In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women’s Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) **ADDITIONAL REQUIREMENTS.**—The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(h) **CLINICAL RESEARCH.**—

(1) **IN GENERAL.**—Not later than 1 year after the date of enactment of this Act, the Director of the National Institutes of Health, in consultation with the Director of the Office of Research on Women’s Health and the Director of the National Institute on Minority Health and Health Disparities, shall update the guidelines established under section 492B(d) of Public Health Service Act (42 U.S.C. 289a-2(d)) in accordance with paragraph (2).

(2) **REQUIREMENTS.**—The updated guidelines described in paragraph (1) shall—

(A) reflect the science regarding sex differences;

(B) improve adherence to the requirements under section 492B of the Public Health Service Act (42 U.S.C. 289a-2), including the reporting requirements under subsection (f) of such section; and

(C) clarify the circumstances under which studies should be designed to support the conduct of analyses to detect significant differences in the intervention effect due to demographic factors related to section 492B of the Public Health Service Act, including in the absence of prior studies that demonstrate a difference in study outcomes on the basis of such factors and considering the effects of the absence of such analyses on the availability of data related to demographic differences.

(i) **APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH.**—

(1) **INPUT FROM EXPERTS.**—Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall convene a workshop of experts on pediatric and older populations to provide input on—

(A) appropriate age groups to be included in research studies involving human subjects; and

(B) acceptable justifications for excluding participants from a range of age groups from human subjects research studies.

(2) **POLICY UPDATES.**—Not later than 180 days after the conclusion of the workshop under paragraph (1), the Director of the National Institutes of Health shall make a determination with respect to whether the policies of the National Institutes of Health on the inclusion of relevant age groups in clinical studies need to be updated, and shall update such policies as appropriate. In making the determination, the Director of the National Institutes of Health shall take into consideration whether such policies—

(A) address the consideration of age as an inclusion variable in research involving human subjects; and

(B) identify the criteria for justification for any age-related exclusions in such research.

(3) **PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.**—The Director of the National Institutes of Health shall—

(A) make the findings and conclusions resulting from the workshop under paragraph (1) and updates to policies in accordance with paragraph (2), as applicable, available to the public on the Internet website of the National Institutes of Health; and

(B) ensure that age-related data reported in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) are made available to the public on the Internet website of the National Institutes of Health.

SEC. 2039. ENHANCING THE RIGOR AND REPRODUCIBILITY OF SCIENTIFIC RESEARCH.

(a) **ESTABLISHMENT.**—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health (referred to in this section as the “Advisory Committee”), appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a), to develop and issue recommendations through the Advisory Committee for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

(b) **CONSIDERATIONS.**—In developing and issuing recommendations through the Advisory Committee under subsection (a), the working group established under such subsection shall consider, as appropriate—

(1) preclinical experiment design, including analysis of sex as a biological variable;

(2) clinical experiment design, including—

(A) the diversity of populations studied for clinical research, with respect to biological, social, and other determinants of health that contribute to health disparities;

(B) the circumstances under which summary information regarding biological, social, and other factors that contribute to health disparities should be reported; and

(C) the circumstances under which clinical studies, including clinical trials, should conduct an analysis of the data collected during the study on the basis of biological, social, and other factors that contribute to health disparities;

(3) applicable levels of rigor in statistical methods, methodology, and analysis;

(4) data and information sharing in accordance with applicable privacy laws and regulations; and

(5) any other matter the working group determines relevant.

(c) **POLICIES.**—Not later than 18 months after the date of enactment of this Act, the Director of the National Institutes of Health shall consider the recommendations developed by the working group and issued by the Advisory Committee under subsection (a) and develop or update policies as appropriate.

(d) **REPORT.**—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health shall issue a report to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives regarding recommendations developed under subsection (a) and any subsequent policy changes implemented, to enhance rigor and reproducibility in scientific research funded by the National Institutes of Health.

(e) **CONFIDENTIALITY.**—Nothing in this section authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 2040. IMPROVING MEDICAL REHABILITATION RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH.

(a) **IN GENERAL.**—Section 452 of the Public Health Service Act (42 U.S.C. 285g-4) is amended—

(1) in subsection (b), by striking “conduct and support” and inserting “conduct, support, and coordination”;

(2) in subsection (c)(1)(C), by striking “of the Center” and inserting “within the Center”;

(3) in subsection (d)—

(A) by striking “(d)(1) In consultation” and all that follows through the end of paragraph (1) and inserting the following:

“(d)(1) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall develop a comprehensive plan (referred to in this section as the ‘Research Plan’) for the conduct, support, and coordination of medical rehabilitation research.”;

(B) in paragraph (2)—

(i) in subparagraph (A), by striking “; and” and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting “; and”;

(iii) by adding at the end the following:

“(C) include goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose described in subsection (b).”;

(C) by striking paragraph (4) and inserting the following:

“(4) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall revise and update the Research Plan periodically, as appropriate, or not less than every 5 years. Not later than 30 days after the Research Plan is so revised and updated, the Director of the Center shall transmit the revised and updated Research Plan to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.”;

(D) by adding at the end the following:

“(5) The Director of the Center, in consultation with the Director of the Institute, shall, prior to revising and updating the Research Plan, prepare a report for the coordinating committee established under subsection (e) and the advisory board established under subsection (f) that describes and analyzes the progress during the preceding fiscal year in achieving the goals and objectives described in paragraph (2)(C) and includes expenditures for rehabilitation research at the National Institutes of Health. The report shall include recommendations for revising and updating the Research Plan, and such initiatives as the Director of the Center and the Director of the Institute determine appropriate. In preparing the report, the Director of the Center and the Director of the Institute shall consult with the Director of the National Institutes of Health.”;

(4) in subsection (e)—

(A) in paragraph (2), by inserting “periodically host a scientific conference or workshop on medical rehabilitation research and” after “The Coordinating Committee shall”; and

(B) in paragraph (3), by inserting “the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health,” after “shall be composed of”;

(5) in subsection (f)(3)(B)—

(A) by redesignating clauses (ix) through (xi) as clauses (x) through (xii), respectively; and

(B) by inserting after clause (viii) the following:

“(ix) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives.”; and

(6) by adding at the end the following:

“(g)(1) The Secretary and the heads of other Federal agencies shall jointly review the programs carried out (or proposed to be carried out) by each such official with respect to medical rehabilitation research and, as appropriate, enter into agreements preventing duplication among such programs.

“(2) The Secretary shall, as appropriate, enter into interagency agreements relating to the coordination of medical rehabilitation research conducted by agencies of the National Institutes of Health and other agencies of the Federal Government.

“(h) For purposes of this section, the term ‘medical rehabilitation research’ means the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.”.

(b) **CONFORMING AMENDMENT.**—Section 3 of the National Institutes of Health Amendments of 1990 (42 U.S.C. 285g-4 note) is amended—

(1) in subsection (a), by striking “IN GENERAL.”; and

(2) by striking subsection (b).

SEC. 2041. TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

(a) **TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.**—

(1) **ESTABLISHMENT.**—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall establish a task force, in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), to be known as the “Task Force on Research Specific to Pregnant Women and Lactating Women” (in this section referred to as the “Task Force”).

(2) **DUTIES.**—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

(3) **MEMBERSHIP.**—

(A) **FEDERAL MEMBERS.**—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

(i) The Director of the Centers for Disease Control and Prevention.

(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

(iii) The Commissioner of Food and Drugs.

(iv) The Director of the Office on Women’s Health.

(v) The Director of the National Vaccine Program Office.

(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

(B) **NON-FEDERAL MEMBERS.**—The Task Force shall be composed of each of the following non-Federal members, including—

(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

(ii) nonprofit organizations with expertise related to the health of women and children;

(iii) relevant industry representatives; and

(iv) other representatives, as appropriate.

(C) **LIMITATIONS.**—The non-Federal members described in subparagraph (B) shall—

(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

(ii) be appointed by the Secretary.

(4) TERMINATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

(D) Identification of Federal activities, including—

(i) the state of research on pregnancy and lactation;

(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research.

SEC. 2042. STREAMLINING NATIONAL INSTITUTES OF HEALTH REPORTING REQUIREMENTS.

(a) TRANS-NATIONAL INSTITUTES OF HEALTH RESEARCH REPORTING.—Section 402A(c)(2) of the

Public Health Service Act (42 U.S.C. 282a(c)(2)) is amended—

(1) by amending subparagraph (B) to read as follows:

“(B) REPORTING.—Not later than 2 years after the date of enactment of 21st Century Cures Act, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 403, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers.”; and

(2) in subparagraphs (D) and (E) by striking “(B)(i)” each place it appears and inserting “(B)”.

(b) FRAUD AND ABUSE REPORTING.—Section 403B of the Public Health Service Act (42 U.S.C. 283a-1) is amended—

(1) by striking subsection (b);

(2) by redesignating subsection (c) as subsection (b); and

(3) in subsection (b) (as so redesignated), by striking “subsections (a) and (b)” and inserting “subsection (a)”.

(c) DOCTORAL DEGREES REPORTING.—Section 403C(a)(2) of the Public Health Service Act (42 U.S.C. 283a-2(a)(2)) is amended by striking “(not including any leaves of absence)”.

(d) VACCINE REPORTING.—Section 404B of the Public Health Service Act (42 U.S.C. 283d) is amended—

(1) by striking subsection (b); and

(2) by striking “(a) DEVELOPMENT OF NEW VACCINES.—The Secretary” and inserting “The Secretary”.

(e) NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES.—Section 479(c) of the Public Health Service Act (42 U.S.C. 287(c)) is amended—

(1) in the subsection heading, by striking “ANNUAL” and inserting “BIENNIAL”; and

(2) in the matter preceding paragraph (1), by striking “an annual report” and inserting “a report on a biennial basis”.

(f) REVIEW OF CENTERS OF EXCELLENCE.—

(1) REPEAL.—Section 404H of the Public Health Service Act (42 U.S.C. 283j) is repealed.

(2) CONFORMING AMENDMENT.—Section 399EE(c) of the Public Health Service Act (42 U.S.C. 280-4(c)) is amended by striking “399CC, 404H,” and inserting “399CC”.

(g) RAPID HIV TEST REPORT.—Section 502(a) of the Ryan White CARE Act Amendments of 2000 (42 U.S.C. 300cc note) is amended—

(1) by striking paragraph (2); and

(2) by redesignating paragraph (3) as paragraph (2).

(h) NATIONAL INSTITUTE OF NURSING RESEARCH.—

(1) REPEAL.—Section 464Y of the Public Health Service Act (42 U.S.C. 285q-3) is repealed.

(2) CONFORMING AMENDMENT.—Section 464X(g) of the Public Health Service Act (42 U.S.C. 285q-2(g)) is amended by striking “biennial report made under section 464Y,” and inserting “triennial report made under section 403”.

SEC. 2043. REIMBURSEMENT FOR RESEARCH SUBSTANCES AND LIVING ORGANISMS.

Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended by section 2035, is further amended—

(1) in the flush matter at the end of subsection (a)—

(A) by redesignating such matter as subsection (h)(1); and

(B) by moving such matter so as to appear at the end of such section; and

(2) in subsection (h) (as so redesignated), by adding at the end the following:

“(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf

of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

“(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.”.

SEC. 2044. SENSE OF CONGRESS ON INCREASED INCLUSION OF UNDERREPRESENTED POPULATIONS IN CLINICAL TRIALS.

It is the sense of Congress that the National Institute on Minority Health and Health Disparities should include within its strategic plan under section 402(m) of the Public Health Service Act (42 U.S.C. 282(m)) ways to increase representation of underrepresented populations in clinical trials.

Subtitle E—Advancement of the National Institutes of Health Research and Data Access

SEC. 2051. TECHNICAL UPDATES TO CLINICAL TRIALS DATABASE.

Section 402(j)(2)(D) of the Public Health Service Act (42 U.S.C. 282(j)(2)(D)) is amended—

(1) in clause (ii)(I), by inserting before the semicolon “, unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval”; and

(2) by adding at the end the following:

“(iii) OPTION TO MAKE CERTAIN CLINICAL TRIAL INFORMATION AVAILABLE EARLIER.—The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

“(iv) COMBINATION PRODUCTS.—An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

“(I) an applicable drug clinical trial, if the Secretary determines under section 503(g) of the Federal Food, Drug, and Cosmetic Act that the primary mode of action of such product is that of a drug or biological product; or

“(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.”.

SEC. 2052. COMPLIANCE ACTIVITIES REPORTS.

(a) DEFINITIONS.—In this section:

(1) APPLICABLE CLINICAL TRIAL.—The term “applicable clinical trial” has the meaning given the term in section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(2) SECRETARY.—The term “Secretary” means the Secretary of Health and Human Services.

(b) REPORT ON ACTIVITIES TO ENCOURAGE COMPLIANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Director of the National Institutes of Health and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that describes education and outreach, guidance, enforcement, and other activities undertaken to encourage compliance with section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)).

(c) REPORTS ON CLINICAL TRIALS.—

(1) IN GENERAL.—Not later than 2 years after the final compliance date under the final rule implementing section 402(j) of the Public Health Service Act, and every 2 years thereafter for the next 4 years, the Secretary, acting through the Director of the National Institutes of Health

and in collaboration with the Commissioner of Food and Drugs, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report describing—

(A) the total number of applicable clinical trials with complete data bank registration information registered during the period for which the report is being prepared (broken down by each year of such reporting period);

(B) the total number of applicable clinical trials registered during the period for which the report is being prepared for which results have been submitted to the data bank (broken down by each year of such reporting period);

(C) the activities undertaken by the Secretary to educate responsible persons about data bank registration and results submission requirements, including through issuance of guidance documents, informational meetings, and training sessions; and

(D) the activities described in the report submitted under subsection (b).

(2) **ACTIONS TO ENFORCE COMPLIANCE.**—After the Secretary has undertaken the educational activities described in paragraph (1)(C), the Secretary shall include in subsequent reports submitted under paragraph (1) the number of actions taken by the Secretary during the period for which the report is being prepared to enforce compliance with data bank registration and results submission requirements.

SEC. 2053. UPDATES TO POLICIES TO IMPROVE DATA.

Section 492B(c) of the Public Health Service Act (42 U.S.C. 289a–2(c)) is amended—

(1) by striking “In the case” and inserting the following:

“(1) **IN GENERAL.**—In the case”; and

(2) by adding at the end the following:

“(2) **REPORTING REQUIREMENTS.**—For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after the date of enactment of the 21st Century Cures Act, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

“(A) and which is an applicable clinical trial as defined in section 402(j), the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 402(j)(3), and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 402(j)(5)(A)(ii) when applicable; and

“(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.”.

SEC. 2054. CONSULTATION.

Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall consult with relevant Federal agencies, including the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the National Institutes of Health, as well as other stakeholders (including patients, researchers, physicians, industry representatives, and developers of health information technology) to receive recommendations with respect to enhancements to the clinical trial registry data bank under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), including with respect to usability, functionality, and search capability.

Subtitle F—Facilitating Collaborative Research

SEC. 2061. NATIONAL NEUROLOGICAL CONDITIONS SURVEILLANCE SYSTEM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by inserting after section 399S the following:

“SEC. 399S-1. SURVEILLANCE OF NEUROLOGICAL DISEASES.

“(a) **IN GENERAL.**—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

“(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

“(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

“(b) **RESEARCH.**—The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

“(c) **CONTENT.**—In carrying out subsection (a), the Secretary—

“(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

“(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

“(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

“(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and

“(C) diagnosis and progression markers;

“(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

“(A) the natural history of the diseases;

“(B) the prevention of the diseases;

“(C) the detection, management, and treatment approaches for the diseases; and

“(D) the development of outcomes measures;

“(4) may address issues identified during the consultation process under subsection (d); and

“(5) initially may address a limited number of neurological diseases.

“(d) **CONSULTATION.**—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

“(1) epidemiologists with experience in disease surveillance or registries;

“(2) representatives of national voluntary health associations that—

“(A) focus on neurological diseases; and

“(B) have demonstrated experience in research, care, or patient services;

“(3) health information technology experts or other information management specialists;

“(4) clinicians with expertise in neurological diseases; and

“(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

“(e) **GRANTS.**—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

“(f) **COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES.**—Subject to subsection (h), the Secretary shall—

“(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

“(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

“(B) to State and local agencies; and

“(2) identify, build upon, leverage, and coordinate among existing data and surveillance

systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

“(g) **PUBLIC ACCESS.**—Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

“(h) **PRIVACY.**—The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

“(i) **REPORTS.**—

“(1) **REPORT ON INFORMATION AND ANALYSES.**—Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

“(2) **IMPLEMENTATION REPORT.**—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

“(A) the development and maintenance of the National Neurological Conditions Surveillance System;

“(B) the type of information collected and stored in the surveillance system;

“(C) the use and availability of such information, including guidelines for such use; and

“(D) the use and coordination of databases that collect or maintain information on neurological diseases.

“(j) **DEFINITION.**—In this section, the term “national voluntary health association” means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

“(k) **AUTHORIZATION OF APPROPRIATIONS.**—To carry out this section, there is authorized to be appropriated \$5,000,000 for each of fiscal years 2018 through 2022.”.

SEC. 2062. TICK-BORNE DISEASES.

(a) **IN GENERAL.**—The Secretary of Health and Human Services (referred to in this section as “the Secretary”) shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

(b) **REPORTS.**—The Secretary shall ensure that each triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

(c) **TICK-BORNE DISEASES WORKING GROUP.**—

(1) **ESTABLISHMENT.**—The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the “Working Group”), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

(2) **RESPONSIBILITIES.**—The working group shall—

(A) not later than 2 years after the date of enactment of this Act, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to the pathogenesis, prevention, diagnosis, and treatment of tick-borne diseases;

(iv) gaps in tick-borne disease research described in clause (iii)(II);

(v) the Working Group's meetings required under paragraph (4); and

(vi) the comments received by the Working Group;

(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(3) MEMBERSHIP.—The members of the working group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

(A) FEDERAL MEMBERS.—Seven Federal members, consisting of one of more representatives of each of the following:

(i) The Office of the Assistant Secretary for Health.

(ii) The Food and Drug Administration.

(iii) The Centers for Disease Control and Prevention.

(iv) The National Institutes of Health.

(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) NON-FEDERAL PUBLIC MEMBERS.—Seven non-Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(4) MEETINGS.—The Working Group shall meet not less than twice each year.

(5) REPORTING.—Not later than 2 years after the date of enactment of this Act, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) make such report publicly available on the Internet website of the Department of Health and Human Services.

(6) APPLICABILITY OF FACa.—The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(7) SUNSET.—The Working Group under this section shall terminate 6 years after the date of enactment of this Act.

SEC. 2063. ACCESSING, SHARING, AND USING HEALTH DATA FOR RESEARCH PURPOSES.

(a) GUIDANCE RELATED TO REMOTE ACCESS.—Not later than 1 year after the date of enact-

ment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue guidance clarifying that subparagraph (B) of section 164.512(i)(1)(ii) of part 164 of the Rule (prohibiting the removal of protected health information by a researcher) does not prohibit remote access to health information by a researcher for such purposes as described in section 164.512(i)(1)(ii) of part 164 of the Rule so long as—

(1) at a minimum, security and privacy safeguards, consistent with the requirements of the Rule, are maintained by the covered entity and the researcher; and

(2) the protected health information is not copied or otherwise retained by the researcher.

(b) GUIDANCE RELATED TO STREAMLINING AUTHORIZATION.—Not later than 1 year after the date of enactment of this Act, the Secretary shall issue guidance on the following:

(1) AUTHORIZATION FOR USE AND DISCLOSURE OF HEALTH INFORMATION.—Clarification of the circumstances under which the authorization for the use or disclosure of protected health information, with respect to an individual, for future research purposes contains a sufficient description of the purpose of the use or disclosure, such as if the authorization—

(A) sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research;

(B) either—

(i) states that the authorization will expire on a particular date or on the occurrence of a particular event; or

(ii) states that the authorization will remain valid unless and until it is revoked by the individual; and

(C) provides instruction to the individual on how to revoke such authorization at any time.

(2) REMINDER OF THE RIGHT TO REVOKE.—Clarification of the circumstances under which it is appropriate to provide an individual with an annual notice or reminder that the individual has the right to revoke such authorization.

(3) REVOCATION OF AUTHORIZATION.—Clarification of appropriate mechanisms by which an individual may revoke an authorization for future research purposes, such as described in paragraph (1)(C).

(c) WORKING GROUP ON PROTECTED HEALTH INFORMATION FOR RESEARCH.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall convene a working group to study and report on the uses and disclosures of protected health information for research purposes, under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).

(2) MEMBERS.—The working group shall include representatives of—

(A) relevant Federal agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Office for Civil Rights;

(B) the research community;

(C) patients;

(D) experts in civil rights, such as privacy rights;

(E) developers of health information technology;

(F) experts in data privacy and security;

(G) health care providers;

(H) bioethicists; and

(I) other experts and entities, as the Secretary determines appropriate.

(3) REPORT.—Not later than 1 year after the date on which the working group is convened under paragraph (1), the working group shall conduct a review and submit a report to the Secretary containing recommendations on whether the uses and disclosures of protected health information for research purposes should be modified to allow protected health information to be

available, as appropriate, for research purposes, including studies to obtain generalizable knowledge, while protecting individuals' privacy rights. In conducting the review and making recommendations, the working group shall—

(A) address, at a minimum—

(i) the appropriate manner and timing of authorization, including whether additional notification to the individual should be required when the individual's protected health information will be used or disclosed for such research;

(ii) opportunities for individuals to set preferences on the manner in which their protected health information is used in research;

(iii) opportunities for patients to revoke authorization;

(iv) notification to individuals of a breach in privacy;

(v) existing gaps in statute, regulation, or policy related to protecting the privacy of individuals; and

(vi) existing barriers to research related to the current restrictions on the uses and disclosures of protected health information; and

(B) consider, at a minimum—

(i) expectations and preferences on how an individual's protected health information is shared and used;

(ii) issues related to specific subgroups of people, such as children, incarcerated individuals, and individuals with a cognitive or intellectual disability impacting capacity to consent;

(iii) relevant Federal and State laws;

(iv) models of facilitating data access and levels of data access, including data segmentation, where applicable;

(v) potential impacts of disclosure and non-disclosure of protected health information on access to health care services; and

(vi) the potential uses of such data.

(4) REPORT SUBMISSION.—The Secretary shall submit the report under paragraph (3) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and shall post such report on the appropriate Internet website of the Department of Health and Human Services.

(5) TERMINATION.—The working group convened under paragraph (1) shall terminate the day after the report under paragraph (3) is submitted to Congress and made public in accordance with paragraph (4).

(d) DEFINITIONS.—In this section:

(1) THE RULE.—References to "the Rule" refer to part 160 or part 164, as appropriate, of title 45, Code of Federal Regulations (or any successor regulation).

(2) PART 164.—References to a specified section of "part 164", refer to such specified section of part 164 of title 45, Code of Federal Regulations (or any successor section).

Subtitle G—Promoting Pediatric Research SEC. 2071. NATIONAL PEDIATRIC RESEARCH NETWORK.

Section 409D(d) of the Public Health Service Act (42 U.S.C. 284h(d)) is amended—

(1) in paragraph (1), by striking "in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of" and inserting "in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support"; and

(2) in paragraph (2)(A) and the first sentence of paragraph (2)(E), by striking "may" each place such term appears and inserting "shall".

SEC. 2072. GLOBAL PEDIATRIC CLINICAL STUDY NETWORK.

It is the sense of Congress that—

(1) the National Institutes of Health should encourage a global pediatric clinical study network by providing grants, contracts, or cooperative agreements to support new and early stage

investigators who participate in the global pediatric clinical study network;

(2) the Secretary of Health and Human Services (referred to in this section as the “Secretary”) should engage with clinical investigators and appropriate authorities outside of the United States, including authorities in the European Union, during the formation of the global pediatric clinical study network to encourage the participation of such investigator and authorities; and

(3) once a global pediatric clinical study network is established and becomes operational, the Secretary should continue to encourage and facilitate the participation of clinical investigators and appropriate authorities outside of the United States, including in the European Union, to participate in the network with the goal of enhancing the global reach of the network.

TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

SEC. 3001. PATIENT EXPERIENCE DATA.

Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amended—

(1) in subsection (a)—

(A) in the subsection heading, by striking “IN GENERAL” and inserting “PATIENT ENGAGEMENT IN DRUGS AND DEVICES”;

(B) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and moving such subparagraphs 2 ems to the right; and

(C) by striking “The Secretary” and inserting the following:

“(1) IN GENERAL.—The Secretary”;

(2) by redesignating subsections (b) through (e) as paragraphs (2) through (5), respectively, and moving such paragraphs 2 ems to the right; and

(3) by adding at the end the following:

“(b) STATEMENT OF PATIENT EXPERIENCE.—

“(1) IN GENERAL.—Following the approval of an application that was submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act at least 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application.

“(2) DATA AND INFORMATION.—The data and information referred to in paragraph (1) are—

“(A) patient experience data;

“(B) information on patient-focused drug development tools; and

“(C) other relevant information, as determined by the Secretary.

“(c) PATIENT EXPERIENCE DATA.—For purposes of this section, the term ‘patient experience data’ includes data that—

“(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

“(2) are intended to provide information about patients’ experiences with a disease or condition, including—

“(A) the impact of such disease or condition, or a related therapy, on patients’ lives; and

“(B) patient preferences with respect to treatment of such disease or condition.”.

SEC. 3002. PATIENT-FOCUSED DRUG DEVELOPMENT GUIDANCE.

(a) PUBLICATION OF GUIDANCE DOCUMENTS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”), acting through the Commissioner of Food and Drugs, shall develop a plan to issue draft and final versions of one or more guidance documents, over a period of 5 years, regarding the collection of patient experience data, and the use of such data and related information in drug development. Not later than

18 months after the date of enactment of this Act, the Secretary shall issue a draft version of at least one such guidance document. Not later than 18 months after the public comment period on the draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(b) PATIENT EXPERIENCE DATA.—For purposes of this section, the term “patient experience data” has the meaning given such term in section 569C of the Federal Food, Drug, and Cosmetic Act (as added by section 3001).

(c) CONTENTS.—The guidance documents described in subsection (a) shall address—

(1) methodological approaches that a person seeking to collect patient experience data for submission to, and proposed use by, the Secretary in regulatory decisionmaking may use, that are relevant and objective and ensure that such data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis;

(2) methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient’s disease;

(3) approaches to identifying and developing methods to measure impacts to patients that will help facilitate collection of patient experience data in clinical trials;

(4) methodologies, standards, and technologies to collect and analyze clinical outcome assessments for purposes of regulatory decisionmaking;

(5) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Secretary may submit such proposed draft guidance to the Secretary;

(6) the format and content required for submissions under this section to the Secretary, including with respect to the information described in paragraph (1);

(7) how the Secretary intends to respond to submissions of information described in paragraph (1), if applicable, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and

(8) how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)), to inform regulatory decisionmaking.

SEC. 3003. STREAMLINING PATIENT INPUT.

Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, that is initiated by the Secretary under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002.

SEC. 3004. REPORT ON PATIENT EXPERIENCE DRUG DEVELOPMENT.

Not later than June 1 of 2021, 2026, and 2031, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall prepare and publish on the Internet website of the Food and Drug Administration a report assessing the use of patient experience data in regulatory decisionmaking, in particular with respect to the review of patient experience data and information on patient-focused drug development tools as part of applications approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

Subtitle B—Advancing New Drug Therapies

SEC. 3011. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following new section:

“SEC. 507. QUALIFICATION OF DRUG DEVELOPMENT TOOLS.

“(a) PROCESS FOR QUALIFICATION.—

“(1) IN GENERAL.—The Secretary shall establish a process for the qualification of drug development tools for a proposed context of use under which—

“(A)(i) a requestor initiates such process by submitting a letter of intent to the Secretary; and

“(ii) the Secretary accepts or declines to accept such letter of intent;

“(B)(i) if the Secretary accepts the letter of intent, a requestor submits a qualification plan to the Secretary; and

“(ii) the Secretary accepts or declines to accept the qualification plan; and

“(C)(i) if the Secretary accepts the qualification plan, the requestor submits to the Secretary a full qualification package;

“(ii) the Secretary determines whether to accept such qualification package for review; and

“(iii) if the Secretary accepts such qualification package for review, the Secretary conducts such review in accordance with this section.

“(2) ACCEPTANCE AND REVIEW OF SUBMISSIONS.—

“(A) IN GENERAL.—Subparagraphs (B), (C), and (D) shall apply with respect to the treatment of a letter of intent, a qualification plan, or a full qualification package submitted under paragraph (1) (referred to in this paragraph as ‘qualification submissions’).

“(B) ACCEPTANCE FACTORS; NONACCEPTANCE.—The Secretary shall determine whether to accept a qualification submission based on factors which may include the scientific merit of the qualification submission. A determination not to accept a submission under paragraph (1) shall not be construed as a final determination by the Secretary under this section regarding the qualification of a drug development tool for its proposed context of use.

“(C) PRIORITIZATION OF QUALIFICATION REVIEW.—The Secretary may prioritize the review of a full qualification package submitted under paragraph (1) with respect to a drug development tool, based on factors determined appropriate by the Secretary, including—

“(i) as applicable, the severity, rarity, or prevalence of the disease or condition targeted by the drug development tool and the availability or lack of alternative treatments for such disease or condition; and

“(ii) the identification, by the Secretary or by biomedical research consortia and other expert stakeholders, of such a drug development tool and its proposed context of use as a public health priority.

“(D) ENGAGEMENT OF EXTERNAL EXPERTS.—The Secretary may, for purposes of the review of qualification submissions, through the use of cooperative agreements, grants, or other appropriate mechanisms, consult with biomedical research consortia and may consider the recommendations of such consortia with respect to the review of any qualification plan submitted under paragraph (1) or the review of any full qualification package under paragraph (3).

“(3) REVIEW OF FULL QUALIFICATION PACKAGE.—The Secretary shall—

“(A) conduct a comprehensive review of a full qualification package accepted under paragraph (1)(C); and

“(B) determine whether the drug development tool at issue is qualified for its proposed context of use.

“(4) QUALIFICATION.—The Secretary shall determine whether a drug development tool is qualified for a proposed context of use based on

the scientific merit of a full qualification package reviewed under paragraph (3).

“(b) EFFECT OF QUALIFICATION.—

“(1) **IN GENERAL.**—A drug development tool determined to be qualified under subsection (a)(4) for a proposed context of use specified by the requestor may be used by any person in such context of use for the purposes described in paragraph (2).

“(2) **USE OF A DRUG DEVELOPMENT TOOL.**—Subject to paragraph (3), a drug development tool qualified under this section may be used for—

“(A) supporting or obtaining approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act; or

“(B) supporting the investigational use of a drug or biological product under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

“(3) RESCISSION OR MODIFICATION.—

“(A) **IN GENERAL.**—The Secretary may rescind or modify a determination under this section to qualify a drug development tool if the Secretary determines that the drug development tool is not appropriate for the proposed context of use specified by the requestor. Such a determination may be based on new information that calls into question the basis for such qualification.

“(B) **MEETING FOR REVIEW.**—If the Secretary rescinds or modifies under subparagraph (A) a determination to qualify a drug development tool, the requestor involved shall, on request, be granted a meeting with the Secretary to discuss the basis of the Secretary’s decision to rescind or modify the determination before the effective date of the rescission or modification.

“(c) TRANSPARENCY.—

“(1) **IN GENERAL.**—Subject to paragraph (3), the Secretary shall make publicly available, and update on at least a biannual basis, on the Internet website of the Food and Drug Administration the following:

“(A) Information with respect to each qualification submission under the qualification process under subsection (a), including—

“(i) the stage of the review process applicable to the submission;

“(ii) the date of the most recent change in stage status;

“(iii) whether external scientific experts were utilized in the development of a qualification plan or the review of a full qualification package; and

“(iv) submissions from requestors under the qualification process under subsection (a), including any data and evidence contained in such submissions, and any updates to such submissions.

“(B) The Secretary’s formal written determinations in response to such qualification submissions.

“(C) Any rescissions or modifications under subsection (b)(3) of a determination to qualify a drug development tool.

“(D) Summary reviews that document conclusions and recommendations for determinations to qualify drug development tools under subsection (a).

“(E) A comprehensive list of—

“(i) all drug development tools qualified under subsection (a); and

“(ii) all surrogate endpoints which were the basis of approval or licensure (as applicable) of a drug or biological product (including in accordance with section 506(c)) under section 505 of this Act or section 351 of the Public Health Service Act.

“(2) **RELATION TO TRADE SECRETS ACT.**—Information made publicly available by the Secretary under paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18, United States Code.

“(3) **APPLICABILITY.**—Nothing in this section shall be construed as authorizing the Secretary to disclose any information contained in an ap-

plication submitted under section 505 of this Act or section 351 of the Public Health Service Act that is confidential commercial or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

“(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed—

“(1) to alter the standards of evidence under subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d), or under section 351 of the Public Health Service Act (as applicable); or

“(2) to limit the authority of the Secretary to approve or license products under this Act or the Public Health Service Act, as applicable (as in effect before the date of the enactment of the 21st Century Cures Act).

“(e) DEFINITIONS.—In this section:

“(1) **BIOMARKER.**—The term ‘biomarker’—

“(A) means a characteristic (such as a physiologic, pathologic, or anatomic characteristic or measurement) that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes, or biological responses to a therapeutic intervention; and

“(B) includes a surrogate endpoint.

“(2) **BIOMEDICAL RESEARCH CONSORTIA.**—The term ‘biomedical research consortia’ means collaborative groups that may take the form of public-private partnerships and may include government agencies, institutions of higher education (as defined in section 101(a) of the Higher Education Act of 1965), patient advocacy groups, industry representatives, clinical and scientific experts, and other relevant entities and individuals.

“(3) **CLINICAL OUTCOME ASSESSMENT.**—The term ‘clinical outcome assessment’ means—

“(A) a measurement of a patient’s symptoms, overall mental state, or the effects of a disease or condition on how the patient functions; and

“(B) includes a patient-reported outcome.

“(4) **CONTEXT OF USE.**—The term ‘context of use’ means, with respect to a drug development tool, the circumstances under which the drug development tool is to be used in drug development and regulatory review.

“(5) **DRUG DEVELOPMENT TOOL.**—The term ‘drug development tool’ includes—

“(A) a biomarker;

“(B) a clinical outcome assessment; and

“(C) any other method, material, or measure that the Secretary determines aids drug development and regulatory review for purposes of this section.

“(6) **PATIENT-REPORTED OUTCOME.**—The term ‘patient-reported outcome’ means a measurement based on a report from a patient regarding the status of the patient’s health condition without amendment or interpretation of the patient’s report by a clinician or any other person.

“(7) **QUALIFICATION.**—The terms ‘qualification’ and ‘qualified’ mean a determination by the Secretary that a drug development tool and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review under this Act.

“(8) **REQUESTOR.**—The term ‘requestor’ means an entity or entities, including a drug sponsor or a biomedical research consortia, seeking to qualify a drug development tool for a proposed context of use under this section.

“(9) **SURROGATE ENDPOINT.**—The term ‘surrogate endpoint’ means a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure, that is not itself a direct measurement of clinical benefit, and—

“(A) is known to predict clinical benefit and could be used to support traditional approval of a drug or biological product; or

“(B) is reasonably likely to predict clinical benefit and could be used to support the accelerated approval of a drug or biological product in accordance with section 506(c).”

(b) GUIDANCE.—

(1) **IN GENERAL.**—The Secretary of Health and Human Services (referred to in this section as

the “Secretary”) shall, in consultation with biomedical research consortia (as defined in subsection (e) of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) and other interested parties through a collaborative public process, issue guidance to implement such section 507 that—

(A) provides a conceptual framework describing appropriate standards and scientific approaches to support the development of biomarkers delineated under the taxonomy established under paragraph (3);

(B) with respect to the qualification process under such section 507—

(i) describes the requirements that entities seeking to qualify a drug development tool under such section shall observe when engaging in such process;

(ii) outlines reasonable timeframes for the Secretary’s review of letters, qualification plans, or full qualification packages submitted under such process; and

(iii) establishes a process by which such entities or the Secretary may consult with biomedical research consortia and other individuals and entities with expert knowledge and insights that may assist the Secretary in the review of qualification plans and full qualification submissions under such section; and

(C) includes such other information as the Secretary determines appropriate.

(2) **TIMING.**—Not later than 3 years after the date of the enactment of this Act, the Secretary shall issue draft guidance under paragraph (1) on the implementation of section 507 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)). The Secretary shall issue final guidance on the implementation of such section not later than 6 months after the date on which the comment period for the draft guidance closes.

(3) TAXONOMY.—

(A) **IN GENERAL.**—For purposes of informing guidance under this subsection, the Secretary shall, in consultation with biomedical research consortia and other interested parties through a collaborative public process, establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug development.

(B) **PUBLIC AVAILABILITY.**—Not later than 2 years after the date of the enactment of this Act, the Secretary shall make such taxonomy publicly available in draft form for public comment. The Secretary shall finalize the taxonomy not later than 1 year after the close of the public comment period.

(c) MEETING AND REPORT.—

(1) **MEETING.**—Not later than 2 years after the date of the enactment of this Act, the Secretary shall convene a public meeting to describe and solicit public input regarding the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) **REPORT.**—Not later than 5 years after the date of the enactment of this Act, the Secretary shall make publicly available on the Internet website of the Food and Drug Administration a report. Such report shall include, with respect to the qualification process under section 507 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), information on—

(A) the number of requests submitted, as a letter of intent, for qualification of a drug development tool (as defined in subsection (e) of such section 507);

(B) the number of such requests accepted and determined to be eligible for submission of a qualification plan or full qualification package (as such terms are defined in subsection (e) of such section 507), respectively;

(C) the number of such requests for which external scientific experts were utilized in the development of a qualification plan or review of a full qualification package;

(D) the number of qualification plans and full qualification packages, respectively, submitted to the Secretary; and

(E) the drug development tools qualified through such qualification process, specified by type of tool, such as a biomarker or clinical outcome assessment (as such terms are defined in subsection (e) of such section 507).

SEC. 3012. TARGETED DRUGS FOR RARE DISEASES.

Subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa et seq.) is amended by inserting after section 529 the following:

“SEC. 529A. TARGETED DRUGS FOR RARE DISEASES.

“(a) **PURPOSE.**—The purpose of this section, through the approach provided for in subsection (b), is to—

“(1) facilitate the development, review, and approval of genetically targeted drugs and variant protein targeted drugs to address an unmet medical need in one or more patient subgroups, including subgroups of patients with different mutations of a gene, with respect to rare diseases or conditions that are serious or life-threatening; and

“(2) maximize the use of scientific tools or methods, including surrogate endpoints and other biomarkers, for such purposes.

“(b) **LEVERAGING OF DATA FROM PREVIOUSLY APPROVED DRUG APPLICATION OR APPLICATIONS.**—The Secretary may, consistent with applicable standards for approval under this Act or section 351(a) of the Public Health Service Act, allow the sponsor of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for a genetically targeted drug or a variant protein targeted drug to rely upon data and information—

“(1) previously developed by the same sponsor (or another sponsor that has provided the sponsor with a contractual right of reference to such data and information); and

“(2) submitted by a sponsor described in paragraph (1) in support of one or more previously approved applications that were submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act,

for a drug that incorporates or utilizes the same or similar genetically targeted technology as the drug or drugs that are the subject of an application or applications described in paragraph (2) or for a variant protein targeted drug that is the same or incorporates or utilizes the same variant protein targeted drug, as the drug or drugs that are the subject of an application or applications described in paragraph (2).

“(c) **DEFINITIONS.**—For purposes of this section—

“(1) the term ‘genetically targeted drug’ means a drug that—

“(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

“(B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and

“(C) incorporates or utilizes a genetically targeted technology;

“(2) the term ‘genetically targeted technology’ means a technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene; and

“(3) the term ‘variant protein targeted drug’ means a drug that—

“(A) is the subject of an application under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act for the treatment of a rare disease or condition (as such term is defined in section 526) that is serious or life-threatening;

“(B) modulates the function of a product of a mutated gene where such mutation is responsible in whole or in part for a given disease or condition; and

“(C) is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition.

“(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to—

“(1) alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act (as authorized prior to the date of enactment of the 21st Century Cures Act), including the standards of evidence, and applicable conditions, for approval under such applicable Act; or

“(2) confer any new rights, beyond those authorized under this Act or the Public Health Service Act prior to enactment of this section, with respect to the permissibility of a sponsor referencing information contained in another application submitted under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.”.

SEC. 3013. REAUTHORIZATION OF PROGRAM TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) **IN GENERAL.**—Section 529(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is amended by striking paragraph (5) and inserting the following:

“(5) **TERMINATION OF AUTHORITY.**—The Secretary may not award any priority review vouchers under paragraph (1) after September 30, 2020, unless the rare pediatric disease product application—

“(A) is for a drug that, not later than September 30, 2020, is designated under subsection (d) as a drug for a rare pediatric disease; and

“(B) is, not later than September 30, 2022, approved under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act.”.

(b) **REPORT.**—The Advancing Hope Act of 2016 (Public Law 114–229) is amended by striking section 3.

SEC. 3014. GAO STUDY OF PRIORITY REVIEW VOUCHER PROGRAMS.

(a) **STUDY.**—The Comptroller General of the United States (referred to in this section as the “Comptroller General”) shall conduct a study addressing the effectiveness and overall impact of the following priority review voucher programs, including any such programs amended or established by this Act:

(1) The neglected tropical disease priority review voucher program under section 524 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n).

(2) The rare pediatric disease priority review voucher program under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff).

(3) The medical countermeasure priority review voucher program under section 565A of the Federal Food, Drug, and Cosmetic Act, as added by section 3086.

(b) **ISSUANCE OF REPORT.**—Not later than January 31, 2020, the Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study under subsection (a).

(c) **CONTENTS OF REPORTS.**—The report submitted under subsection (b) shall address—

(1) for each drug for which a priority review voucher has been awarded as of initiation of the study—

(A) the indications for which the drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a));

(B) whether, and to what extent, the voucher impacted the sponsor’s decision to develop the drug; and

(C) whether, and to what extent, the approval or licensure of the drug, as applicable and appropriate—

(i) addressed a global unmet need related to the treatment or prevention of a neglected tropical disease, including whether the sponsor of a drug coordinated with international development organizations;

(ii) addressed an unmet need related to the treatment of a rare pediatric disease; or

(iii) affected the Nation’s preparedness against a chemical, biological, radiological, or nuclear threat, including naturally occurring threats;

(2) for each drug for which a priority review voucher has been used—

(A) the indications for which such drug is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), pursuant to an application under section 505(b)(1) of such Act, or licensed under section 351(a) of the Public Health Service Act (42 U.S.C. 262);

(B) the value of the voucher, if transferred; and

(C) the length of time between the date on which the voucher was awarded and the date on which the voucher was used; and

(3) an analysis of the priority review voucher programs described in subsection (a), including—

(A) the resources used by the Food and Drug Administration in reviewing drugs for which vouchers were used, including the effect of the programs on the Food and Drug Administration’s review of drugs for which priority review vouchers were not awarded or used;

(B) whether any improvements to such programs are necessary to appropriately target incentives for the development of drugs that would likely not otherwise be developed, or developed in as timely a manner, and, as applicable and appropriate—

(i) address global unmet needs related to the treatment or prevention of neglected tropical diseases, including in countries in which neglected tropical diseases are endemic; or

(ii) address unmet needs related to the treatment of rare pediatric diseases; and

(C) whether the sunset of the rare pediatric disease program and medical countermeasure program has had an impact on the program, including any potential unintended consequences.

(d) **PROTECTION OF NATIONAL SECURITY.**—The Comptroller General shall conduct the study and issue reports under this section in a manner that does not compromise national security.

SEC. 3015. AMENDMENTS TO THE ORPHAN DRUG GRANTS.

Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a), by striking paragraph (1) and inserting the following: “(1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses,”; and

(2) in subsection (b)(1)—

(A) in subparagraph (A)(ii), by striking “and” after the semicolon;

(B) in subparagraph (B), by striking the period and inserting “; and”;

(C) by adding at the end the following:

“(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

“(i) develop or validate a drug development tool related to a rare disease or condition; or

“(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.”.

SEC. 3016. GRANTS FOR STUDYING CONTINUOUS DRUG MANUFACTURING.

(a) *IN GENERAL.*—The Secretary of Health and Human Services may award grants to institutions of higher education and nonprofit organizations for the purpose of studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.

(b) *DEFINITIONS.*—In this section—

(1) the term “drug” has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(2) the term “biological product” has the meaning given such term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)); and

(3) the term “institution of higher education” has the meaning given such term in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)).

Subtitle C—Modern Trial Design and Evidence Development**SEC. 3021. NOVEL CLINICAL TRIAL DESIGNS.**

(a) *PROPOSALS FOR USE OF NOVEL CLINICAL TRIAL DESIGNS FOR DRUGS AND BIOLOGICAL PRODUCTS.*—For purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall conduct a public meeting and issue guidance in accordance with subsection (b).

(b) *GUIDANCE ADDRESSING USE OF NOVEL CLINICAL TRIAL DESIGNS.*—

(1) *IN GENERAL.*—The Secretary, acting through the Commissioner of Food and Drugs, shall update or issue guidance addressing the use of complex adaptive and other novel trial design in the development and regulatory review and approval or licensure for drugs and biological products.

(2) *CONTENTS.*—The guidance under paragraph (1) shall address—

(A) the use of complex adaptive and other novel trial designs, including how such clinical trials proposed or submitted help to satisfy the substantial evidence standard under section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d));

(B) how sponsors may obtain feedback from the Secretary on technical issues related to modeling and simulations prior to—

(i) completion of such modeling or simulations; or

(ii) the submission of resulting information to the Secretary;

(C) the types of quantitative and qualitative information that should be submitted for review; and

(D) recommended analysis methodologies.

(3) *PUBLIC MEETING.*—Prior to updating or issuing the guidance required by paragraph (1), the Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patient advocacy organizations, consumer groups, and disease research foundations, through a public meeting to be held not later than 18 months after the date of enactment of this Act.

(4) *TIMING.*—The Secretary shall update or issue a draft version of the guidance required by paragraph (1) not later than 18 months after the date of the public meeting required by paragraph (3) and finalize such guidance not later than 1 year after the date on which the public comment period for the draft guidance closes.

SEC. 3022. REAL WORLD EVIDENCE.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505E (21 U.S.C. 355f) the following:

“SEC. 505F. UTILIZING REAL WORLD EVIDENCE.

“(a) *IN GENERAL.*—The Secretary shall establish a program to evaluate the potential use of real world evidence—

“(1) to help to support the approval of a new indication for a drug approved under section 505(c); and

“(2) to help to support or satisfy postapproval study requirements.

“(b) *REAL WORLD EVIDENCE DEFINED.*—In this section, the term “real world evidence” means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials.

“(c) *PROGRAM FRAMEWORK.*—

“(1) *IN GENERAL.*—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall establish a draft framework for implementation of the program under this section.

“(2) *CONTENTS OF FRAMEWORK.*—The framework shall include information describing—

“(A) the sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

“(B) the gaps in data collection activities;

“(C) the standards and methodologies for collection and analysis of real world evidence; and

“(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

“(3) *CONSULTATION.*—

“(A) *IN GENERAL.*—In developing the program framework under this subsection, the Secretary shall consult with regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties.

“(B) *PROCESS.*—The consultation under subparagraph (A) may be carried out through approaches such as—

“(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate;

“(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

“(iii) public workshops with the entities described in such subparagraph.

“(d) *PROGRAM IMPLEMENTATION.*—The Secretary shall, not later than 2 years after the date of enactment of the 21st Century Cures Act and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real world evidence.

“(e) *GUIDANCE FOR INDUSTRY.*—The Secretary shall—

“(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

“(A) the circumstances under which sponsors of drugs and the Secretary may rely on real world evidence for the purposes described in paragraphs (1) and (2) of subsection (a); and

“(B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes;

“(2) not later than 5 years after the date of enactment of the 21st Century Cures Act, issue draft guidance for industry as described in paragraph (1); and

“(3) not later than 18 months after the close of the public comment period for the draft guidance described in paragraph (2), issue revised draft guidance or final guidance.

“(f) *RULE OF CONSTRUCTION.*—

“(1) *IN GENERAL.*—Subject to paragraph (2), nothing in this section prohibits the Secretary from using real world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such unspecified use.

“(2) *STANDARDS OF EVIDENCE AND SECRETARY’S AUTHORITY.*—This section shall not be construed to alter—

“(A) the standards of evidence under—

“(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

“(ii) section 351(a) of the Public Health Service Act; or

“(B) the Secretary’s authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.”

SEC. 3023. PROTECTION OF HUMAN RESEARCH SUBJECTS.

(a) *IN GENERAL.*—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

(b) *AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.*—The Secretary shall, as appropriate—

(1) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules as may be necessary—

(A) to reduce regulatory duplication and unnecessary delays;

(B) to modernize such provisions in the context of multisite and cooperative research projects; and

(C) to protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs, in a manner consistent with subparagraph (B); and

(2) ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may—

(A) use joint or shared review;

(B) rely upon the review of—

(i) an independent institutional review board; or

(ii) an institutional review board of an entity other than the sponsor of the research; or

(C) use similar arrangements to avoid duplication of effort.

(c) *CONSULTATION.*—In harmonizing or modifying regulations or guidance under this section, the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, patient groups, and others).

(d) *TIMING.*—The Secretary shall complete the harmonization described in subsection (a) not later than 3 years after the date of enactment of this Act.

(e) *PROGRESS REPORT.*—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

(f) *DEFINITIONS.*—

(1) *HUMAN SUBJECT REGULATIONS.*—In this section:

(A) *FDA HUMAN SUBJECT REGULATIONS.*—The term “FDA Human Subject Regulations” means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

(B) *HHS HUMAN SUBJECT REGULATIONS.*—The term “HHS Human Subject Regulations” means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

(C) *VULNERABLE POPULATION RULES.*—The term “vulnerable population rules” means—

(i) except in the case of research described in clause (ii), the provisions of subparts B through D of part 46, Code of Federal Regulations (or any successor regulations); and

(ii) in the case of research that is subject to FDA Human Subject Regulations, the provisions applicable to vulnerable populations under part 56 of title 21, Code of Federal Regulations (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

(2) **INSTITUTIONAL REVIEW BOARD DEFINED.**—In this section, the term “institutional review board” has the meaning that applies to the term “institutional review board” under the HHS Human Subject Regulations.

(B) **LEAD INSTITUTIONAL REVIEW BOARD.**—The term “lead institutional review board” means an institutional review board that otherwise meets the requirements of the HHS Human Subject Regulations and enters into a written agreement with an institution, another institutional review board, a sponsor, or a principal investigator to approve and oversee human subject research that is conducted at multiple locations. References to an institutional review board include an institutional review board that serves a single institution and a lead institutional review board.

SEC. 3024. INFORMED CONSENT WAIVER OR ALTERATION FOR CLINICAL INVESTIGATIONS.

(a) **DEVICES.**—Section 520(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(3)) is amended—

(1) in subparagraph (D), by striking “except where subject to such conditions as the Secretary may prescribe, the investigator” and inserting the following: “except where, subject to such conditions as the Secretary may prescribe—

“(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

“(ii) the investigator”; and

(2) in the matter following subparagraph (D), by striking “subparagraph (D)” and inserting “subparagraph (D)(ii)”.

(b) **DRUGS.**—Section 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(4)) is amended by striking “except where it is not feasible or it is contrary to the best interests of such human beings” and inserting “except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings”.

Subtitle D—Patient Access to Therapies and Information

SEC. 3031. SUMMARY LEVEL REVIEW.

(a) **FFDCA.**—Section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) is amended by adding at the end the following:

“(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

“(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

“(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

“(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

“(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

“(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

“(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

“(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

“(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

“(D) In this paragraph—

“(i) the term ‘qualified indication’ means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

“(ii) the term ‘qualified data summary’ means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.”.

(b) **PHSA.**—Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended by adding at the end the following:

“(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

“(ii) In this subparagraph, the terms ‘qualified indication’ and ‘qualified data summary’ have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.”.

SEC. 3032. EXPANDED ACCESS POLICY.

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561 (21 U.S.C. 360bbb) the following:

“SEC. 561A. EXPANDED ACCESS POLICY REQUIRED FOR INVESTIGATIONAL DRUGS.

“(a) **IN GENERAL.**—The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 561(b) for provision of such a drug.

“(b) **PUBLIC AVAILABILITY OF EXPANDED ACCESS POLICY.**—The policies under subsection (a) shall be made public and readily available, such as by posting such policies on a publicly available Internet website. Such policies may be generally applicable to all investigational drugs of such manufacturer or distributor.

“(c) **CONTENT OF POLICY.**—A policy described in subsection (a) shall include—

“(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

“(2) procedures for making such requests;

“(3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests;

“(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and

“(5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for such drug that is required under section 402(j)(2)(A)(ii)(II)(gg) of the Public Health Service Act.

“(d) **NO GUARANTEE OF ACCESS.**—The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

“(e) **REVISED POLICY.**—Nothing in this section shall prevent a manufacturer or distributor from revising a policy required under this section at any time.

“(f) **APPLICATION.**—This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the later of—

“(1) the date that is 60 calendar days after the date of enactment of the 21st Century Cures Act; or

“(2) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational drug.”.

SEC. 3033. ACCELERATED APPROVAL FOR REGENERATIVE ADVANCED THERAPIES.

(a) **IN GENERAL.**—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by transferring subsection (e) (relating to construction) so that it appears before subsection (f) (relating to awareness efforts); and

(2) by adding at the end the following:

“(g) **REGENERATIVE ADVANCED THERAPY.**—

“(1) **IN GENERAL.**—The Secretary, at the request of the sponsor of a drug, shall facilitate an efficient development program for, and expedite review of, such drug if the drug qualifies as a regenerative advanced therapy under the criteria described in paragraph (2).

“(2) **CRITERIA.**—A drug is eligible for designation as a regenerative advanced therapy under this subsection if—

“(A) the drug is a regenerative medicine therapy (as defined in paragraph (8));

“(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

“(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

“(3) **REQUEST FOR DESIGNATION.**—The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

“(4) **DESIGNATION.**—Not later than 60 calendar days after the receipt of a request under paragraph (3), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (2). If the Secretary determines that the drug meets the criteria, the Secretary shall designate the drug as a regenerative advanced therapy and shall take such actions as are appropriate under paragraph (1). If the Secretary determines that a drug does not meet the criteria for such designation, the Secretary shall include with the determination a written description of the rationale for such determination.

“(5) **ACTIONS.**—The sponsor of a regenerative advanced therapy shall be eligible for the actions to expedite development and review of such therapy under subsection (a)(3)(B), including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (c).

“(6) **ACCESS TO EXPEDITED APPROVAL PATHWAYS.**—An application for a regenerative advanced therapy under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act may be—

“(A) eligible for priority review, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012; and

“(B) eligible for accelerated approval under subsection (c), as agreed upon pursuant to subsection (a)(3)(B), through, as appropriate—

“(i) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or

“(ii) reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

“(7) **POSTAPPROVAL REQUIREMENTS.**—The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the postapproval requirements under subsection

(c) may, as appropriate, fulfill such requirements, as the Secretary may require, through—

“(A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records;

“(B) the collection of larger confirmatory data sets, as agreed upon pursuant to subsection (a)(3)(B); or

“(C) postapproval monitoring of all patients treated with such therapy prior to approval of the therapy.

“(B) **DEFINITION.**—For purposes of this section, the term ‘regenerative medicine therapy’ includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations.”.

(b) **RULE OF CONSTRUCTION.**—Nothing in this section and the amendments made by this section shall be construed to alter the authority of the Secretary of Health and Human Services—

(1) to approve drugs pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and section 351 of the Public Health Service Act (42 U.S.C. 262) as authorized prior to the date of enactment of the 21st Century Cures Act, including the standards of evidence, and applicable conditions, for approval under such Acts; or

(2) to alter the authority of the Secretary to require postapproval studies pursuant to such Acts, as authorized prior to the date of enactment of the 21st Century Cures Act.

(c) **CONFORMING AMENDMENT.**—Section 506(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(e)(1)) is amended by inserting “and the 21st Century Cures Act” after “Food and Drug Administration Safety and Innovation Act”.

SEC. 3034. GUIDANCE REGARDING DEVICES USED IN THE RECOVERY, ISOLATION, OR DELIVERY OF REGENERATIVE ADVANCED THERAPIES.

(a) **DRAFT GUIDANCE.**—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance clarifying how, in the context of regenerative advanced therapies, the Secretary will evaluate devices used in the recovery, isolation, or delivery of regenerative advanced therapies. In doing so, the Secretary shall specifically address—

(1) how the Food and Drug Administration intends to simplify and streamline regulatory requirements for combination device and cell or tissue products;

(2) what, if any, intended uses or specific attributes would result in a device used with a regenerative therapy product to be classified as a class III device;

(3) when the Food and Drug Administration considers it is necessary, if ever, for the intended use of a device to be limited to a specific intended use with only one particular type of cell; and

(4) application of the least burdensome approach to demonstrate how a device may be used with more than one cell type.

(b) **FINAL GUIDANCE.**—Not later than 12 months after the close of the period for public comment on the draft guidance under subsection (a), the Secretary of Health and Human Services shall finalize such guidance.

SEC. 3035. REPORT ON REGENERATIVE ADVANCED THERAPIES.

(a) **REPORT TO CONGRESS.**—Before March 1 of each calendar year, the Secretary of Health and Human Services shall, with respect to the previous calendar year, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(1) the number and type of applications for approval of regenerative advanced therapies filed, approved or licensed as applicable, withdrawn, or denied; and

(2) how many of such applications or therapies, as applicable, were granted accelerated approval or priority review.

(b) **REGENERATIVE ADVANCED THERAPY.**—In this section, the term “regenerative advanced therapy” has the meaning given such term in section 506(g) of the Federal Food, Drug, and Cosmetic Act, as added by section 3033 of this Act.

SEC. 3036. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506F the following:

“SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

“(a) **IN GENERAL.**—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.

“(b) **ACTIVITIES.**—

“(1) **IN GENERAL.**—In carrying out this section, the Secretary shall continue to—

“(A) identify opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

“(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

“(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

“(2) **REGULATIONS AND GUIDANCE.**—Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

“(c) **DEFINITIONS.**—For purposes of this section, the terms ‘regenerative medicine therapy’ and ‘regenerative advanced therapy’ have the meanings given such terms in section 506(g).”.

SEC. 3037. HEALTH CARE ECONOMIC INFORMATION.

Section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)) is amended—

(1) by striking “(a) If its” and inserting “(a)(1) If its”;

(2) by striking “a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations” and inserting “a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement”;

(3) by striking “directly relates” and inserting “relates”;

(4) by striking “and is based on competent and reliable scientific evidence. The require-

ments set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph” and inserting “, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act. The requirements set forth in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph”; and

(5) by striking “In this paragraph, the term” and all that follows and inserting the following:

“(2)(A) For purposes of this paragraph, the term ‘health care economic information’ means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

“(B) Such term does not include any analysis that relates only to an indication that is not approved under section 505 or under section 351 of the Public Health Service Act for such drug.”.

SEC. 3038. COMBINATION PRODUCT INNOVATION.

(a) **IN GENERAL.**—Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) by striking paragraph (3);

(2) by redesignating paragraph (2) as paragraph (7);

(3) by redesignating paragraphs (4) and (5) as paragraphs (8) and (9), respectively;

(4) by striking “(g)(1)” and all that follows through the end of paragraph (1) and inserting the following:

“(g)(1)(A) The Secretary shall, in accordance with this subsection, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

“(B) The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

“(C) For purposes of this subsection, the term ‘primary mode of action’ means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

“(D) The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

“(i) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

“(ii) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

“(iii) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

“(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body.

“(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)—

“(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to

such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination; and

“(ii)(I) the sponsor of the combination product may propose one or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of such product;

“(II) if the sponsor proposes any such studies, the Secretary and the sponsor of such product shall collaborate and seek to reach agreement, within a reasonable time of such proposal, not to exceed 90 calendar days, on the design of such studies; and

“(III) if an agreement is reached under subclause (II) and the sponsor conducts one or more of such studies, the Secretary shall consider the data resulting from any such study when reevaluating the determination of the primary mode of action of such product, and unless and until such reevaluation has occurred and the Secretary issues a new determination, the determination of the Secretary under subparagraph (D) shall remain in effect.

“(2)(A)(i) To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on such combination product. If the Secretary concludes that a determination of the primary mode of action pursuant to paragraph (1)(D) is necessary, the sponsor may request such meeting only after the Secretary makes such determination. If the sponsor submits a written meeting request, the Secretary shall, not later than 75 calendar days after receiving such request, meet with the sponsor of such combination product.

“(ii) A meeting under clause (i) may—

“(I) address the standards and requirements for market approval or clearance of the combination product;

“(II) address other issues relevant to such combination product, such as requirements related to postmarket modification of such combination product and good manufacturing practices applicable to such combination product; and

“(III) identify elements under subclauses (I) and (II) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding such elements, at the time a request for such meeting is made.

“(iii) Any agreement under this subparagraph shall be in writing and made part of the administrative record by the Secretary.

“(iv) Any such agreement shall remain in effect, except—

“(I) upon the written agreement of the Secretary and the sponsor or applicant; or

“(II) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior than such director, in consultation with consulting centers and the Office, as appropriate, that an issue essential to determining whether the standard for market clearance or other applicable standard under this Act or the Public Health Service Act applicable to the combination product has been identified since the agreement was reached, or that deviating from the agreement is otherwise justifiable based on scientific evidence, for public health reasons.

“(3) For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (4), the Secretary may require that the sponsor of such combination product submit to the Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this Act or the Public Health Service Act, including any incremental risks and benefits posed by such combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or

substantial equivalence for the approved constituent part relied upon by the applicant in accordance with paragraph (5).

“(4) For purposes of paragraph (3), an approved constituent part is—

“(A) a drug constituent part of a combination product being reviewed in a single application or request under section 515, 510(k), or 513(f)(2) (submitted in accordance with paragraph (5)), that is an approved drug, provided such application or request complies with paragraph (5);

“(B) a device constituent part approved under section 515 that is referenced by the sponsor and that is available for use by the Secretary under section 520(h)(4); or

“(C) any constituent part that was previously approved, cleared, or classified under section 505, 510(k), 513(f)(2), or 515 of this Act for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 760(a)(2).

“(5)(A) If an application is submitted under section 515 or 510(k) or a request is submitted under section 513(f)(2), consistent with any determination made under paragraph (1)(D), for a combination product containing as a constituent part an approved drug—

“(i) the application or request shall include the certification or statement described in section 505(b)(2); and

“(ii) the applicant or requester shall provide notice as described in section 505(b)(3).

“(B) For purposes of this paragraph and paragraph (4), the term ‘approved drug’ means an active ingredient—

“(i) that was in an application previously approved under section 505(c);

“(ii) where such application is relied upon by the applicant submitting the application or request described in subparagraph (A);

“(iii) for which full reports of investigations that have been made to show whether such drug is safe for use and whether such drug is effective in use were not conducted by or for the applicant submitting the application or request described in subparagraph (A); and

“(iv) for which the applicant submitting the application or request described in subparagraph (A) has not obtained a right of reference or use from the person by or for whom the investigations described in clause (iii) were conducted.

“(C) The following provisions shall apply with respect to an application or request described in subparagraph (A) to the same extent and in the same manner as if such application or request were an application described in section 505(b)(2) that referenced the approved drug:

“(i) Subparagraphs (A), (B), (C), and (D) of section 505(c)(3).

“(ii) Clauses (ii), (iii), and (iv) of section 505(c)(3)(E).

“(iii) Subsections (b) and (c) of section 505A.

“(iv) Section 505E(a).

“(v) Section 527(a).

“(D) Notwithstanding any other provision of this subsection, an application or request for classification for a combination product described in subparagraph (A) shall be considered an application submitted under section 505(b)(2) for purposes of section 271(e)(2)(A) of title 35, United States Code.

“(6) Nothing in this subsection shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.”;

(5) in paragraph (8) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) by amending clause (i) to read as follows:

“(i) In carrying out this subsection, the Office shall help to ensure timely and effective premarket review that involves more than one agency center by coordinating such reviews, overseeing the timeliness of such reviews, and overseeing the alignment of feedback regarding such reviews.”;

(ii) in clause (ii), by inserting “and alignment” after “the timeliness” each place it appears; and

(iii) by adding at the end the following new clauses:

“(iii) The Office shall ensure that, with respect to a combination product, a designated person or persons in the primary agency center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate communications to and from any consulting center involved in such premarket review, if requested by such primary agency center or any such consulting center. Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

“(iv) The Office shall, with respect to the premarket review of a combination product—

“(I) ensure that any meeting between the Secretary and the sponsor of such product is attended by each agency center involved in the review, as appropriate;

“(II) ensure that each consulting agency center has completed its premarket review and provided the results of such review to the primary agency center in a timely manner; and

“(III) ensure that each consulting center follows the guidance described in clause (vi) and advises, as appropriate, on other relevant regulations, guidances, and policies.

“(v) In seeking agency action with respect to a combination product, the sponsor of such product—

“(I) shall identify the product as a combination product; and

“(II) may request in writing the participation of representatives of the Office in meetings related to such combination product, or to have the Office otherwise engage on such regulatory matters concerning the combination product.

“(vi) Not later than 4 years after the date of enactment of the 21st Century Cures Act, and after a public comment period of not less than 60 calendar days, the Secretary shall issue a final guidance that describes—

“(I) the structured process for managing pre-submission interactions with sponsors developing combination products;

“(II) the best practices for ensuring that the feedback in such pre-submission interactions represents the Agency’s best advice based on the information provided during such pre-submission interactions;

“(III) the information that is required to be submitted with a meeting request under paragraph (2), how such meetings relate to other types of meetings in the Food and Drug Administration, and the form and content of any agreement reached through a meeting under such paragraph (2);”;

(B) in subparagraph (G)—

(i) in the matter preceding clause (i), by inserting “(except with respect to clause (iv), beginning not later than one year after the date of the enactment of the 21st Century Cures Act)” after “enactment of this paragraph”;

(ii) in clause (ii), by striking “and” at the end;

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

(iv) by adding at the end the following new clause:

“(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product’s sponsor.”;

(6) in paragraph (9) (as redesignated by paragraph (3))—

(A) in subparagraph (C)—

(i) in clause (i), by striking the comma at the end and inserting a semicolon;

(ii) in clause (ii), by striking “, and” at the end and inserting a semicolon;

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

(iv) by adding at the end the following:

“(iv) *de novo* classification under section 513(a)(1).”; and

(B) by adding at the end the following:

“(D) The terms ‘premarket review’ and ‘reviews’ include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application, notification, or request for classification submitted under section 505, 510(k), 513(f)(2), 515, or 520 of this Act or under section 351 of the Public Health Service Act, including with respect to investigational use of the product.”.

(b) **INFORMATION FOR APPROVAL OF COMBINATION PRODUCTS.**—Section 520(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(h)(4)) is amended—

(1) in subparagraph (A), by striking “Any information” and inserting “Subject to subparagraph (C), any information”; and

(2) by adding at the end the following new subparagraph:

“(C) No information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) may be used to approve or clear any application submitted under section 515 or 510(k) or to classify a product under section 513(f)(2) for a combination product containing as a constituent part an approved drug (as defined in section 503(g)(5)(B)) unless—

“(i) the application includes the certification or statement referenced in section 503(g)(5)(A);

“(ii) the applicant provides notice as described in section 503(g)(5)(A); and

“(iii) the Secretary’s approval of such application is subject to the provisions in section 503(g)(5)(C).”.

(c) **VARIATIONS FROM CGMP STREAMLINED APPROACH.**—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the “Secretary”) shall identify types of combination products and manufacturing processes with respect to which the Secretary proposes that good manufacturing processes may be adopted that vary from the requirements set forth in section 4.4 of title 21, Code of Federal Regulations (or any successor regulations) or that the Secretary proposes can satisfy the requirements in section 4.4 through alternative or streamlined mechanisms. The Secretary shall identify such types, variations from such requirements, and such mechanisms, in a proposed list published in the Federal Register. After a public comment period regarding the appropriate good manufacturing practices for such types, the Secretary shall publish a final list in the Federal Register, notwithstanding section 553 of title 5, United States Code. The Secretary shall evaluate such types, variations, and mechanisms using a risk-based approach. The Secretary shall periodically review such final list.

Subtitle E—Antimicrobial Innovation and Stewardship

SEC. 3041. ANTIMICROBIAL RESISTANCE MONITORING.

(a) **IN GENERAL.**—Section 319E of the Public Health Service Act (42 U.S.C. 247d-5) is amended—

(1) by redesignating subsections (f) and (g) as subsections (l) and (m), respectively; and

(2) by inserting after subsection (e), the following:

“(f) **MONITORING AT FEDERAL HEALTH CARE FACILITIES.**—The Secretary shall encourage reporting on aggregate antimicrobial drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service and shall provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.

“(g) **REPORT ON ANTIMICROBIAL RESISTANCE IN HUMANS AND USE OF ANTIMICROBIAL DRUGS.**—Not later than 1 year after the date of enactment of the 21st Century Cures Act, and annually thereafter, the Secretary shall prepare and make publicly available data and information concerning—

“(1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including such drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act;

“(2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and

“(3) coordination between the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs with respect to the monitoring of—

“(A) any applicable resistance under paragraph (1); and

“(B) drugs approved under section 506(h) of the Federal Food, Drug, and Cosmetic Act.

“(h) **INFORMATION RELATED TO ANTIMICROBIAL STEWARDSHIP PROGRAMS.**—The Secretary shall, as appropriate, disseminate guidance, educational materials, or other appropriate materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.

“(i) **SUPPORTING STATE-BASED ACTIVITIES TO COMBAT ANTIMICROBIAL RESISTANCE.**—The Secretary shall continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance. Such efforts may include activities to related to—

“(1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs;

“(2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and

“(3) promoting antimicrobial stewardship.

“(j) **ANTIMICROBIAL RESISTANCE AND STEWARDSHIP ACTIVITIES.**—

“(1) **IN GENERAL.**—For the purposes of supporting stewardship activities, examining changes in antimicrobial resistance, and evaluating the effectiveness of section 506(h) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall—

“(A) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities); and

“(B) evaluate—

“(i) antimicrobial resistance data using a standardized approach; and

“(ii) trends in the utilization of drugs approved under such section 506(h) with respect to patient populations.

“(2) **USE OF SYSTEMS.**—The Secretary shall use available systems, including the National Healthcare Safety Network or other systems identified by the Secretary, to fulfill the requirements or conduct activities under this section.

“(k) **ANTIMICROBIAL.**—For purposes of subsections (f) through (j), the term ‘antimicrobial’ includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth of other microorganisms, as appropriate.”.

(b) **AVAILABILITY OF DATA.**—The Secretary shall make the data collected pursuant to this subsection public. Nothing in this subsection shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 3042. LIMITED POPULATION PATHWAY.

Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by section 3033, is further amended by adding at the end the following:

“(h) **LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL AND ANTIFUNGAL DRUGS.**—

“(1) **IN GENERAL.**—The Secretary may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a limited population drug pursuant to this subsection only if—

“(A) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs;

“(B) the standards for approval under section 505(c) and (d), or the standards for licensure under section 351 of the Public Health Service Act, as applicable, are met; and

“(C) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.

“(2) **BENEFIT-RISK CONSIDERATION.**—The Secretary’s determination of safety and effectiveness of an antibacterial or antifungal drug shall reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such limited population. Such drug may be approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

“(3) **ADDITIONAL REQUIREMENTS.**—A drug approved under this subsection shall be subject to the following requirements, in addition to any other applicable requirements of this Act:

“(A) **LABELING.**—To indicate that the safety and effectiveness of a drug approved under this subsection has been demonstrated only with respect to a limited population—

“(i) all labeling and advertising of an antibacterial or antifungal drug approved under this subsection shall contain the statement ‘Limited Population’ in a prominent manner and adjacent to, and not more prominent than—

“(I) the proprietary name of such drug, if any; or

“(II) if there is no proprietary name, the established name of the drug, if any, as defined in section 503(e)(3), or, in the case of a drug that is a biological product, the proper name, as defined by regulation; and

“(ii) the prescribing information for the drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: ‘This drug is indicated for use in a limited and specific population of patients.’.

“(B) **PROMOTIONAL MATERIAL.**—The sponsor of an antibacterial or antifungal drug subject to this subsection shall submit to the Secretary copies of all promotional materials related to such drug at least 30 calendar days prior to dissemination of the materials.

“(4) **OTHER PROGRAMS.**—A sponsor of a drug that seeks approval of a drug under this subsection may also seek designation or approval, as applicable, of such drug under other applicable sections or subsections of this Act or the Public Health Service Act.

“(5) **GUIDANCE.**—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. The Secretary shall publish final guidance within 18 months of the close of the public comment period on such draft guidance. The Secretary may approve antibacterial and antifungal drugs under this subsection prior to issuing guidance under this paragraph.

“(6) **ADVICE.**—The Secretary shall provide prompt advice to the sponsor of a drug for

which the sponsor seeks approval under this subsection to enable the sponsor to plan a development program to obtain the necessary data for such approval, and to conduct any additional studies that would be required to gain approval of such drug for use in a broader population.

“(7) **TERMINATION OF LIMITATIONS.**—If, after approval of a drug under this subsection, the Secretary approves a broader indication for such drug under section 505(b) or section 351(a) of the Public Health Service Act, the Secretary may remove any postmarketing conditions, including requirements with respect to labeling and review of promotional materials under paragraph (3), applicable to the approval of the drug under this subsection.

“(8) **RULES OF CONSTRUCTION.**—Nothing in this subsection shall be construed to alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act, including the standards of evidence and applicable conditions for approval under such Acts, the standards of approval of a drug under such Acts, or to alter the authority of the Secretary to monitor drugs pursuant to such Acts.

“(9) **REPORTING AND ACCOUNTABILITY.**—

“(A) **BIENNIAL REPORTING.**—The Secretary shall report to Congress not less often than once every 2 years on the number of requests for approval, and the number of approvals, of an antibacterial or antifungal drug under this subsection.

“(B) **GAO REPORT.**—Not later than December 2021, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the coordination of activities required under section 319E of the Public Health Service Act. Such report shall include a review of such activities, and the extent to which the use of the pathway established under this subsection has streamlined premarket approval for antibacterial or antifungal drugs for limited populations, if such pathway has functioned as intended, if such pathway has helped provide for safe and effective treatment for patients, if such premarket approval would be appropriate for other categories of drugs, and if the authorities under this subsection have affected antibacterial or antifungal resistance.”

SEC. 3043. PRESCRIBING AUTHORITY.

Nothing in this subtitle, or an amendment made by this subtitle, shall be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under subsection (h) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) (as added by section 3042), by health care professionals, or to limit the practice of health care.

SEC. 3044. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS; ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.

(a) **IN GENERAL.**—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 511 the following:

“SEC. 511A. SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA FOR MICROORGANISMS.

“(a) **PURPOSE; IDENTIFICATION OF CRITERIA.**—“(1) **PURPOSE.**—The purpose of this section is to clarify the Secretary’s authority to—

“(A) efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health, due to, among other things, the constant evolution of microorganisms that leads to the development of resistance to drugs that have been effective in decreasing morbidity and mortality for patients, which warrants unique management of antimicrobial drugs that is inappropriate for most other drugs in order to delay or prevent the development of further resistance to existing therapies;

“(B) provide for public notice of the availability of recognized interpretive criteria and interpretive criteria standards; and

“(C) clear under section 510(k), classify under section 513(f)(2), or approve under section 515, antimicrobial susceptibility testing devices utilizing updated, recognized susceptibility test interpretive criteria to characterize the in vitro susceptibility of particular bacteria, fungi, or other microorganisms, as applicable, to antimicrobial drugs.

“(2) **IDENTIFICATION OF CRITERIA.**—The Secretary shall identify appropriate susceptibility test interpretive criteria with respect to antimicrobial drugs—

“(A) if such criteria are available on the date of approval of the drug under section 505 of this Act or licensure of the drug under section 351 of the Public Health Service Act (as applicable), upon such approval or licensure; or

“(B) if such criteria are unavailable on such date, on the date on which such criteria are available for such drug.

“(3) **BASES FOR INITIAL IDENTIFICATION.**—The Secretary shall identify appropriate susceptibility test interpretive criteria under paragraph (2), based on the Secretary’s review of, to the extent available and relevant—

“(A) preclinical and clinical data, including pharmacokinetic, pharmacodynamic, and epidemiological data;

“(B) the relationship of susceptibility test interpretive criteria to morbidity and mortality associated with the disease or condition for which such drug is used; and

“(C) such other evidence and information as the Secretary considers appropriate.

“(b) **SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA WEBSITE.**—

“(1) **IN GENERAL.**—Not later than 1 year after the date of the enactment of the 21st Century Cures Act, the Secretary shall establish, and maintain thereafter, on the website of the Food and Drug Administration, a dedicated website that contains a list of any appropriate new or updated susceptibility test interpretive criteria standards and interpretive criteria in accordance with paragraph (2) (referred to in this section as the ‘Interpretive Criteria Website’).

“(2) **LISTING OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA STANDARDS AND INTERPRETIVE CRITERIA.**—

“(A) **IN GENERAL.**—The list described in paragraph (1) shall consist of any new or updated susceptibility test interpretive criteria standards that are—

“(i) established by a nationally or internationally recognized standard development organization that—

“(I) establishes and maintains procedures to address potential conflicts of interest and ensure transparent decisionmaking;

“(II) holds open meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decisionmaking; and

“(III) permits its standards to be made publicly available, through the National Library of Medicine or another similar source acceptable to the Secretary; and

“(ii) recognized in whole, or in part, by the Secretary under subsection (c).

“(B) **OTHER LIST.**—The Interpretive Criteria Website shall, in addition to the list described in subparagraph (A), include a list of interpretive criteria, if any, that the Secretary has determined to be appropriate with respect to legally marketed antimicrobial drugs, where—

“(i) the Secretary does not recognize, in whole or in part, an interpretive criteria standard described under subparagraph (A) otherwise applicable to such a drug;

“(ii) the Secretary withdraws under subsection (c)(1)(A) recognition of a standard, in whole or in part, otherwise applicable to such a drug;

“(iii) the Secretary approves an application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, with respect to marketing of such a drug for which

there are no relevant interpretive criteria included in a standard recognized by the Secretary under subsection (c); or

“(iv) because the characteristics of such a drug differ from other drugs with the same active ingredient, the interpretive criteria with respect to such drug—

“(I) differ from otherwise applicable interpretive criteria included in a standard listed under subparagraph (A) or interpretive criteria otherwise listed under this subparagraph; and

“(II) are determined by the Secretary to be appropriate for the drug.

“(C) **REQUIRED STATEMENTS.**—The Interpretive Criteria Website shall include statements conveying—

“(i) that the website provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to a certain drug (or drugs);

“(ii) that—

“(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the susceptibility information described in clause (i) to be included on the website; and

“(II) the clinical significance of such susceptibility information in such instances is unknown;

“(iii) that the approved product labeling for specific drugs provides the uses for which the Secretary has approved the product; and

“(iv) any other information that the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria included on the website.

“(3) **NOTICE.**—Not later than the date on which the Interpretive Criteria Website is established, the Secretary shall publish a notice of that establishment in the Federal Register.

“(4) **INAPPLICABILITY OF MISBRANDING PROVISION.**—The inclusion in the approved labeling of an antimicrobial drug of a reference or hyperlink to the Interpretive Criteria Website, in and of itself, shall not cause the drug to be misbranded in violation of section 502.

“(5) **TRADE SECRETS AND CONFIDENTIAL INFORMATION.**—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code.

“(c) **RECOGNITION OF SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA.**—

“(1) **EVALUATION AND PUBLICATION.**—

“(A) **IN GENERAL.**—Beginning on the date of the establishment of the Interpretive Criteria Website, and at least every 6 months thereafter, the Secretary shall—

“(i) evaluate any appropriate new or updated susceptibility test interpretive criteria standards established by a nationally or internationally recognized standard development organization described in subsection (b)(2)(A)(i); and

“(ii) publish on the public website of the Food and Drug Administration a notice—

“(I) withdrawing recognition of any different susceptibility test interpretive criteria standard, in whole or in part;

“(II) recognizing the new or updated standards;

“(III) recognizing one or more parts of the new or updated interpretive criteria specified in such a standard and declining to recognize the remainder of such standard; and

“(IV) making any necessary updates to the lists under subsection (b)(2).

“(B) **UPON APPROVAL OF A DRUG.**—Upon the approval of an initial or supplemental application for an antimicrobial drug under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, where such approval is based on susceptibility test interpretive criteria which differ from those contained in a standard recognized, or from those otherwise

listed, by the Secretary pursuant to this subsection, or for which there are no relevant interpretive criteria standards recognized, or interpretive criteria otherwise listed, by the Secretary pursuant to this subsection, the Secretary shall update the lists under subparagraphs (A) and (B) of subsection (b)(2) to include the susceptibility test interpretive criteria upon which such approval was based.

“(2) BASES FOR UPDATING INTERPRETIVE CRITERIA STANDARDS.—In evaluating new or updated susceptibility test interpretive criteria standards under paragraph (1)(A), the Secretary may consider—

“(A) the Secretary’s determination that such a standard is not applicable to a particular drug because the characteristics of the drug differ from other drugs with the same active ingredient;

“(B) information provided by interested third parties, including public comment on the annual compilation of notices published under paragraph (3);

“(C) any bases used to identify susceptibility test interpretive criteria under subsection (a)(2); and

“(D) such other information or factors as the Secretary determines appropriate.

“(3) ANNUAL COMPILATION OF NOTICES.—Each year, the Secretary shall compile the notices published under paragraph (1)(A) and publish such compilation in the Federal Register and provide for public comment. If the Secretary receives comments, the Secretary shall review such comments and, if the Secretary determines appropriate, update pursuant to this subsection susceptibility test interpretive criteria standards or criteria—

“(A) recognized by the Secretary under this subsection; or

“(B) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

“(4) RELATION TO SECTION 514(C).—Any susceptibility test interpretive standard recognized under this subsection or any criteria otherwise listed under subsection (b)(2)(B) shall be deemed to be recognized as a standard by the Secretary under section 514(c)(1).

“(5) VOLUNTARY USE OF INTERPRETIVE CRITERIA.—Nothing in this section prohibits a person from seeking approval or clearance of a drug or device, or changes to the drug or the device, on the basis of susceptibility test interpretive criteria which differ from those contained in a standard recognized, or from those otherwise listed, by the Secretary pursuant to subsection (b)(2).

“(d) ANTIMICROBIAL DRUG LABELING.—

“(1) DRUGS MARKETED PRIOR TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—

“(A) IN GENERAL.—With respect to an antimicrobial drug lawfully introduced or delivered for introduction into interstate commerce for commercial distribution before the establishment of the Interpretive Criteria Website, a holder of an approved application under section 505 of this Act or section 351 of the Public Health Service Act, as applicable, for each such drug, not later than 1 year after establishment of the Interpretive Criteria Website described in subsection (b)(1), shall remove susceptibility test interpretive criteria, if any, and related information from the approved drug labeling and replace it with a reference to the Interpretive Criteria Website.

“(B) LABELING CHANGES.—The labeling changes required by this section shall be considered a minor change under section 314.70 of title 21, Code of Federal Regulations (or any successor regulations) that may be implemented through documentation in the next applicable annual report.

“(2) DRUGS MARKETED SUBSEQUENT TO ESTABLISHMENT OF INTERPRETIVE CRITERIA WEBSITE.—With respect to antimicrobial drugs approved on or after the date of the establishment of the Interpretive Criteria Website described in subsection (b)(1), the labeling for such a drug shall

include, in lieu of susceptibility test interpretive criteria and related information, a reference to such Website.

“(e) SPECIAL CONDITION FOR MARKETING OF ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—

“(1) IN GENERAL.—Notwithstanding sections 501, 502, 505, 510, 513, and 515, if the conditions specified in paragraph (2) are met (in addition to other applicable provisions under this chapter) with respect to an antimicrobial susceptibility testing device described in subsection (f)(1), the Secretary may authorize the marketing of such device for a use described in such subsection.

“(2) CONDITIONS APPLICABLE TO ANTIMICROBIAL SUSCEPTIBILITY TESTING DEVICES.—The conditions specified in this paragraph are the following:

“(A) The device is used to make a determination of susceptibility using susceptibility test interpretive criteria that are—

“(i) included in a standard recognized by the Secretary under subsection (c); or

“(ii) otherwise listed on the Interpretive Criteria Website under subsection (b)(2).

“(B) The labeling of such device includes statements conveying—

“(i) that the device provides information about the in vitro susceptibility of bacteria, fungi, or other microorganisms, as applicable to antimicrobial drugs;

“(ii) that—

“(I) the safety and efficacy of such drugs in treating clinical infections due to such bacteria, fungi, or other microorganisms, as applicable, may or may not have been established in adequate and well-controlled clinical trials in order for the device to report the susceptibility of such bacteria, fungi, or other microorganisms, as applicable, to such drugs; and

“(II) the clinical significance of such susceptibility information in those instances is unknown;

“(iii) that the approved labeling for drugs tested using such a device provides the uses for which the Secretary has approved such drugs; and

“(iv) any other information the Secretary determines appropriate to adequately convey the meaning of the data supporting the recognition or listing of susceptibility test interpretive criteria standards or susceptibility test interpretive criteria described in subparagraph (A).

“(C) The antimicrobial susceptibility testing device meets all other requirements to be cleared under section 510(k), classified under section 513(f)(2), or approved under section 515.

“(f) DEFINITIONS.—In this section:

“(1) The term ‘antimicrobial susceptibility testing device’ means a device that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).

“(2) The term ‘qualified infectious disease product’ means a qualified infectious disease product designated under section 505E(d).

“(3) The term ‘susceptibility test interpretive criteria’ means—

“(A) one or more specific numerical values which characterize the susceptibility of bacteria or other microorganisms to the drug tested; and

“(B) related categorizations of such susceptibility, including categorization of the drug as susceptible, intermediate, resistant, or such other term as the Secretary determines appropriate.

“(4)(A) The term ‘antimicrobial drug’ means, subject to subparagraph (B), a systemic antibacterial or antifungal drug that—

“(i) is intended for human use in the treatment of a disease or condition caused by a bacterium or fungus;

“(ii) may include a qualified infectious disease product designated under section 505E(d); and

“(iii) is subject to section 503(b)(1).

“(B) If provided by the Secretary through regulations, such term may include—

“(i) drugs other than systemic antibacterial and antifungal drugs; and

“(ii) biological products (as such term is defined in section 351 of the Public Health Service Act) to the extent such products exhibit antimicrobial activity.

“(5) The term ‘interpretive criteria standard’ means a compilation of susceptibility test interpretive criteria developed by a standard development organization that meets the criteria set forth in subsection (b)(2)(A)(i).

“(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

“(1) alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard under section 505(d)) or under section 351 of the Public Health Service Act (as applicable); or

“(2) with respect to clearing devices under section 510(k), classifying devices under section 513(f)(2), or approving devices under section 515—

“(A) apply with respect to any drug, device, or biological product, in any context other than an antimicrobial drug and an antimicrobial susceptibility testing device that uses susceptibility test interpretive criteria to characterize and report the susceptibility of certain bacteria, fungi, or other microorganisms, as applicable, to such drug to reflect patient morbidity and mortality in accordance with this section; or

“(B) unless specifically stated, have any effect on authorities provided under other sections of this Act, including any regulations issued under such sections.”

(b) CONFORMING AMENDMENTS.—

(1) REPEAL OF PRIOR RELATED AUTHORITY.—Section 1111 of the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 247d-5a), relating to identification of clinically susceptible concentrations of antimicrobials, is repealed.

(2) ADDITION TO CATEGORIES OF MISBRANDED DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

“(dd) If it is an antimicrobial drug, as defined in section 511A(f), and its labeling fails to conform with the requirements under section 511A(d).”

(3) RECOGNITION OF INTERPRETIVE CRITERIA STANDARD AS DEVICE STANDARD.—Section 514(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)(1)(A)) is amended by inserting after “the Secretary shall, by publication in the Federal Register” the following: “(or, with respect to a susceptibility test interpretive criteria standard under section 511A, by posting on the Interpretive Criteria Website in accordance with such section)”

(c) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the progress made in implementing section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a), as added by subsection (a).

(d) REQUESTS FOR UPDATES TO INTERPRETIVE CRITERIA WEBSITE.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information from interested parties regarding updating the lists established under section 511A(b) of the Federal Food, Drug, and Cosmetic Act and posted on the Interpretive Criteria Website established under section 511A(c) of such Act.

Subtitle F—Medical Device Innovations

SEC. 3051. BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 515B, as added by section 3034(b), the following:

“SEC. 515C. BREAKTHROUGH DEVICES.

“(a) **PURPOSE.**—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration’s review of, devices that represent breakthrough technologies.

“(b) **ESTABLISHMENT OF PROGRAM.**—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

“(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

“(2)(A) that represent breakthrough technologies;

“(B) for which no approved or cleared alternatives exist;

“(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

“(D) the availability of which is in the best interest of patients.

“(c) **REQUEST FOR DESIGNATION.**—A sponsor of a device may request that the Secretary designate such device for expedited development and priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a notification under section 510(k), or a petition for classification under section 513(f)(2).

“(d) **DESIGNATION PROCESS.**—

“(1) **IN GENERAL.**—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

“(2) **REVIEW.**—Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

“(3) **WITHDRAWAL.**—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

“(A) was designated under this section; or

“(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the 21st Century Cures Act.

“(e) **EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.**—

“(1) **ACTIONS.**—For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

“(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

“(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (c) for the device;

“(C) adopt an efficient process for timely dispute resolution;

“(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

“(E) expedite the Secretary’s review of manufacturing and quality systems compliance, as applicable;

“(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any con-

sultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor’s device and provide the sponsor the opportunity to recommend such external experts;

“(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); and

“(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

“(2) **ADDITIONAL ACTIONS.**—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

“(A) coordinate with the sponsor regarding early agreement on a data development plan;

“(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

“(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

“(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

“(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

“(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

“(f) **PRIORITY REVIEW GUIDANCE.**—

“(1) **CONTENT.**—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

“(A) set forth the process by which a person may seek a designation under subsection (d);

“(B) provide a template for requests under subsection (c);

“(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

“(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

“(2) **PROCESS.**—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

“(g) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to affect—

“(1) the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B) and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

“(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

“(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

“(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.”

(b) **DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.**—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is amended by inserting “a request for designation under section 515C,” after “application under section 515.”

(c) **TERMINATION OF PREVIOUS PROGRAM.**—

(1) **IN GENERAL.**—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) **CONFORMING AMENDMENT.**—Section 737(5) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 379i(5)) is amended by striking “515(d)(6)” and inserting “515(d)(5)”.

(d) **REPORT.**—On January 1, 2019, the Secretary of Health and Human Services shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) on the program under section 515C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in bringing safe and effective devices included in such program to patients as soon as possible; and

(2) that includes recommendations, if any, to strengthen the program to better meet patient device needs in a manner as timely as possible.

SEC. 3052. HUMANITARIAN DEVICE EXEMPTION.

(a) **IN GENERAL.**—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in paragraph (1) by striking “fewer than 4,000” and inserting “not more than 8,000”;

(2) in paragraph (2)(A) by striking “fewer than 4,000” and inserting “not more than 8,000”; and

(3) in paragraph (6)(A)(ii), by striking “4,000” and inserting “8,000”.

(b) **GUIDANCE DOCUMENT ON PROBABLE BENEFIT.**—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that defines the criteria for establishing “probable benefit” as that term is used in section 520(m)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(2)(C)).

SEC. 3053. RECOGNITION OF STANDARDS.

(a) **IN GENERAL.**—Section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (B) the following new subparagraphs:

“(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

“(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

“(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

“(II) issue to the person who submitted such request a response in writing that states the Secretary’s rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

“(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

“(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

“(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition

under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition.”; and

(2) by adding at the end the following:

“(4) The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee’s area of device review.”.

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and update, if necessary, previously published guidance and standard operating procedures identifying the principles for recognizing standards, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.

SEC. 3054. CERTAIN CLASS I AND CLASS II DEVICES.

(a) CLASS I DEVICES.—Section 510(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(l)) is amended—

(1) by striking “A report under subsection (k)” and inserting “(1) A report under subsection (k)”;

(2) by adding at the end the following new paragraph:

“(2) Not later than 120 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

“(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

“(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.”.

(b) CLASS II DEVICES.—Section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) by striking “(m)(1)” and all that follows through “by the Secretary.” and inserting the following:

“(m)(1) The Secretary shall—

“(A) not later than 90 days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

“(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

“(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

“(B) not later than 210 calendar days after the date of enactment of the 21st Century Cures Act, publish in the Federal Register a list representing the Secretary’s final determination with respect to the devices contained in the list published under subparagraph (A).”;

(2) in paragraph (2)—

(A) by striking “1 day after the date of publication of a list under this subsection,” and inserting “1 calendar day after the date of publication of the final list under paragraph (1)(B).”;

(B) by striking “30-day period” and inserting “60-calendar-day period”;

(C) by adding at the end the following new paragraph:

“(3) Upon the publication of the final list under paragraph (1)(B)—

“(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

“(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.”.

SEC. 3055. CLASSIFICATION PANELS.

(a) CLASSIFICATION PANELS.—Paragraph (5) of section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended—

(1) by striking “(5)” and inserting “(5)(A)”;

(2) by adding at the end the following:

“(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

“(i) ensure that adequate expertise is represented on the classification panel to assess—

“(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

“(II) the technology of the device; and

“(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

“(C) For purposes of subparagraph (B)(i), the term ‘adequate expertise’ means that the membership of the classification panel includes—

“(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

“(ii) at least one voting member who is knowledgeable about the technology of the device.

“(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical device submissions to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.”.

(b) PANEL REVIEW PROCESS.—Section 513(b)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(6)) is amended—

(1) in subparagraph (A)(iii), by inserting before the period at the end “, including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person’s organization to address such specific issues in the time provided”;

(2) by striking subparagraph (B) and inserting the following new subparagraph:

“(B)(i) Any meeting of a classification panel with respect to the review of a device shall—

“(I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and

“(II) encourage free and open participation by all interested persons.

“(ii) Following the initial presentations described in clause (i), the panel may—

“(I) pose questions to a designated representative described in subparagraph (A)(iii); and

“(II) consider the responses to such questions in the panel’s review of the device.”.

SEC. 3056. INSTITUTIONAL REVIEW BOARD FLEXIBILITY.

Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended—

(1) in subsection (g)(3)—

(A) in subparagraph (A)(i)—

(i) by striking “local”;

(ii) by striking “which has been”;

(B) in subparagraph (B), by striking “a local institutional” and inserting “an institutional”;

(2) in subsection (m)(4)—

(A) by striking subparagraph (A) and inserting the following:

“(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and”;

(B) in subparagraph (B), by striking “a local institutional” and inserting “an institutional”;

and

(C) in the matter following subparagraph (B), by striking “local”.

SEC. 3057. CLIA WAIVER IMPROVEMENTS.

(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

(1) revises “Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy” of the guidance entitled “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” and dated January 30, 2008; and

(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes.

SEC. 3058. LEAST BURDENSOME DEVICE REVIEW.

(a) IN GENERAL.—Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

“(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

“(1) The Secretary shall—

“(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

“(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

“(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

“(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

“(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

“(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

“(D) summarize the findings of such audit in a final audit report; and

“(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

“(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

“(ii) on the Internet website of the Food and Drug Administration.”

(b) **PREMARKET APPLICATIONS.**—Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended by adding at the end the following:

“(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

“(B) For purposes of subparagraph (A), the term ‘necessary’ means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

“(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

“(D) Nothing in this paragraph alters the standards for premarket approval of a device.”

(c) **RATIONALE FOR SIGNIFICANT DECISIONS REGARDING DEVICES.**—Section 517A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by adding at the end the following:

“(3) **APPLICATION OF LEAST BURDENSOME REQUIREMENTS.**—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 513(i)(1)(D), section 513(a)(3)(D), and section 515(c)(5), as applicable.”

SEC. 3059. CLEANING INSTRUCTIONS AND VALIDATION DATA REQUIREMENT.

(a) **IN GENERAL.**—Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) is amended by adding at the end the following:

“(g) **REUSABLE MEDICAL DEVICES.**—

“(1) **IN GENERAL.**—Not later than 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

“(A) instructions for use, which have been validated in a manner specified by the Secretary; and

“(B) validation data, the types of which shall be specified by the Secretary; regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

“(2) **REVISION OF LIST.**—The Secretary shall revise the list under paragraph (2), as the Secretary determines appropriate, with notice in the Federal Register.

“(3) **CONTENT OF REPORTS.**—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.”

(b) **DEVICE MODIFICATIONS.**—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue final guidance regarding when a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is required to be submitted for a modification or change to a legally marketed device. Such final guidance shall be issued not later than 1 year after the date on which the comment period closes for the draft guidance on such subject.

SEC. 3060. CLARIFYING MEDICAL SOFTWARE REGULATION.

(a) **IN GENERAL.**—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

“(o) **REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.**—

“(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

“(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

“(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

“(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

“(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

“(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

“(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

“(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

“(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

“(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

“(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

“(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

“(2) In the case of a product with multiple functions that contains—

“(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

“(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

“(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1) shall not be excluded from the definition of device under section 201(h) if—

“(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

“(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

“(B) Subparagraph (A) shall apply only if the Secretary—

“(i) publishes a notification and proposed order in the Federal Register;

“(ii) includes in such notification the Secretary’s finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i); and

“(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

“(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

“(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

“(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

“(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

“(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

“(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

“(A) exercise enforcement discretion as to any device subject to regulation under this Act;

“(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

“(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).”

(b) **REPORTS.**—The Secretary of Health and Human Services (referred to in this subsection as the “Secretary”), after consultation with agencies and offices of the Department of Health and Human Services involved in health information technology, shall publish a report, not later than 2 years after the date of enactment of this Act and every 2 years thereafter, that—

(1) includes input from outside experts, such as representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise, as determined by the Secretary;

(2) examines information available to the Secretary on any risks and benefits to health associated with software functions described in section 520(o)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) (as amended by subsection (a)); and

(3) summarizes findings regarding the impact of such software functions on patient safety, including best practices to promote safety, education, and competency related to such functions.

(c) **CLASSIFICATION OF ACCESSORIES.**—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by adding at the end the following:

“(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.”

(d) CONFORMING AMENDMENT.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end the following: “The term ‘device’ does not include software functions excluded pursuant to section 520(o).”.

Subtitle G—Improving Scientific Expertise and Outreach at FDA

SEC. 3071. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH AND BIOMEDICAL PRODUCT ASSESSMENT SERVICE.

(a) HIRING AND RETENTION AUTHORITY.—Section 228 of the Public Health Service Act (42 U.S.C. 237) is amended—

(1) in the section heading, by inserting “AND BIOMEDICAL PRODUCT ASSESSMENT” after “RESEARCH”;

(2) in subsection (a)—

(A) in paragraph (1), by striking “Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members” and inserting “Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the ‘Service’), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment”;

(B) by amending paragraph (2) to read as follows:

“(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service.”; and

(C) by adding at the end the following:

“(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.”;

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking “or clinical research evaluation” and inserting “, clinical research evaluation, or biomedical product assessment”;

(B) in paragraph (1), by inserting “or a doctoral or master’s level degree in engineering, bioinformatics, or a related or emerging field,” after the comma;

(4) in subsection (d)(2), by striking “and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5, United States Code” and inserting “and shall not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code”;

(5) by striking subsection (e); and

(6) by redesignating subsections (f) and (g) as subsections (e) and (f), respectively.

(b) GAO STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the effectiveness of the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made by subsection (a) and the impact of such amendments, if any, on all agencies or departments of the Department of Health and Human Services, and, not later than 4 years after the date of enactment of this Act, shall submit a report based on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENT OF STUDY AND REPORT.—The study and report under paragraph (1) shall include an examination of the extent to which recruitment and retention of outstanding and qualified scientific, medical, or technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment have improved or otherwise have been affected by the amendments to section 228 of the Public Health Service Act (42 U.S.C. 237) made

by subsection (a), including by determining, during the period between the date of enactment of this Act and the completion of the study—

(A) the total number of members recruited and retained under the Senior Biomedical Research and Biomedical Product Assessment Service under such section 228, and the effect of increasing the number of members eligible for such Service;

(B) the number of members of such Senior Biomedical Research and Biomedical Product Assessment Service hired with a doctoral level degree in biomedicine or a related field, and the number of such members hired with a doctoral or master’s level degree in engineering, bioinformatics, or a related or emerging field; and

(C) the number of Senior Biomedical Research and Biomedical Product Assessment Service members that have been hired by each agency or department of the Department of Health and Human Services, and how such Department assigns such members to each agency or department.

SEC. 3072. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

(a) IN GENERAL.—The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 714 (21 U.S.C. 379d–3) the following:

“SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

“(a) IN GENERAL.—The Secretary may, notwithstanding title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Such positions shall be within the competitive service.

“(b) COMPENSATION.—

“(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and set—

“(A) the annual rate of pay of any individual appointed under subsection (a); and

“(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of the 21st Century Cures Act.

“(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

“(3) PUBLIC AVAILABILITY.—The annual rate of pay provided to an individual in accordance with this section shall be publicly available information.

“(c) RULE OF CONSTRUCTION.—The authorities under this section shall not be construed to affect the authority provided under section 714.

“(d) REPORT ON WORKFORCE PLANNING.—

“(1) IN GENERAL.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including—

“(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary’s strategic plan for addressing such needs, including through use of the authority under this section; and

“(B) a recruitment and retention plan for hiring qualified scientific, technical, and profes-

sional candidates, which may include the use of—

“(i) recruitment through nongovernmental recruitment or placement agencies;

“(ii) recruitment through academic institutions;

“(iii) recruitment or hiring bonuses, if applicable;

“(iv) recruitment using targeted direct hiring authorities; and

“(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

“(2) RECOMMENDATIONS.—The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.”.

(b) GAO STUDY AND REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the ability of the Food and Drug Administration to hire, train, and retain qualified scientific, technical, and professional staff, not including contractors, necessary to fulfill the mission of the Food and Drug Administration to protect and promote public health. Not later than January 1, 2022, the Comptroller General shall submit a report on such study to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(2) CONTENTS OF STUDY.—The Comptroller General shall include in the study and report under paragraph (1)—

(A) information about the progress of the Food and Drug Administration in recruiting and retaining qualified scientific, technical, and professional staff outstanding in the field of biomedical research, clinical research evaluation, and biomedical product assessment;

(B) the extent to which critical staffing needs exist at the Food and Drug Administration, and barriers to hiring, training, and retaining qualified staff, if any;

(C) an examination of the recruitment and retention strategies of the Food and Drug Administration, including examining any strategic workforce plan, focused on improving scientific, technical, and professional staff recruitment and retention; and

(D) recommendations for potential improvements that would address staffing needs of the Food and Drug Administration.

SEC. 3073. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

(a) IN GENERAL.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

“SEC. 1014. FOOD AND DRUG ADMINISTRATION INTERCENTER INSTITUTES.

“(a) IN GENERAL.—The Secretary shall establish one or more Intercenter Institutes within the Food and Drug Administration (referred to in this section as an ‘Institute’) for a major disease area or areas. With respect to the major disease area of focus of an Institute, such Institute shall develop and implement processes for coordination of activities, as applicable to such major disease area or areas, among the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health (for the purposes of this section, referred to as the ‘Centers’). Such activities may include—

“(1) coordination of staff from the Centers with diverse product expertise in the diagnosis, cure, mitigation, treatment, or prevention of the specific diseases relevant to the major disease area of focus of the Institute;

“(2) streamlining, where appropriate, the review of medical products to diagnose, cure, mitigate, treat, or prevent the specific diseases relevant to the major disease area of focus of the

Institute, applying relevant standards under sections 505, 510(k), 513(f)(2), and 515 of this Act and section 351 of the Public Health Service Act, and other applicable authorities;

“(3) promotion of scientific programs within the Centers related to the major disease area of focus of the Institute;

“(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

“(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

“(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

“(b) PUBLIC PROCESS.—The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

“(c) TIMING.—The Secretary shall establish at least one Institute under subsection (a) before the date that is 1 year after the date of enactment of the 21st Century Cures Act.

“(d) TERMINATION OF INSTITUTES.—The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.”

(b) TECHNICAL AMENDMENTS.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended—

(1) by redesignating section 1012 as section 1013; and

(2) by redesignating the second section 1011 (with respect to improving the training of State, local, territorial, and tribal food safety officials), as added by section 209(a) of the FDA Food Safety Modernization Act (Public Law 111–353), as section 1012.

SEC. 3074. SCIENTIFIC ENGAGEMENT.

(a) IN GENERAL.—Scientific meetings that are attended by scientific or medical personnel, or other professionals, of the Department of Health and Human Services for whom attendance at such meeting is directly related to their professional duties and the mission of the Department—

(1) shall not be considered conferences for the purposes of complying with Federal reporting requirements contained in annual appropriations Acts or in this section; and

(2) shall not be considered conferences for purposes of a restriction contained in an annual appropriations Act, based on Office of Management and Budget Memorandum M-12-12 or any other regulation restricting travel to such meeting.

(b) LIMITATION.—Nothing in this section shall be construed to exempt travel for scientific meetings from Federal regulations relating to travel.

(c) REPORTS.—Not later than 90 days after the end of the fiscal year, each operating division of the Department of Health and Human Services shall prepare, and post on an Internet website of the operating division, an annual report on scientific meeting attendance and related travel spending for each fiscal year. Such report shall include—

(1) general information concerning the scientific meeting activities involved;

(2) information concerning the total amount expended for such meetings;

(3) a description of all such meetings that were attended by scientific or medical personnel, or other professionals, of each such operating division where the total amount expended by the operating division associated with each such meeting were in excess of \$30,000, including—

(A) the total amount of meeting expenses incurred by the operating division for such meeting;

(B) the location of such meeting;

(C) the date of such meeting;

(D) a brief explanation on how such meeting advanced the mission of the operating division; and

(E) the total number of individuals whose travel expenses or other scientific meeting expenses were paid by the operating division; and

(4) with respect to any such meeting where the total expenses to the operating division exceeded \$150,000, a description of the exceptional circumstances that necessitated the expenditure of such amounts.

SEC. 3075. DRUG SURVEILLANCE.

(a) NEW DRUGS.—Section 505(k)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), as amended by section 2074, is further amended—

(1) in subparagraph (A), by striking “, bi-weekly screening” and inserting “screenings”;

(2) in subparagraph (B), as redesignated by section 2074(1)(C), by striking the period at the end and inserting “; and”;

(3) by adding at the end the following:

“(C) make available on the Internet website of the Food and Drug Administration—

“(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

“(ii) criteria for public posting of adverse event signals.”

(b) FAERS REVISION.—Section 505(r)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(r)(2)(D)) is amended by striking “, by 18 months” and all that follows through the semicolon at the end of the subparagraph and inserting “and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act.”

(c) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)(5)) is amended—

(1) in the matter preceding subparagraph (A), by inserting “or other advisory committee” after “(or successor committee)”;

(2) in subparagraph (B), by striking “at least annually,” and inserting “periodically”.

SEC. 3076. REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

(a) BOARD OF DIRECTORS.—

(1) COMPOSITION AND SIZE.—Section 770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—

(A) by redesignating clause (ii) as clause (iii);

(B) by inserting after clause (i) the following:

“(ii) ADDITIONAL MEMBERS.—The Board, through amendments to the bylaws of the Foundation, may provide that the number of voting members of the Board shall be a number (to be specified in such amendment) greater than 14. Any Board positions that are established by any such amendment shall be appointed (by majority vote) by the individuals who, as of the date of such amendment, are voting members of the Board and persons so appointed may represent any of the categories specified in subclauses (I) through (V) of clause (i), so long as no more than 30 percent of the total voting members of the Board (including members whose positions are established by such amendment) are representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries.”; and

(C) in clause (iii)(I), as redesignated by subparagraph (A), by striking “The ex officio members shall ensure” and inserting “The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure”.

(2) FEDERAL EMPLOYEES ALLOWED TO SERVE ON BOARD.—Clause (iii)(II) of section

770(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(1)(C)), as redesignated by paragraph (1)(A), is amended by adding at the end the following: “For purposes of this section, the term ‘employee of the Federal Government’ does not include a special Government employee, as that term is defined in section 202(a) of title 18, United States Code.”

(3) STAGGERED TERMS.—Subparagraph (A) of section 770(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended to read as follows:

“(A) TERM.—The term of office of each member of the Board appointed under paragraph (1)(C)(i), and the term of office of any member of the Board whose position is established pursuant to paragraph (1)(C)(ii), shall be 4 years, except that—

“(i) the terms of offices for the members of the Board initially appointed under paragraph (1)(C)(i) shall expire on a staggered basis as determined by the ex officio members; and

“(ii) the terms of office for the persons initially appointed to positions established pursuant to paragraph (1)(C)(ii) may be made to expire on a staggered basis, as determined by the individuals who, as of the date of the amendment establishing such positions, are members of the Board.”

(b) EXECUTIVE DIRECTOR COMPENSATION.—Section 770(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall not be greater than the compensation of the Commissioner”.

(c) SEPARATION OF FUNDS.—Section 770(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(m)) is amended by striking “are held in separate accounts from funds received from entities under subsection (i)” and inserting “are managed as individual programmatic funds under subsection (i), according to best accounting practices”.

Subtitle H—Medical Countermeasures Innovation

SEC. 3081. MEDICAL COUNTERMEASURE GUIDELINES.

Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(1) in subsection (a), by adding at the end the following:

“(3) UTILIZATION GUIDELINES.—The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 319F–1), qualified pandemic and epidemic products (as defined in section 319F–3), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile.”; and

(2) in subsection (g)—

(A) by amending paragraph (4) to read as follows:

“(4) REPORT ON SECURITY COUNTERMEASURE PROCUREMENT.—Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than \$1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

“(A) in meeting the security countermeasure needs identified under this section; and

“(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 2811(d)).”

SEC. 3082. CLARIFYING BARDA CONTRACTING AUTHORITY.

(a) IN GENERAL.—Section 319F–2(g) of the Public Health Service Act (42 U.S.C. 247d–6b(g)) is amended by adding at the end the following:

“(5) CLARIFICATION ON CONTRACTING AUTHORITY.—The Secretary, acting through the Director of the Biomedical Advanced Research and

Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 319L), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 319L.”.

(b) BARDA CONTRACTING AUTHORITY.—Section 319L(c)(3) of the Public Health Service Act (42 U.S.C. 247d–7c) is amended by inserting “, including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section” before the period.

SEC. 3083. COUNTERMEASURE BUDGET PLAN.

Section 2811(b)(7) of the Public Health Service Act (42 U.S.C. 300hh–10(b)(7)) is amended—

(1) in the matter preceding subparagraph (A), by striking the first sentence and inserting “Develop, and update not later than March 1 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) for each such threat.”;

(2) in subparagraph (C), by striking “; and” and inserting a semicolon;

(3) in subparagraph (D), by striking “to the appropriate committees of Congress upon request.” and inserting “, not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and”;

(4) by adding at the end the following:

“(E) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.”.

SEC. 3084. MEDICAL COUNTERMEASURES INNOVATION.

Section 319L(c)(4) of the Public Health Service Act (42 U.S.C. 247d–7c(e)(4)) is amended by adding at the end the following:

“(E) MEDICAL COUNTERMEASURES INNOVATION PARTNER.—

“(i) IN GENERAL.—To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to—

“(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

“(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

“(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

“(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

“(ii) ELIGIBILITY.—

“(I) IN GENERAL.—To be eligible to enter into an agreement under clause (i) an entity shall—

“(aa) be an independent, nonprofit entity;

“(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

“(cc) have experience in promoting novel technology innovation;

“(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

“(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

“(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

“(gg) not be within the Department of Health and Human Services.

“(II) PARTNERING EXPERIENCE.—In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

“(iii) NOT AGENCY.—An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5, United States Code.

“(iv) DIRECTION.—Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

“(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

“(II) develop a description of work to be performed by the entity under the agreement;

“(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

“(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

“(V) ensure, as a condition of the agreement that the entity—

“(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

“(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

“(cc) provides monthly accounting on the use of funds provided under such agreement; and

“(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

“(v) SUPPLEMENT NOT SUPPLANT.—Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

“(vi) NO ESTABLISHMENT OF ENTITY.—To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

“(vii) TRANSPARENCY AND OVERSIGHT.—Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

“(viii) INDEPENDENT EVALUATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act, the Comptroller General of the United States shall conduct an inde-

pendent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

“(ix) SUNSET.—This subparagraph shall have no force or effect after September 30, 2022.”.

SEC. 3085. STREAMLINING PROJECT BIOSHIELD PROCUREMENT.

Section 319F–2(c) of the Public Health Service Act (42 U.S.C. 247d–6b(c)) is amended—

(1) in paragraph (4)(A)(ii), by striking “make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure” and inserting “and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable”;

(2) in paragraph (6)—

(A) by striking subparagraphs (A), (B), and (E);

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (A) and (B), respectively;

(C) by amending subparagraph (A), as so redesignated, to read as follows:

“(A) NOTICE TO APPROPRIATE CONGRESSIONAL COMMITTEES.—The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection.”; and

(D) in the heading, by striking “RECOMMENDATION FOR PRESIDENT’S APPROVAL” and inserting “RECOMMENDATIONS FOR PROCUREMENT”;

(3) in paragraph (7)—

(A) by striking subparagraphs (A) and (B) and inserting the following:

“(A) PAYMENTS FROM SPECIAL RESERVE FUND.—The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph.”; and

(B) by redesignating subparagraph (C) as subparagraph (B).

SEC. 3086. ENCOURAGING TREATMENTS FOR AGENTS THAT PRESENT A NATIONAL SECURITY THREAT.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by inserting after section 565 the following:

“SEC. 565A. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR AGENTS THAT PRESENT NATIONAL SECURITY THREATS.

“(a) DEFINITIONS.—In this section:

“(1) HUMAN DRUG APPLICATION.—The term ‘human drug application’ has the meaning given such term in section 735(1).

“(2) PRIORITY REVIEW.—The term ‘priority review’, with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

“(3) PRIORITY REVIEW VOUCHER.—The term ‘priority review voucher’ means a voucher

issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351(a) of the Public Health Service Act after the date of approval of the material threat medical countermeasure application.

“(4) MATERIAL THREAT MEDICAL COUNTERMEASURE APPLICATION.—The term ‘material threat medical countermeasure application’ means an application that—

“(A) is a human drug application for a drug intended for use—

“(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F-2(c)(2)(A)(ii) of the Public Health Service Act; or

“(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent; and

“(B) the Secretary determines eligible for priority review;

“(C) is approved after the date of enactment of the 21st Century Cures Act; and

“(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351(a) of the Public Health Service Act.

“(b) PRIORITY REVIEW VOUCHER.—

“(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

“(2) TRANSFERABILITY.—The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351(a) of the Public Health Service Act will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

“(3) NOTIFICATION.—

“(A) IN GENERAL.—The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

“(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

“(c) PRIORITY REVIEW USER FEE.—

“(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

“(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

“(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fis-

cal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

“(4) PAYMENT.—

“(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used.

“(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

“(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

“(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

“(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

“(6) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

“(d) NOTICE OF ISSUANCE OF VOUCHER AND APPROVAL OF PRODUCTS UNDER VOUCHER.—The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

“(1) The Secretary issues a priority review voucher under this section.

“(2) The Secretary approves a drug pursuant to an application submitted under section 505(b) of this Act or section 351(a) of the Public Health Service Act for which the sponsor of the application used a priority review voucher issued under this section.

“(e) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this Act, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this Act with respect to such drug.

“(f) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of medical countermeasures.

“(g) SUNSET.—The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.”

SEC. 3087. PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

“(f) DETERMINATION WITH RESPECT TO PAPERWORK REDUCTION ACT WAIVER DURING A PUBLIC HEALTH EMERGENCY.—

“(1) DETERMINATION.—If the Secretary determines, after consultation with such public health officials as may be necessary, that—

“(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or

“(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

“(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44, United States Code (com-

monly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

“(2) TRANSPARENCY.—If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

“(3) EFFECTIVENESS OF WAIVER.—Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

“(4) TERMINATION OF WAIVER.—Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

“(5) LIMITATIONS.—

“(A) PERIOD OF WAIVER.—The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

“(B) SUBSEQUENT COMPLIANCE.—An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44, United States Code, and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.”

SEC. 3088. CLARIFYING FOOD AND DRUG ADMINISTRATION EMERGENCY USE AUTHORIZATION.

(a) AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3) is amended—

(1) in subsection (a)(2)—

(A) in subparagraph (A)—

(i) by striking “or 515” and inserting “512, or 515”; and

(ii) by inserting “or conditionally approved under section 571 of this Act” after “Public Health Service Act”; and

(B) in subparagraph (B), by inserting “conditionally approved under section 571,” after “approved,” each place the term appears;

(2) in subsection (b)(4), by striking the second comma after “determination”;

(3) in subsection (e)(3)(B), by striking “section 503(b)” and inserting “subsection (b) or (f) of section 503 or under section 504”;

(4) in subsection (f)(2)—

(A) by inserting “, or an animal to which,” after “to a patient to whom”; and

(B) by inserting “or by the veterinarian caring for such animal, as applicable” after “attending physician”;

(5) in subsection (g)(1), by inserting “conditional approval under section 571,” after “approval,”;

(6) in subsection (h)(1), by striking “or section 520(g)” and inserting “512(j), or 520(g)”;

(7) in subsection (k), by striking “section 520(g),” and inserting “512(j), or 520(g)”.

(b) NEW ANIMAL DRUGS.—Section 512(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(a)(1)) is amended—

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

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

(3) by inserting after subparagraph (C) the following:

“(D) there is in effect an authorization pursuant to section 564 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to any conditions of such authorization.”.

(c) EMERGENCY USE OF MEDICAL PRODUCTS.—Section 564A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a) is amended—

(1) in subsection (a)(1)(A), by inserting “, conditionally approved under section 571,” after “chapter”;

(2) in subsection (d), by striking “sections 503(b) and 520(e)” and inserting “subsections (b) and (f) of section 503, section 504, and section 520(e)”.

(d) PRODUCTS HELD FOR EMERGENCY USE.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3b(2)) is amended—

(1) in subparagraph (A)—

(A) by inserting “or conditionally approved under section 571 of this Act” after “Public Health Service Act”;

(B) by striking “or 515” and inserting “512, or 515”;

(2) in subparagraph (B), by striking “or 520” and inserting “512, or 520”.

Subtitle I—Vaccine Access, Certainty, and Innovation

SEC. 3091. PREDICTABLE REVIEW TIMELINES OF VACCINES BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.

(a) CONSIDERATION OF NEW VACCINES.—Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the “Advisory Committee”) shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.

(b) ADDITIONAL INFORMATION.—If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee’s first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee shall provide an update on the status of such committee’s review.

(c) CONSIDERATION FOR BREAKTHROUGH THERAPIES AND FOR POTENTIAL USE DURING PUBLIC HEALTH EMERGENCY.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—

(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or

(2) could be used in a public health emergency.

(d) DEFINITION.—In this section, the terms “Advisory Committee on Immunization Practices” and “Advisory Committee” mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C.

217a), acting through the Director of the Centers for Disease Control and Prevention.”.

SEC. 3092. REVIEW OF PROCESSES AND CONSISTENCY OF ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES RECOMMENDATIONS.

(a) REVIEW.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the processes used by the Advisory Committee on Immunization Practices in formulating and issuing recommendations pertaining to vaccines, including with respect to consistency.

(b) CONSIDERATIONS.—The review under subsection (a) shall include an assessment of—

(1) the criteria used to evaluate new and existing vaccines, including the identification of any areas for which flexibility in evaluating such criteria is necessary and the reason for such flexibility;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the work groups of the Advisory Committee on Immunization Practices are consistent among such groups, including the identification of reasons for any variation.

(c) STAKEHOLDERS.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) REPORT.—Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress, and make publicly available, a report on the results of the review under subsection (a), including any recommendations on improving the consistency of the processes described in such subsection.

(e) DEFINITION.—In this section, the term “Advisory Committee on Immunization Practices” means the Advisory Committee on Immunization Practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.

SEC. 3093. ENCOURAGING VACCINE INNOVATION.

(a) VACCINE MEETINGS.—The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics.

(b) REPORT ON VACCINE INNOVATION.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the “Secretary”), in collaboration with appropriate agencies or offices within the Department of Health and Human Services, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post publicly on the Internet website of the Department of Health and Human Services, a report on ways to promote innovation in the development of vaccines that minimize the burden of infectious disease.

(2) CONTENTS.—The report described in paragraph (1) shall review the current status of vaccine development and, as appropriate—

(A) consider the optimal process to determine which vaccines would be beneficial to public health and how information on such vaccines is disseminated to key stakeholders;

(B) examine and identify whether obstacles exist that inhibit the development of beneficial vaccines; and

(C) make recommendations about how best to remove any obstacles identified under subparagraph (B) in order to promote and incentivize vaccine innovation and development.

(3) CONSULTATION.—In preparing the report under this subsection, the Secretary may consult with—

(A) representatives of relevant Federal agencies and departments, including the Department of Defense and the Department of Veterans Affairs;

(B) academic researchers;

(C) developers and manufacturers of vaccines;

(D) medical and public health practitioners;

(E) representatives of patient, policy, and advocacy organizations; and

(F) representatives of other entities, as the Secretary determines appropriate.

(c) UPDATES RELATED TO MATERNAL IMMUNIZATION.—

(1) ADDITIONAL VACCINES.—Section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) is amended by adding at the end the following:

“(3) VACCINES RECOMMENDED FOR USE IN PREGNANT WOMEN.—The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.”.

(2) PETITION CONTENT.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended by adding at the end the following:

“(f) MATERNAL IMMUNIZATION.—

“(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

“(2) DEFINITION.—As used in this subsection, the term ‘child’ shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1, United States Code, except that, for purposes of this subsection, such section 8 shall be applied as if the term ‘include’ in subsection (a) of such section were replaced with the term ‘mean’.”.

(3) PETITIONERS.—Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(b)(2)) is amended by adding “A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.” at the end.

Subtitle J—Technical Corrections

SEC. 3101. TECHNICAL CORRECTIONS.

(a) FFDCA.—

(1) REFERENCES.—Except as otherwise expressly provided, whenever in this subsection an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) AMENDMENTS.—

(A) PROHIBITED ACTS.—Section 301(r) (21 U.S.C. 331(r)) is amended by inserting “, drug,” after “device” each place the term appears.

(B) NEW DRUGS.—Section 505 (21 U.S.C. 355) is amended—

(i) in subsection (d), in the last sentence, by striking “premarket approval” and inserting “marketing approval”;

(ii) in subsection (q)(5)(A), by striking “subsection (b)(2) or (j) of the Act or 351(k)” and inserting “subsection (b)(2) or (j) of this section or section 351(k)”.

(B) examine and identify whether obstacles exist that inhibit the development of beneficial vaccines; and

(C) make recommendations about how best to remove any obstacles identified under subparagraph (B) in order to promote and incentivize vaccine innovation and development.

(3) CONSULTATION.—In preparing the report under this subsection, the Secretary may consult with—

(A) representatives of relevant Federal agencies and departments, including the Department of Defense and the Department of Veterans Affairs;

(B) academic researchers;

(C) developers and manufacturers of vaccines;

(D) medical and public health practitioners;

(E) representatives of patient, policy, and advocacy organizations; and

(F) representatives of other entities, as the Secretary determines appropriate.

(c) UPDATES RELATED TO MATERNAL IMMUNIZATION.—

(1) ADDITIONAL VACCINES.—Section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) is amended by adding at the end the following:

“(3) VACCINES RECOMMENDED FOR USE IN PREGNANT WOMEN.—The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.”.

(2) PETITION CONTENT.—Section 2111 of the Public Health Service Act (42 U.S.C. 300aa–11) is amended by adding at the end the following:

“(f) MATERNAL IMMUNIZATION.—

“(1) IN GENERAL.—Notwithstanding any other provision of law, for purposes of this subtitle, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

“(2) DEFINITION.—As used in this subsection, the term ‘child’ shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1, United States Code, except that, for purposes of this subsection, such section 8 shall be applied as if the term ‘include’ in subsection (a) of such section were replaced with the term ‘mean’.”.

(3) PETITIONERS.—Section 2111(b)(2) of the Public Health Service Act (42 U.S.C. 300aa–11(b)(2)) is amended by adding “A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.” at the end.

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505–1(h)(21 U.S.C. 355–1(h)) is amended—

(i) in paragraph (2)(A)(iii)—
(I) in the clause heading, by striking “LABEL” and inserting “LABELING”;

(II) by striking “label” each place the term appears and inserting “labeling”;

(III) by striking “sponsor” and inserting “responsible person”; and

(ii) in paragraph (8), by striking “and (7).” and inserting “and (7)”.

(D) PEDIATRIC STUDY PLANS.—Section 505B (21 U.S.C. 355c) is amended—

(i) in subsection (e)—
(I) in paragraph (2)—

(aa) in subparagraph (A), by inserting “study” after “initial pediatric” each place the term appears; and

(bb) in subparagraph (B), in the subparagraph heading, by striking “INITIAL PLAN” and inserting “INITIAL PEDIATRIC STUDY PLAN”;

(II) in paragraph (5), in the paragraph heading, by inserting “AGREED INITIAL PEDIATRIC STUDY” before “PLAN”; and

(III) in paragraph (6), by striking “agreed initial pediatric plan” and inserting “agreed initial pediatric study plan”; and

(ii) in subsection (f)(1), by inserting “and any significant amendments to such plans,” after “agreed initial pediatric study plans.”

(E) DISCONTINUANCE OR INTERRUPTION IN THE PRODUCTION OF LIVE-SAVING DRUGS.—Section 506C (21 U.S.C. 356c) is amended—

(i) in subsection (c), by striking “discontinuation” and inserting “discontinuance”; and

(ii) in subsection (g)(1), by striking “section 505(j) that could help” and inserting “section 505(f), that could help”.

(F) ANNUAL REPORTING ON DRUG SHORTAGES.—Section 506C–1(a) (21 U.S.C. 331(a)) is amended, in the matter before paragraph (1)—

(i) by striking “Not later than the end of calendar year 2013, and not later than the end of each calendar year thereafter,” and inserting “Not later than March 31 of each calendar year,”; and

(ii) by inserting “, with respect to the preceding calendar year,” after “a report”.

(G) DRUG SHORTAGE LIST.—Section 506E(b)(3)(E) (21 U.S.C. 356e(b)(3)(E)) is amended by striking “discontinuation” and inserting “discontinuance”.

(H) INSPECTIONS OF ESTABLISHMENTS.—Section 510(h) (21 U.S.C. 360(h)) is amended—

(i) in paragraph (4), in the matter preceding subparagraph (A), by striking “establishing the risk-based schedule” and inserting “establishing a risk-based schedule”; and

(ii) in paragraph (6)—

(I) in subparagraph (A), by striking “fiscal” and inserting “calendar” each place the term appears; and

(II) in subparagraph (B), by striking “an active ingredient of a drug, a finished drug product, or an excipient of a drug” and inserting “an active ingredient of a drug or a finished drug product”.

(I) CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE.—Section 513(f)(2)(A) (21 U.S.C. 360c(f)(2)(A)) is amended—

(i) in clause (i), by striking “within 30 days”; and

(ii) in clause (iv), by striking “low-moderate” and inserting “low to moderate”.

(J) PREMARKET APPROVAL.—Section 515(a)(1) (21 U.S.C. 360e(a)(1)) is amended by striking “subject to an order” and inserting “subject to an order”.

(K) PROGRAM TO IMPROVE THE DEVICE RECALL SYSTEM.—Section 518A (21 U.S.C. 360h–1) is amended—

(i) by striking subsection (c); and

(ii) by redesignating subsection (d) as subsection (c).

(L) UNIQUE DEVICE IDENTIFIER.—Section 519(f) (21 U.S.C. 360i(f)) is amended by striking “and life sustaining” and inserting “or life sustaining”.

(M) PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.—Section 524(c)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(c)(4)(A)) is amended by striking “Services Act” and inserting “Service Act”.

(N) PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.—Section 524A (21 U.S.C. 360m–1) is amended—

(i) by striking “If the Secretary” and inserting the following:

“(a) IN GENERAL.—If the Secretary”;

(ii) by striking “any” and inserting “the first”; and

(iii) by adding at the end the following:

“(b) CONSTRUCTION.—Nothing in this section shall prohibit the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 505(b) that otherwise meets the criteria for the Secretary to grant priority review.”.

(O) CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.—Section 569(a)(2)(A) (21 U.S.C. 360bbb–8(a)(2)(A)) is amended, in the first sentence, by striking “subsection (c)” and inserting “subsection (b)”.

(P) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section 569A(c) (21 U.S.C. 360bbb–8a(c)) is amended by inserting “or under the Public Health Service Act” after “this Act”.

(Q) USE OF CLINICAL INVESTIGATION DATA FROM OUTSIDE THE UNITED STATES.—Section 569B (21 U.S.C. 360bbb–8b) is amended by striking “drug or device” and inserting “drug, biological product, or device” each place the term appears.

(R) MEDICAL GASES DEFINITIONS.—Section 575(1)(H) (21 U.S.C. 360ddd(1)(H)) is amended—

(i) by inserting “for a new drug” after “any period of exclusivity”; and

(ii) by inserting “for any period of exclusivity for a new animal drug under section 512(c)(2)(F),” after “section 505A,”.

(S) REGULATION OF MEDICAL GASES.—Section 576(a) (21 U.S.C. 360ddd–1(a)) is amended—

(i) in the matter preceding subparagraph (A) of paragraph (1), by inserting “who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce” after “any person”; and

(ii) in paragraph (3)—

(I) in subparagraph (A)—

(aa) in clause (i)(VIII), by inserting “for a new drug” after “any period of exclusivity”; and

(bb) in clause (ii), in the matter preceding subsection (I), by inserting “the” before “final use”; and

(II) in subparagraph (B)—

(aa) in clause (i), by inserting “for a new drug” after “any period of exclusivity”; and

(bb) in clause (ii), by inserting a comma after “drug product”.

(T) INAPPLICABILITY OF DRUG FEES TO DESIGNATED MEDICAL GASES.—Section 577 (21 U.S.C. 360ddd–2) is amended by inserting “or 740(a)” after “section 736(a)”.

(U) CONFLICTS OF INTEREST.—Section 712(e)(1)(B) (21 U.S.C. 379d–1(e)(1)(B)) is amended by striking “services” and inserting “service”.

(V) AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.—Section 744H(A) (21 U.S.C. 379j–52(a)) is amended—

(i) in paragraph (1)(A)(v), by striking “Biosimilars User Fee Act of 2012” and inserting “Biosimilar User Fee Act of 2012”; and

(ii) in paragraph (2)(B), by striking “Biosimilars User Fee Act of 2012” and inserting “Biosimilar User Fee Act of 2012”.

(W) REGISTRATION OF COMMERCIAL IMPORTERS.—

(i) AMENDMENT.—Section 801(s)(2) (21 U.S.C. 381(s)(2)) is amended by adding at the end the following:

“(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subpara-

graph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.”.

(ii) CONFORMING AMENDMENT.—Section 714 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1074) is amended by striking subsection (d).

(X) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809(a)(2) (21 U.S.C. 384a(2)) is amended by striking “conduction” and inserting “conducting”.

(b) FDASIA.—

(1) FINDINGS RELATING TO DRUG APPROVAL.—Section 901(a)(1)(A) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 21 U.S.C. 356 note) is amended by striking “serious and life-threatening diseases” and inserting “serious or life-threatening diseases”.

(2) REPORTING OF INCLUSION OF DEMOGRAPHIC SUBGROUPS.—Section 907 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1092, 1093) is amended—

(A) in the section heading, by striking “BIOLOGICS” in the heading and inserting “BIOLOGICAL PRODUCTS”; and

(B) in subsection (a)(2)(B), by striking “applications for new drug applications” and inserting “new drug applications”.

(3) COMBATING PRESCRIPTION DRUG ABUSE.—Section 1122 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144; 126 Stat. 1112, 1113) is amended—

(A) in subsection (a)(2), by striking “dependence” and inserting “dependence”; and

(B) in subsection (c), by striking “promulgate” and inserting “issue”.

SEC. 3102. COMPLETED STUDIES.

The Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505(k)(5) (21 U.S.C. 355(k)(5))—
(A) in subparagraph (A), by inserting “and” after the semicolon;

(B) by striking subparagraph (B); and

(C) by redesignating subparagraph (C) as subparagraph (B);

(2) in section 505A (21 U.S.C. 355a), by striking subsection (p);

(3) in section 505B (21 U.S.C. 355c)—
(A) by striking subsection (l); and

(B) by redesignating subsection (m) as subsection (l); and

(4) in section 523 (21 U.S.C. 360m), by striking subsection (d).

TITLE IV—DELIVERY

SEC. 4001. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

(a) IN GENERAL.—The Health Information Technology for Economic and Clinical Health Act (title XIII of division A of Public Law 111–5) is amended—

(1) by adding at the end of part 1 of subtitle A the following:

“SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS.

“(a) REDUCTION IN BURDEN GOAL.—The Secretary of Health and Human Services (referred to in this section as the ‘Secretary’), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

“(1) establish a goal with respect to the reduction of regulatory or administrative burdens

(such as documentation requirements) relating to the use of electronic health records;

“(2) develop a strategy for meeting the goal established under paragraph (1); and

“(3) develop recommendations for meeting the goal established under paragraph (1).

“(b) STRATEGY AND RECOMMENDATIONS.—

“(1) IN GENERAL.—To achieve the goal established under subsection (a)(1), the Secretary, in consultation with the entities described in such subsection, shall, not later than 1 year after the date of enactment of the 21st Century Cures Act, develop a strategy and recommendations to meet the goal in accordance with this subsection.

“(2) STRATEGY.—The strategy developed under paragraph (1) shall address the regulatory and administrative burdens (such as documentation requirements) relating to the use of electronic health records. Such strategy shall include broad public comment and shall prioritize—

“(A)(i) incentives for meaningful use of certified EHR technology for eligible professionals and hospitals under sections 1848(a)(7) and 1886(b)(3)(B)(ix), respectively, of the Social Security Act (42 U.S.C. 1395w-4(a)(7), 1395ww(b)(3)(B)(ix));

“(ii) the program for making payments under section 1903(a)(3)(F) of the Social Security Act (42 U.S.C. 1396b(a)(3)(F)) to encourage the adoption and use of certified EHR technology by Medicaid providers;

“(iii) the Merit-based Incentive Payment System under section 1848(q) of the Social Security Act (42 U.S.C. 1395w-4(g));

“(iv) alternative payment models (as defined in section 1833(z)(3)(C) of the Social Security Act (42 U.S.C. 1395l(z)(3)(C)));

“(v) the Hospital Value-Based Purchasing Program under section 1886(o) of the Social Security Act (42 U.S.C. 1395ww(o)); and

“(vi) other value-based payment programs, as the Secretary determines appropriate;

“(B) health information technology certification;

“(C) standards and implementation specifications, as appropriate;

“(D) activities that provide individuals access to their electronic health information;

“(E) activities related to protecting the privacy of electronic health information;

“(F) activities related to protecting the security of electronic health information;

“(G) activities related to facilitating health and clinical research;

“(H) activities related to public health;

“(I) activities related to aligning and simplifying quality measures across Federal programs and other payers;

“(J) activities related to reporting clinical data for administrative purposes; and

“(K) other areas, as the Secretary determines appropriate.

“(3) RECOMMENDATIONS.—The recommendations developed under paragraph (1) shall address—

“(A) actions that improve the clinical documentation experience;

“(B) actions that improve patient care;

“(C) actions to be taken by the Secretary and by other entities; and

“(D) other areas, as the Secretary determines appropriate, to reduce the reporting burden required of health care providers.

“(4) FACILITY.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the development of the goal, strategies, or recommendations described in this section.

“(c) APPLICATION OF CERTAIN REGULATORY REQUIREMENTS.—A physician (as defined in section 1861(r)(1) of the Social Security Act), to the extent consistent with applicable State law, may delegate electronic medical record documentation requirements specified in regulations promulgated by the Centers for Medicare & Medicaid Services to a person performing a scribe function who is not such physician if such physician has signed and verified the documentation.”; and

(2) in the table of contents in section 13001(b), by inserting after the item relating to section 13102 the following:

“13103. Assisting doctors and hospitals in improving the quality and care for patients.”.

(b) CERTIFICATION OF HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj-11(c)(5)) is amended by adding at the end the following:

“(C) HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES AND SITES OF SERVICE.—

“(i) IN GENERAL.—The National Coordinator shall encourage, keep, or recognize, through existing authorities, the voluntary certification of health information technology under the program developed under subparagraph (A) for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed.

“(ii) SPECIFIC MEDICAL SPECIALTIES.—The Secretary shall accept public comment on specific medical specialties and sites of service, in addition to those described in clause (i), for the purpose of selecting additional specialties and sites of service as necessary.

“(iii) HEALTH INFORMATION TECHNOLOGY FOR PEDIATRICS.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health information technology for use by pediatric health providers to support the health care of children. Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall adopt certification criteria under section 3004 to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.”.

(c) MEANINGFUL USE STATISTICS.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the HIT Advisory Committee of the Office of the National Coordinator for Health Information Technology, a report concerning attestation statistics for the Medicare and Medicaid EHR Meaningful Use Incentive programs to assist in informing standards adoption and related practices. Such statistics shall include attestation information delineated by State, including, to the extent practicable, the number of providers who did not meet the minimum criteria necessary to attest for the Medicare and Medicaid EHR Meaningful Use Incentive programs for a calendar year, and shall be made publicly available on the Internet website of the Secretary on at least a quarterly basis.

(2) AUTHORITY TO ALTER FORMAT.—The Secretary of Health and Human Services may alter the format of the reports on the attestation of eligible health care professionals following the first performance year of the Merit-based Incentive Payment System to account for changes arising from the implementation of such payment system.

SEC. 4002. TRANSPARENT REPORTING ON USABILITY, SECURITY, AND FUNCTIONALITY.

(a) ENHANCEMENTS TO CERTIFICATION.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj-11), as amended by section 4001(b), is further amended by adding at the end the following:

“(D) CONDITIONS OF CERTIFICATION.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements

under this title, that the health information technology developer or entity—

“(i) does not take any action that constitutes information blocking as defined in section 3022(a);

“(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

“(iii) does not prohibit or restrict communication regarding—

“(I) the usability of the health information technology;

“(II) the interoperability of the health information technology;

“(III) the security of the health information technology;

“(IV) relevant information regarding users' experiences when using the health information technology;

“(V) the business practices of developers of health information technology related to exchanging electronic health information; and

“(VI) the manner in which a user of the health information technology has used such technology;

“(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

“(v) has successfully tested the real world use of the technology for interoperability (as defined in section 3000) in the type of setting in which such technology would be marketed;

“(vi) provides to the Secretary an attestation that the developer or entity—

“(I) has not engaged in any of the conduct described in clause (i);

“(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii);

“(III) does not prohibit or restrict communication as described in clause (iii);

“(IV) has published information in accordance with clause (iv);

“(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and

“(VI) has undertaken real world testing as described in clause (v); and

“(vii) submits reporting criteria in accordance with section 3009A(b).”.

“(E) COMPLIANCE WITH CONDITIONS OF CERTIFICATION.—The Secretary may encourage compliance with the conditions of certification described in subparagraph (D) and take action to discourage noncompliance, as appropriate.”.

(b) EHR SIGNIFICANT HARDSHIP EXCEPTION.—

(1) APPLICATION TO ELIGIBLE PROFESSIONALS.—

(A) IN CASE OF DECERTIFICATION.—Section 1848(a)(7)(B) of the Social Security Act (42 U.S.C. 1395w-4(a)(7)(B)) is amended by inserting after the first sentence the following new sentence: “The Secretary shall exempt an eligible professional from the application of the payment adjustment under subparagraph (A) with respect to a year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such professional has been decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.”.

(B) CONTINUED APPLICATION UNDER MIPS.—Section 1848(o)(2)(D) of the Social Security Act (42 U.S.C. 1395w-4(o)(2)(D)) is amended by adding at the end the following new sentence: “The

provisions of subparagraphs (B) and (D) of subsection (a)(7), shall apply to assessments of MIPS eligible professionals under subsection (q) with respect to the performance category described in subsection (q)(2)(A)(iv) in an appropriate manner which may be similar to the manner in which such provisions apply with respect to payment adjustments made under subsection (a)(7)(A).”.

(2) APPLICATION TO ELIGIBLE HOSPITALS.—Section 1886(b)(3)(B)(ix)(II) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ix)(II)) is amended by inserting after the first sentence the following new sentence: “The Secretary shall exempt an eligible hospital from the application of the payment adjustment under subclause (I) with respect to a fiscal year, subject to annual renewal, if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by such hospital is decertified under a program kept or recognized pursuant to section 3001(c)(5) of the Public Health Service Act.”.

(c) ELECTRONIC HEALTH RECORD REPORTING PROGRAM.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at the end the following:

“SEC. 3009A. ELECTRONIC HEALTH RECORD REPORTING PROGRAM.

“(a) REPORTING CRITERIA.—

“(1) CONVENING OF STAKEHOLDERS.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall convene stakeholders, as described in paragraph (2), for the purpose of developing the reporting criteria in accordance with paragraph (3).

“(2) DEVELOPMENT OF REPORTING CRITERIA.—The reporting criteria under this subsection shall be developed through a public, transparent process that reflects input from relevant stakeholders, including—

“(A) health care providers, including primary care and specialty care health care professionals;

“(B) hospitals and hospital systems;

“(C) health information technology developers;

“(D) patients, consumers, and their advocates;

“(E) data sharing networks, such as health information exchanges;

“(F) authorized certification bodies and testing laboratories;

“(G) security experts;

“(H) relevant manufacturers of medical devices;

“(I) experts in health information technology market economics;

“(J) public and private entities engaged in the evaluation of health information technology performance;

“(K) quality organizations, including the consensus based entity described in section 1890 of the Social Security Act;

“(L) experts in human factors engineering and the measurement of user-centered design; and

“(M) other entities or individuals, as the Secretary determines appropriate.

“(3) CONSIDERATIONS FOR REPORTING CRITERIA.—The reporting criteria developed under this subsection—

“(A) shall include measures that reflect categories including—

“(i) security;

“(ii) usability and user-centered design;

“(iii) interoperability;

“(iv) conformance to certification testing; and

“(v) other categories, as appropriate to measure the performance of electronic health record technology;

“(B) may include categories such as—

“(i) enabling the user to order and view the results of laboratory tests, imaging tests, and other diagnostic tests;

“(ii) submitting, editing, and retrieving data from registries such as clinician-led clinical data registries;

“(iii) accessing and exchanging information and data from and through health information exchanges;

“(iv) accessing and exchanging information and data from medical devices;

“(v) accessing and exchanging information and data held by Federal, State, and local agencies and other applicable entities useful to a health care provider or other applicable user in the furtherance of patient care;

“(vi) accessing and exchanging information from other health care providers or applicable users;

“(vii) accessing and exchanging patient generated information;

“(viii) providing the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format;

“(ix) providing accurate patient information for the correct patient, including exchanging such information, and avoiding the duplication of patients records; and

“(x) other categories regarding performance, accessibility, as the Secretary determines appropriate; and

“(C) shall be designed to ensure that small and startup health information technology developers are not unduly disadvantaged by the reporting criteria.

“(4) MODIFICATIONS.—After the reporting criteria have been developed under paragraph (3), the Secretary may convene stakeholders and conduct a public comment period for the purpose of modifying the reporting criteria developed under such paragraph.

“(b) PARTICIPATION.—As a condition of maintaining certification under section 3001(c)(5)(D), a developer of certified electronic health records shall submit to an appropriate recipient of a grant, contract, or agreement under subsection (c)(1) responses to the criteria developed under subsection (a), with respect to all certified technology offered by such developer.

“(c) REPORTING PROGRAM.—

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall award grants, contracts, or agreements to independent entities on a competitive basis to support the convening of stakeholders as described in subsection (a)(2), collect the information required to be reported in accordance with the criteria established as described subsection (a)(3), and develop and implement a process in accordance with paragraph (5) and report such information to the Secretary.

“(2) APPLICATIONS.—An independent entity that seeks a grant, contract, or agreement under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a description of—

“(A) the proposed method for reviewing and summarizing information gathered based on reporting criteria established under subsection (a);

“(B) if applicable, the intended focus on a specific subset of certified electronic health record technology users, such as health care providers, including primary care, specialty care, and care provided in rural settings; hospitals and hospital systems; and patients, consumers, and patients and consumer advocates;

“(C) the plan for widely distributing reports described in paragraph (6);

“(D) the period for which the grant, contract, or agreement is requested, which may be up to 2 years; and

“(E) the budget for reporting program participation, and whether the eligible independent entity intends to continue participation after the period of the grant, contract, or agreement.

“(3) CONSIDERATIONS FOR INDEPENDENT ENTITIES.—In awarding grants, contracts, and agreements under paragraph (1), the Secretary shall give priority to independent entities with appropriate expertise in health information

technology usability, interoperability, and security (especially entities with such expertise in electronic health records) with respect to—

“(A) health care providers, including primary care, specialty care, and care provided in rural settings;

“(B) hospitals and hospital systems; and

“(C) patients, consumers, and patient and consumer advocates.

“(4) LIMITATIONS.—

“(A) ASSESSMENT AND REDETERMINATION.—Not later than 4 years after the date of enactment of the 21st Century Cures Act and every 2 years thereafter, the Secretary, in consultation with stakeholders, shall—

“(i) assess performance of the recipients of the grants, contracts, and agreements under paragraph (1) based on quality and usability of reports described in paragraph (6); and

“(ii) re-determine grants, contracts, and agreements as necessary.

“(B) PROHIBITIONS ON PARTICIPATION.—The Secretary may not award a grant, contract, or cooperative agreement under paragraph (1) to—

“(i) a proprietor of certified health information technology or a business affiliate of such a proprietor;

“(ii) a developer of certified health information technology; or

“(iii) a State or local government agency.

“(5) FEEDBACK.—Based on reporting criteria established under subsection (a), the recipients of grants, contracts, and agreements under paragraph (1) shall develop and implement a process to collect and verify confidential feedback on such criteria from—

“(A) health care providers, patients, and other users of certified electronic health record technology; and

“(B) developers of certified electronic health record technology.

“(6) REPORTS.—

“(A) DEVELOPMENT OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall report on the information reported to such recipient pursuant to subsection (a) and the user feedback collected under paragraph (5) by preparing summary reports and detailed reports of such information.

“(B) DISTRIBUTION OF REPORTS.—Each recipient of a grant, contract, or agreement under paragraph (1) shall submit the reports prepared under subparagraph (A) to the Secretary for public distribution in accordance with subsection (d).

“(d) PUBLICATION.—The Secretary shall distribute widely, as appropriate, and publish, on the Internet website of the Office of the National Coordinator—

“(1) the reporting criteria developed under subsection (a); and

“(2) the summary and detailed reports under subsection (c)(6).

“(e) REVIEW.—Each recipient of a grant, contract, or agreement under paragraph (1) shall develop and implement a process through which participating electronic health record technology developers may review and recommend changes to the reports created under subsection (c)(6) for products developed by such developer prior to the publication of such report under subsection (d).

“(f) ADDITIONAL RESOURCES.—The Secretary may provide additional resources on the Internet website of the Office of the National Coordinator to better inform consumers of health information technology. Such reports may be carried out through partnerships with private organizations with appropriate expertise.”.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated \$15,000,000 for purposes of carrying out subparagraph (D) of section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11) (as added by subsection (a)) and section 3009A of the Public Health Service Act (as added by subsection (b)), including for purposes of administering any contracts, grants, or agreements, to remain available until expended.

SEC. 4003. INTEROPERABILITY.

(a) DEFINITION.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended—

(1) by redesignating paragraphs (10) through (14), as paragraphs (11) through (15), respectively; and

(2) by inserting after paragraph (9) the following:

“(10) INTEROPERABILITY.—The term ‘interoperability’, with respect to health information technology, means such health information technology that—

“(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

“(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

“(C) does not constitute information blocking as defined in section 3022(a).”

(b) SUPPORT FOR INTEROPERABLE NETWORK EXCHANGE.—Section 3001(c) of the Public Health Service Act (42 U.S.C. 300jj-11(c)) is amended by adding at the end the following:

“(9) SUPPORT FOR INTEROPERABLE NETWORKS EXCHANGE.—

“(A) IN GENERAL.—The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

“(B) ESTABLISHING A TRUSTED EXCHANGE FRAMEWORK.—

“(i) IN GENERAL.—Not later than 6 months after the date of enactment of the 21st Century Cures Act, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

“(I) a common method for authenticating trusted health information network participants;

“(II) a common set of rules for trusted exchange;

“(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

“(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement.

“(ii) TECHNICAL ASSISTANCE.—The National Coordinator, in collaboration with the National Institute of Standards and Technology, shall provide technical assistance on how to implement the trusted exchange framework and common agreement under this paragraph.

“(iii) PILOT TESTING.—The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 13201 of the Health Information Technology for Economic and Clinical Health Act). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

“(C) PUBLICATION OF A TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—Not later than 1 year after convening stakeholders

under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed or supported under subparagraph (B). Such trusted exchange framework and common agreement shall be published in a manner that protects proprietary and security information, including trade secrets and any other protected intellectual property.

“(D) DIRECTORY OF PARTICIPATING HEALTH INFORMATION NETWORKS.—

“(i) IN GENERAL.—Not later than 2 years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement developed or supported under paragraph (B).

“(ii) PROCESS.—The Secretary shall, through notice and comment rulemaking, establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.

“(E) APPLICATION OF THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—As appropriate, Federal agencies contracting or entering into agreements with health information exchange networks may require that as each such network upgrades health information technology or trust and operational practices, such network may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).

“(F) RULE OF CONSTRUCTION.—

“(i) GENERAL ADOPTION.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement.

“(ii) ADOPTION WHEN EXCHANGE OF INFORMATION IS WITHIN NETWORK.—Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement for the exchange of electronic health information between participants of the same network.

“(iii) EXISTING FRAMEWORKS AND AGREEMENTS.—The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.

“(iv) APPLICATION BY FEDERAL AGENCIES.—Notwithstanding clauses (i), (ii), and (iii), Federal agencies may require the adoption of the trusted exchange framework and common agreement published under subparagraph (C) for health information exchanges contracting with or entering into agreements pursuant to subparagraph (E).

“(v) CONSIDERATION OF ONGOING WORK.—In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.”

(c) PROVIDER DIGITAL CONTACT INFORMATION INDEX.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the “Secretary”) shall, directly or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals and health facilities.

(2) USE OF EXISTING INDEX.—In establishing the initial index under paragraph (1), the Secretary may utilize an existing provider directory to make such digital contact information available.

(3) CONTACT INFORMATION.—An index established under this subsection shall ensure that

contact information is available at the individual health care provider level and at the health facility or practice level.

(4) RULE OF CONSTRUCTION.—

(A) IN GENERAL.—The purpose of this subsection is to encourage the exchange of electronic health information by providing the most useful, reliable, and comprehensive index of providers possible. In furthering such purpose, the Secretary shall include all health professionals and health facilities applicable to provide a useful, reliable, and comprehensive index for use in the exchange of health information.

(B) LIMITATION.—In no case shall exclusion from the index of providers be used as a measure to achieve objectives other than the objectives described in subparagraph (A).

(d) STANDARDS DEVELOPMENT ORGANIZATIONS.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14) is amended by adding at the end the following:

“(c) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this section, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.”

(e) HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.—

(1) IN GENERAL.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended by striking sections 3002 (42 U.S.C. 300jj-12) and 3003 (42 U.S.C. 300jj-13) and inserting the following:

“SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.

“(a) ESTABLISHMENT.—There is established a Health Information Technology Advisory Committee (referred to in this section as the ‘HIT Advisory Committee’) to recommend to the National Coordinator, consistent with the implementation of the strategic plan described in section 3001(c)(3), policies, and, for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Such Committee shall serve to unify the roles of, and replace, the HIT Policy Committee and the HIT Standards Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

“(b) DUTIES.—

“(1) RECOMMENDATIONS ON POLICY FRAMEWORK TO ADVANCE AN INTEROPERABLE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—

“(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 3001(c)(3) for advancing the target areas described in this subsection. Such policy framework shall seek to prioritize achieving advancements in the target areas specified in subparagraph (B) of paragraph (2) and may, to the extent consistent with this section, incorporate policy recommendations made by the HIT Policy Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

“(B) UPDATES.—The HIT Advisory Committee shall propose updates to such recommendations to the policy framework and make new recommendations, as appropriate.

“(2) GENERAL DUTIES AND TARGET AREAS.—

“(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Such recommendations shall include recommended standards, architectures, and software schemes for access to electronic individually identifiable health information across disparate systems including user

vetting, authentication, privilege management, and access control.

“(B) PRIORITY TARGET AREAS.—For purposes of this section, the HIT Advisory Committee shall make recommendations under subparagraph (A) with respect to at least each of the following target areas:

“(i) Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.

“(ii) The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of the regulation promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.

“(iii) The facilitation of secure access by an individual to such individual’s protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age-related and other disability, cognitive impairment, or dementia.

“(iv) Subject to subparagraph (D), any other target area that the HIT Advisory Committee identifies as an appropriate target area to be considered under this subparagraph.

“(C) ADDITIONAL TARGET AREAS.—For purposes of this section, the HIT Advisory Committee may make recommendations under subparagraph (A), in addition to areas described in subparagraph (B), with respect to any of the following areas:

“(i) The use of health information technology to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, reducing medical errors, improving population health, reducing chronic disease, and advancing research and education.

“(ii) The use of technologies that address the needs of children and other vulnerable populations.

“(iii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including at a minimum, race, ethnicity, primary language, and gender information.

“(iv) The use of self-service, telemedicine, home health care, and remote monitoring technologies.

“(v) The use of technologies that meet the needs of diverse populations.

“(vi) The use of technologies that support—

“(I) data for use in quality and public reporting programs;

“(II) public health; or

“(III) drug safety.

“(vii) The use of technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in a health information network or transported outside of the secure facilities or systems where the disclosing covered entity is responsible for security conditions.

“(viii) The use of a certified health information technology for each individual in the United States.

“(D) AUTHORITY FOR TEMPORARY ADDITIONAL PRIORITY TARGET AREAS.—For purposes of subparagraph (B)(iv), the HIT Advisory Committee may identify an area to be considered for pur-

poses of recommendations under this subsection as a target area described in subparagraph (B) if—

“(i) the area is so identified for purposes of responding to new circumstances that have arisen in the health information technology community that affect the interoperability, privacy, or security of health information, or affect patient safety; and

“(ii) at least 30 days prior to treating such area as if it were a target area described in subparagraph (B), the National Coordinator provides adequate notice to Congress of the intent to treat such area as so described.

“(E) FOCUS OF COMMITTEE WORK.—It is the sense of Congress that the HIT Advisory Committee shall focus its work on the priority areas described in subparagraph (B) before proceeding to other work under subparagraph (C).

“(3) RULES RELATING TO RECOMMENDATIONS FOR STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

“(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a), which may include standards, implementation specifications, and certification criteria that have been developed, harmonized, or recognized by the HIT Advisory Committee or predecessor committee. The HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the Committee.

“(B) HARMONIZATION.—The HIT Advisory Committee may recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specification.

“(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Advisory Committee for purposes of recommendations under paragraph (2)(B), shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

“(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under paragraph (2)(B) shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

“(E) SPECIAL RULE RELATED TO INTEROPERABILITY.—Any recommendation made by the HIT Advisory Committee after the date of the enactment of this subparagraph with respect to interoperability of health information technology shall be consistent with interoperability as described in section 3000.

“(4) FORUM.—The HIT Advisory Committee shall serve as a forum for the participation of a broad range of stakeholders with specific expertise in policies, including technical expertise, relating to the matters described in paragraphs (1), (2), and (3) to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of health information technology infrastructure nationally and locally that allows for the electronic access, exchange, and use of health information.

“(5) SCHEDULE.—Not later than 30 days after the date on which the HIT Advisory Committee first meets, such HIT Advisory Committee shall develop a schedule for the assessment of policy recommendations developed under paragraph (1). The HIT Advisory Committee shall update

such schedule annually. The Secretary shall publish such schedule in the Federal Register.

“(6) PUBLIC INPUT.—The HIT Advisory Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (5) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

“(c) MEASURED PROGRESS IN ADVANCING PRIORITY AREAS.—

“(1) IN GENERAL.—For purposes of this section, the National Coordinator, in collaboration with the Secretary, shall establish, and update as appropriate, objectives and benchmarks for advancing and measuring the advancement of the priority target areas described in subsection (b)(2)(B).

“(2) ANNUAL PROGRESS REPORTS ON ADVANCING INTEROPERABILITY.—

“(A) IN GENERAL.—The HIT Advisory Committee, in consultation with the National Coordinator, shall annually submit to the Secretary and Congress a report on the progress made during the preceding fiscal year in—

“(i) achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information; and

“(ii) meeting the objectives and benchmarks described in paragraph (1).

“(B) CONTENT.—Each such report shall include, for a fiscal year—

“(i) a description of the work conducted by the HIT Advisory Committee during the preceding fiscal year with respect to the areas described in subsection (b)(2)(B);

“(ii) an assessment of the status of the infrastructure described in subparagraph (A), including the extent to which electronic health information is appropriately and readily available to enhance the access, exchange, and the use of electronic health information between users and across technology offered by different developers;

“(iii) the extent to which advancements have been achieved with respect to areas described in subsection (b)(2)(B);

“(iv) an analysis identifying existing gaps in policies and resources for—

“(I) achieving the objectives and benchmarks established under paragraph (1); and

“(II) furthering interoperability throughout the health information technology infrastructure;

“(v) recommendations for addressing the gaps identified in clause (iii); and

“(vi) a description of additional initiatives as the HIT Advisory Committee and National Coordinator determine appropriate.

“(3) SIGNIFICANT ADVANCEMENT DETERMINATION.—The Secretary shall periodically, based on the reports submitted under this subsection, review the target areas described in subsection (b)(2)(B), and, based on the objectives and benchmarks established under paragraph (1), the Secretary shall determine if significant advancement has been achieved with respect to such an area. Such determination shall be taken into consideration by the HIT Advisory Committee when determining to what extent the Committee makes recommendations for an area other than an area described in subsection (b)(2)(B).

“(d) MEMBERSHIP AND OPERATIONS.—

“(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Advisory Committee.

“(2) MEMBERSHIP.—The membership of the HIT Advisory Committee shall—

“(A) include at least 25 members, of which—

“(i) no fewer than 2 members are advocates for patients or consumers of health information technology;

“(ii) 3 members are appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human

Services and 1 of whom shall be a public health official;

“(iii) 2 members are appointed by the majority leader of the Senate;

“(iv) 2 members are appointed by the minority leader of the Senate;

“(v) 2 members are appointed by the Speaker of the House of Representatives;

“(vi) 2 members are appointed by the minority leader of the House of Representatives; and

“(vii) such other members are appointed by the Comptroller General of the United States; and

“(B) at least reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity.

“(3) PARTICIPATION.—The members of the HIT Advisory Committee shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Committee.

“(4) TERMS.—

“(A) IN GENERAL.—The terms of the members of the HIT Advisory Committee shall be for 3 years, except that the Secretary shall designate staggered terms of the members first appointed.

“(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Advisory Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Advisory Committee shall be filled in the manner in which the original appointment was made.

“(C) LIMITS.—Members of the HIT Advisory Committee shall be limited to two 3-year terms, for a total of not to exceed 6 years of service on the Committee.

“(5) OUTSIDE INVOLVEMENT.—The HIT Advisory Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies and standards for the electronic exchange and use of health information, including in the areas of health information privacy and security.

“(6) QUORUM.—A majority of the members of the HIT Advisory Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

“(7) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

“(8) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Advisory Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not-for-profit entities that work in the public interest as a party of their mission.

“(e) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Advisory Committee.

“(f) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Advisory Committee under this section.”

(2) TECHNICAL AND CONFORMING AMENDMENTS.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended—

(A) by striking—

(i) “HIT Policy Committee” and “HIT Standards Committee” each place that such terms appear (other than within the term “HIT Policy Committee and the HIT Standards Committee” or within the term “HIT Policy Committee or the HIT Standards Committee”) and inserting “HIT Advisory Committee”;

(ii) “HIT Policy Committee and the HIT Standards Committee” each place that such term appears and inserting “HIT Advisory Committee”; and

(iii) “HIT Policy Committee or the HIT Standards Committee” each place that such term appears and inserting “HIT Advisory Committee”; (B) in section 3000 (42 U.S.C. 300jj)—

(i) by striking paragraphs (7) and (8) and redesignating paragraphs (9) through (14) as paragraphs (8) through (13), respectively; and

(ii) by inserting after paragraph (6) the following paragraph:

“(7) HIT ADVISORY COMMITTEE.—The term ‘HIT Advisory Committee’ means such Committee established under section 3002(a).”;

(C) in section 3001(c) (42 U.S.C. 300jj–11(c))—

(i) in paragraph (1)(A), by striking “under section 3003” and inserting “under section 3002”;

(ii) in paragraph (2), by striking subparagraph (B) and inserting the following:

“(B) HIT ADVISORY COMMITTEE.—The National Coordinator shall be a leading member in the establishment and operations of the HIT Advisory Committee and shall serve as a liaison between that Committee and the Federal Government.”;

(D) in section 3004(b)(3) (42 U.S.C. 300jj–14(b)(3)), by striking “3003(b)(2)” and inserting “3002(b)(4)”;

(E) in section 3007(b) (42 U.S.C. 300jj–17(b)), by striking “3003(a)” and inserting “3002(a)(2)”;

(F) in section 3008 (42 U.S.C. 300jj–18)—

(i) in subsection (b), by striking “or 3003”; and

(ii) in subsection (c), by striking “3003(b)(1)(A)” and inserting “3002(b)(2)”.

(3) TRANSITION TO THE HIT ADVISORY COMMITTEE.—The Secretary of Health and Human Services shall provide for an orderly and timely transition to the HIT Advisory Committee established under amendments made by this section.

(f) PRIORITIES FOR ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), as amended by subsection (e), is further amended by inserting after section 3002 the following:

“SEC. 3003. SETTING PRIORITIES FOR STANDARDS ADOPTION.

“(a) IDENTIFYING PRIORITIES.—

“(1) IN GENERAL.—Not later than 6 months after the date on which the HIT Advisory Committee first meets, the National Coordinator shall periodically convene the HIT Advisory Committee to—

“(A) identify priority uses of health information technology, focusing on priorities—

“(i) arising from the implementation of the incentive programs for the meaningful use of certified EHR technology, the Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary;

“(ii) related to the quality of patient care;

“(iii) related to public health;

“(iv) related to clinical research;

“(v) related to the privacy and security of electronic health information;

“(vi) related to innovation in the field of health information technology;

“(vii) related to patient safety;

“(viii) related to the usability of health information technology;

“(ix) related to individuals' access to electronic health information; and

“(x) other priorities determined appropriate by the Secretary;

“(B) identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities identified in subparagraph (A); and

“(C) publish a report summarizing the findings of the analysis conducted under subparagraphs (A) and (B) and make appropriate recommendations.

“(2) PRIORITIZATION.—In identifying such standards and implementation specifications under paragraph (1)(B), the HIT Advisory Committee shall prioritize standards and implementation specifications developed by consensus-based standards development organizations.

“(3) GUIDELINES FOR REVIEW OF EXISTING STANDARDS AND SPECIFICATIONS.—In consultation with the consensus-based entity described in section 1890 of the Social Security Act and other appropriate Federal agencies, the analysis of existing standards under paragraph (1)(B) shall include an evaluation of the need for a core set of common data elements and associated value sets to enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.

“(b) REVIEW OF ADOPTED STANDARDS.—

“(1) IN GENERAL.—Beginning 5 years after the date of enactment of the 21st Century Cures Act and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to—

“(A) maintain the use of such standards and implementation specifications; or

“(B) phase out such standards and implementation specifications.

“(2) PRIORITIES.—The HIT Advisory Committee, in collaboration with the National Institute for Standards and Technology, shall annually and through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.

“(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the use or adoption of novel standards that improve upon the existing health information technology infrastructure and facilitate the secure exchange of health information.”

SEC. 4004. INFORMATION BLOCKING.

Subtitle C of title XXX of the Public Health Service Act (42 U.S.C. 300jj–51 et seq.) is amended by adding at the end the following:

“SEC. 3022. INFORMATION BLOCKING.

“(a) DEFINITION.—

“(1) IN GENERAL.—In this section, the term ‘information blocking’ means a practice that—

“(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

“(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

“(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

“(2) PRACTICES DESCRIBED.—The information blocking practices described in paragraph (1) may include—

“(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

“(B) implementing health information technology in nonstandard ways that are likely to

substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

“(C) implementing health information technology in ways that are likely to—

“(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or

“(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

“(3) RULEMAKING.—The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

“(4) NO ENFORCEMENT BEFORE EXCEPTION IDENTIFIED.—The term ‘information blocking’ does not include any practice or conduct occurring prior to the date that is 30 days after the date of enactment of the 21st Century Cures Act.

“(5) CONSULTATION.—The Secretary may consult with the Federal Trade Commission in promulgating regulations under this subsection, to the extent that such regulations define practices that are necessary to promote competition and consumer welfare.

“(6) APPLICATION.—The term ‘information blocking’, with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.

“(7) CLARIFICATION.—In carrying out this section, the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this title.

“(b) INSPECTOR GENERAL AUTHORITY.—

“(1) IN GENERAL.—The inspector general of the Department of Health and Human Services (referred to in this section as the ‘Inspector General’) may investigate any claim that—

“(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

“(i) submitted a false attestation under section 3001(c)(5)(D)(vii); or

“(ii) engaged in information blocking;

“(B) a health care provider engaged in information blocking; or

“(C) a health information exchange or network engaged in information blocking.

“(2) PENALTIES.—

“(A) DEVELOPERS, NETWORKS, AND EXCHANGES.—Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed \$1,000,000 per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

“(B) PROVIDERS.—Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.

“(C) PROCEDURE.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b) of such section) shall

apply to a civil money penalty applied under this paragraph in the same manner as such provisions apply to a civil money penalty or proceeding under such section 1128A(a).

“(D) RECOVERED PENALTY FUNDS.—The amounts recovered under this paragraph shall be allocated as follows:

“(i) ANNUAL OPERATING EXPENSES.—Each year following the establishment of the authority under this subsection, the Office of the Inspector General shall provide to the Secretary an estimate of the costs to carry out investigations under this section. Such estimate may include reasonable reserves to account for variance in annual amounts recovered under this paragraph. There is authorized to be appropriated for purposes of carrying out this section an amount equal to the amount specified in such estimate for the fiscal year.

“(ii) APPLICATION TO OTHER PROGRAMS.—The amounts recovered under this paragraph and remaining after amounts are made available under clause (i) shall be transferred to the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act, in such proportion as the Secretary determines appropriate.

“(E) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office of the Inspector General to carry out this section \$10,000,000, to remain available until expended.

“(3) RESOLUTION OF CLAIMS.—

“(A) IN GENERAL.—The Office of the Inspector General, if such Office determines that a consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) will resolve an information blocking claim, may refer such instances of information blocking to the Office for Civil Rights of the Department of Health and Human Services for resolution.

“(B) LIMITATION ON LIABILITY.—If a health care provider or health information technology developer makes information available based on a good faith reliance on consultations with the Office for Civil Rights of the Department of Health and Human Services pursuant to a referral under subparagraph (A), with respect to such information, the health care provider or developer shall not be liable for such disclosure or disclosures made pursuant to subparagraph (A).

“(c) IDENTIFYING BARRIERS TO EXCHANGE OF CERTIFIED HEALTH INFORMATION TECHNOLOGY.—

“(1) TRUSTED EXCHANGE DEFINED.—In this section, the term ‘trusted exchange’ with respect to certified electronic health records means that the certified electronic health record technology has the technical capability to enable secure health information exchange between users and multiple certified electronic health record technology systems.

“(2) GUIDANCE.—The National Coordinator, in consultation with the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on common legal, governance, and security barriers that prevent the trusted exchange of electronic health information.

“(3) REFERRAL.—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services may refer to the Inspector General instances or patterns of refusal to exchange health information with an individual or entity using certified electronic health record technology that is technically capable of trusted exchange and under conditions when exchange is legally permissible.

“(d) ADDITIONAL PROVISIONS.—

“(1) INFORMATION SHARING PROVISIONS.—The National Coordinator may serve as a technical consultant to the Inspector General and the Federal Trade Commission for purposes of car-

rying out this section. The National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (b) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.

“(2) PROTECTION FROM DISCLOSURE OF INFORMATION.—Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

“(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

“(B) shall be exempt from mandatory disclosure under section 552 of title 5, United States Code, as provided by subsection (b)(3) of such section; and

“(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

“(3) STANDARDIZED PROCESS.—

“(A) IN GENERAL.—The National Coordinator shall implement a standardized process for the public to submit reports on claims of—

“(i) health information technology products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

“(ii) actions described in subsection (b)(1) that result in information blocking as described in subsection (a); and

“(iii) any other act described in subsection (a).

“(B) COLLECTION OF INFORMATION.—The standardized process implemented under subparagraph (A) shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

“(4) NONDUPLICATION OF PENALTY STRUCTURES.—In carrying out this subsection, the Secretary shall, to the extent possible, ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before the date of the enactment of this section.”

SEC. 4005. LEVERAGING ELECTRONIC HEALTH RECORDS TO IMPROVE PATIENT CARE.

(a) REQUIREMENT RELATING TO REGISTRIES.—

(1) IN GENERAL.—To be certified in accordance with title XXX of the Public Health Service Act (42 U.S.C. 300ff et seq.), electronic health records shall be capable of transmitting to, and where applicable, receiving and accepting data from, registries in accordance with standards recognized by the Office of the National Coordinator for Health Information Technology, including clinician-led clinical data registries, that are also certified to be technically capable of receiving and accepting from, and where applicable, transmitting data to certified electronic health record technology in accordance with such standards.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the certification of registries beyond the technical capability to exchange data in accordance with applicable recognized standards.

(b) DEFINITION.—For purposes of this Act, the term ‘clinician-led clinical data registry’ means a clinical data repository—

(1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such organization’s controlled affiliate, devoted to the

care of a population defined by a particular disease, condition, exposure or therapy;

(2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;

(3) that provides feedback to participants who submit reports to the repository;

(4) that meets standards for data quality including—

(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and

(B) being subject to regular data checks or audits to verify completeness and validity; and

(5) that provides ongoing participant training and support.

(c) **TREATMENT OF HEALTH INFORMATION TECHNOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.**—

(1) **IN GENERAL.**—In applying part C of title IX of the Public Health Service Act (42 U.S.C. 299b–21 et seq.), a health information technology developer shall be treated as a provider (as defined in section 921 of such Act) for purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of health information technology that could result in improved patient safety, health care quality, or health care outcomes.

(2) **REPORT.**—Not later than 4 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning best practices and current trends voluntarily provided, without identifying individual providers or disclosing or using protected health information or individually identifiable information, by patient safety organizations to improve the integration of health information technology into clinical practice.

SEC. 4006. EMPOWERING PATIENTS AND IMPROVING PATIENT ACCESS TO THEIR ELECTRONIC HEALTH INFORMATION.

(a) **USE OF HEALTH INFORMATION EXCHANGES FOR PATIENT ACCESS.**—Section 3009 of the Public Health Service Act (42 U.S.C. 300j–19) is amended by adding at the end the following:

“(c) **PROMOTING PATIENT ACCESS TO ELECTRONIC HEALTH INFORMATION THROUGH HEALTH INFORMATION EXCHANGES.**—

“(1) **IN GENERAL.**—The Secretary shall use existing authorities to encourage partnerships between health information exchange organizations and networks and health care providers, health plans, and other appropriate entities with the goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

“(2) **EDUCATION OF PROVIDERS.**—The Secretary, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall—

“(A) educate health care providers on ways of leveraging the capabilities of health information exchanges (or other relevant platforms) to provide patients with access to their electronic health information;

“(B) clarify misunderstandings by health care providers about using health information exchanges (or other relevant platforms) for patient access to electronic health information; and

“(C) to the extent practicable, educate providers about health information exchanges (or other relevant platforms) that employ some or all of the capabilities described in paragraph (1).

“(3) **REQUIREMENTS.**—In carrying out paragraph (1), the Secretary, in coordination with the Office for Civil Rights, shall issue guidance to health information exchanges related to best practices to ensure that the electronic health information provided to patients is—

“(A) private and secure;

“(B) accurate;

“(C) verifiable; and

“(D) where a patient’s authorization to exchange information is required by law, easily exchanged pursuant to such authorization.

“(4) **RULE OF CONSTRUCTION.**—Nothing in this subsection shall be construed to preempt State laws applicable to patient consent for the access of information through a health information exchange (or other relevant platform) that provide protections to patients that are greater than the protections otherwise provided for under applicable Federal law.

“(d) **EFFORTS TO PROMOTE ACCESS TO HEALTH INFORMATION.**—The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services shall jointly promote patient access to health information in a manner that would ensure that such information is available in a form convenient for the patient, in a reasonable manner, without burdening the health care provider involved.

“(e) **ACCESSIBILITY OF PATIENT RECORDS.**—

“(1) **ACCESSIBILITY AND UPDATING OF INFORMATION.**—

“(A) **IN GENERAL.**—The Secretary, in consultation with the National Coordinator, shall promote policies that ensure that a patient’s electronic health information is accessible to that patient and the patient’s designees, in a manner that facilitates communication with the patient’s health care providers and other individuals, including researchers, consistent with such patient’s consent.

“(B) **UPDATING EDUCATION ON ACCESSING AND EXCHANGING PERSONAL HEALTH INFORMATION.**—To promote awareness that an individual has a right of access to inspect, obtain a copy of, and transmit to a third party a copy of such individual’s protected health information pursuant to the Health Information Portability and Accountability Act, Privacy Rule (subpart E of part 164 of title 45, Code of Federal Regulations), the Director of the Office for Civil Rights, in consultation with the National Coordinator, shall assist individuals and health care providers in understanding a patient’s rights to access and protect personal health information under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), including providing best practices for requesting personal health information in a computable format, including using patient portals or third-party applications and common cases when a provider is permitted to exchange and provide access to health information.”

“(2) **CERTIFYING USABILITY FOR PATIENTS.**—In carrying out certification programs under section 3001(c)(5), the National Coordinator may require that—

“(A) the certification criteria support—

“(i) patient access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically;

“(ii) the patient’s ability to electronically communicate patient-reported information (such as family history and medical history); and

“(iii) patient access to their personal electronic health information for research at the option of the patient; and

“(B) the HIT Advisory Committee develop and prioritize standards, implementation specifications, and certification criteria required to help support patient access to electronic health information, patient usability, and support for technologies that offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.”

(b) **ACCESS TO INFORMATION IN AN ELECTRONIC FORMAT.**—Section 13405(e) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17935) is amended—

(1) in paragraph (1), by striking “and” at the end;

(2) by redesignating paragraph (2) as paragraph (3); and

(3) by inserting after paragraph (1), the following:

“(2) if the individual makes a request to a business associate for access to, or a copy of, protected health information about the individual, or if an individual makes a request to a business associate to grant such access to, or transmit such copy directly to, a person or entity designated by the individual, a business associate may provide the individual with such access or copy, which may be in an electronic form, or grant or transmit such access or copy to such person or entity designated by the individual; and”

SEC. 4007. GAO STUDY ON PATIENT MATCHING.

(a) **IN GENERAL.**—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to—

(1) review the policies and activities of the Office of the National Coordinator for Health Information Technology and other relevant stakeholders, which may include standards development organizations, experts in the technical aspects of health information technology, health information technology developers, providers of health services, health care suppliers, health care payers, health care quality organizations, States, health information technology policy experts, and other appropriate entities, to ensure appropriate patient matching to protect patient privacy and security with respect to electronic health records and the exchange of electronic health information; and

(2) survey ongoing efforts related to the policies and activities described in paragraph (1) and the effectiveness of such efforts occurring in the private sector.

(b) **AREAS OF CONCENTRATION.**—In conducting the study under subsection (a), the Comptroller General shall—

(1) evaluate current methods used in certified electronic health records for patient matching based on performance related to factors such as—

- (A) the privacy of patient information;
- (B) the security of patient information;
- (C) improving matching rates;
- (D) reducing matching errors; and
- (E) reducing duplicate records; and

(2) determine whether the Office of the National Coordinator for Health Information Technology could improve patient matching by taking steps including—

(A) defining additional data elements to assist in patient data matching;

(B) agreeing on a required minimum set of elements that need to be collected and exchanged;

(C) requiring electronic health records to have the ability to make certain fields required and use specific standards; and

(D) other options recommended by the relevant stakeholders consulted pursuant to subsection (a).

(c) **REPORT.**—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of Congress a report concerning the findings of the study conducted under subsection (a).

SEC. 4008. GAO STUDY ON PATIENT ACCESS TO HEALTH INFORMATION.

(a) **STUDY.**—

(1) **IN GENERAL.**—The Comptroller General of the United States (referred to in this section as the “Comptroller General”) shall build on prior Government Accountability Office studies and other literature review and conduct a study to review patient access to their own protected health information, including barriers to such patient access and complications or difficulties providers experience in providing access to patients. In conducting such study, the Comptroller General shall consider the increase in adoption of health information technology and the increasing prevalence of protected health information that is maintained electronically.

(2) **AREAS OF CONCENTRATION.**—In conducting the review under paragraph (1), the Comptroller General shall consider—

(A) instances when covered entities charge individuals, including patients, third parties, and health care providers, for record requests, including records that are requested in an electronic format;

(B) examples of the amounts and types of fees charged to individuals for record requests, including instances when the record is requested to be transmitted to a third party;

(C) the extent to which covered entities are unable to provide the access requested by individuals in the form and format requested by the individual, including examples of such instances;

(D) instances in which third parties may request protected health information through patients' individual right of access, including instances where such requests may be used to circumvent appropriate fees that may be charged to third parties;

(E) opportunities that permit covered entities to charge appropriate fees to third parties for patient records while providing patients with access to their protected health information at low or no cost;

(F) the ability of providers to distinguish between requests originating from an individual that require limitation to a cost-based fee and requests originating from third parties that may not be limited to cost-based fees; and

(G) other circumstances that may inhibit the ability of providers to provide patients with access to their records, and the ability of patients to gain access to their records.

(b) **REPORT.**—Not later than 18 months after the date of enactment of this Act, the Comptroller General shall submit a report to Congress on the findings of the study conducted under subsection (a).

SEC. 4009. IMPROVING MEDICARE LOCAL COVERAGE DETERMINATIONS.

(a) **IN GENERAL.**—Section 1862(l)(5) of the Social Security Act (42 U.S.C. 1395y(l)(5)) is amended by adding at the end the following new subparagraph:

“(D) **LOCAL COVERAGE DETERMINATIONS.**—The Secretary shall require each Medicare administrative contractor that develops a local coverage determination to make available on the Internet website of such contractor and on the Medicare Internet website, at least 45 days before the effective date of such determination, the following information:

“(i) Such determination in its entirety.

“(ii) Where and when the proposed determination was first made public.

“(iii) Hyperlinks to the proposed determination and a response to comments submitted to the contractor with respect to such proposed determination.

“(iv) A summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence.

“(v) An explanation of the rationale that supports such determination.”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply with respect to local coverage determinations that are proposed or revised on or after the date that is 180 days after the date of enactment of this Act.

SEC. 4010. MEDICARE PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.

Section 1808 of the Social Security Act (42 U.S.C. 1395b–9) is amended by adding at the end the following new subsection:

“(d) **PHARMACEUTICAL AND TECHNOLOGY OMBUDSMAN.**—

“(1) **IN GENERAL.**—Not later than 12 months after the date of enactment of this paragraph, the Secretary shall provide for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

“(A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this title; and

“(B) are with respect to coverage, coding, or payment under this title for such products.

“(2) **APPLICATION.**—The second sentence of subsection (c)(2) shall apply to the ombudsman under subparagraph (A) in the same manner as such sentence applies to the Medicare Beneficiary Ombudsman under subsection (c).”.

SEC. 4011. MEDICARE SITE-OF-SERVICE PRICE TRANSPARENCY.

Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

“(t) **SITE-OF-SERVICE PRICE TRANSPARENCY.**—

“(1) **IN GENERAL.**—In order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under this title, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable Internet website, with respect to an appropriate number of such items and services—

“(A) the estimated payment amount for the item or service under the outpatient department fee schedule under subsection (t) of section 1833 and the ambulatory surgical center payment system under subsection (i) of such section; and

“(B) the estimated amount of beneficiary liability applicable to the item or service.

“(2) **CALCULATION OF ESTIMATED BENEFICIARY LIABILITY.**—For purposes of paragraph (1)(B), the estimated amount of beneficiary liability, with respect to an item or service, is the amount for such item or service for which an individual who does not have coverage under a Medicare supplemental policy certified under section 1882 or any other supplemental insurance coverage is responsible.

“(3) **IMPLEMENTATION.**—In carrying out this subsection, the Secretary—

“(A) shall include in the notice described in section 1804(a) a notification of the availability of the estimated amounts made available under paragraph (1); and

“(B) may utilize mechanisms in existence on the date of enactment of this subsection, such as the portion of the Internet website of the Centers for Medicare & Medicaid Services on which information comparing physician performance is posted (commonly referred to as the Physician Compare Internet website), to make available such estimated amounts under such paragraph.

“(4) **FUNDING.**—For purposes of implementing this subsection, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Centers for Medicare & Medicaid Services Program Management Account, of \$6,000,000 for fiscal year 2017, to remain available until expended.”.

SEC. 4012. TELEHEALTH SERVICES IN MEDICARE.

(a) **PROVISION OF INFORMATION BY CENTERS FOR MEDICARE & MEDICAID SERVICES.**—Not later than 1 year after the date of enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall provide to the committees of jurisdiction of the House of Representatives and the Senate information on the following:

(1) The populations of Medicare beneficiaries, such as those who are dually eligible for the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) and those with chronic conditions, whose care may be improved most in terms of quality and efficiency by the expansion, in a manner that meets or exceeds the existing in-person standard of care under the Medicare program under such title XVIII, of telehealth services under section 1834(m)(4) of such Act (42 U.S.C. 1395m(m)(4)).

(2) Activities by the Center for Medicare and Medicaid Innovation which examine the use of

telehealth services in models, projects, or initiatives funded through section 1115A of such Act (42 U.S.C. 1315a).

(3) The types of high-volume services (and related diagnoses) under such title XVIII which might be suitable to be furnished using telehealth.

(4) Barriers that might prevent the expansion of telehealth services under section 1834(m)(4) of the Social Security Act (42 U.S.C. 1395m(m)(4)) beyond such services that are in effect as of the date of enactment of this Act.

(b) **PROVISION OF INFORMATION BY MEDPAC.**—Not later than March 15, 2018, the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6) shall, using quantitative and qualitative research methods, provide information to the committees of jurisdiction of the House of Representatives and the Senate that identifies—

(1) the telehealth services for which payment can be made, as of the date of enactment of this Act, under the fee-for-service program under parts A and B of title XVIII of such Act;

(2) the telehealth services for which payment can be made, as of such date, under private health insurance plans; and

(3) with respect to services identified under paragraph (2) but not under paragraph (1), ways in which payment for such services might be incorporated into such fee-for-service program (including any recommendations for ways to accomplish this incorporation).

(c) **SENSE OF CONGRESS.**—It is the sense of Congress that—

(1) eligible originating sites should be expanded beyond those originating sites described in section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)); and

(2) any expansion of telehealth services under the Medicare program under title XVIII of such Act should—

(A) recognize that telemedicine is the delivery of safe, effective, quality health care services, by a health care provider, using technology as the mode of care delivery;

(B) meet or exceed the conditions of coverage and payment with respect to the Medicare program if the service was furnished in person, including standards of care, unless specifically addressed in subsequent legislation; and

(C) involve clinically appropriate means to furnish such services.

TITLE V—SAVINGS

SEC. 5001. SAVINGS IN THE MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)), as amended by section 704(h) of the Comprehensive Addiction and Recovery Act of 2016, is amended by striking “\$140,000,000” and inserting “\$270,000,000”.

SEC. 5002. MEDICAID REIMBURSEMENT TO STATES FOR DURABLE MEDICAL EQUIPMENT.

Section 1903(i)(27) of the Social Security Act (42 U.S.C. 1396b(i)(27)) is amended by striking “January 1, 2019” and inserting “January 1, 2018”.

SEC. 5003. PENALTIES FOR VIOLATIONS OF GRANTS, CONTRACTS, AND OTHER AGREEMENTS.

(a) **IN GENERAL.**—Section 1128A of the Social Security Act (42 U.S.C. 1320a–7a) is amended by adding at the end the following new subsections:

“(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

“(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

“(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or

misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

“(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

“(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

“(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements; shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than \$10,000 for each specified claim; in cases under paragraph (2), not more than \$50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than \$50,000 for each false record or statement; in cases under paragraph (4), not more than \$50,000 for each false record or statement or \$10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than \$15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

“(p) The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

“(q) For purposes of this subsection and subsections (o) and (p):

“(1) The term ‘Department’ means the Department of Health and Human Services.

“(2) The term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

“(3) The term ‘other agreement’ includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regard-

less of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

“(4) The term ‘program beneficiary’ means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

“(5) The term ‘recipient’ includes a subcontractor or subcontractor.

“(6) The term ‘specified State agency’ means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

“(r) For purposes of this section, the term ‘specified claim’ means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

“(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

“(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department’s behalf or to advance a Department program or interest, and if the Department—

“(A) provides or has provided any portion of the money or property requested or demanded; or

“(B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

“(s) For purposes of subsection (o), the term ‘obligation’ means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.”.

(b) CONFORMING AMENDMENTS.—Section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) is amended—

(1) in subsection (e), by inserting “or specified claim” after “claim” in the first sentence; and

(2) in subsection (f)—

(A) in the matter preceding paragraph (1)—

(i) by inserting “or specified claim (as defined in subsection (r))” after “district where the claim”; and

(ii) by inserting “(or, with respect to a person described in subsection (o), the person)” after “claimant”; and

(B) in the matter following paragraph (4), by inserting “(or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6)),” after “or a State agency”.

SEC. 5004. REDUCING OVERPAYMENTS OF INFUSION DRUGS.

(a) TREATMENT OF INFUSION DRUGS FURNISHED THROUGH DURABLE MEDICAL EQUIPMENT.—Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended—

(1) in subparagraph (C), by inserting “(and including a drug or biological described in subparagraph (D)(i) furnished on or after January 1, 2017)” after “2005”; and

(2) in subparagraph (D)—

(A) by striking “infusion drugs” and inserting “infusion drugs or biologicals” each place it appears; and

(B) in clause (i)—

(i) by striking “2004” and inserting “2004, and before January 1, 2017”; and

(ii) by striking “for such drug”.

(b) NONINCLUSION OF DME INFUSION DRUGS UNDER DME COMPETITIVE ACQUISITION PROGRAMS.—

(1) IN GENERAL.—Section 1847(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w-3(a)(2)(A)) is amended—

(A) by striking “and excluding” and inserting “, excluding”; and

(B) by inserting before the period at the end the following: “, and excluding drugs and biologicals described in section 1842(o)(1)(D)”.

(2) CONFORMING AMENDMENT.—Section 1842(o)(1)(D)(ii) of the Social Security Act (42 U.S.C. 1395u(o)(1)(D)(ii)) is amended by striking “2007” and inserting “2007, and before the date of the enactment of the 21st Century Cures Act.”.

SEC. 5005. INCREASING OVERSIGHT OF TERMINATION OF MEDICAID PROVIDERS.

(a) INCREASED OVERSIGHT AND REPORTING.—

(1) STATE REPORTING REQUIREMENTS.—Section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)) is amended—

(A) by redesignating paragraph (8) as paragraph (9); and

(B) by inserting after paragraph (7) the following new paragraph:

“(8) PROVIDER TERMINATIONS.—

“(A) IN GENERAL.—Beginning on July 1, 2018, in the case of a notification under subsection (a)(41) with respect to a termination for a reason specified in section 455.101 of title 42, Code of Federal Regulations (as in effect on November 1, 2015) or for any other reason specified by the Secretary, of the participation of a provider of services or any other person under the State plan (or under a waiver of the plan), the State, not later than 30 days after the effective date of such termination submits to the Secretary with respect to any such provider or person, as appropriate—

“(i) the name of such provider or person;

“(ii) the provider type of such provider or person;

“(iii) the specialty of such provider’s or person’s practice;

“(iv) the date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of such provider or person (if applicable);

“(v) the reason for the termination;

“(vi) a copy of the notice of termination sent to the provider or person;

“(vii) the date on which such termination is effective, as specified in the notice; and

“(viii) any other information required by the Secretary.

(B) EFFECTIVE DATE DEFINED.—For purposes of this paragraph, the term ‘effective date’ means, with respect to a termination described in subparagraph (A), the later of—

“(i) the date on which such termination is effective, as specified in the notice of such termination; or

“(ii) the date on which all appeal rights applicable to such termination have been exhausted or the timeline for any such appeal has expired.”.

(2) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u-2(d)) is amended by adding at the end the following new paragraph:

“(5) CONTRACT REQUIREMENT FOR MANAGED CARE ENTITIES.—With respect to any contract with a managed care entity under section 1903(m) or 1905(t)(3) (as applicable), no later than July 1, 2018, such contract shall include a provision that providers of services or persons terminated (as described in section 1902(kk)(8)) from participation under this title, title XVIII, or title XXI shall be terminated from participating under this title as a provider in any network of such entity that serves individuals eligible to receive medical assistance under this title.”.

(3) TERMINATION NOTIFICATION DATABASE.—Section 1902 of the Social Security Act (42 U.S.C.

1396a) is amended by adding at the end the following new subsection:

“(1) **TERMINATION NOTIFICATION DATABASE.**—In the case of a provider of services or any other person whose participation under this title or title XXI is terminated (as described in subsection (kk)(8)), the Secretary shall, not later than 30 days after the date on which the Secretary is notified of such termination under subsection (a)(41) (as applicable), review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 1395cc note; Public Law 111-148).”

(4) **NO FEDERAL FUNDS FOR ITEMS AND SERVICES FURNISHED BY TERMINATED PROVIDERS.**—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended—

(A) in subsection (i)(2)—
(i) in subparagraph (A), by striking the comma at the end and inserting a semicolon;
(ii) in subparagraph (B), by striking “or” at the end; and
(iii) by adding at the end the following new subparagraph:

“(D) beginning on July 1, 2018, under the plan by any provider of services or person whose participation in the State plan is terminated (as described in section 1902(kk)(8)) after the date that is 60 days after the date on which such termination is included in the database or other system under section 1902(II); or”;

(B) in subsection (m), by inserting after paragraph (2) the following new paragraph:

“(3) No payment shall be made under this title to a State with respect to expenditures incurred by the State for payment for services provided by a managed care entity (as defined under section 1932(a)(1)) under the State plan under this title (or under a waiver of the plan) unless the State—

“(A) beginning on July 1, 2018, has a contract with such entity that complies with the requirement specified in section 1932(d)(5); and

“(B) beginning on January 1, 2018, complies with the requirement specified in section 1932(d)(6)(A).”

(5) **DEVELOPMENT OF UNIFORM TERMINOLOGY FOR REASONS FOR PROVIDER TERMINATION.**—Not later than July 1, 2017, the Secretary of Health and Human Services shall, in consultation with the heads of State agencies administering State Medicaid plans (or waivers of such plans), issue regulations establishing uniform terminology to be used with respect to specifying reasons under subparagraph (A)(v) of paragraph (8) of section 1902(kk) of the Social Security Act (42 U.S.C. 1396a(kk)), as added by paragraph (1), for the termination (as described in such paragraph (8)) of the participation of certain providers in the Medicaid program under title XIX of such Act or the Children’s Health Insurance Program under title XXI of such Act.

(6) **CONFORMING AMENDMENT.**—Section 1902(a)(41) of the Social Security Act (42 U.S.C. 1396a(a)(41)) is amended by striking “provide that whenever” and inserting “provide, in accordance with subsection (kk)(8) (as applicable), that whenever”.

(b) **INCREASING AVAILABILITY OF MEDICAID PROVIDER INFORMATION.**—

(1) **FFS PROVIDER ENROLLMENT.**—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended by inserting after paragraph (77) the following new paragraph:

“(78) provide that, not later than January 1, 2017, in the case of a State that pursuant to its State plan or waiver of the plan for medical assistance pays for medical assistance on a fee-for-service basis, the State shall require each provider furnishing items and services to, or ordering, prescribing, referring, or certifying eligibility for, services for individuals eligible to receive medical assistance under such plan to enroll with the State agency and provide to the State agency the provider’s identifying informa-

tion, including the name, specialty, date of birth, Social Security number, national provider identifier (if applicable), Federal taxpayer identification number, and the State license or certification number of the provider (if applicable).”

(2) **MANAGED CARE PROVIDER ENROLLMENT.**—Section 1932(d) of the Social Security Act (42 U.S.C. 1396u-2(d)), as amended by subsection (a)(2), is amended by adding at the end the following new paragraph:

“(6) **ENROLLMENT OF PARTICIPATING PROVIDERS.**—

“(A) **IN GENERAL.**—Beginning not later than January 1, 2018, a State shall require that, in order to participate as a provider in the network of a managed care entity that provides services to, or orders, prescribes, refers, or certifies eligibility for services for, individuals who are eligible for medical assistance under the State plan under this title (or under a waiver of the plan) and who are enrolled with the entity, the provider is enrolled consistent with section 1902(kk) with the State agency administering the State plan under this title. Such enrollment shall include providing to the State agency the provider’s identifying information, including the name, specialty, date of birth, Social Security number, national provider identifier, Federal taxpayer identification number, and the State license or certification number of the provider.

“(B) **RULE OF CONSTRUCTION.**—Nothing in subparagraph (A) shall be construed as requiring a provider described in such subparagraph to provide services to individuals who are not enrolled with a managed care entity under this title.”

(c) **COORDINATION WITH CHIP.**—

(1) **IN GENERAL.**—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)) is amended—

(A) by redesignating subparagraphs (B), (C), (D), (E), (F), (G), (H), (I), (J), (K), (L), (M), (N), and (O) as subparagraphs (D), (E), (F), (G), (H), (I), (J), (K), (M), (N), (O), (P), (Q), and (R), respectively;

(B) by inserting after subparagraph (A) the following new subparagraphs:

“(B) Section 1902(a)(39) (relating to termination of participation of certain providers).

“(C) Section 1902(a)(78) (relating to enrollment of providers participating in State plans providing medical assistance on a fee-for-service basis).”

(C) by inserting after subparagraph (K) (as redesignated by subparagraph (A)) the following new subparagraph:

“(L) Section 1903(m)(3) (relating to limitation on payment with respect to managed care).”;

(D) in subparagraph (P) (as redesignated by subparagraph (A)), by striking “(a)(2)(C) and (h)” and inserting “(a)(2)(C) (relating to Indian enrollment), (d)(5) (relating to contract requirement for managed care entities), (d)(6) (relating to enrollment of providers participating with a managed care entity), and (h) (relating to special rules with respect to Indian enrollees, Indian health care providers, and Indian managed care entities).”

(2) **EXCLUDING FROM MEDICAID PROVIDERS EXCLUDED FROM CHIP.**—Section 1902(a)(39) of the Social Security Act (42 U.S.C. 1396a(a)(39)) is amended by striking “title XVIII or any other State plan under this title” and inserting “title XVIII, any other State plan under this title (or waiver of the plan), or any State child health plan under title XXI (or waiver of the plan) and such termination is included by the Secretary in any database or similar system developed pursuant to section 6401(b)(2) of the Patient Protection and Affordable Care Act”.

(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed as changing or limiting the appeal rights of providers or the process for appeals of States under the Social Security Act.

(e) **OIG REPORT.**—Not later than March 31, 2020, the Inspector General of the Department of

Health and Human Services shall submit to Congress a report on the implementation of the amendments made by this section. Such report shall include the following:

(1) An assessment of the extent to which providers who are included under subsection (1) of section 1902 of the Social Security Act (42 U.S.C. 1396a) (as added by subsection (a)(3)) in the database or similar system referred to in such subsection are terminated (as described in paragraph (8) of subsection (kk) of such section, as added by subsection (a)(1)) from participation in all State plans under title XIX of such Act (or waivers of such plans).

(2) Information on the amount of Federal financial participation paid to States under section 1903 of such Act in violation of the limitation on such payment specified in subparagraph (D) of subsection (i)(2) of such section and paragraph (3) of subsection (m) of such section, as added by subsection (a)(4).

(3) An assessment of the extent to which contracts with managed care entities under title XIX of such Act comply with the requirement specified in paragraph (5) of section 1932(d) of such Act, as added by subsection (a)(2).

(4) An assessment of the extent to which providers have been enrolled under section 1902(a)(78) or 1932(d)(6)(A) of such Act (42 U.S.C. 1396a(a)(78), 1396u-2(d)(6)(A)) with State agencies administering State plans under title XIX of such Act (or waivers of such plans).

SEC. 5006. REQUIRING PUBLICATION OF FEE-FOR-SERVICE PROVIDER DIRECTORY.

(a) **IN GENERAL.**—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (81), by striking “and” at the end;

(2) in paragraph (82), by striking the period at the end and inserting “; and”; and

(3) by inserting after paragraph (82) the following new paragraph:

“(83) provide that, not later than January 1, 2017, in the case of a State plan (or waiver of the plan) that provides medical assistance on a fee-for-service basis or through a primary care case-management system described in section 1915(b)(1) (other than a primary care case management entity (as defined by the Secretary)), the State shall publish (and update on at least an annual basis) on the public website of the State agency administering the State plan, a directory of the physicians described in subsection (mm) and, at State option, other providers described in such subsection that—

“(A) includes—

“(i) with respect to each such physician or provider—

“(I) the name of the physician or provider;

“(II) the specialty of the physician or provider;

“(III) the address at which the physician or provider provides services; and

“(IV) the telephone number of the physician or provider; and

“(ii) with respect to any such physician or provider participating in such a primary care case-management system, information regarding—

“(I) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title; and

“(II) the physician’s or provider’s cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the skilled medical interpreter providing interpretation services at the physician’s or provider’s office; and

“(B) may include, at State option, with respect to each such physician or provider—

“(i) the Internet website of such physician or provider; or

“(ii) whether the physician or provider is accepting as new patients individuals who receive medical assistance under this title.”

(b) **DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.**—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section

5005(a)(3), is further amended by adding at the end the following new subsection:

“(mm) **DIRECTORY PHYSICIAN OR PROVIDER DESCRIBED.**—A physician or provider described in this subsection is—

“(1) in the case of a physician or provider of a provider type for which the State agency, as a condition on receiving payment for items and services furnished by the physician or provider to individuals eligible to receive medical assistance under the State plan, requires the enrollment of the physician or provider with the State agency, a physician or a provider that—

“(A) is enrolled with the agency as of the date on which the directory is published or updated (as applicable) under subsection (a)(83); and

“(B) received payment under the State plan in the 12-month period preceding such date; and

“(2) in the case of a physician or provider of a provider type for which the State agency does not require such enrollment, a physician or provider that received payment under the State plan (or a waiver of the plan) in the 12-month period preceding the date on which the directory is published or updated (as applicable) under subsection (a)(83).”.

(c) **RULE OF CONSTRUCTION.**—

(1) **IN GENERAL.**—The amendment made by subsection (a) shall not be construed to apply in the case of a State (as defined for purposes of title XIX of the Social Security Act) in which all the individuals enrolled in the State plan under such title (or under a waiver of such plan), other than individuals described in paragraph (2), are enrolled with a medicaid managed care organization (as defined in section 1903(m)(1)(A) of such Act (42 U.S.C. 1396b(m)(1)(A))), including prepaid inpatient health plans and prepaid ambulatory health plans (as defined by the Secretary of Health and Human Services).

(2) **INDIVIDUALS DESCRIBED.**—An individual described in this paragraph is an individual who is an Indian (as defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)) or an Alaska Native.

(d) **EXCEPTION FOR STATE LEGISLATION.**—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), which the Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet one or more additional requirements imposed by amendments made by this section, the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

SEC. 5007. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS TRUSTS.

(a) **IN GENERAL.**—Section 1917(d)(4)(A) of the Social Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended by inserting “the individual,” after “for the benefit of such individual by”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply to trusts established on or after the date of the enactment of this Act.

SEC. 5008. ELIMINATING FEDERAL FINANCIAL PARTICIPATION WITH RESPECT TO EXPENDITURES UNDER MEDICAID FOR AGENTS USED FOR COSMETIC PURPOSES OR HAIR GROWTH.

(a) **IN GENERAL.**—Section 1903(i)(21) of the Social Security Act (42 U.S.C. 1396b(i)(21)) is amended by inserting “section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and” after “drugs described in”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply with respect to calendar quarters beginning on or after the date of the enactment of this Act.

SEC. 5009. AMENDMENT TO THE PREVENTION AND PUBLIC HEALTH FUND.

Section 4002(b) of the Patient Protection and Affordable Care Act (42 U.S.C. 300u–11(b)) is amended—

(1) in paragraph (3), by striking “\$1,250,000,000” and inserting “\$900,000,000”;

(2) in paragraph (4), by striking “\$1,500,000,000” and inserting “\$1,000,000,000”;

(3) by striking paragraph (5) and inserting the following:

“(5) for fiscal year 2022, \$1,500,000,000;

“(6) for fiscal year 2023, \$1,000,000,000;

“(7) for fiscal year 2024, \$1,700,000,000; and

“(8) for fiscal year 2025 and each fiscal year thereafter, \$2,000,000,000.”.

SEC. 5010. STRATEGIC PETROLEUM RESERVE DRAWDOWN.

(a) **DRAWDOWN AND SALE.**—

(1) **IN GENERAL.**—Notwithstanding section 161 of the Energy Policy and Conservation Act (42 U.S.C. 6241), except as provided in subsections (b) and (c), the Secretary of Energy shall drawdown and sell from the Strategic Petroleum Reserve—

(A) 10,000,000 barrels of crude oil during fiscal year 2017;

(B) 9,000,000 barrels of crude oil during fiscal year 2018; and

(C) 6,000,000 barrels of crude oil during fiscal year 2019.

(2) **DEPOSIT OF AMOUNTS RECEIVED FROM SALE.**—Amounts received from a sale under paragraph (1) shall be deposited in the general fund of the Treasury during the fiscal year in which the sale occurs.

(b) **EMERGENCY PROTECTION.**—The Secretary shall not draw down and sell crude oil under this section in quantities that would limit the authority to sell petroleum products under section 161(h) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)) in the full quantity authorized by that subsection.

(c) **STRATEGIC PETROLEUM DRAWDOWN LIMITATIONS.**—Subparagraphs (C) and (D) of section 161(h)(2) of the Energy Policy and Conservation Act (42 U.S.C. 6241(h)(2)(C) and (D)) are both amended by striking “500,000,000” and inserting “450,000,000”.

SEC. 5011. RESCISSION OF PORTION OF ACA TERRITORY FUNDING.

Of the unobligated amounts available under section 1323(c)(1) of the Patient Protection and Affordable Care Act (42 U.S.C. 18043(c)(1)), \$464,000,000 is rescinded immediately upon the date of the enactment of this Act.

SEC. 5012. MEDICARE COVERAGE OF HOME INFUSION THERAPY.

(a) **IN GENERAL.**—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

(A) by striking “and” at the end of subparagraph (EE);

(B) by inserting “and” at the end of subparagraph (FF); and

(C) by inserting at the end the following new subparagraph:

“(GG) home infusion therapy (as defined in subsection (iii)(1));”;

(2) by adding at the end the following new subsection:

“(iii) **HOME INFUSION THERAPY.**—(1) The term ‘home infusion therapy’ means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual’s home (as defined in paragraph (3)(B)) to an individual—

“(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

“(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in

coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

“(2) The items and services described in this paragraph are the following:

“(A) Professional services, including nursing services, furnished in accordance with the plan.

“(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

“(3) For purposes of this subsection:

“(A) The term ‘applicable provider’ means—

“(i) a physician;

“(ii) a nurse practitioner; and

“(iii) a physician assistant.

“(B) The term ‘home’ means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

“(C) The term ‘home infusion drug’ means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

“(i) Insulin pump systems.

“(ii) A self-administered drug or biological on a self-administered drug exclusion list.

“(D)(i) The term ‘qualified home infusion therapy supplier’ means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that—

“(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

“(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

“(III) is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

“(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

“(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.”.

(b) **PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.**—Section 1834 of the Social Security Act (42 U.S.C. 1395m), as amended by section 4011, is further amended by adding at the end the following new subsection:

“(u) **PAYMENT AND RELATED REQUIREMENTS FOR HOME INFUSION THERAPY.**—

“(1) **PAYMENT.**—

“(A) **SINGLE PAYMENT.**—

“(i) **IN GENERAL.**—Subject to clause (iii) and subparagraphs (B) and (C), the Secretary shall implement a payment system under which a single payment is made under this title to a qualified home infusion therapy supplier for items and services described in subparagraphs (A) and (B) of section 1861(iii)(2) furnished by a qualified home infusion therapy supplier (as defined in section 1861(iii)(3)(D)) in coordination with the furnishing of home infusion drugs (as defined in section 1861(iii)(3)(C)) under this part.

“(ii) **UNIT OF SINGLE PAYMENT.**—A unit of single payment under the payment system implemented under this subparagraph is for each infusion drug administration calendar day in the individual’s home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type.

“(iii) **LIMITATION.**—The single payment amount determined under this subparagraph

after application of subparagraph (B) and paragraph (3) shall not exceed the amount determined under the fee schedule under section 1848 for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day.

“(B) REQUIRED ADJUSTMENTS.—The Secretary shall adjust the single payment amount determined under subparagraph (A) for home infusion therapy services under section 1861(iii)(1) to reflect other factors such as—

“(i) a geographic wage index and other costs that may vary by region; and

“(ii) patient acuity and complexity of drug administration.

“(C) DISCRETIONARY ADJUSTMENTS.—

“(i) IN GENERAL.—Subject to clause (ii), the Secretary may adjust the single payment amount determined under subparagraph (A) (after application of subparagraph (B)) to reflect outlier situations and other factors as the Secretary determines appropriate.

“(ii) REQUIREMENT OF BUDGET NEUTRALITY.—Any adjustment under this subparagraph shall be made in a budget neutral manner.

“(2) CONSIDERATIONS.—In developing the payment system under this subsection, the Secretary may consider the costs of furnishing infusion therapy in the home, consult with home infusion therapy suppliers, consider payment amounts for similar items and services under this part and part A, and consider payment amounts established by Medicare Advantage plans under part C and in the private insurance market for home infusion therapy (including average per treatment day payment amounts by type of home infusion therapy).

“(3) ANNUAL UPDATES.—

“(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall update the single payment amount under this subsection from year to year beginning in 2022 by increasing the single payment amount from the prior year by the percentage increase in the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

“(B) ADJUSTMENT.—For each year, the Secretary shall reduce the percentage increase described in subparagraph (A) by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II). The application of the preceding sentence may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

“(4) AUTHORITY TO APPLY PRIOR AUTHORIZATION.—The Secretary may, as determined appropriate by the Secretary, apply prior authorization for home infusion therapy services under section 1861(iii)(1).

“(5) ACCREDITATION OF QUALIFIED HOME INFUSION THERAPY SUPPLIERS.—

“(A) FACTORS FOR DESIGNATION OF ACCREDITATION ORGANIZATIONS.—The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

“(i) The ability of the organization to conduct timely reviews of accreditation applications.

“(ii) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D)).

“(iii) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

“(iv) Such other factors as the Secretary determines appropriate.

“(B) DESIGNATION.—Not later than January 1, 2021, the Secretary shall designate organizations to accredit suppliers furnishing home infusion therapy. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

“(C) REVIEW AND MODIFICATION OF LIST OF ACCREDITATION ORGANIZATIONS.—

“(i) IN GENERAL.—The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A). Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

“(ii) SPECIAL RULE FOR ACCREDITATIONS DONE PRIOR TO REMOVAL FROM LIST OF DESIGNATED ACCREDITATION ORGANIZATIONS.—In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

“(D) RULE FOR ACCREDITATIONS MADE PRIOR TO DESIGNATION.—In the case of a supplier that is accredited before January 1, 2021, by an accreditation organization designated by the Secretary under subparagraph (B) as of January 1, 2019, such supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2023, for the remaining period such accreditation is in effect.

“(6) NOTIFICATION OF INFUSION THERAPY OPTIONS AVAILABLE PRIOR TO FURNISHING HOME INFUSION THERAPY.—Prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan described in section 1861(iii)(1) for the individual shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy under this part.”

(c) CONFORMING AMENDMENTS.—

(1) PAYMENT REFERENCE.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking “and” before “(AA)”;

(B) by inserting before the semicolon at the end the following: “, and (BB) with respect to home infusion therapy, the amount paid shall be an amount equal to 80 percent of the lesser of the actual charge for the services or the amount determined under section 1834(u)”.

(2) DIRECT PAYMENT.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)) is amended—

(A) by striking “and” before “(H)”;

(B) by inserting before the period at the end the following: “, and (I) in the case of home infusion therapy, payment shall be made to the qualified home infusion therapy supplier”.

(3) EXCLUSION FROM HOME HEALTH SERVICES.—Section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)) is amended, in the first sentence, by inserting the following before the period at the end: “and home infusion therapy (as defined in subsection (iii)(i))”.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 2021.

DIVISION B—HELPING FAMILIES IN MENTAL HEALTH CRISIS

SEC. 6000. SHORT TITLE.

This division may be cited as the “Helping Families in Mental Health Crisis Reform Act of 2016”.

TITLE VI—STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A—Leadership

SEC. 6001. ASSISTANT SECRETARY FOR MENTAL HEALTH AND SUBSTANCE USE.

(a) ASSISTANT SECRETARY.—Section 501(c) of the Public Health Service Act (42 U.S.C. 290aa(c)) is amended to read as follows:

“(c) ASSISTANT SECRETARY AND DEPUTY ASSISTANT SECRETARY.—

“(1) ASSISTANT SECRETARY.—The Administration shall be headed by an official to be known as the Assistant Secretary for Mental Health and Substance Use (hereinafter in this title referred to as the ‘Assistant Secretary’) who shall be appointed by the President, by and with the advice and consent of the Senate.

“(2) DEPUTY ASSISTANT SECRETARY.—The Assistant Secretary, with the approval of the Secretary, may appoint a Deputy Assistant Secretary and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.”

(b) TRANSFER OF AUTHORITIES.—The Secretary of Health and Human Services shall delegate to the Assistant Secretary for Mental Health and Substance Use all duties and authorities that—

(1) as of the day before the date of enactment of this Act, were vested in the Administrator of the Substance Abuse and Mental Health Services Administration; and

(2) are not terminated by this Act.

(c) CONFORMING AMENDMENTS.—Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.), as amended by the previous provisions of this section, is further amended—

(1) by striking “Administrator of the Substance Abuse and Mental Health Services Administration” each place it appears and inserting “Assistant Secretary for Mental Health and Substance Use”; and

(2) by striking “Administrator” or “ADMINISTRATOR” each place it appears (including in any headings) and inserting “Assistant Secretary” or “ASSISTANT SECRETARY”, respectively, except where the term “Administrator” appears—

(A) in each of subsections (e) and (f) of section 501 of such Act (42 U.S.C. 290aa), including the headings of such subsections, within the term “Associate Administrator”;

(B) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term “Administrator of the Health Resources and Services Administration”;

(C) in section 507(b)(6) of such Act (42 U.S.C. 290bb(b)(6)), within the term “Administrator of the Centers for Medicare & Medicaid Services”;

(D) in section 519B(c)(1)(B) of such Act (42 U.S.C. 290bb-25b(c)(1)(B)), within the term “Administrator of the National Highway Traffic Safety Administration”; or

(E) in each of sections 519B(c)(1)(B), 520C(a), and 520D(a) of such Act (42 U.S.C. 290bb-25b(c)(1)(B), 290bb-34(a), 290bb-35(a)), within the term “Administrator of the Office of Juvenile Justice and Delinquency Prevention”.

(d) REFERENCES.—After executing subsections (a), (b), and (c), any reference in statute, regulation, or guidance to the Administrator of the Substance Abuse and Mental Health Services Administration shall be construed to be a reference to the Assistant Secretary for Mental Health and Substance Use.

SEC. 6002. STRENGTHENING THE LEADERSHIP OF THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by section 6001, is further amended—

(1) in subsection (b)—

(A) in the subsection heading, by striking “AGENCIES” and inserting “CENTERS”; and

(B) in the matter preceding paragraph (1), by striking “entities” and inserting “Centers”;

(2) in subsection (d)—

(A) in paragraph (1)—

(i) by striking “agencies” each place the term appears and inserting “Centers”; and

(ii) by striking “such agency” and inserting “such Center”;

(B) in paragraph (2)—

(i) by striking “agencies” and inserting “Centers”;

(ii) by striking “with respect to substance abuse” and inserting “with respect to substance use disorders”; and

(iii) by striking “and individuals who are substance abusers” and inserting “and individuals with substance use disorders”;

(C) in paragraph (5), by striking “substance abuse” and inserting “substance use disorder”;

(D) in paragraph (6)—

(i) by striking “the Centers for Disease Control” and inserting “the Centers for Disease Control and Prevention.”;

(ii) by striking “Administration develop” and inserting “Administration, develop”;

(iii) by striking “HIV or tuberculosis among substance abusers and individuals with mental illness” and inserting “HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders.”; and

(iv) by striking “illnesses” at the end and inserting “diseases or disorders”;

(E) in paragraph (7), by striking “abuse utilizing anti-addiction medications, including methadone” and inserting “use disorders, including services that utilize drugs or devices approved or cleared by the Food and Drug Administration for the treatment of substance use disorders”;

(F) in paragraph (8)—

(i) by striking “Agency for Health Care Policy Research” and inserting “Agency for Healthcare Research and Quality”;

(ii) by striking “treatment and prevention” and inserting “prevention and treatment”;

(G) in paragraph (9)—

(i) by inserting “and maintenance” after “development”;

(ii) by striking “Agency for Health Care Policy Research” and inserting “Agency for Healthcare Research and Quality”;

(iii) by striking “treatment and prevention services” and inserting “prevention, treatment, and recovery support services and are appropriately incorporated into programs carried out by the Administration”;

(H) in paragraph (10), by striking “abuse” and inserting “use disorder”;

(I) by striking paragraph (11) and inserting the following:

“(11) work with relevant agencies of the Department of Health and Human Services on integrating mental health promotion and substance use disorder prevention with general health promotion and disease prevention and integrating mental and substance use disorders treatment services with physical health treatment services.”;

(J) in paragraph (13)—

(i) in the matter preceding subparagraph (A), by striking “this title, assure that” and inserting “this title or part B of title XIX, or grant programs otherwise funded by the Administration”;

(ii) in subparagraph (A)—

(I) by inserting “require that” before “all grants”;

(II) by striking “and” at the end;

(iii) by redesignating subparagraph (B) as subparagraph (C);

(iv) by inserting after subparagraph (A) the following:

“(B) ensure that the director of each Center of the Administration consistently documents the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded.”;

(v) in subparagraph (C), as so redesignated—
(I) by inserting “require that” before “all grants”;

(II) in clause (ii), by inserting “and” after the semicolon at the end;

(vi) by adding at the end the following:

“(D) inform a State when any funds are awarded through such a grant to any entity within such State.”;

(K) in paragraph (16), by striking “abuse and mental health information” and inserting “use disorder information, including evidence-based and promising best practices for prevention, treatment, and recovery support services for individuals with mental and substance use disorders.”;

(L) in paragraph (17)—

(i) by striking “substance abuse” and inserting “substance use disorder”;

(ii) by striking “and” at the end;

(M) in paragraph (18), by striking the period and inserting a semicolon;

(N) by adding at the end the following:

“(19) consult with State, local, and tribal governments, nongovernmental entities, and individuals with mental illness, particularly adults with a serious mental illness, children with a serious emotional disturbance, and the family members of such adults and children, with respect to improving community-based and other mental health services;

“(20) collaborate with the Secretary of Defense and the Secretary of Veterans Affairs to improve the provision of mental and substance use disorder services provided by the Department of Defense and the Department of Veterans Affairs to members of the Armed Forces, veterans, and the family members of such members and veterans, including through the provision of services using the telehealth capabilities of the Department of Defense and the Department of Veterans Affairs;

“(21) collaborate with the heads of relevant Federal agencies and departments, States, communities, and nongovernmental experts to improve mental and substance use disorders services for chronically homeless individuals, including by designing strategies to provide such services in supportive housing;

“(22) work with States and other stakeholders to develop and support activities to recruit and retain a workforce addressing mental and substance use disorders;

“(23) collaborate with the Attorney General and representatives of the criminal justice system to improve mental and substance use disorders services for individuals who have been arrested or incarcerated;

“(24) after providing an opportunity for public input, set standards for grant programs under this title for mental and substance use disorders services and prevention programs, which standards may address—

“(A) the capacity of the grantee to implement the award;

“(B) requirements for the description of the program implementation approach;

“(C) the extent to which the grant plan submitted by the grantee as part of its application must explain how the grantee will reach the population of focus and provide a statement of need, which may include information on how the grantee will increase access to services and a description of measurable objectives for improving outcomes;

“(D) the extent to which the grantee must collect and report on required performance measures; and

“(E) the extent to which the grantee is proposing to use evidence-based practices; and

“(25) advance, through existing programs, the use of performance metrics, including those based on the recommendations on performance metrics from the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016.”;

(3) in subsection (m), by adding at the end the following:

“(4) EMERGENCY RESPONSE.—Amounts made available for carrying out this subsection shall remain available through the end of the fiscal year following the fiscal year for which such amounts are appropriated.”.

SEC. 6003. CHIEF MEDICAL OFFICER.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 and 6002, is further amended—

(1) by redesignating subsections (g) through (j) and subsections (k) through (o) as subsections (h) through (k) and subsections (m) through (q), respectively;

(2) in subsection (e)(3)(C), by striking “subsection (k)” and inserting “subsection (m)”;

(3) in subsection (f)(2)(C)(iii), by striking “subsection (k)” and inserting “subsection (m)”;

(4) by inserting after subsection (f) the following:

“(g) CHIEF MEDICAL OFFICER.—

“(1) IN GENERAL.—The Assistant Secretary, with the approval of the Secretary, shall appoint a Chief Medical Officer to serve within the Administration.

“(2) ELIGIBLE CANDIDATES.—The Assistant Secretary shall select the Chief Medical Officer from among individuals who—

“(A) have a doctoral degree in medicine or osteopathic medicine;

“(B) have experience in the provision of mental or substance use disorder services;

“(C) have experience working with mental or substance use disorder programs;

“(D) have an understanding of biological, psychosocial, and pharmaceutical treatments of mental or substance use disorders; and

“(E) are licensed to practice medicine in one or more States.

“(3) DUTIES.—The Chief Medical Officer shall—

“(A) serve as a liaison between the Administration and providers of mental and substance use disorders prevention, treatment, and recovery services;

“(B) assist the Assistant Secretary in the evaluation, organization, integration, and coordination of programs operated by the Administration;

“(C) promote evidence-based and promising best practices, including culturally and linguistically appropriate practices, as appropriate, for the prevention and treatment of, and recovery from, mental and substance use disorders, including serious mental illness and serious emotional disturbances;

“(D) participate in regular strategic planning with the Administration;

“(E) coordinate with the Assistant Secretary for Planning and Evaluation to assess the use of performance metrics to evaluate activities within the Administration related to mental and substance use disorders; and

“(F) coordinate with the Assistant Secretary to ensure mental and substance use disorders grant programs within the Administration consistently utilize appropriate performance metrics and evaluation designs.”.

SEC. 6004. IMPROVING THE QUALITY OF BEHAVIORAL HEALTH PROGRAMS.

Section 505 of the Public Health Service Act (42 U.S.C. 290aa-4), as amended by section 6001(c), is amended—

(1) by striking the section designation and heading and inserting the following:

“SEC. 505. CENTER FOR BEHAVIORAL HEALTH STATISTICS AND QUALITY.”;

(2) by redesignating subsections (a) through (d) as subsections (b) through (e), respectively;

(3) before subsection (b), as redesignated by paragraph (2), by inserting the following:

“(a) IN GENERAL.—The Assistant Secretary shall maintain within the Administration a Center for Behavioral Health Statistics and Quality (in this section referred to as the ‘Center’). The Center shall be headed by a Director (in this section referred to as the ‘Director’) appointed

by the Secretary from among individuals with extensive experience and academic qualifications in research and analysis in behavioral health care or related fields.”;

(4) in subsection (b), as redesignated by paragraph (2)—

(A) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(B) by striking “The Secretary, acting” and all that follows through “year on—” and inserting “The Director shall—”

“(1) coordinate the Administration’s integrated data strategy, including by collecting data each year on—”;

(C) in the subparagraph (B), as redesignated by subparagraph (A), by striking “Assistant Secretary” and inserting “Director”;

(D) by adding at the end the following new paragraphs:

“(2) provide statistical and analytical support for activities of the Administration;

“(3) recommend a core set of performance metrics to evaluate activities supported by the Administration; and

“(4) coordinate with the Assistant Secretary, the Assistant Secretary for Planning and Evaluation, and the Chief Medical Officer appointed under section 501(g), as appropriate, to improve the quality of services provided by programs of the Administration and the evaluation of activities carried out by the Administration.”.

(5) in subsection (c), as so redesignated—

(A) by striking “With respect to the activities” and inserting “MENTAL HEALTH.—With respect to the activities”;

(B) by striking “Assistant Secretary” each place it appears and inserting “Director”;

(C) by striking “subsection (a)” and inserting “subsection (b)(1)”;

(6) in subsection (d), as so redesignated—

(A) by striking the subsection designation and all that follows through “With respect to the activities” and inserting the following:

“(d) SUBSTANCE ABUSE.—

“(1) IN GENERAL.—With respect to the activities”;

(B) in paragraph (1)—

(i) in the matter before subparagraph (A)—

(I) by striking “subsection (a)” and inserting “subsection (b)(1)”;

(II) by striking “Assistant Secretary” each place it appears and inserting “Director”;

(ii) in subparagraph (B), by inserting “in coordination with the Centers for Disease Control and Prevention” before the semicolon at the end; and

(C) in paragraph (2), by striking “ANNUAL SURVEYS” and inserting “ANNUAL SURVEYS; PUBLIC AVAILABILITY OF DATA.—Annual surveys”;

(7) in subsection (e), as so redesignated—

(A) by striking “After consultation” and inserting “CONSULTATION.—After consultation”;

(B) by striking “Assistant Secretary shall develop” and inserting “Assistant Secretary shall use existing standards and best practices to develop”.

SEC. 6005. STRATEGIC PLAN.

Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as amended by sections 6001 through 6003, is further amended by inserting after subsection (k), as redesignated by section 6003, the following:

“(1) STRATEGIC PLAN.—

“(1) IN GENERAL.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall develop and carry out a strategic plan in accordance with this subsection for the planning and operation of activities carried out by the Administration, including evidence-based programs.

“(2) COORDINATION.—In developing and carrying out the strategic plan under this subsection, the Assistant Secretary shall take into consideration the findings and recommendations of the Assistant Secretary for Planning and

Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016 and the report of the Interdepartmental Serious Mental Illness Coordinating Committee under section 6031 of such Act.

“(3) PUBLICATION OF PLAN.—Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall—

“(A) submit the strategic plan developed under paragraph (1) to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

“(B) post such plan on the Internet website of the Administration.

“(4) CONTENTS.—The strategic plan developed under paragraph (1) shall—

“(A) identify strategic priorities, goals, and measurable objectives for mental and substance use disorders activities and programs operated and supported by the Administration, including priorities to prevent or eliminate the burden of mental and substance use disorders;

“(B) identify ways to improve the quality of services for individuals with mental and substance use disorders, and to reduce homelessness, arrest, incarceration, violence, including self-directed violence, and unnecessary hospitalization of individuals with a mental or substance use disorder, including adults with a serious mental illness or children with a serious emotional disturbance;

“(C) ensure that programs provide, as appropriate, access to effective and evidence-based prevention, diagnosis, intervention, treatment, and recovery services, including culturally and linguistically appropriate services, as appropriate, for individuals with a mental or substance use disorder;

“(D) identify opportunities to collaborate with the Health Resources and Services Administration to develop or improve—

“(i) initiatives to encourage individuals to pursue careers (especially in rural and underserved areas and with rural and underserved populations) as psychiatrists, including child and adolescent psychiatrists, psychologists, psychiatric nurse practitioners, physician assistants, clinical social workers, certified peer support specialists, licensed professional counselors, or other licensed or certified mental health or substance use disorder professionals, including such professionals specializing in the diagnosis, evaluation, or treatment of adults with a serious mental illness or children with a serious emotional disturbance; and

“(ii) a strategy to improve the recruitment, training, and retention of a workforce for the treatment of individuals with mental or substance use disorders, or co-occurring disorders;

“(E) identify opportunities to improve collaboration with States, local governments, communities, and Indian tribes and tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act); and

“(F) specify a strategy to disseminate evidence-based and promising best practices related to prevention, diagnosis, early intervention, treatment, and recovery services related to mental illness, particularly for adults with a serious mental illness and children with a serious emotional disturbance, and for individuals with a substance use disorder.”.

SEC. 6006. BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.

(a) IN GENERAL.—Section 501 of the Public Health Service Act (42 U.S.C. 290aa), as so amended, is further amended by amending subsection (m), as redesignated by section 6003, to read as follows:

“(m) BIENNIAL REPORT CONCERNING ACTIVITIES AND PROGRESS.—Not later than September 30, 2020, and every 2 years thereafter, the Assistant Secretary shall prepare and submit to the Committee on Energy and Commerce and the

Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and post on the Internet website of the Administration, a report containing at a minimum—

“(1) a review of activities conducted or supported by the Administration, including progress toward strategic priorities, goals, and objectives identified in the strategic plan developed under subsection (1);

“(2) an assessment of programs and activities carried out by the Assistant Secretary, including the extent to which programs and activities under this title and part B of title XIX meet identified goals and performance measures developed for the respective programs and activities;

“(3) a description of the progress made in addressing gaps in mental and substance use disorders prevention, treatment, and recovery services and improving outcomes by the Administration, including with respect to serious mental illnesses, serious emotional disturbances, and co-occurring disorders;

“(4) a description of the manner in which the Administration coordinates and partners with other Federal agencies and departments related to mental and substance use disorders, including activities related to—

“(A) the implementation and dissemination of research findings into improved programs, including with respect to how advances in serious mental illness and serious emotional disturbance research have been incorporated into programs;

“(B) the recruitment, training, and retention of a mental and substance use disorders workforce;

“(C) the integration of mental disorder services, substance use disorder services, and physical health services;

“(D) homelessness; and

“(E) veterans;

“(5) a description of the manner in which the Administration promotes coordination by grantees under this title, and part B of title XIX, with State or local agencies; and

“(6) a description of the activities carried out under section 501A(e), with respect to mental and substance use disorders, including—

“(A) the number and a description of grants awarded;

“(B) the total amount of funding for grants awarded;

“(C) a description of the activities supported through such grants, including outcomes of programs supported; and

“(D) information on how the National Mental Health and Substance Use Policy Laboratory is consulting with the Assistant Secretary for Planning and Evaluation and collaborating with the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Behavioral Health Statistics and Quality, and the Center for Mental Health Services to carry out such activities; and

“(7) recommendations made by the Assistant Secretary for Planning and Evaluation under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 to improve programs within the Administration, and actions taken in response to such recommendations to improve programs within the Administration.

The Assistant Secretary may meet reporting requirements established under this title by providing the contents of such reports as an addendum to the biennial report established under this subsection, notwithstanding the timeline of other reporting requirements in this title. Nothing in this subsection shall be construed to alter the content requirements of such reports or authorize the Assistant Secretary to alter the timeline of any such reports to be less frequent than biennially, unless as specified in this title.”.

(b) CONFORMING AMENDMENT.—Section 508(p) of the Public Health Service Act (42 U.S.C. 290bb-1(p)) is amended by striking “section 501(k)” and inserting “section 501(m)”.

SEC. 6007. AUTHORITIES OF CENTERS FOR MENTAL HEALTH SERVICES, SUBSTANCE ABUSE PREVENTION, AND SUBSTANCE ABUSE TREATMENT.

(a) CENTER FOR MENTAL HEALTH SERVICES.—Section 520(b) of the Public Health Service Act (42 U.S.C. 290bb–31(b)) is amended—

(1) by redesignating paragraphs (3) through (15) as paragraphs (4) through (16), respectively;

(2) by inserting after paragraph (2) the following:

“(3) collaborate with the Director of the National Institute of Mental Health and the Chief Medical Officer, appointed under section 501(g), to ensure that, as appropriate, programs related to the prevention and treatment of mental illness and the promotion of mental health and recovery support are carried out in a manner that reflects the best available science and evidence-based practices, including culturally and linguistically appropriate services, as appropriate;”;

(3) in paragraph (5), as so redesignated, by inserting “, including through programs that reduce risk and promote resiliency” before the semicolon;

(4) in paragraph (6), as so redesignated, by inserting “in collaboration with the Director of the National Institute of Mental Health,” before “develop”;

(5) in paragraph (8), as so redesignated, by inserting “, increase meaningful participation of individuals with mental illness in programs and activities of the Administration,” before “and protect the legal”;

(6) in paragraph (10), as so redesignated, by striking “professional and paraprofessional personnel pursuant to section 303” and inserting “health paraprofessional personnel and health professionals”;

(7) in paragraph (11), as so redesignated, by inserting “and tele-mental health” after “rural mental health”;

(8) in paragraph (12), as so redesignated, by striking “establish a clearinghouse for mental health information to assure the widespread dissemination of such information” and inserting “disseminate mental health information, including evidence-based practices,”;

(9) in paragraph (15), as so redesignated, by striking “and” at the end;

(10) in paragraph (16), as so redesignated, by striking the period and inserting “; and”;

(11) by adding at the end the following:

“(17) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded.”.

(b) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE PREVENTION.—Section 515 of the Public Health Service Act (42 U.S.C. 290bb–21) is amended—

(1) in the section heading, by striking “OFFICE” and inserting “CENTER”;

(2) in subsection (a)—

(A) by striking “an Office” and inserting “a Center”; and

(B) by striking “The Office” and inserting “The Prevention Center”; and

(3) in subsection (b)—

(A) in paragraph (1), by inserting “through the reduction of risk and the promotion of resiliency” before the semicolon;

(B) by redesignating paragraphs (3) through (11) as paragraphs (4) through (12), respectively;

(C) by inserting after paragraph (2) the following:

“(3) collaborate with the Director of the National Institute on Drug Abuse, the Director of the National Institute on Alcohol Abuse and Alcoholism, and States to promote the study of substance abuse prevention and the dissemination and implementation of research findings that will improve the delivery and effectiveness of substance abuse prevention activities;”;

(D) in paragraph (4), as so redesignated, by striking “literature on the adverse effects of cocaine free base (known as crack)” and inserting

“educational information on the effects of drugs abused by individuals, including drugs that are emerging as abused drugs”;

(E) in paragraph (6), as so redesignated—

(i) by striking “substance abuse counselors” and inserting “health professionals who provide substance use and misuse prevention and treatment services”; and

(ii) by striking “drug abuse education, prevention,” and inserting “illicit drug use education and prevention”;

(F) by amending paragraph (7), as so redesignated, to read as follows:

“(7) in cooperation with the Director of the Centers for Disease Control and Prevention, develop and disseminate educational materials to increase awareness for individuals at greatest risk for substance use disorders to prevent the transmission of communicable diseases, such as HIV, hepatitis, tuberculosis, and other communicable diseases;”;

(G) in paragraph (9), as so redesignated—

(i) by striking “to discourage” and inserting “that reduce the risk of”; and

(ii) by inserting before the semicolon “and promote resiliency”;

(H) in paragraph (11), as so redesignated, by striking “and” after the semicolon;

(I) in paragraph (12), as so redesignated, by striking the period and inserting a semicolon; and

(J) by adding at the end the following:

“(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

“(14) assist and support States in preventing illicit drug use, including emerging illicit drug use issues.”.

(c) DIRECTOR OF THE CENTER FOR SUBSTANCE ABUSE TREATMENT.—Section 507 of the Public Health Service Act (42 U.S.C. 290bb) is amended—

(1) in subsection (a)—

(A) by striking “treatment of substance abuse” and inserting “treatment of substance use disorders”; and

(B) by striking “abuse treatment systems” and inserting “use disorder treatment systems”; and

(2) in subsection (b)—

(A) in paragraph (1), by striking “abuse” and inserting “use disorder”;

(B) in paragraph (3), by striking “abuse” and inserting “use disorder”;

(C) in paragraph (4), by striking “individuals who abuse drugs” and inserting “individuals who illicitly use drugs”;

(D) in paragraph (9), by striking “carried out by the Director”;

(E) by striking paragraph (10);

(F) by redesignating paragraphs (11) through (14) as paragraphs (10) through (13), respectively;

(G) in paragraph (12), as so redesignated, by striking “; and” and inserting a semicolon; and

(H) by striking paragraph (13), as so redesignated, and inserting the following:

“(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded; and

“(14) work with States, providers, and individuals in recovery, and their families, to promote the expansion of recovery support services and systems of care oriented toward recovery.”.

SEC. 6008. ADVISORY COUNCILS.

Section 502(b) of the Public Health Service Act (42 U.S.C. 290aa–1(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (E), by striking “and” after the semicolon;

(B) by redesignating subparagraph (F) as subparagraph (J); and

(C) by inserting after subparagraph (E), the following:

“(F) the Chief Medical Officer, appointed under section 501(g);

“(G) the Director of the National Institute of Mental Health for the advisory councils appointed under subsections (a)(1)(A) and (a)(1)(D);

“(H) the Director of the National Institute on Drug Abuse for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C);

“(I) the Director of the National Institute on Alcohol Abuse and Alcoholism for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C); and”;

(2) in paragraph (3), by adding at the end the following:

“(C) Not less than half of the members of the advisory council appointed under subsection (a)(1)(D)—

“(i) shall—

“(I) have a medical degree;

“(II) have a doctoral degree in psychology; or

“(III) have an advanced degree in nursing or social work from an accredited graduate school or be a certified physician assistant; and

“(ii) shall specialize in the mental health field.

“(D) Not less than half of the members of the advisory councils appointed under subsections (a)(1)(B) and (a)(1)(C)—

“(i) shall—

“(I) have a medical degree;

“(II) have a doctoral degree; or

“(III) have an advanced degree in nursing, public health, behavioral or social sciences, or social work from an accredited graduate school or be a certified physician assistant; and

“(ii) shall have experience in the provision of substance use disorder services or the development and implementation of programs to prevent substance misuse.”.

SEC. 6009. PEER REVIEW.

Section 504(b) of the Public Health Service Act (42 U.S.C. 290aa–3(b)) is amended by adding at the end the following: “In the case of any such peer review group that is reviewing a grant, cooperative agreement, or contract related to mental illness treatment, not less than half of the members of such peer review group shall be licensed and experienced professionals in the prevention, diagnosis, or treatment of, or recovery from, mental illness or co-occurring mental illness and substance use disorders and have a medical degree, a doctoral degree in psychology, or an advanced degree in nursing or social work from an accredited program, and the Secretary, in consultation with the Assistant Secretary, shall, to the extent possible, ensure such peer review groups include broad geographic representation, including both urban and rural representatives.”.

Subtitle B—Oversight and Accountability

SEC. 6021. IMPROVING OVERSIGHT OF MENTAL AND SUBSTANCE USE DISORDERS PROGRAMS THROUGH THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation, shall ensure efficient and effective planning and evaluation of mental and substance use disorders prevention and treatment programs and related activities.

(b) EVALUATION STRATEGY.—In carrying out subsection (a), the Assistant Secretary for Planning and Evaluation shall, not later than 180 days after the date of enactment of this Act, develop a strategy for conducting ongoing evaluations that identifies priority programs to be evaluated by the Assistant Secretary for Planning and Evaluation and priority programs to be evaluated by other relevant offices and agencies within the Department of Health and Human Services. The strategy shall—

(1) include a plan for evaluating programs related to mental and substance use disorders, including co-occurring disorders, across agencies, as appropriate, including programs related to—

(A) prevention, intervention, treatment, and recovery support services, including such services for adults with a serious mental illness or children with a serious emotional disturbance;

(B) the reduction of homelessness and incarceration among individuals with a mental or substance use disorder; and

(C) public health and health services; and

(2) include a plan for assessing the use of performance metrics to evaluate activities carried out by entities receiving grants, contracts, or cooperative agreements related to mental and substance use disorders prevention and treatment services under title V or title XIX of the Public Health Service Act (42 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

(c) CONSULTATION.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall consult, as appropriate, with the Assistant Secretary for Mental Health and Substance Use, the Chief Medical Officer of the Substance Abuse and Mental Health Services Administration appointed under section 501(g) of the Public Health Service Act (42 U.S.C. 290aa(g)), as amended by section 6003, the Behavioral Health Coordinating Council of the Department of Health and Human Services, other agencies within the Department of Health and Human Services, and other relevant Federal departments and agencies.

(d) RECOMMENDATIONS.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall provide recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, and the Congress on improving the quality of prevention and treatment programs and activities related to mental and substance use disorders, including recommendations for the use of performance metrics. The Assistant Secretary for Mental Health and Substance Use shall include such recommendations in the biennial report required by subsection 501(m) of the Public Health Service Act, as redesignated by section 6003 of this Act.

SEC. 6022. REPORTING FOR PROTECTION AND ADVOCACY ORGANIZATIONS.

(a) PUBLIC AVAILABILITY OF REPORTS.—Section 105(a)(7) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10805(a)(7)) is amended by striking “is located a report” and inserting “is located, and made publicly available, a report”.

(b) DETAILED ACCOUNTING.—Section 114(a) of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10824(a)) is amended—

(1) in paragraph (3), by striking “and” at the end;

(2) in paragraph (4), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following:

“(5) using data from the existing required annual program progress reports submitted by each system funded under this title, a detailed accounting for each such system of how funds are spent, disaggregated according to whether the funds were received from the Federal Government, the State government, a local government, or a private entity.”.

SEC. 6023. GAO STUDY.

(a) IN GENERAL.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services and the Assistant Secretary for Mental Health and Substance Use, shall conduct an independent evaluation, and submit a report, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, on programs funded by allotments made under title I of the Protection and Advocacy for Individuals with Mental Illness Act (42 U.S.C. 10801 et seq.).

(b) CONTENTS.—The report and evaluation required under subsection (a) shall include—

(1) a review of the programs described in such subsection that are carried out by State agencies and such programs that are carried out by private, nonprofit organizations; and

(2) a review of the compliance of the programs described in subsection (a) with statutory and regulatory responsibilities, such as—

(A) responsibilities relating to family engagement;

(B) responsibilities relating to the grievance procedure for clients or prospective clients of the system to assure that individuals with mental illness have full access to the services of the system, for individuals who have received or are receiving mental health services, and for family members of such individuals with mental illness, or representatives of such individuals or family members, to assure that the eligible system is operating in compliance with the provisions of the Protection and Advocacy for Individuals with Mental Illness Act, as required to be established by section 105(a)(9) of such Act (42 U.S.C. 10805(a)(9));

(C) investigation of alleged abuse and neglect of persons with mental illness;

(D) availability of adequate medical and behavioral health treatment;

(E) denial of rights for persons with mental illness; and

(F) compliance with the Federal prohibition on lobbying.

Subtitle C—Interdepartmental Serious Mental Illness Coordinating Committee

SEC. 6031. INTERDEPARTMENTAL SERIOUS MENTAL ILLNESS COORDINATING COMMITTEE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 3 months after the date of enactment of this Act, the Secretary of Health and Human Services, or the designee of the Secretary, shall establish a committee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the “Committee”).

(2) FEDERAL ADVISORY COMMITTEE ACT.—Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the Committee.

(b) MEETINGS.—The Committee shall meet not fewer than 2 times each year.

(c) RESPONSIBILITIES.—Not later than 1 year after the date of enactment of this Act, and 5 years after such date of enactment, the Committee shall submit to Congress and any other relevant Federal department or agency a report including—

(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional disturbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including public health outcomes such as—

(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, interaction with the criminal justice system, homelessness, and unemployment;

(B) increased rates of employment and enrollment in educational and vocational programs;

(C) quality of mental and substance use disorders treatment services; or

(D) any other criteria as may be determined by the Secretary; and

(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

(d) COMMITTEE EXTENSION.—Upon the submission of the second report under subsection (c), the Secretary shall submit a recommendation to Congress on whether to extend the operation of the Committee.

(e) MEMBERSHIP.—

(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

(B) the Assistant Secretary for Mental Health and Substance Use;

(C) the Attorney General;

(D) the Secretary of Veterans Affairs;

(E) the Secretary of Defense;

(F) the Secretary of Housing and Urban Development;

(G) the Secretary of Education;

(H) the Secretary of Labor;

(I) the Administrator of the Centers for Medicare & Medicaid Services; and

(J) the Commissioner of Social Security.

(2) NON-FEDERAL MEMBERS.—The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

(A) at least 2 members shall be an individual who has received treatment for a diagnosis of a serious mental illness;

(B) at least 1 member shall be a parent or legal guardian of an adult with a history of a serious mental illness or a child with a history of a serious emotional disturbance;

(C) at least 1 member shall be a representative of a leading research, advocacy, or service organization for adults with a serious mental illness;

(D) at least 2 members shall be—

(i) a licensed psychiatrist with experience in treating serious mental illnesses;

(ii) a licensed psychologist with experience in treating serious mental illnesses or serious emotional disturbances;

(iii) a licensed clinical social worker with experience treating serious mental illnesses or serious emotional disturbances; or

(iv) a licensed psychiatric nurse, nurse practitioner, or physician assistant with experience in treating serious mental illnesses or serious emotional disturbances;

(E) at least 1 member shall be a licensed mental health professional with a specialty in treating children and adolescents with a serious emotional disturbance;

(F) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with minorities;

(G) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with medically underserved populations;

(H) at least 1 member shall be a State certified mental health peer support specialist;

(I) at least 1 member shall be a judge with experience in adjudicating cases related to criminal justice or serious mental illness;

(J) at least 1 member shall be a law enforcement officer or corrections officer with extensive experience in interfacing with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(K) at least 1 member shall have experience providing services for homeless individuals and working with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis.

(3) TERMS.—A member of the Committee appointed under subsection (e)(2) shall serve for a term of 3 years, and may be reappointed for 1 or more additional 3-year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

(f) WORKING GROUPS.—In carrying out its functions, the Committee may establish working

groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

(g) SUNSET.—The Committee shall terminate on the date that is 6 years after the date on which the Committee is established under subsection (a)(1).

TITLE VII—ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

SEC. 7001. ENCOURAGING INNOVATION AND EVIDENCE-BASED PROGRAMS.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by inserting after section 501 (42 U.S.C. 290aa) the following:

“SEC. 501A. NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY.

“(a) IN GENERAL.—There shall be established within the Administration a National Mental Health and Substance Use Policy Laboratory (referred to in this section as the ‘Laboratory’).

“(b) RESPONSIBILITIES.—The Laboratory shall—

“(1) continue to carry out the authorities and activities that were in effect for the Office of Policy, Planning, and Innovation as such Office existed prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016;

“(2) identify, coordinate, and facilitate the implementation of policy changes likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services;

“(3) work with the Center for Behavioral Health Statistics and Quality to collect, as appropriate, information from grantees under programs operated by the Administration in order to evaluate and disseminate information on evidence-based practices, including culturally and linguistically appropriate services, as appropriate, and service delivery models;

“(4) provide leadership in identifying and coordinating policies and programs, including evidence-based programs, related to mental and substance use disorders;

“(5) periodically review programs and activities operated by the Administration relating to the diagnosis or prevention of, treatment for, and recovery from, mental and substance use disorders to—

“(A) identify any such programs or activities that are duplicative;

“(B) identify any such programs or activities that are not evidence-based, effective, or efficient; and

“(C) formulate recommendations for coordinating, eliminating, or improving programs or activities identified under subparagraph (A) or (B) and merging such programs or activities into other successful programs or activities; and

“(6) carry out other activities as deemed necessary to continue to encourage innovation and disseminate evidence-based programs and practices.

“(c) EVIDENCE-BASED PRACTICES AND SERVICE DELIVERY MODELS.—

“(1) IN GENERAL.—In carrying out subsection (b)(3), the Laboratory—

“(A) may give preference to models that improve—

“(i) the coordination between mental health and physical health providers;

“(ii) the coordination among such providers and the justice and corrections system; and

“(iii) the cost effectiveness, quality, effectiveness, and efficiency of health care services furnished to adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

“(B) may include clinical protocols and practices that address the needs of individuals with early serious mental illness.

“(2) CONSULTATION.—In carrying out this section, the Laboratory shall consult with—

“(A) the Chief Medical Officer appointed under section 501(g);

“(B) representatives of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, on an ongoing basis;

“(C) other appropriate Federal agencies;

“(D) clinical and analytical experts with expertise in psychiatric medical care and clinical psychological care, health care management, education, corrections health care, and mental health court systems, as appropriate; and

“(E) other individuals and agencies as determined appropriate by the Assistant Secretary.

“(d) DEADLINE FOR BEGINNING IMPLEMENTATION.—The Laboratory shall begin implementation of this section not later than January 1, 2018.

“(e) PROMOTING INNOVATION.—

“(1) IN GENERAL.—The Assistant Secretary, in coordination with the Laboratory, may award grants to States, local governments, Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), educational institutions, and nonprofit organizations to develop evidence-based interventions, including culturally and linguistically appropriate services, as appropriate, for—

“(A) evaluating a model that has been scientifically demonstrated to show promise, but would benefit from further applied development, for—

“(i) enhancing the prevention, diagnosis, intervention, and treatment of, and recovery from, mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders; or

“(ii) integrating or coordinating physical health services and mental and substance use disorders services; and

“(B) expanding, replicating, or scaling evidence-based programs across a wider area to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness, serious mental illness, serious emotional disturbances, and substance use disorders, primarily by—

“(i) applying such evidence-based programs to the delivery of care, including by training staff in effective evidence-based treatments; or

“(ii) integrating such evidence-based programs into models of care across specialties and jurisdictions.

“(2) CONSULTATION.—In awarding grants under this subsection, the Assistant Secretary shall, as appropriate, consult with the Chief Medical Officer, appointed under section 501(g), the advisory councils described in section 502, the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, as appropriate.

“(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

“(A) to carry out paragraph (1)(A), \$7,000,000 for the period of fiscal years 2018 through 2020; and

“(B) to carry out paragraph (1)(B), \$7,000,000 for the period of fiscal years 2018 through 2020.”

SEC. 7002. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by inserting after section 543 of such Act (42 U.S.C. 290dd–2) the following:

“SEC. 543A. PROMOTING ACCESS TO INFORMATION ON EVIDENCE-BASED PROGRAMS AND PRACTICES.

“(a) IN GENERAL.—The Assistant Secretary shall, as appropriate, improve access to reliable and valid information on evidence-based programs and practices, including information on the strength of evidence associated with such programs and practices, related to mental and substance use disorders for States, local commu-

nities, nonprofit entities, and other stakeholders, by posting on the Internet website of the Administration information on evidence-based programs and practices that have been reviewed by the Assistant Secretary in accordance with the requirements of this section.

“(b) APPLICATIONS.—

“(1) APPLICATION PERIOD.—In carrying out subsection (a), the Assistant Secretary may establish a period for the submission of applications for evidence-based programs and practices to be posted publicly in accordance with subsection (a).

“(2) NOTICE.—In establishing the application period under paragraph (1), the Assistant Secretary shall provide for the public notice of such application period in the Federal Register. Such notice may solicit applications for evidence-based programs and practices to address gaps in information identified by the Assistant Secretary, the National Mental Health and Substance Use Policy Laboratory established under section 501A, or the Assistant Secretary for Planning and Evaluation, including pursuant to the evaluation and recommendations under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 or priorities identified in the strategic plan under section 501(l).

“(c) REQUIREMENTS.—The Assistant Secretary may establish minimum requirements for the applications submitted under subsection (b), including applications related to the submission of research and evaluation.

“(d) REVIEW AND RATING.—

“(1) IN GENERAL.—The Assistant Secretary shall review applications prior to public posting in accordance with subsection (a), and may prioritize the review of applications for evidence-based programs and practices that are related to topics included in the notice provided under subsection (b)(2).

“(2) SYSTEM.—In carrying out paragraph (1), the Assistant Secretary may utilize a rating and review system, which may include information on the strength of evidence associated with the evidence-based programs and practices and a rating of the methodological rigor of the research supporting the applications.

“(3) PUBLIC ACCESS TO METRICS AND RATING.—The Assistant Secretary shall make the metrics used to evaluate applications under this section, and any resulting ratings of such applications, publicly available.”

SEC. 7003. PRIORITY MENTAL HEALTH NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 520A of the Public Health Service Act (42 U.S.C. 290bb–32) is amended—

(1) in subsection (a)—

(A) in paragraph (4), by inserting before the period “, which may include technical assistance centers”; and

(B) in the flush sentence following paragraph (4)—

(i) by inserting “, contracts,” before “or cooperative agreements”; and

(ii) by striking “Indian tribes and tribal organizations” and inserting “Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or”; and

(2) by amending subsection (f) to read as follows:

“(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$394,550,000 for each of fiscal years 2018 through 2022.”

SEC. 7004. PRIORITY SUBSTANCE USE DISORDER TREATMENT NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 509 of the Public Health Service Act (42 U.S.C. 290bb–2) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “abuse” and inserting “use disorder”;

(B) in paragraph (3), by inserting before the period “that permit States, local governments, communities, and Indian tribes and tribal organizations (as the terms ‘Indian tribes’ and ‘tribal organizations’ are defined in section 4 of the Indian Self-Determination and Education Assistance Act) to focus on emerging trends in substance abuse and co-occurrence of substance use disorders with mental illness or other conditions”; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting “, contracts,” before “or cooperative agreements”; and

(ii) by striking “Indian tribes and tribal organizations,” and inserting “Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or”;

(2) in subsection (b)—

(A) in paragraph (1), by striking “abuse” and inserting “use disorder”; and

(B) in paragraph (2), by striking “abuse” and inserting “use disorder”;

(3) in subsection (e), by striking “abuse” and inserting “use disorder”; and

(4) in subsection (f), by striking “\$300,000,000” and all that follows through the period and inserting “\$333,806,000 for each of fiscal years 2018 through 2022.”.

SEC. 7005. PRIORITY SUBSTANCE USE DISORDER PREVENTION NEEDS OF REGIONAL AND NATIONAL SIGNIFICANCE.

Section 516 of the Public Health Service Act (42 U.S.C. 290bb–22) is amended—

(1) in the section heading, by striking “**ABUSE**” and inserting “**USE DISORDER**”;

(2) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “abuse” and inserting “use disorder”;

(B) in paragraph (3), by inserting before the period “, including such programs that focus on emerging drug abuse issues”; and

(C) in the flush sentence following paragraph (3)—

(i) by inserting “, contracts,” before “or cooperative agreements”; and

(ii) by striking “Indian tribes and tribal organizations,” and inserting “Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or”;

(3) in subsection (b)—

(A) in paragraph (1), by striking “abuse” and inserting “use disorder”; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking “;” and “at the end and inserting “;”;

(ii) in subparagraph (B)—

(I) by striking “abuse” and inserting “use disorder”; and

(II) by striking the period and inserting “; and”;

(iii) by adding at the end the following:

“(C) substance use disorder prevention among high-risk groups.”;

(4) in subsection (e), by striking “abuse” and inserting “use disorder”; and

(5) in subsection (f), by striking “\$300,000,000” and all that follows through the period and inserting “\$211,148,000 for each of fiscal years 2018 through 2022.”.

TITLE VIII—SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

SEC. 8001. COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) **FORMULA GRANTS.**—Section 1911(b) of the Public Health Service Act (42 U.S.C. 300x(b)) is amended—

(1) by redesignating paragraphs (1) through (3) as paragraphs (2) through (4), respectively; and

(2) by inserting before paragraph (2) (as so redesignated) the following:

“(1) providing community mental health services for adults with a serious mental illness and children with a serious emotional disturbance as defined in accordance with section 1912(c).”.

(b) **STATE PLAN.**—Section 1912(b) of the Public Health Service Act (42 U.S.C. 300x–1(b)) is amended—

(1) in paragraph (3), by redesignating subparagraphs (A) through (C) as clauses (i) through (iii), respectively, and realigning the margins accordingly;

(2) by redesignating paragraphs (1) through (5) as subparagraphs (A) through (E), respectively, and realigning the margins accordingly;

(3) in the matter preceding subparagraph (A) (as so redesignated), by striking “With respect to” and all that follows through “are as follows:” and inserting “In accordance with subsection (a), a State shall submit to the Secretary a plan every two years that, at a minimum, includes each of the following:”;

(4) by inserting before subparagraph (A) (as so redesignated) the following:

“(1) **SYSTEM OF CARE.**—A description of the State’s system of care that contains the following:”;

(5) by striking subparagraph (A) (as so redesignated) and inserting the following:

“(A) **COMPREHENSIVE COMMUNITY-BASED HEALTH SYSTEMS.**—The plan shall—

“(i) identify the single State agency to be responsible for the administration of the program under the grant, including any third party who administers mental health services and is responsible for complying with the requirements of this part with respect to the grant;

“(ii) provide for an organized community-based system of care for individuals with mental illness, and describe available services and resources in a comprehensive system of care, including services for individuals with co-occurring disorders;

“(iii) include a description of the manner in which the State and local entities will coordinate services to maximize the efficiency, effectiveness, quality, and cost-effectiveness of services and programs to produce the best possible outcomes (including health services, rehabilitation services, employment services, housing services, educational services, substance use disorder services, legal services, law enforcement services, social services, child welfare services, medical and dental care services, and other support services to be provided with Federal, State, and local public and private resources) with other agencies to enable individuals receiving services to function outside of inpatient or residential institutions, to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act;

“(iv) include a description of how the State promotes evidence-based practices, including those evidence-based programs that address the needs of individuals with early serious mental illness regardless of the age of the individual at onset, provide comprehensive individualized treatment, or integrate mental and physical health services;

“(v) include a description of case management services;

“(vi) include a description of activities that seek to engage adults with a serious mental illness or children with a serious emotional disturbance and their caregivers where appropriate in making health care decisions, including activities that enhance communication among individuals, families, caregivers, and treatment providers; and

“(vii) as appropriate to, and reflective of, the uses the State proposes for the block grant funds, include—

“(I) a description of the activities intended to reduce hospitalizations and hospital stays using the block grant funds;

“(II) a description of the activities intended to reduce incidents of suicide using the block grant funds;

“(III) a description of how the State integrates mental health and primary care using the block grant funds, which may include providing, in the case of individuals with co-occurring mental and substance use disorders, both mental and substance use disorders services in primary care settings or arrangements to provide primary and specialty care services in community-based mental and substance use disorders settings; and

“(IV) a description of recovery and recovery support services for adults with a serious mental illness and children with a serious emotional disturbance.”;

(6) in subparagraph (B) (as so redesignated)—

(A) by striking “The plan contains” and inserting “The plan shall contain”; and

(B) by striking “presents quantitative targets to be achieved in the implementation of the system described in paragraph (1)” and inserting “present quantitative targets and outcome measures for programs and services provided under this subpart”;

(7) in subparagraph (C) (as so redesignated)—

(A) by striking “serious emotional disturbance” in the matter preceding clause (i) (as so redesignated) and all that follows through “substance abuse services” in clause (i) (as so redesignated) and inserting the following: “a serious emotional disturbance (as defined pursuant to subsection (c)), the plan shall provide for a system of integrated social services, educational services, child welfare services, juvenile justice services, law enforcement services, and substance use disorder services”;

(B) by striking “Education Act;” and inserting “Education Act.”; and

(C) by striking clauses (ii) and (iii) (as so redesignated);

(8) in subparagraph (D) (as so redesignated), by striking “plan describes” and inserting “plan shall describe”;

(9) in subparagraph (E) (as so redesignated)—

(A) in the subparagraph heading by striking “SYSTEMS” and inserting “SERVICES”;

(B) in the first sentence, by striking “plan describes” and all that follows through “and provides for” and inserting “plan shall describe the financial resources available, the existing mental health workforce, and the workforce trained in treating individuals with co-occurring mental and substance use disorders, and shall provide for”; and

(C) in the second sentence—

(i) by striking “further describes” and inserting “shall further describe”; and

(ii) by striking “involved.” and inserting “involved, and the manner in which the State intends to comply with each of the funding agreements in this subpart and subpart III.”;

(10) by striking the flush matter at the end; and

(11) by adding at the end the following:

“(2) **GOALS AND OBJECTIVES.**—The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.”.

(c) **EARLY SERIOUS MENTAL ILLNESS.**—Section 1920 of the Public Health Service Act (42 U.S.C. 300x–9) is amended by adding at the end the following:

“(c) **EARLY SERIOUS MENTAL ILLNESS.**—

“(1) **IN GENERAL.**—Except as provided in paragraph (2), a State shall expend not less than 10 percent of the amount the State receives for carrying out this section for each fiscal year to support evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders, regardless of the age of the individual at onset.

“(2) **STATE FLEXIBILITY.**—In lieu of expending 10 percent of the amount the State receives

under this section for a fiscal year as required under paragraph (1), a State may elect to expend not less than 20 percent of such amount by the end of such succeeding fiscal year.”.

(d) **ADDITIONAL PROVISIONS.**—Section 1915(b) of the Public Health Service Act (42 U.S.C. 300x-4(b)) is amended—

(1) in paragraph (3)—

(A) by striking “The Secretary” and inserting the following:

“(A) **IN GENERAL.**—The Secretary”;

(B) by striking “paragraph (1) if” and inserting “paragraph (1) in whole or in part if”;

(C) by striking “State justify the waiver.” and inserting “State in the fiscal year involved or in the previous fiscal year justify the waiver”;

(D) by adding at the end the following:

“(B) **DATE CERTAIN FOR ACTION UPON REQUEST.**—The Secretary shall approve or deny a request for a waiver under this paragraph not later than 120 days after the date on which the request is made.

“(C) **APPLICABILITY OF WAIVER.**—A waiver provided by the Secretary under this paragraph shall be applicable only to the fiscal year involved.”; and

(2) in paragraph (4)—

(A) in subparagraph (A)—

(i) by inserting after the subparagraph designation the following: “**IN GENERAL.**—”;

(ii) by striking “In making a grant” and inserting the following:

“(i) **DETERMINATION.**—In making a grant”;

and

(iii) by inserting at the end the following:

“(ii) **ALTERNATIVE.**—A State that has failed to comply with paragraph (1) and would otherwise be subject to a reduction in the State’s allotment under section 1911 may, upon request by the State, in lieu of having the amount of the allotment under section 1911 for the State reduced for the fiscal year of the grant, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement.”; and

(B) in subparagraph (B)—

(i) by inserting after the subparagraph designation the following: “**SUBMISSION OF INFORMATION TO THE SECRETARY.**—”;

(ii) by striking “subparagraph (A)” and inserting “subparagraph (A)(i)”.

(e) **APPLICATION FOR GRANT.**—Section 1917(a) of the Public Health Service Act (42 U.S.C. 300x-6(a)) is amended—

(1) in paragraph (1), by striking “1941” and inserting “1942(a)”;

(2) in paragraph (5), by striking “1915(b)(3)(B)” and inserting “1915(b)”.

(f) **FUNDING.**—Section 1920 of the Public Health Service Act (42 U.S.C. 300x-9) is amended—

(1) in subsection (a)—

(A) by striking “section 505” and inserting “section 505(c)”;

(B) by striking “\$450,000,000” and all that follows through the period and inserting “\$532,571,000 for each of fiscal years 2018 through 2022.”; and

(2) in subsection (b)(2) by striking “sections 505 and” and inserting “sections 505(c) and”.

SEC. 8002. SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT.

(a) **FORMULA GRANTS.**—Section 1921(b) of the Public Health Service Act (42 U.S.C. 300x-21(b)) is amended—

(1) by inserting “carrying out the plan developed in accordance with section 1932(b) and for” after “for the purpose of”;

(2) by striking “abuse” and inserting “use disorders”.

(b) **OUTREACH TO PERSONS WHO INJECT DRUGS.**—Section 1923(b) of the Public Health Service Act (42 U.S.C. 300x-23(b)) is amended—

(1) in the subsection heading, by striking “REGARDING INTRAVENOUS SUBSTANCE ABUSE” and

inserting “TO PERSONS WHO INJECT DRUGS”; and

(2) by striking “for intravenous drug abuse” and inserting “for persons who inject drugs”.

(c) **REQUIREMENTS REGARDING TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS.**—Section 1924 of the Public Health Service Act (42 U.S.C. 300x-24) is amended—

(1) in subsection (a)(1)—

(A) in the matter preceding subparagraph (A), by striking “substance abuse” and inserting “substance use disorders”;

(B) in subparagraph (A), by striking “such abuse” and inserting “such disorders”;

(2) in subsection (b)—

(A) in paragraph (1)(A), by striking “substance abuse” and inserting “substance use disorders”;

(B) in paragraph (2), by inserting “and Prevention” after “Disease Control”;

(C) in paragraph (3)—

(i) in the paragraph heading, by striking “ABUSE” and inserting “USE DISORDERS”;

(ii) by striking “substance abuse” and inserting “substance use disorders”;

(D) in paragraph (6)(B), by striking “substance abuse” and inserting “substance use disorders”;

(3) by striking subsection (d); and

(4) by redesignating subsection (e) as subsection (d).

(d) **GROUP HOMES.**—Section 1925 of the Public Health Service Act (42 U.S.C. 300x-25) is amended—

(1) in the section heading, by striking “RECOVERING SUBSTANCE ABUSERS” and inserting “PERSONS IN RECOVERY FROM SUBSTANCE USE DISORDERS”;

(2) in subsection (a), in the matter preceding paragraph (1), by striking “recovering substance abusers” and inserting “persons in recovery from substance use disorders”.

(e) **ADDITIONAL AGREEMENTS.**—Section 1928 of the Public Health Service Act (42 U.S.C. 300x-28) is amended—

(1) in subsection (a), by striking “(relative to fiscal year 1992)”;

(2) by striking subsection (b) and inserting the following:

“(b) **PROFESSIONAL DEVELOPMENT.**—A funding agreement for a grant under section 1921 is that the State involved will ensure that prevention, treatment, and recovery personnel operating in the State’s substance use disorder prevention, treatment, and recovery systems have an opportunity to receive training, on an ongoing basis, concerning—

“(1) recent trends in substance use disorders in the State;

“(2) improved methods and evidence-based practices for providing substance use disorder prevention and treatment services;

“(3) performance-based accountability;

“(4) data collection and reporting requirements; and

“(5) any other matters that would serve to further improve the delivery of substance use disorder prevention and treatment services within the State.”; and

(3) in subsection (d)(1), by striking “substance abuse” and inserting “substance use disorders”.

(f) **REPEAL.**—Section 1929 of the Public Health Service Act (42 U.S.C. 300x-29) is repealed.

(g) **MAINTENANCE OF EFFORT.**—Section 1930 of the Public Health Service Act (42 U.S.C. 300x-30) is amended—

(1) in subsection (c)(1), by striking “in the State justify the waiver” and inserting “exist in the State, or any part of the State, to justify the waiver”;

(2) in subsection (d), by inserting at the end the following:

“(3) **ALTERNATIVE.**—A State that has failed to comply with this section and would otherwise be subject to a reduction in the State’s allotment under section 1921, may, upon request by the State, in lieu of having the State’s allotment under section 1921 reduced, agree to comply

with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement.”.

(h) **RESTRICTIONS ON EXPENDITURES.**—Section 1931(b)(1) of the Public Health Service Act (42 U.S.C. 300x-31(b)(1)) is amended by striking “substance abuse” and inserting “substance use disorders”.

(i) **APPLICATION.**—Section 1932 of the Public Health Service Act (42 U.S.C. 300x-32) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “subsections (c) and (d)(2)” and inserting “subsection (c)”;

(B) in paragraph (5), by striking “the information required in section 1930(c)(2), and”;

(2) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

“(1) **IN GENERAL.**—In order for a State to be in compliance with subsection (a)(6), the State shall submit to the Secretary a plan that, at a minimum, includes the following:

“(A) A description of the State’s system of care that—

“(i) identifies the single State agency responsible for the administration of the program, including any third party who administers substance use disorder services and is responsible for complying with the requirements of the grant;

“(ii) provides information on the need for substance use disorder prevention and treatment services in the State, including estimates on the number of individuals who need treatment, who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

“(iii) provides aggregate information on the number of individuals in treatment within the State, including the number of such individuals who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

“(iv) provides a description of the system that is available to provide services by modality, including the provision of recovery support services;

“(v) provides a description of the State’s comprehensive statewide prevention efforts, including the number of individuals being served in the system, target populations, and priority needs, and provides a description of the amount of funds from the prevention set-aside expended on primary prevention;

“(vi) provides a description of the financial resources available;

“(vii) describes the existing substance use disorders workforce and workforce trained in treating co-occurring substance use and mental disorders;

“(viii) includes a description of how the State promotes evidence-based practices; and

“(ix) describes how the State integrates substance use disorder services and primary health care, which in the case of those individuals with co-occurring mental health and substance use disorders may include providing both mental health and substance use disorder services in primary care settings or providing primary and specialty care services in community-based mental health and substance use disorder service settings.

“(B) The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

“(C) A description of how the State will comply with each funding agreement for a grant under section 1921 that is applicable to the State, including a description of the manner in which the State intends to expend grant funds.”; and

(B) in paragraph (2)—

(i) in the paragraph heading, by striking “AUTHORITY OF SECRETARY REGARDING MODIFICATIONS” and inserting “MODIFICATIONS”;

(ii) by striking “As a condition” and inserting the following:

“(A) AUTHORITY OF SECRETARY.—As a condition,”; and

(iii) by adding at the end the following:

“(B) STATE REQUEST FOR MODIFICATION.—If the State determines that a modification to such plan is necessary, the State may request the Secretary to approve the modification. Any such modification shall be in accordance with paragraph (1) and section 1941.”; and

(C) in paragraph (3), by inserting, “, including any modification under paragraph (2)” after “subsection (a)(6)”;

(3) in subsection (e)(2), by striking “section 1922(c)” and inserting “section 1922(b)”.

(j) DEFINITIONS.—Section 1934 of the Public Health Service Act (42 U.S.C. 300x–34) is amended—

(1) in paragraph (3), by striking “substance abuse” and inserting “substance use disorders”;

(2) in paragraph (7), by striking “substance abuse” and inserting “substance use disorders”.

(k) FUNDING.—Section 1935 of the Public Health Service Act (42 U.S.C. 300x–35) is amended—

(1) in subsection (a)—

(A) by striking “section 505” and inserting “section 505(d)”;

(B) by striking “\$2,000,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003” and inserting “\$1,858,079,000 for each of fiscal years 2018 through 2022.”; and

(2) in subsection (b)(1)(B) by striking “sections 505 and” and inserting “sections 505(d) and”.

SEC. 8003. ADDITIONAL PROVISIONS RELATED TO THE BLOCK GRANTS.

Subpart III of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–51 et seq.) is amended—

(1) in section 1943(a)(3) (42 U.S.C. 300x–53(a)(3)), by striking “section 505” and inserting “subsections (c) and (d) of section 505”;

(2) in section 1953(b) (42 U.S.C. 300x–63(b)), by striking “substance abuse” and inserting “substance use disorder”;

(3) by adding at the end the following:

“SEC. 1957. PUBLIC HEALTH EMERGENCIES.

“In the case of a public health emergency (as determined under section 319), the Secretary, on a State by State basis, may, as the circumstances of the emergency reasonably require and for the period of the emergency, grant an extension, or waive application deadlines or compliance with any other requirement, of a grant authorized under section 521, 1911, or 1921 or an allotment authorized under Public Law 99–319 (42 U.S.C. 10801 et seq.).”

“SEC. 1958. JOINT APPLICATIONS.

“The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall permit a joint application to be submitted for grants under subpart I and subpart II upon the request of a State. Such application may be jointly reviewed and approved by the Secretary with respect to such subparts, consistent with the purposes and authorized activities of each such grant program. A State submitting such a joint application shall otherwise meet the requirements with respect to each such subpart.”

SEC. 8004. STUDY OF DISTRIBUTION OF FUNDS UNDER THE SUBSTANCE ABUSE PREVENTION AND TREATMENT BLOCK GRANT AND THE COMMUNITY MENTAL HEALTH SERVICES BLOCK GRANT.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall through a grant or contract, or through an agreement with a third party, conduct a study on the formulas for distribution of funds under the substance abuse prevention and treatment block grant, and the community mental health services block grant, under part B of title XIX of the Public Health Service Act (42 U.S.C. 300x et seq.) and recommend changes if necessary. Such study shall include—

(1) an analysis of whether the distributions under such block grants accurately reflect the need for the services under the grants in the States;

(2) an examination of whether the indices used under the formulas for distribution of funds under such block grants are appropriate, and if not, alternatives recommended by the Secretary;

(3) where recommendations are included under paragraph (2) for the use of different indices, a description of the variables and data sources that should be used to determine the indices;

(4) an evaluation of the variables and data sources that are being used for each of the indices involved, and whether such variables and data sources accurately represent the need for services, the cost of providing services, and the ability of the States to pay for such services;

(5) the effect that the minimum allotment requirements for each such block grant have on each State’s final allotment and the effect of such requirements, if any, on each State’s formula-based allotment;

(6) recommendations for modifications to the minimum allotment provisions to ensure an appropriate distribution of funds; and

(7) any other information that the Secretary determines appropriate.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report containing the findings and recommendations of the study conducted under subsection (a) and the study conducted under section 9004(g).

TITLE IX—PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE

Subtitle A—Helping Individuals and Families

SEC. 9001. GRANTS FOR TREATMENT AND RECOVERY FOR HOMELESS INDIVIDUALS.

Section 506 of the Public Health Service Act (42 U.S.C. 290aa–5) is amended—

(1) in subsection (a), by striking “substance abuse” and inserting “substance use disorder”;

(2) in subsection (b)—

(A) in paragraphs (1) and (3), by striking “substance abuse” each place the term appears and inserting “substance use disorder”; and

(B) in paragraph (4), by striking “substance abuse” and inserting “a substance use disorder”;

(3) in subsection (c)—

(A) in paragraph (1), by striking “substance abuse disorder” and inserting “substance use disorder”;

(B) in paragraph (2)—

(i) in subparagraph (A), by striking “substance abuse” and inserting “a substance use disorder”;

(ii) in subparagraph (B), by striking “substance abuse” and inserting “substance use disorder”;

(4) in subsection (e), by striking “, \$50,000,000 for fiscal year 2001, and such sums as may be

necessary for each of the fiscal years 2002 and 2003” and inserting “\$41,304,000 for each of fiscal years 2018 through 2022”.

SEC. 9002. GRANTS FOR JAIL DIVERSION PROGRAMS.

Section 520G of the Public Health Service Act (42 U.S.C. 290bb–38) is amended—

(1) by striking “substance abuse” each place such term appears and inserting “substance use disorder”;

(2) in subsection (a)—

(A) by striking “Indian tribes, and tribal organizations” and inserting “and Indian tribes and tribal organizations (as the terms ‘Indian tribes’ and ‘tribal organizations’ are defined in section 4 of the Indian Self-Determination and Education Assistance Act)”; and

(B) by inserting “or a health facility or program operated by or in accordance with a contract or grant with the Indian Health Service,” after “entities,”;

(3) in subsection (c)(2)(A)(i), by striking “the best known” and inserting “evidence-based”;

(4) by redesignating subsections (d) through (i) as subsections (e) through (j), respectively;

(5) by inserting after subsection (c) the following:

“(d) SPECIAL CONSIDERATION REGARDING VETERANS.—In awarding grants under subsection (a), the Secretary shall, as appropriate, give special consideration to entities proposing to use grant funding to support jail diversion services for veterans.”;

(6) in subsection (e), as so redesignated—

(A) in paragraph (3), by striking “; and” and inserting a semicolon;

(B) in paragraph (4), by striking the period and inserting “; and”; and

(C) by adding at the end the following:

“(5) develop programs to divert individuals prior to booking or arrest.”; and

(7) in subsection (j), as so redesignated, by striking “\$10,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003” and inserting “\$4,269,000 for each of fiscal years 2018 through 2022”.

SEC. 9003. PROMOTING INTEGRATION OF PRIMARY AND BEHAVIORAL HEALTH CARE.

Section 520K of the Public Health Service Act (42 U.S.C. 290bb–42) is amended to read as follows:

“SEC. 520K. INTEGRATION INCENTIVE GRANTS AND COOPERATIVE AGREEMENTS.

“(a) DEFINITIONS.—In this section:

“(1) ELIGIBLE ENTITY.—The term ‘eligible entity’ means a State, or other appropriate State agency, in collaboration with 1 or more qualified community programs as described in section 1913(b)(1) or 1 or more community health centers as described in section 330.

“(2) INTEGRATED CARE.—The term ‘integrated care’ means collaborative models or practices offering mental and physical health services, which may include practices that share the same space in the same facility.

“(3) SPECIAL POPULATION.—The term ‘special population’ means—

“(A) adults with a mental illness who have co-occurring physical health conditions or chronic diseases;

“(B) adults with a serious mental illness who have co-occurring physical health conditions or chronic diseases;

“(C) children and adolescents with a serious emotional disturbance with co-occurring physical health conditions or chronic diseases; or

“(D) individuals with a substance use disorder.

“(b) GRANTS AND COOPERATIVE AGREEMENTS.—

“(1) IN GENERAL.—The Secretary may award grants and cooperative agreements to eligible entities to support the improvement of integrated care for primary care and behavioral health care in accordance with paragraph (2).

“(2) PURPOSES.—A grant or cooperative agreement awarded under this section shall be designed to—

“(A) promote full integration and collaboration in clinical practices between primary and behavioral health care;

“(B) support the improvement of integrated care models for primary care and behavioral health care to improve the overall wellness and physical health status of adults with a serious mental illness or children with a serious emotional disturbance; and

“(C) promote integrated care services related to screening, diagnosis, prevention, and treatment of mental and substance use disorders, and co-occurring physical health conditions and chronic diseases.

“(c) APPLICATIONS.—

“(1) IN GENERAL.—An eligible entity seeking a grant or cooperative agreement under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

“(2) CONTENTS.—The contents described in this paragraph are—

“(A) a description of a plan to achieve fully collaborative agreements to provide services to special populations;

“(B) a document that summarizes the policies, if any, that serve as barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

“(C) a description of partnerships or other arrangements with local health care providers to provide services to special populations;

“(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient outcomes and facilitate evaluations across participating projects; and

“(E) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

“(d) GRANT AND COOPERATIVE AGREEMENT AMOUNTS.—

“(1) TARGET AMOUNT.—The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be \$2,000,000.

“(2) ADJUSTMENT PERMITTED.—The Secretary, taking into consideration the quality of the application and the number of eligible entities that received grants under this section prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, may adjust the target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

“(3) LIMITATION.—An eligible entity receiving funding under this section may not allocate more than 10 percent of funds awarded under this section to administrative functions, and the remaining amounts shall be allocated to health facilities that provide integrated care.

“(e) DURATION.—A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

“(f) REPORT ON PROGRAM OUTCOMES.—An eligible entity receiving a grant or cooperative agreement under this section shall submit an annual report to the Secretary that includes—

“(1) the progress made to reduce barriers to integrated care as described in the entity’s application under subsection (c); and

“(2) a description of functional outcomes of special populations, including—

“(A) with respect to adults with a serious mental illness, participation in supportive housing or independent living programs, attendance in social and rehabilitative programs, participation in job training opportunities, satisfactory performance in work settings, attendance at scheduled medical and mental health appointments, and compliance with prescribed medication regimens;

“(B) with respect to individuals with co-occurring mental illness and physical health conditions and chronic diseases, attendance at scheduled medical and mental health appoint-

ments, compliance with prescribed medication regimens, and participation in learning opportunities related to improved health and lifestyle practices; and

“(C) with respect to children and adolescents with a serious emotional disturbance who have co-occurring physical health conditions and chronic diseases, attendance at scheduled medical and mental health appointments, compliance with prescribed medication regimens, and participation in learning opportunities at school and extracurricular activities.

“(g) TECHNICAL ASSISTANCE FOR PRIMARY-BEHAVIORAL HEALTH CARE INTEGRATION.—

“(1) IN GENERAL.—The Secretary may provide appropriate information, training, and technical assistance to eligible entities that receive a grant or cooperative agreement under this section, in order to help such entities meet the requirements of this section, including assistance with—

“(A) development and selection of integrated care models;

“(B) dissemination of evidence-based interventions in integrated care;

“(C) establishment of organizational practices to support operational and administrative success; and

“(D) other activities, as the Secretary determines appropriate.

“(2) ADDITIONAL DISSEMINATION OF TECHNICAL INFORMATION.—The information and resources provided by the Secretary under paragraph (1) shall, as appropriate, be made available to States, political subdivisions of States, Indian tribes or tribal organizations (as defined in section 4 of the Indian Self-Determination and Education Assistance Act), outpatient mental health and addiction treatment centers, community mental health centers that meet the criteria under section 1913(c), certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1861(aa) of the Social Security Act, other community-based organizations, or other entities engaging in integrated care activities, as the Secretary determines appropriate.

“(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$51,878,000 for each of fiscal years 2018 through 2022.”

SEC. 9004. PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS.

(a) FORMULA GRANTS TO STATES.—Section 521 of the Public Health Service Act (42 U.S.C. 290cc-21) is amended by striking “1991 through 1994” and inserting “2018 through 2022”.

(b) PURPOSE OF GRANTS.—Section 522 of the Public Health Service Act (42 U.S.C. 290cc-22) is amended—

(1) in subsection (a)(1)(B), by striking “substance abuse” and inserting “a substance use disorder”;

(2) in subsection (b)(6), by striking “substance abuse” and inserting “substance use disorder”;

(3) in subsection (c), by striking “substance abuse” and inserting “a substance use disorder”;

(4) in subsection (e)—

(A) in paragraph (1), by striking “substance abuse” and inserting “a substance use disorder”; and

(B) in paragraph (2), by striking “substance abuse” and inserting “substance use disorder”;

(5) by striking subsection (g) and redesignating subsections (h) and (i) as (g) and (h), accordingly; and

(6) in subsection (g), as redesignated by paragraph (5), by striking “substance abuse” each place such term appears and inserting “substance use disorder”.

(c) DESCRIPTION OF INTENDED EXPENDITURES OF GRANT.—Section 527 of the Public Health Service Act (42 U.S.C. 290cc-27) is amended by striking “substance abuse” each place such term appears and inserting “substance use disorder”.

(d) TECHNICAL ASSISTANCE.—Section 530 of the Public Health Service Act (42 U.S.C. 290cc-30) is

amended by striking “through the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse” and inserting “acting through the Assistant Secretary”.

(e) DEFINITIONS.—Section 534(4) of the Public Health Service Act (42 U.S.C. 290cc-34(4)) is amended to read as follows:

“(4) SUBSTANCE USE DISORDER SERVICES.—The term ‘substance use disorder services’ has the meaning given the term ‘substance abuse services’ in section 330(h)(5)(C).”

(f) FUNDING.—Section 535(a) of the Public Health Service Act (42 U.S.C. 290cc-35(a)) is amended by striking “\$75,000,000 for each of the fiscal years 2001 through 2003” and inserting “\$64,635,000 for each of fiscal years 2018 through 2022”.

(g) STUDY CONCERNING FORMULA.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Assistant Secretary for Mental Health and Substance Use (referred to in this section as the “Assistant Secretary”) shall conduct a study concerning the formula used under section 524 of the Public Health Service Act (42 U.S.C. 290cc-24) for making allotments to States under section 521 of such Act (42 U.S.C. 290cc-21). Such study shall include an evaluation of quality indicators of need for purposes of revising the formula for determining the amount of each allotment for the fiscal years following the submission of the study.

(2) REPORT.—In accordance with section 8004(b), the Assistant Secretary shall submit to the committees of Congress described in such section a report concerning the results of the study conducted under paragraph (1).

SEC. 9005. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.) is amended by inserting after section 520E-2 (42 U.S.C. 290bb-36b) the following:

“SEC. 520E-3. NATIONAL SUICIDE PREVENTION LIFELINE PROGRAM.

“(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Suicide Prevention Lifeline program (referred to in this section as the ‘program’), authorized under section 520A and in effect prior to the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016.

“(b) ACTIVITIES.—In maintaining the program, the activities of the Secretary shall include—

“(1) coordinating a network of crisis centers across the United States for providing suicide prevention and crisis intervention services to individuals seeking help at any time, day or night;

“(2) maintaining a suicide prevention hotline to link callers to local emergency, mental health, and social services resources; and

“(3) consulting with the Secretary of Veterans Affairs to ensure that veterans calling the suicide prevention hotline have access to a specialized veterans’ suicide prevention hotline.

“(c) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$7,198,000 for each of fiscal years 2018 through 2022.”

SEC. 9006. CONNECTING INDIVIDUALS AND FAMILIES WITH CARE.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.), as amended by section 9005, is further amended by inserting after section 520E-3 the following:

“SEC. 520E-4. TREATMENT REFERRAL ROUTING SERVICE.

“(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary, shall maintain the National Treatment Referral Routing Service (referred to in this section as the ‘Routing Service’) to assist individuals and families in locating mental and substance use disorders treatment providers.

“(b) **ACTIVITIES OF THE SECRETARY.**—To maintain the Routing Service, the activities of the Assistant Secretary shall include administering—

“(1) a nationwide, telephone number providing year-round access to information that is updated on a regular basis regarding local behavioral health providers and community-based organizations in a manner that is confidential, without requiring individuals to identify themselves, is in languages that include at least English and Spanish, and is at no cost to the individual using the Routing Service; and

“(2) an Internet website to provide a searchable, online treatment services locator of behavioral health treatment providers and community-based organizations, which shall include information on the name, location, contact information, and basic services provided by such providers and organizations.

“(c) **REMOVING PRACTITIONER CONTACT INFORMATION.**—In the event that the Internet website described in subsection (b)(2) contains information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 303(g)(2)(B) of the Controlled Substances Act, the Assistant Secretary—

“(1) shall provide an opportunity to such practitioner to have the contact information of the practitioner removed from the website at the request of the practitioner; and

“(2) may evaluate other methods to periodically update the information displayed on such website.

“(d) **RULE OF CONSTRUCTION.**—Nothing in this section shall be construed to prevent the Assistant Secretary from using any unobligated amounts otherwise made available to the Administration to maintain the Routing Service.”.

SEC. 9007. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

Section 520F of the Public Health Service Act (42 U.S.C. 290bb-37) is amended to read as follows:

“SEC. 520F. STRENGTHENING COMMUNITY CRISIS RESPONSE SYSTEMS.

“(a) **IN GENERAL.**—The Secretary shall award competitive grants to—

“(1) State and local governments and Indian tribes and tribal organizations, to enhance community-based crisis response systems; or

“(2) States to develop, maintain, or enhance a database of beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities, for adults with a serious mental illness, children with a serious emotional disturbance, or individuals with a substance use disorder.

“(b) **APPLICATIONS.**—

“(1) **IN GENERAL.**—To receive a grant under subsection (a), an entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

“(2) **COMMUNITY-BASED CRISIS RESPONSE PLAN.**—An application for a grant under subsection (a)(1) shall include a plan for—

“(A) promoting integration and coordination between local public and private entities engaged in crisis response, including first responders, emergency health care providers, primary care providers, law enforcement, court systems, health care payers, social service providers, and behavioral health providers;

“(B) developing memoranda of understanding with public and private entities to implement crisis response services;

“(C) addressing gaps in community resources for crisis intervention and prevention; and

“(D) developing models for minimizing hospital readmissions, including through appropriate discharge planning.

“(3) **BEDS DATABASE PLAN.**—An application for a grant under subsection (a)(2) shall include a plan for developing, maintaining, or enhancing a real-time, Internet-based bed database to

collect, aggregate, and display information about beds in inpatient psychiatric facilities and crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities to facilitate the identification and designation of facilities for the temporary treatment of individuals in mental or substance use disorder crisis.

“(c) **DATABASE REQUIREMENTS.**—A bed database described in this section is a database that—

“(1) includes information on inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder facilities in the State involved, including contact information for the facility or unit;

“(2) provides real-time information about the number of beds available at each facility or unit and, for each available bed, the type of patient that may be admitted, the level of security provided, and any other information that may be necessary to allow for the proper identification of appropriate facilities for treatment of individuals in mental or substance use disorder crisis; and

“(3) enables searches of the database to identify available beds that are appropriate for the treatment of individuals in mental or substance use disorder crisis.

“(d) **EVALUATION.**—An entity receiving a grant under subsection (a)(1) shall submit to the Secretary, at such time, in such manner, and containing such information as the Secretary may reasonably require, a report, including an evaluation of the effect of such grant on—

“(1) local crisis response services and measures for individuals receiving crisis planning and early intervention supports;

“(2) individuals reporting improved functional outcomes; and

“(3) individuals receiving regular followup care following a crisis.

“(e) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section, \$12,500,000 for the period of fiscal years 2018 through 2022.”.

SEC. 9008. GARRETT LEE SMITH MEMORIAL ACT REAUTHORIZATION.

(a) **SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER.**—Section 520C of the Public Health Service Act (42 U.S.C. 290bb-34), as amended by section 6001, is further amended—

(1) in the section heading, by striking “**YOUTH INTERAGENCY RESEARCH, TRAINING, AND TECHNICAL ASSISTANCE CENTERS**” and inserting “**SUICIDE PREVENTION TECHNICAL ASSISTANCE CENTER**”;

(2) in subsection (a), by striking “acting through the Assistant Secretary for Mental Health and Substance Use” and all that follows through the period at the end of paragraph (2) and inserting “acting through the Assistant Secretary, shall establish a research, training, and technical assistance resource center to provide appropriate information, training, and technical assistance to States, political subdivisions of States, federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations regarding the prevention of suicide among all ages, particularly among groups that are at a high risk for suicide.”;

(3) by striking subsections (b) and (c);

(4) by redesignating subsection (d) as subsection (b);

(5) in subsection (b), as so redesignated—

(A) in the subsection heading, by striking “**ADDITIONAL CENTER**” and inserting “**RESPONSIBILITIES OF THE CENTER**”;

(B) in the matter preceding paragraph (1), by striking “The additional research” and all that follows through “nonprofit organizations for” and inserting “The center established under subsection (a) shall conduct activities for the purpose of”;

(C) by striking “youth suicide” each place such term appears and inserting “suicide”;

(D) in paragraph (1)—

(i) by striking “the development or continuation of” and inserting “developing and continuing”; and

(ii) by inserting “for all ages, particularly among groups that are at a high risk for suicide” before the semicolon at the end;

(E) in paragraph (2), by inserting “for all ages, particularly among groups that are at a high risk for suicide” before the semicolon at the end;

(F) in paragraph (3), by inserting “and tribal” after “statewide”;

(G) in paragraph (5), by inserting “and prevention” after “intervention”;

(H) in paragraph (8), by striking “in youth”;

(I) in paragraph (9), by striking “and behavioral health” and inserting “health and substance use disorder”;

(J) in paragraph (10), by inserting “conducting” before “other”;

(6) by striking subsection (e) and inserting the following:

“(c) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated \$5,988,000 for each of fiscal years 2018 through 2022.

“(d) **ANNUAL REPORT.**—Not later than 2 years after the date of enactment of this subsection, the Secretary shall submit to Congress a report on the activities carried out by the center established under subsection (a) during the year involved, including the potential effects of such activities, and the States, organizations, and institutions that have worked with the center.”.

(b) **YOUTH SUICIDE EARLY INTERVENTION AND PREVENTION STRATEGIES.**—Section 520E of the Public Health Service Act (42 U.S.C. 290bb-36) is amended—

(1) in paragraph (1) of subsection (a) and in subsection (c), by striking “substance abuse” each place such term appears and inserting “substance use disorder”;

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking “ensure that each State is awarded only 1 grant or cooperative agreement under this section” and inserting “ensure that a State does not receive more than 1 grant or cooperative agreement under this section at any 1 time”; and

(ii) by striking “been awarded” and inserting “received”;

(B) by adding after paragraph (2) the following:

“(3) **CONSIDERATION.**—In awarding grants under this section, the Secretary shall take into consideration the extent of the need of the applicant, including the incidence and prevalence of suicide in the State and among the populations of focus, including rates of suicide determined by the Centers for Disease Control and Prevention for the State or population of focus.”;

(3) in subsection (g)(2), by striking “2 years after the date of enactment of this section,” and insert “2 years after the date of enactment of Helping Families in Mental Health Crisis Reform Act of 2016.”; and

(4) by striking subsection (m) and inserting the following:

“(m) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated \$30,000,000 for each of fiscal years 2018 through 2022.”.

SEC. 9009. ADULT SUICIDE PREVENTION.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.) is amended by adding at the end the following:

“SEC. 520L. ADULT SUICIDE PREVENTION.

“(a) **GRANTS.**—

“(1) **IN GENERAL.**—The Assistant Secretary shall award grants to eligible entities described in paragraph (2) to implement suicide prevention and intervention programs, for individuals

who are 25 years of age or older, that are designed to raise awareness of suicide, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide.

“(2) **ELIGIBLE ENTITIES.**—To be eligible to receive a grant under this section, an entity shall be a community-based primary care or behavioral health care setting, an emergency department, a State mental health agency (or State health agency with mental or behavioral health functions), public health agency, a territory of the United States, or an Indian tribe or tribal organization (as the terms ‘Indian tribe’ and ‘tribal organization’ are defined in section 4 of the Indian Self-Determination and Education Assistance Act).

“(3) **USE OF FUNDS.**—The grants awarded under paragraph (1) shall be used to implement programs, in accordance with such paragraph, that include one or more of the following components:

“(A) Screening for suicide risk, suicide intervention services, and services for referral for treatment for individuals at risk for suicide.

“(B) Implementing evidence-based practices to provide treatment for individuals at risk for suicide, including appropriate followup services.

“(C) Raising awareness and reducing stigma of suicide.

“(b) **EVALUATIONS AND TECHNICAL ASSISTANCE.**—The Assistant Secretary shall—

“(1) evaluate the activities supported by grants awarded under subsection (a), and disseminate, as appropriate, the findings from the evaluation; and

“(2) provide appropriate information, training, and technical assistance, as appropriate, to eligible entities that receive a grant under this section, in order to help such entities to meet the requirements of this section, including assistance with selection and implementation of evidence-based interventions and frameworks to prevent suicide.

“(c) **DURATION.**—A grant under this section shall be for a period of not more than 5 years.

“(d) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section \$30,000,000 for the period of fiscal years 2018 through 2022.”

SEC. 9010. MENTAL HEALTH AWARENESS TRAINING GRANTS.

Section 520J of the Public Health Service Act (42 U.S.C. 290bb-41) is amended—

(1) in the section heading, by inserting “**MENTAL HEALTH AWARENESS**” before “**TRAINING**”; and

(2) in subsection (b)—

(A) in the subsection heading, by striking “**ILLNESS**” and inserting “**HEALTH**”;

(B) in paragraph (1), by inserting “**veterans, law enforcement, and other categories of individuals, as determined by the Secretary,**” after “**emergency services personnel**”;

(C) in paragraph (5)—

(i) in the matter preceding subparagraph (A), by striking “**to**” and inserting “**for evidence-based programs that provide training and education in accordance with paragraph (1) on matters including**”; and

(ii) by striking subparagraphs (A) through (C) and inserting the following:

“(A) recognizing the signs and symptoms of mental illness; and

“(B)(i) resources available in the community for individuals with a mental illness and other relevant resources; or

“(ii) safely de-escalating crisis situations involving individuals with a mental illness.”; and

(D) in paragraph (7), by striking “, \$25,000,000” and all that follows through the period at the end and inserting “\$14,693,000 for each of fiscal years 2018 through 2022.”

SEC. 9011. SENSE OF CONGRESS ON PRIORITIZING AMERICAN INDIANS AND ALASKA NATIVE YOUTH WITHIN SUICIDE PREVENTION PROGRAMS.

(a) **FINDINGS.**—The Congress finds as follows:

(1) Suicide is the eighth leading cause of death among American Indians and Alaska Natives across all ages.

(2) Among American Indians and Alaska Natives who are 10 to 34 years of age, suicide is the second leading cause of death.

(3) The suicide rate among American Indian and Alaska Native adolescents and young adults ages 15 to 34 (17.9 per 100,000) is approximately 1.3 times higher than the national average for that age group (13.3 per 100,000).

(b) **SENSE OF CONGRESS.**—It is the sense of Congress that the Secretary of Health and Human Services, in carrying out suicide prevention and intervention programs, should prioritize programs and activities for populations with disproportionately high rates of suicide, such as American Indians and Alaska Natives.

SEC. 9012. EVIDENCE-BASED PRACTICES FOR OLDER ADULTS.

Section 520A(e) of the Public Health Service Act (42 U.S.C. 290bb-32(e)) is amended by adding at the end the following:

“(3) **GERIATRIC MENTAL DISORDERS.**—The Secretary shall, as appropriate, provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric mental disorders and co-occurring mental health and substance use disorders among geriatric populations, as well as disseminate information about such evidence-based practices to States and nongrantees throughout the United States.”

SEC. 9013. NATIONAL VIOLENT DEATH REPORTING SYSTEM.

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, is encouraged to improve, particularly through the inclusion of additional States, the National Violent Death Reporting System as authorized by title III of the Public Health Service Act (42 U.S.C. 241 et seq.). Participation in the system by the States shall be voluntary.

SEC. 9014. ASSISTED OUTPATIENT TREATMENT.

Section 224 of the Protecting Access to Medicare Act of 2014 (42 U.S.C. 290aa note) is amended—

(1) in subsection (e), by striking “and 2018,” and inserting “2018, 2019, 2020, 2021, and 2022.”; and

(2) in subsection (g)—

(A) in paragraph (1), by striking “2018” and inserting “2022”; and

(B) in paragraph (2), by striking “is authorized to be appropriated to carry out this section \$15,000,000 for each of fiscal years 2015 through 2018” and inserting “are authorized to be appropriated to carry out this section \$15,000,000 for each of fiscal years 2015 through 2017, \$20,000,000 for fiscal year 2018, \$19,000,000 for each of fiscal years 2019 and 2020, and \$18,000,000 for each of fiscal years 2021 and 2022.”

SEC. 9015. ASSERTIVE COMMUNITY TREATMENT PROGRAM.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.), as amended by section 9009, is further amended by adding at the end the following:

“SEC. 520M. ASSERTIVE COMMUNITY TREATMENT PROGRAM.

“(a) **IN GENERAL.**—The Assistant Secretary shall award grants to eligible entities—

“(1) to establish assertive community treatment programs for adults with a serious mental illness; or

“(2) to maintain or expand such programs.

“(b) **ELIGIBLE ENTITIES.**—To be eligible to receive a grant under this section, an entity shall be a State, political subdivision of a State, Indian tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), mental health system, health care facility, or any other entity the Assistant Secretary deems appropriate.

“(c) **SPECIAL CONSIDERATION.**—In selecting among applicants for a grant under this section, the Assistant Secretary may give special consideration to the potential of the applicant’s program to reduce hospitalization, homelessness, and involvement with the criminal justice system while improving the health and social outcomes of the patient.

“(d) **ADDITIONAL ACTIVITIES.**—The Assistant Secretary shall—

“(1) not later than the end of fiscal year 2021, submit a report to the appropriate congressional committees on the grant program under this section, including an evaluation of—

“(A) any cost savings and public health outcomes such as mortality, suicide, substance use disorders, hospitalization, and use of services;

“(B) rates of involvement with the criminal justice system of patients;

“(C) rates of homelessness among patients; and

“(D) patient and family satisfaction with program participation; and

“(2) provide appropriate information, training, and technical assistance to grant recipients under this section to help such recipients to establish, maintain, or expand their assertive community treatment programs.

“(e) **AUTHORIZATION OF APPROPRIATIONS.**—

“(1) **IN GENERAL.**—To carry out this section, there is authorized to be appropriated \$5,000,000 for the period of fiscal years 2018 through 2022.

“(2) **USE OF CERTAIN FUNDS.**—Of the funds appropriated to carry out this section in any fiscal year, not more than 5 percent shall be available to the Assistant Secretary for carrying out subsection (d).”

SEC. 9016. SOBER TRUTH ON PREVENTING UNDERAGE DRINKING REAUTHORIZATION.

Section 519B of the Public Health Service Act (42 U.S.C. 290bb-25b) is amended—

(1) in subsection (c)(3), by striking “fiscal year 2007” and all that follows through the period at the end and inserting “each of the fiscal years 2018 through 2022.”;

(2) in subsection (d)(4), by striking “fiscal year 2007” and all that follows through the period at the end and inserting “each of the fiscal years 2018 through 2022.”;

(3) in subsection (e)(1)(I), by striking “fiscal year 2007” and all that follows through the period at the end and inserting “each of the fiscal years 2018 through 2022.”;

(4) in subsection (f)(2), by striking “\$6,000,000 for fiscal year 2007” and all that follows through the period at the end and inserting “\$3,000,000 for each of the fiscal years 2018 through 2022.”; and

(5) by adding at the end the following new subsection:

“(g) **REDUCING UNDERAGE DRINKING THROUGH SCREENING AND BRIEF INTERVENTION.**—

“(1) **GRANTS TO PEDIATRIC HEALTH CARE PROVIDERS TO REDUCE UNDERAGE DRINKING.**—The Assistant Secretary may make grants to eligible entities to increase implementation of practices for reducing the prevalence of alcohol use among individuals under the age of 21, including college students.

“(2) **PURPOSES.**—Grants under this subsection shall be made to improve—

“(A) screening children and adolescents for alcohol use;

“(B) offering brief interventions to children and adolescents to discourage such use;

“(C) educating parents about the dangers of, and methods of discouraging, such use;

“(D) diagnosing and treating alcohol use disorders; and

“(E) referring patients, when necessary, to other appropriate care.

“(3) **USE OF FUNDS.**—An entity receiving a grant under this subsection may use such funding for the purposes identified in paragraph (2) by—

“(A) providing training to health care providers;

“(B) disseminating best practices, including culturally and linguistically appropriate best practices, as appropriate, and developing and distributing materials; and

“(C) supporting other activities, as determined appropriate by the Assistant Secretary.

“(4) APPLICATION.—To be eligible to receive a grant under this subsection, an entity shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information as the Assistant Secretary may require. Each application shall include—

“(A) a description of the entity;

“(B) a description of activities to be completed;

“(C) a description of how the services specified in paragraphs (2) and (3) will be carried out and the qualifications for providing such services; and

“(D) a timeline for the completion of such activities.

“(5) DEFINITIONS.—For the purpose of this subsection:

“(A) BRIEF INTERVENTION.—The term ‘brief intervention’ means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient’s alcohol use, and any realized or potential consequences of such use, to effect the desired related behavioral change.

“(B) CHILDREN AND ADOLESCENTS.—The term ‘children and adolescents’ means any person under 21 years of age.

“(C) ELIGIBLE ENTITY.—The term ‘eligible entity’ means an entity consisting of pediatric health care providers and that is qualified to support or provide the activities identified in paragraph (2).

“(D) PEDIATRIC HEALTH CARE PROVIDER.—The term ‘pediatric health care provider’ means a provider of primary health care to individuals under the age of 21 years.

“(E) SCREENING.—The term ‘screening’ means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.”

SEC. 9017. CENTER AND PROGRAM REPEALS.

Part B of title V of the Public Health Service Act (42 U.S.C. 290bb et seq.) is amended by striking section 506B (42 U.S.C. 290aa–5b), the second section 514 (42 U.S.C. 290bb–9) relating to methamphetamine and amphetamine treatment initiatives, and each of sections 514A, 517, 519A, 519C, 519E, 520B, 520D, and 520H (42 U.S.C. 290bb–8, 290bb–23, 290bb–25a, 290bb–25c, 290bb–25e, 290bb–33, 290bb–35, and 290bb–39).

Subtitle B—Strengthening the Health Care Workforce

SEC. 9021. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

Section 756 of the Public Health Service Act (42 U.S.C. 294e–1) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “of higher education”; and

(B) by striking paragraphs (1) through (4) and inserting the following:

“(1) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing (which may include master’s and doctoral level programs), social work, school social work, substance use disorder prevention and treatment, marriage and family therapy, occupational therapy, school counseling, or professional counseling, including such programs with a focus on child and adolescent mental health and transitional-age youth;

“(2) accredited doctoral, internship, and post-doctoral residency programs of health service psychology (including clinical psychology,

counseling, and school psychology) for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, as well as the development of faculty in health service psychology;

“(3) accredited master’s and doctoral degree programs of social work for the development and implementation of interdisciplinary training of social work graduate students for providing behavioral health services, including substance use disorder prevention and treatment services, and the development of faculty in social work; and

“(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training in a behavioral health-related paraprofessional field with preference for preservice or in-service training of paraprofessional child and adolescent mental health workers.”;

(2) in subsection (b)—

(A) by striking paragraph (5);

(B) by redesignating paragraphs (1) through (4) as paragraphs (2) through (5), respectively;

(C) by inserting before paragraph (2), as so redesignated, the following:

“(1) an ability to recruit and place the students described in subsection (a) in areas with a high need and high demand population;”;

(D) in paragraph (3), as so redesignated, by striking “subsection (a)” and inserting “paragraph (2), especially individuals with mental disorder symptoms or diagnoses, particularly children and adolescents, and transitional-age youth”;

(E) in paragraph (4), as so redesignated, by striking “;” and inserting “; and”; and

(F) in paragraph (5), as so redesignated, by striking “; and” and inserting a period;

(3) in subsection (c), by striking “authorized under subsection (a)(1)” and inserting “awarded under paragraphs (2) and (3) of subsection (a)”;

(4) by amending subsection (d) to read as follows:

“(d) PRIORITY.—In selecting grant recipients under this section, the Secretary shall give priority to—

“(1) programs that have demonstrated the ability to train psychology, psychiatry, and social work professionals to work in integrated care settings for purposes of recipients under paragraphs (1), (2), and (3) of subsection (a); and

“(2) programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships for purposes of recipients under subsection (a)(4).”; and

(5) by striking subsection (e) and inserting the following:

“(e) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary shall include in the biennial report submitted to Congress under section 501(m) an assessment on the effectiveness of the grants under this section—

“(1) providing graduate students support for experiential training (internship or field placement);

“(2) recruiting students interested in behavioral health practice;

“(3) recruiting students in accordance with subsection (b)(1);

“(4) developing and implementing interprofessional training and integration within primary care;

“(5) developing and implementing accredited field placements and internships; and

“(6) collecting data on the number of students trained in behavioral health care and the number of available accredited internships and field placements.

“(f) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years 2018 through 2022, there

are authorized to be appropriated to carry out this section \$50,000,000, to be allocated as follows:

“(1) For grants described in subsection (a)(1), \$15,000,000.

“(2) For grants described in subsection (a)(2), \$15,000,000.

“(3) For grants described in subsection (a)(3), \$10,000,000.

“(4) For grants described in subsection (a)(4), \$10,000,000.”

SEC. 9022. STRENGTHENING THE MENTAL AND SUBSTANCE USE DISORDERS WORKFORCE.

Part D of title VII of the Public Health Service Act (42 U.S.C. 294 et seq.) is amended by adding at the end the following:

“SEC. 760. TRAINING DEMONSTRATION PROGRAM.

“(a) IN GENERAL.—The Secretary shall establish a training demonstration program to award grants to eligible entities to support—

“(1) training for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services;

“(2) training for nurse practitioners, physician assistants, health service psychologists, and social workers to provide mental and substance use disorders services in underserved community-based settings that integrate primary care and mental and substance use disorders services; and

“(3) establishing, maintaining, or improving academic units or programs that—

“(A) provide training for students or faculty, including through clinical experiences and research, to improve the ability to be able to recognize, diagnose, and treat mental and substance use disorders, with a special focus on addiction; or

“(B) develop evidence-based practices or recommendations for the design of the units or programs described in subparagraph (A), including curriculum content standards.

“(b) ACTIVITIES.—

“(1) TRAINING FOR RESIDENTS AND FELLOWS.—A recipient of a grant under subsection (a)(1)—

“(A) shall use the grant funds—

“(i)(I) to plan, develop, and operate a training program for medical psychiatry residents and fellows in addiction medicine practicing in eligible entities described in subsection (c)(1); or

“(ii) to train new psychiatric residents and fellows in addiction medicine to provide and expand access to integrated mental and substance use disorders services; and

“(ii) to provide at least 1 training track that is—

“(I) a virtual training track that includes an in-person rotation at a teaching health center or in a community-based setting, followed by a virtual rotation in which the resident or fellow continues to support the care of patients at the teaching health center or in the community-based setting through the use of health information technology and, as appropriate, telehealth services;

“(II) an in-person training track that includes a rotation, during which the resident or fellow practices at a teaching health center or in a community-based setting; or

“(III) an in-person training track that includes a rotation during which the resident practices in a community-based setting that specializes in the treatment of infants, children, adolescents, or pregnant or postpartum women; and

“(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such training.

“(2) TRAINING FOR OTHER PROVIDERS.—A recipient of a grant under subsection (a)(2)—

“(A) shall use the grant funds to plan, develop, or operate a training program to provide

mental and substance use disorders services in underserved, community-based settings, as appropriate, that integrate primary care and mental and substance use disorders prevention and treatment services; and

“(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such program.

“(3) **ACADEMIC UNITS OR PROGRAMS.**—A recipient of a grant under subsection (a)(3) shall enter into a partnership with organizations such as an education accrediting organization (such as the Liaison Committee on Medical Education, the Accreditation Council for Graduate Medical Education, the Commission on Osteopathic College Accreditation, the Accreditation Commission for Education in Nursing, the Commission on Collegiate Nursing Education, the Accreditation Council for Pharmacy Education, the Council on Social Work Education, American Psychological Association Commission on Accreditation, or the Accreditation Review Commission on Education for the Physician Assistant) to carry out activities under subsection (a)(3).

“(c) **ELIGIBLE ENTITIES.**—

“(1) **TRAINING FOR RESIDENTS AND FELLOWS.**—To be eligible to receive a grant under subsection (a)(1), an entity shall—

“(A) be a consortium consisting of—

“(i) at least one teaching health center; and
“(ii) the sponsoring institution (or parent institution of the sponsoring institution) of—

“(I) a psychiatry residency program that is accredited by the Accreditation Council of Graduate Medical Education (or the parent institution of such a program); or

“(II) a fellowship in addiction medicine, as determined appropriate by the Secretary; or

“(B) be an entity described in subparagraph (A)(ii) that provides opportunities for residents or fellows to train in community-based settings that integrate primary care with mental and substance use disorders prevention and treatment services.

“(2) **TRAINING FOR OTHER PROVIDERS.**—To be eligible to receive a grant under subsection (a)(2), an entity shall be—

“(A) a teaching health center (as defined in section 749A(f));

“(B) a Federally qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act);

“(C) a community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act);

“(D) a rural health clinic (as defined in section 1861(aa) of the Social Security Act);

“(E) a health center operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

“(F) an entity with a demonstrated record of success in providing training for nurse practitioners, physician assistants, health service psychologists, and social workers.

“(3) **ACADEMIC UNITS OR PROGRAMS.**—To be eligible to receive a grant under subsection (a)(3), an entity shall be a school of medicine or osteopathic medicine, a nursing school, a physician assistant training program, a school of pharmacy, a school of social work, an accredited public or nonprofit private hospital, an accredited medical residency program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant.

“(d) **PRIORITY.**—

“(1) **IN GENERAL.**—In awarding grants under subsection (a)(1) or (a)(2), the Secretary shall give priority to eligible entities that—

“(A) demonstrate sufficient size, scope, and capacity to undertake the requisite training of an appropriate number of psychiatric residents,

fellows, nurse practitioners, physician assistants, or social workers in addiction medicine per year to meet the needs of the area served;

“(B) demonstrate experience in training providers to practice team-based care that integrates mental and substance use disorder prevention and treatment services with primary care in community-based settings;

“(C) demonstrate experience in using health information technology and, as appropriate, telehealth to support—

“(i) the delivery of mental and substance use disorders services at the eligible entities described in subsections (c)(1) and (c)(2); and

“(ii) community health centers in integrating primary care and mental and substance use disorders treatment; or

“(D) have the capacity to expand access to mental and substance use disorders services in areas with demonstrated need, as determined by the Secretary, such as tribal, rural, or other underserved communities.

“(2) **ACADEMIC UNITS OR PROGRAMS.**—In awarding grants under subsection (a)(3), the Secretary shall give priority to eligible entities that—

“(A) have a record of training the greatest percentage of mental and substance use disorders providers who enter and remain in these fields or who enter and remain in settings with integrated primary care and mental and substance use disorder prevention and treatment services;

“(B) have a record of training individuals who are from underrepresented minority groups, including native populations, or from a rural or disadvantaged background;

“(C) provide training in the care of vulnerable populations such as infants, children, adolescents, pregnant and postpartum women, older adults, homeless individuals, victims of abuse or trauma, individuals with disabilities, and other groups as defined by the Secretary;

“(D) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals; or

“(E) provide training in cultural competency and health literacy.

“(e) **DURATION.**—Grants awarded under this section shall be for a minimum of 5 years.

“(f) **STUDY AND REPORT.**—

“(1) **STUDY.**—

“(A) **IN GENERAL.**—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall conduct a study on the results of the demonstration program under this section.

“(B) **DATA SUBMISSION.**—Not later than 90 days after the completion of the first year of the training program and each subsequent year that the program is in effect, each recipient of a grant under subsection (a) shall submit to the Secretary such data as the Secretary may require for analysis for the report described in paragraph (2).

“(2) **REPORT TO CONGRESS.**—Not later than 1 year after receipt of the data described in paragraph (1)(B), the Secretary shall submit to Congress a report that includes—

“(A) an analysis of the effect of the demonstration program under this section on the quality, quantity, and distribution of mental and substance use disorders services;

“(B) an analysis of the effect of the demonstration program on the prevalence of untreated mental and substance use disorders in the surrounding communities of health centers participating in the demonstration; and

“(C) recommendations on whether the demonstration program should be expanded.

“(g) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section \$10,000,000 for each of fiscal years 2018 through 2022.”

SEC. 9023. CLARIFICATION ON CURRENT ELIGIBILITY FOR LOAN REPAYMENT PROGRAMS.

The Administrator of the Health Resources and Services Administration shall clarify the eli-

gibility pursuant to section 338B(b)(1)(B) of the Public Health Service Act (42 U.S.C. 2541-1(b)(1)(B)) of child and adolescent psychiatrists for the National Health Service Corps Loan Repayment Program under subpart III of part D of title III of such Act (42 U.S.C. 2541 et seq.).

SEC. 9024. MINORITY FELLOWSHIP PROGRAM.

Title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) is amended by adding at the end the following:

“PART K—MINORITY FELLOWSHIP PROGRAM

“SEC. 597. FELLOWSHIPS.

“(a) **IN GENERAL.**—The Secretary shall maintain a program, to be known as the Minority Fellowship Program, under which the Secretary shall award fellowships, which may include stipends, for the purposes of—

“(1) increasing the knowledge of mental and substance use disorders practitioners on issues related to prevention, treatment, and recovery support for individuals who are from racial and ethnic minority populations and who have a mental or substance use disorder;

“(2) improving the quality of mental and substance use disorder prevention and treatment services delivered to racial and ethnic minority populations; and

“(3) increasing the number of culturally competent mental and substance use disorders professionals who teach, administer services, conduct research, and provide direct mental or substance use disorder services to racial and ethnic minority populations.

“(b) **TRAINING COVERED.**—The fellowships awarded under subsection (a) shall be for postbaccalaureate training (including for master’s and doctoral degrees) for mental and substance use disorder treatment professionals, including in the fields of psychiatry, nursing, social work, psychology, marriage and family therapy, mental health counseling, and substance use disorder and addiction counseling.

“(c) **AUTHORIZATION OF APPROPRIATIONS.**—To carry out this section, there are authorized to be appropriated \$12,669,000 for each of fiscal years 2018 through 2022.”

SEC. 9025. LIABILITY PROTECTIONS FOR HEALTH PROFESSIONAL VOLUNTEERS AT COMMUNITY HEALTH CENTERS.

Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following:

“(q)(1) For purposes of this section, a health professional volunteer at a deemed entity described in subsection (g)(4) shall, in providing a health professional service eligible for funding under section 330 to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

“(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

“(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

“(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

“(C) The health care practitioner does not receive any compensation for the service from the individual, the entity described in subsection (g)(4), or any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual, which may include travel expenses to or from the site of services.

“(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

“(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable Federal and State laws regarding the provision of the service.

“(F) At the time the service is provided, the entity described in subsection (g)(4) maintains relevant documentation certifying that the health care practitioner meets the requirements of this subsection.

“(3) Subsection (g) (other than paragraphs (3) and (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (4), and subject to the following:

“(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

“(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

“(i) with respect to the health care practitioner, the entity submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

“(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

“(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services performed on behalf of the entity sponsoring the health care practitioner pursuant to subparagraph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

“(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

“(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer under subparagraph (C) for purposes of carrying out this subsection.

“(B)(i) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be paid pursuant to this section during the calendar year that begins in the following fiscal year.

“(ii) Subsection (k)(1)(B) applies to the estimate under clause (i) regarding health professional volunteers to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

“(iii) The report shall include a summary of the data relied upon for the estimate in clause (i), including the number of claims filed and paid from the previous calendar year.

“(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate ac-

counts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

“(5)(A) This subsection shall take effect on October 1, 2017, except as provided in subparagraph (B) and paragraph (6).

“(B) Effective on the date of the enactment of this subsection—

“(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

“(ii) reports under paragraph (4)(B) may be submitted to Congress.

“(6) Beginning on October 1, 2022, this subsection shall cease to have any force or effect.”

SEC. 9026. REPORTS.

(a) WORKFORCE DEVELOPMENT REPORT.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, shall conduct a study and publicly post on the appropriate Internet website of the Department of Health and Human Services a report on the adult and pediatric mental health and substance use disorder workforce in order to inform Federal, State, and local efforts related to workforce enhancement.

(2) CONTENTS.—The report under this subsection shall contain—

(A) national and State-level projections of the supply and demand of the mental health and substance use disorder health workforce, disaggregated by profession;

(B) an assessment of the mental health and substance use disorder workforce capacity, strengths, and weaknesses as of the date of the report, including the extent to which primary care providers are preventing, screening, or referring for mental and substance use disorder services;

(C) information on trends within the mental health and substance use disorder provider workforce, including the number of individuals expected to enter the mental health workforce over the next 5 years; and

(D) any additional information determined by the Administrator of the Health Resources and Services Administration, in consultation with the Assistant Secretary for Mental Health and Substance Use, to be relevant to the mental health and substance use disorder provider workforce.

(b) PEER-SUPPORT SPECIALIST PROGRAMS.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on peer-support specialist programs in up to 10 States that receive funding from the Substance Abuse and Mental Health Services Administration.

(2) CONTENTS OF STUDY.—In conducting the study under paragraph (1), the Comptroller General of the United States shall examine and identify best practices, in the States selected pursuant to such paragraph, related to training and credential requirements for peer-support specialist programs, such as—

(A) hours of formal work or volunteer experience related to mental and substance use disorders conducted through such programs;

(B) types of peer-support specialist exams required for such programs in the selected States;

(C) codes of ethics used by such programs in the selected States;

(D) required or recommended skill sets for such programs in the selected States; and

(E) requirements for continuing education.

(3) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the study conducted under paragraph (1).

Subtitle C—Mental Health on Campus Improvement

SEC. 9031. MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES ON CAMPUS.

Section 520E–2 of the Public Health Service Act (42 U.S.C. 290bb–36b) is amended—

(1) in the section heading, by striking “AND BEHAVIORAL HEALTH” and inserting “HEALTH AND SUBSTANCE USE DISORDER”;

(2) in subsection (a)—

(A) by striking “Services,” and inserting “Services and”;

(B) by striking “and behavioral health problems” and inserting “health or substance use disorders”;

(C) by striking “substance abuse” and inserting “substance use disorders”; and

(D) by adding after, “suicide attempts,” the following: “prevent mental and substance use disorders, reduce stigma, and improve the identification and treatment for students at risk.”;

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking “for—” and inserting “for one or more of the following.”; and

(B) by striking paragraphs (1) through (6) and inserting the following:

“(1) Educating students, families, faculty, and staff to increase awareness of mental and substance use disorders.

“(2) The operation of hotlines.

“(3) Preparing informational material.

“(4) Providing outreach services to notify students about available mental and substance use disorder services.

“(5) Administering voluntary mental and substance use disorder screenings and assessments.

“(6) Supporting the training of students, faculty, and staff to respond effectively to students with mental and substance use disorders.

“(7) Creating a network infrastructure to link institutions of higher education with health care providers who treat mental and substance use disorders.

“(8) Providing mental and substance use disorders prevention and treatment services to students, which may include recovery support services and programming and early intervention, treatment, and management, including through the use of telehealth services.

“(9) Conducting research through a counseling or health center at the institution of higher education involved regarding improving the behavioral health of students through clinical services, outreach, prevention, or academic success, in a manner that is in compliance with all applicable personal privacy laws.

“(10) Supporting student groups on campus, including athletic teams, that engage in activities to educate students, including activities to reduce stigma surrounding mental and behavioral disorders, and promote mental health.

“(11) Employing appropriately trained staff.

“(12) Developing and supporting evidence-based and emerging best practices, including a focus on culturally and linguistically appropriate best practices.”;

(4) in subsection (c)(5), by striking “substance abuse” and inserting “substance use disorder”;

(5) in subsection (d)—

(A) in the matter preceding paragraph (1), by striking “An institution of higher education desiring a grant under this section” and inserting “To be eligible to receive a grant under this section, an institution of higher education”;

(B) by striking paragraph (1) and inserting—

“(1) A description of the population to be targeted by the program carried out under the grant, including veterans whenever possible and appropriate, and of identified mental and substance use disorder needs of students at the institution of higher education.”;

(C) in paragraph (2), by inserting “, which may include, as appropriate and in accordance with subsection (b)(7), a plan to seek input from relevant stakeholders in the community, including appropriate public and private entities, in

order to carry out the program under the grant” before the period at the end; and

(D) by adding after paragraph (5) the following new paragraphs:

“(6) An outline of the objectives of the program carried out under the grant.

“(7) For an institution of higher education proposing to use the grant for an activity described in paragraph (8) or (9) of subsection (b), a description of the policies and procedures of the institution of higher education that are related to applicable laws regarding access to, and sharing of, treatment records of students at any campus-based mental health center or partner organization, including the policies and State laws governing when such records can be accessed and shared for non-treatment purposes and a description of the process used by the institution of higher education to notify students of these policies and procedures, including the extent to which written consent is required.

“(8) An assurance that grant funds will be used to supplement and not supplant any other Federal, State, or local funds available to carry out activities of the type carried out under the grant.”;

(6) in subsection (e)(1), by striking “and behavioral health problems” and inserting “health and substance use disorders”;

(7) in subsection (f)(2)—

(A) by striking “and behavioral health” and inserting “health and substance use disorder”;

(B) by striking “suicide and substance abuse” and inserting “suicide and substance use disorders”;

(8) by redesignating subsection (h) as subsection (i);

(9) by inserting after subsection (g) the following new subsection:

“(h) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to grantees in carrying out this section.”; and

(10) in subsection (i), as redesignated by paragraph (8), by striking “\$5,000,000 for fiscal year 2005” and all that follows through the period at the end and inserting “\$7,000,000 for each of fiscal years 2018 through 2022.”.

SEC. 9032. INTERAGENCY WORKING GROUP ON COLLEGE MENTAL HEALTH.

(a) PURPOSE.—It is the purpose of this section to provide for the establishment of a College Campus Task Force to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(b) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall establish a College Campus Task Force (referred to in this section as the “Task Force”) to discuss mental and behavioral health concerns on campuses of institutions of higher education.

(c) MEMBERSHIP.—The Task Force shall be composed of a representative from each Federal agency (as appointed by the head of the agency) that has jurisdiction over, or is affected by, mental health and education policies and projects, including—

(1) the Department of Education;

(2) the Department of Health and Human Services;

(3) the Department of Veterans Affairs; and

(4) such other Federal agencies as the Assistant Secretary for Mental Health and Substance Use, in consultation with the Secretary, determines to be appropriate.

(d) DUTIES.—The Task Force shall—

(1) serve as a centralized mechanism to coordinate a national effort to—

(A) discuss and evaluate evidence and knowledge on mental and behavioral health services available to, and the prevalence of mental illness among, the age population of students attending institutions of higher education in the United States;

(B) determine the range of effective, feasible, and comprehensive actions to improve mental and behavioral health on campuses of institutions of higher education;

(C) examine and better address the needs of the age population of students attending institutions of higher education dealing with mental illness;

(D) survey Federal agencies to determine which policies are effective in encouraging, and how best to facilitate outreach without duplicating, efforts relating to mental and behavioral health promotion;

(E) establish specific goals within and across Federal agencies for mental health promotion, including determinations of accountability for reaching those goals;

(F) develop a strategy for allocating responsibilities and ensuring participation in mental and behavioral health promotion, particularly in the case of competing agency priorities;

(G) coordinate plans to communicate research results relating to mental and behavioral health amongst the age population of students attending institutions of higher education to enable reporting and outreach activities to produce more useful and timely information;

(H) provide a description of evidence-based practices, model programs, effective guidelines, and other strategies for promoting mental and behavioral health on campuses of institutions of higher education;

(I) make recommendations to improve Federal efforts relating to mental and behavioral health promotion on campuses of institutions of higher education and to ensure Federal efforts are consistent with available standards, evidence, and other programs in existence as of the date of enactment of this Act;

(J) monitor Federal progress in meeting specific mental and behavioral health promotion goals as they relate to settings of institutions of higher education; and

(K) examine and disseminate best practices related to intracampus sharing of treatment records;

(2) consult with national organizations with expertise in mental and behavioral health, especially those organizations working with the age population of students attending institutions of higher education; and

(3) consult with and seek input from mental health professionals working on campuses of institutions of higher education as appropriate.

(e) MEETINGS.—

(1) IN GENERAL.—The Task Force shall meet not fewer than three times each year.

(2) ANNUAL CONFERENCE.—The Secretary shall sponsor an annual conference on mental and behavioral health in settings of institutions of higher education to enhance coordination, build partnerships, and share best practices in mental and behavioral health promotion, data collection, analysis, and services.

(f) DEFINITION.—In this section, the term “institution of higher education” has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$1,000,000 for the period of fiscal years 2018 through 2022.

SEC. 9033. IMPROVING MENTAL HEALTH ON COLLEGE CAMPUSES.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

“SEC. 549. MENTAL AND BEHAVIORAL HEALTH OUTREACH AND EDUCATION ON COLLEGE CAMPUSES.

“(a) PURPOSE.—It is the purpose of this section to increase access to, and reduce the stigma associated with, mental health services to ensure that students at institutions of higher education have the support necessary to successfully complete their studies.

“(b) NATIONAL PUBLIC EDUCATION CAMPAIGN.—The Secretary, acting through the Assistant Secretary and in collaboration with the Director of the Centers for Disease Control and Prevention, shall convene an interagency, public-private sector working group to plan, estab-

lish, and begin coordinating and evaluating a targeted public education campaign that is designed to focus on mental and behavioral health on the campuses of institutions of higher education. Such campaign shall be designed to—

“(1) improve the general understanding of mental health and mental disorders;

“(2) encourage help-seeking behaviors relating to the promotion of mental health, prevention of mental disorders, and treatment of such disorders;

“(3) make the connection between mental and behavioral health and academic success; and

“(4) assist the general public in identifying the early warning signs and reducing the stigma of mental illness.

“(c) COMPOSITION.—The working group convened under subsection (b) shall include—

“(1) mental health consumers, including students and family members;

“(2) representatives of institutions of higher education;

“(3) representatives of national mental and behavioral health associations and associations of institutions of higher education;

“(4) representatives of health promotion and prevention organizations at institutions of higher education;

“(5) representatives of mental health providers, including community mental health centers; and

“(6) representatives of private-sector and public-sector groups with experience in the development of effective public health education campaigns.

“(d) PLAN.—The working group under subsection (b) shall develop a plan that—

“(1) targets promotional and educational efforts to the age population of students at institutions of higher education and individuals who are employed in settings of institutions of higher education, including through the use of roundtables;

“(2) develops and proposes the implementation of research-based public health messages and activities;

“(3) provides support for local efforts to reduce stigma by using the National Health Information Center as a primary point of contact for information, publications, and service program referrals; and

“(4) develops and proposes the implementation of a social marketing campaign that is targeted at the population of students attending institutions of higher education and individuals who are employed in settings of institutions of higher education.

“(e) DEFINITION.—In this section, the term ‘institution of higher education’ has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

“(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$1,000,000 for the period of fiscal years 2018 through 2022.”.

TITLE X—STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS

SEC. 10001. PROGRAMS FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.

(a) COMPREHENSIVE COMMUNITY MENTAL HEALTH SERVICES FOR CHILDREN WITH A SERIOUS EMOTIONAL DISTURBANCE.—Section 561(a)(1) of the Public Health Service Act (42 U.S.C. 290ff(a)(1)) is amended by inserting “, which may include efforts to identify and serve children at risk” before the period.

(b) REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF GRANTS.—Section 562(b) of the Public Health Service Act (42 U.S.C. 290ff-1(b)) is amended by striking “will not provide an individual with access to the system if the individual is more than 21 years of age” and inserting “will provide an individual with access to the system through the age of 21 years”.

(c) ADDITIONAL PROVISIONS.—Section 564(f) of the Public Health Service Act (42 U.S.C. 290ff-

3(f)) is amended by inserting “(and provide a copy to the State involved)” after “to the Secretary”.

(d) GENERAL PROVISIONS.—Section 565 of the Public Health Service Act (42 U.S.C. 290ff–4) is amended—

(1) in subsection (b)(1)—

(A) in the matter preceding subparagraph (A), by striking “receiving a grant under section 561(a)” and inserting “, regardless of whether such public entity is receiving a grant under section 561(a)”; and

(B) in subparagraph (B), by striking “pursuant to” and inserting “described in”;

(2) in subsection (d)(1), by striking “not more than 21 years of age” and inserting “through the age of 21 years”; and

(3) in subsection (f)(1), by striking “\$100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003” and inserting “\$119,026,000 for each of fiscal years 2018 through 2022”.

SEC. 10002. INCREASING ACCESS TO PEDIATRIC MENTAL HEALTH CARE.

Title III of the Public Health Service Act is amended by inserting after section 330L of such Act (42 U.S.C. 254c–18) the following new section:

“SEC. 330M PEDIATRIC MENTAL HEALTH CARE ACCESS GRANTS.

“(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants to States, political subdivisions of States, and Indian tribes and tribal organizations (for purposes of this section, as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)) to promote behavioral health integration in pediatric primary care by—

“(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

“(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

“(b) PROGRAM REQUIREMENTS.—

“(1) IN GENERAL.—A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which a grant under such subsection may be used, shall—

“(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

“(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

“(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers’ preferred mechanisms for receiving consultation, training, and technical assistance;

“(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

“(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

“(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

“(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, and licensed mental health professionals, such as psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

“(H) assist with referrals to specialty care and community or behavioral health resources; and

“(I) establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health problems.

“(2) PEDIATRIC MENTAL HEALTH TEAMS.—In this subsection, the term ‘pediatric mental health team’ means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical mental health professional, such as a psychologist, social worker, or mental health counselor. Such a team may be regionally based.

“(c) APPLICATION.—A State, political subdivision of a State, Indian tribe, or tribal organization seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such grant.

“(d) EVALUATION.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such grant to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

“(e) ACCESS TO BROADBAND.—In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

“(f) MATCHING REQUIREMENT.—The Secretary may not award a grant under this section unless the State, political subdivision of a State, Indian tribe, or tribal organization involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, Indian tribe, or tribal organization in carrying out the purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the grant.

“(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated, \$9,000,000 for the period of fiscal years 2018 through 2022.”.

SEC. 10003. SUBSTANCE USE DISORDER TREATMENT AND EARLY INTERVENTION SERVICES FOR CHILDREN AND ADOLESCENTS.

The first section 514 of the Public Health Service Act (42 U.S.C. 290bb–7), relating to substance abuse treatment services for children and adolescents, is amended—

(1) in the section heading, by striking “ABUSE TREATMENT” and inserting “USE DISORDER TREATMENT AND EARLY INTERVENTION”;

(2) by striking subsection (a) and inserting the following:

“(a) IN GENERAL.—The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Indian tribes or tribal organizations (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), or health facilities or programs operated by or in accordance with a contract or grant with the Indian Health Service, for the purpose of—

“(1) providing early identification and services to meet the needs of children and adolescents who are at risk of substance use disorders;

“(2) providing substance use disorder treatment services for children, including children and adolescents with co-occurring mental illness and substance use disorders; and

“(3) providing assistance to pregnant women, and parenting women, with substance use disorders, in obtaining treatment services, linking mothers to community resources to support independent family lives, and staying in recovery so

that children are in safe, stable home environments and receive appropriate health care services.”;

(3) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

“(1) apply evidence-based and cost-effective methods.”;

(B) in paragraph (2)—

(i) by striking “treatment”; and

(ii) by inserting “substance abuse,” after “child welfare.”;

(C) in paragraph (3), by striking “substance abuse disorders” and inserting “substance use disorders, including children and adolescents with co-occurring mental illness and substance use disorders.”;

(D) in paragraph (5), by striking “treatment,” and inserting “services; and”;

(E) in paragraph (6), by striking “substance abuse treatment; and” and inserting “treatment.”; and

(F) by striking paragraph (7); and

(4) in subsection (f), by striking “\$40,000,000” and all that follows through the period and inserting “\$29,605,000 for each of fiscal years 2018 through 2022.”.

SEC. 10004. CHILDREN’S RECOVERY FROM TRAUMA.

The first section 582 of the Public Health Service Act (42 U.S.C. 290hh–1; relating to grants to address the problems of persons who experience violence related stress) is amended—

(1) in subsection (a), by striking “developing programs” and all that follows through the period at the end and inserting the following: “developing and maintaining programs that provide for—

“(1) the continued operation of the National Child Traumatic Stress Initiative (referred to in this section as the ‘NCTSI’), which includes a cooperative agreement with a coordinating center, that focuses on the mental, behavioral, and biological aspects of psychological trauma response, prevention of the long-term consequences of child trauma, and early intervention services and treatment to address the long-term consequences of child trauma; and

“(2) the development of knowledge with regard to evidence-based practices for identifying and treating mental, behavioral, and biological disorders of children and youth resulting from witnessing or experiencing a traumatic event.”;

(2) in subsection (b)—

(A) by striking “subsection (a) related” and inserting “subsection (a)(2) (related)”;

(B) by striking “treating disorders associated with psychological trauma” and inserting “treating mental, behavioral, and biological disorders associated with psychological trauma”;

and

(C) by striking “mental health agencies and programs that have established clinical and basic research” and inserting “universities, hospitals, mental health agencies, and other programs that have established clinical expertise and research”;

(3) by redesignating subsections (c) through (g) as subsections (g) through (k), respectively;

(4) by inserting after subsection (b), the following:

“(c) CHILD OUTCOME DATA.—The NCTSI coordinating center described in subsection (a)(1) shall collect, analyze, report, and make publicly available, as appropriate, NCTSI-wide child treatment process and outcome data regarding the early identification and delivery of evidence-based treatment and services for children and families served by the NCTSI grantees.

“(d) TRAINING.—The NCTSI coordinating center shall facilitate the coordination of training initiatives in evidence-based and trauma-informed treatments, interventions, and practices offered to NCTSI grantees, providers, and partners.

“(e) DISSEMINATION AND COLLABORATION.—The NCTSI coordinating center shall, as appropriate, collaborate with—

“(1) the Secretary, in the dissemination of evidence-based and trauma-informed interventions, treatments, products, and other resources to appropriate stakeholders; and

“(2) appropriate agencies that conduct or fund research within the Department of Health and Human Services, for purposes of sharing NCTSI expertise, evaluation data, and other activities, as appropriate.

“(f) REVIEW.—The Secretary shall, consistent with the peer-review process, ensure that NCTSI applications are reviewed by appropriate experts in the field as part of a consensus-review process. The Secretary shall include review criteria related to expertise and experience in child trauma and evidence-based practices.”;

(5) in subsection (g) (as so redesignated), by striking “with respect to centers of excellence are distributed equitably among the regions of the country” and inserting “are distributed equitably among the regions of the United States”;

(6) in subsection (i) (as so redesignated), by striking “recipient may not exceed 5 years” and inserting “recipient shall not be less than 4 years, but shall not exceed 5 years”;

(7) in subsection (j) (as so redesignated), by striking “\$50,000,000” and all that follows through “2006” and inserting “\$46,887,000 for each of fiscal years 2018 through 2022”.

SEC. 10005. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.) is amended by inserting after section 317L (42 U.S.C. 247b–13) the following:

“SEC. 317L–1. SCREENING AND TREATMENT FOR MATERNAL DEPRESSION.

“(a) GRANTS.—The Secretary shall make grants to States to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression.

“(b) APPLICATION.—To seek a grant under this section, a State shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. At a minimum, any such application shall include explanations of—

“(1) how a program, or programs, will increase the percentage of women screened and treated, as appropriate, for maternal depression in 1 or more communities; and

“(2) how a program, or programs, if expanded, would increase access to screening and treatment services for maternal depression.

“(c) PRIORITY.—In awarding grants under this section, the Secretary may give priority to States proposing to improve or enhance access to screening services for maternal depression in primary care settings.

“(d) USE OF FUNDS.—The activities eligible for funding through a grant under subsection (a)—

“(1) shall include—

“(A) providing appropriate training to health care providers; and

“(B) providing information to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and

“(2) may include—

“(A) enabling health care providers (including obstetrician-gynecologists, pediatricians, psychiatrists, mental health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely) to aid in the treatment of pregnant and parenting women;

“(B) establishing linkages with and among community-based resources, including mental health resources, primary care resources, and support groups; and

“(C) utilizing telehealth services for rural areas and medically underserved areas (as defined in section 330I(a)).

“(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$5,000,000 for each of fiscal years 2018 through 2022.”.

SEC. 10006. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

Part Q of title III of the Public Health Service Act (42 U.S.C. 280h et seq.) is amended by adding at the end the following:

“SEC. 399Z–2. INFANT AND EARLY CHILDHOOD MENTAL HEALTH PROMOTION, INTERVENTION, AND TREATMENT.

“(a) GRANTS.—The Secretary shall—

“(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

“(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

“(B) multigenerational therapy and other services that support the caregiving relationship; and

“(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and linguistically appropriate, and can be replicated in other appropriate settings.

“(b) ELIGIBLE CHILDREN AND ENTITIES.—In this section:

“(1) ELIGIBLE CHILD.—The term ‘eligible child’ means a child from birth to not more than 12 years of age who—

“(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

“(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

“(2) ELIGIBLE ENTITY.—The term ‘eligible entity’ means a human services agency or nonprofit institution that—

“(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

“(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

“(c) APPLICATION.—An eligible entity seeking a grant 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) USE OF FUNDS FOR EARLY INTERVENTION AND TREATMENT PROGRAMS.—An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

“(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

“(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early

intervention specialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

“(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

“(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

“(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

“(e) MATCHING FUNDS.—The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

“(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated \$20,000,000 for the period of fiscal years 2018 through 2022.”.

TITLE XI—COMPASSIONATE COMMUNICATION ON HIPAA

SEC. 11001. SENSE OF CONGRESS.

(a) FINDINGS.—Congress finds the following:

(1) According to the National Survey on Drug Use and Health, in 2015, there were approximately 9,800,000 adults in the United States with serious mental illness.

(2) The Substance Abuse and Mental Health Services Administration defines the term “serious mental illness” as an illness affecting individuals 18 years of age or older as having, at any time in the past year, a diagnosable mental, behavioral, or emotional disorder that results in serious functional impairment and substantially interferes with or limits one or more major life activities.

(3) In reporting on the incidence of serious mental illness, the Substance Abuse and Mental Health Services Administration includes major depression, schizophrenia, bipolar disorder, and other mental disorders that cause serious impairment.

(4) Adults with a serious mental illness are at a higher risk for chronic physical illnesses and premature death.

(5) According to the World Health Organization, adults with a serious mental illness have lifespans that are 10 to 25 years shorter than those without serious mental illness. The vast majority of these deaths are due to chronic physical medical conditions, such as cardiovascular, respiratory, and infectious diseases, as well as diabetes and hypertension.

(6) According to the World Health Organization, the majority of deaths of adults with a serious mental illness that are due to physical medical conditions are preventable.

(7) Supported decision making can facilitate care decisions in areas where serious mental illness may impact the capacity of an individual to determine a course of treatment while still allowing the individual to make decisions independently.

(8) Help should be provided to adults with a serious mental illness to address their acute or chronic physical illnesses, make informed choices about treatment, and understand and follow through with appropriate treatment.

(9) There is confusion in the health care community regarding permissible practices under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (commonly known as “HIPAA”). This confusion may hinder appropriate communication of health care information or treatment preferences with appropriate caregivers.

(b) SENSE OF CONGRESS.—It is the sense of Congress that clarification is needed regarding the privacy rule promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) regarding existing permitted uses and disclosures of health information by health care professionals to communicate with caregivers of adults with a serious mental illness to facilitate treatment.

SEC. 11002. CONFIDENTIALITY OF RECORDS.

Not later than 1 year after the date on which the Secretary of Health and Human Services (in this title referred to as the “Secretary”) first finalizes regulations updating part 2 of title 42, Code of Federal Regulations, relating to confidentiality of alcohol and drug abuse patient records, after the date of enactment of this Act, the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy.

SEC. 11003. CLARIFICATION ON PERMITTED USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—The Secretary, acting through the Director of the Office for Civil Rights, shall ensure that health care providers, professionals, patients and their families, and others involved in mental or substance use disorder treatment have adequate, accessible, and easily comprehensible resources relating to appropriate uses and disclosures of protected health information under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(b) GUIDANCE.—

(1) ISSUANCE.—In carrying out subsection (a), not later than 1 year after the date of enactment of this section, the Secretary shall issue guidance clarifying the circumstances under which, consistent with regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, a health care provider or covered entity may use or disclose protected health information.

(2) CIRCUMSTANCES ADDRESSED.—The guidance issued under this section shall address circumstances including those that—

(A) require the consent of the patient;

(B) require providing the patient with an opportunity to object;

(C) are based on the exercise of professional judgment regarding whether the patient would object when the opportunity to object cannot practicably be provided because of the incapacity of the patient or an emergency treatment circumstance; and

(D) are determined, based on the exercise of professional judgment, to be in the best interest of the patient when the patient is not present or otherwise incapacitated.

(3) COMMUNICATION WITH FAMILY MEMBERS AND CAREGIVERS.—In addressing the circumstances described in paragraph (2), the guidance issued under this section shall clarify permitted uses or disclosures of protected health information for purposes of—

(A) communicating with a family member of the patient, caregiver of the patient, or other individual, to the extent that such family member, caregiver, or individual is involved in the care of the patient;

(B) in the case that the patient is an adult, communicating with a family member of the patient, caregiver of the patient, or other individual involved in the care of the patient;

(C) in the case that the patient is a minor, communicating with the parent or caregiver of the patient;

(D) involving the family members or caregivers of the patient, or others involved in the patient’s care or care plan, including facilitating treatment and medication adherence;

(E) listening to the patient, or receiving information with respect to the patient from the family or caregiver of the patient;

(F) communicating with family members of the patient, caregivers of the patient, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others; and

(G) communicating to law enforcement and family members or caregivers of the patient about the admission of the patient to receive care at, or the release of a patient from, a facility for an emergency psychiatric hold or involuntary treatment.

SEC. 11004. DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS.

(a) INITIAL PROGRAMS AND MATERIALS.—Not later than 1 year after the date of the enactment of this Act, the Secretary, in consultation with appropriate experts, shall identify the following model programs and materials, or (in the case that no such programs or materials exist) recognize private or public entities to develop and disseminate each of the following:

(1) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists, including child and adolescent psychiatrists, psychologists, counselors, therapists, nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) regarding the permitted uses and disclosures, consistent with the standards governing the privacy and security of individually identifiable health information promulgated by the Secretary under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and such part C, of the protected health information of patients seeking or undergoing mental or substance use disorder treatment.

(2) A model program and materials for training patients and their families regarding their rights to protect and obtain information under the standards and regulations specified in paragraph (1).

(b) PERIODIC UPDATES.—The Secretary shall—

(1) periodically review and update the model programs and materials identified or developed under subsection (a); and

(2) disseminate the updated model programs and materials to the individuals described in subsection (a).

(c) COORDINATION.—The Secretary shall carry out this section in coordination with the Director of the Office for Civil Rights within the Department of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, the Administrator of the Health Resources and Services Administration, and the heads of other relevant agencies within the Department of Health and Human Services.

(d) INPUT OF CERTAIN ENTITIES.—In identifying, reviewing, or updating the model programs and materials under subsections (a) and (b), the Secretary shall solicit the input of relevant national, State, and local associations; medical societies; licensing boards; providers of mental and substance use disorder treatment; organizations with expertise on domestic violence, sexual assault, elder abuse, and child abuse; and organizations representing patients and consumers and the families of patients and consumers.

(e) FUNDING.—There are authorized to be appropriated to carry out this section—

(1) \$4,000,000 for fiscal year 2018;

(2) \$2,000,000 for each of fiscal years 2019 and 2020; and

(3) \$1,000,000 for each of fiscal years 2021 and 2022.

TITLE XII—MEDICAID MENTAL HEALTH COVERAGE

SEC. 12001. RULE OF CONSTRUCTION RELATED TO MEDICAID COVERAGE OF MENTAL HEALTH SERVICES AND PRIMARY CARE SERVICES FURNISHED ON THE SAME DAY.

Nothing in title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) shall be construed as prohibiting separate payment under the State plan under such title (or under a waiver of the plan) for the provision of a mental health service or primary care service under such plan, with respect to an individual, because such service is—

(1) a primary care service furnished to the individual by a provider at a facility on the same day a mental health service is furnished to such individual by such provider (or another provider) at the facility; or

(2) a mental health service furnished to the individual by a provider at a facility on the same day a primary care service is furnished to such individual by such provider (or another provider) at the facility.

SEC. 12002. STUDY AND REPORT RELATED TO MEDICAID MANAGED CARE REGULATION.

(a) STUDY.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall conduct a study on coverage under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) of services provided through a Medicaid managed care organization (as defined in section 1903(m) of such Act (42 U.S.C. 1396b(m))) or a prepaid inpatient health plan (as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation)) with respect to individuals over the age of 21 and under the age of 65 for the treatment of a mental health disorder in institutions for mental diseases (as defined in section 1905(i) of such Act (42 U.S.C. 1396d(i))). Such study shall include information on the following:

(1) The extent to which States, including the District of Columbia and each territory or possession of the United States, are providing capitated payments to such organizations or plans for enrollees who are receiving services in institutions for mental diseases.

(2) The number of individuals receiving medical assistance under a State plan under such title XIX, or a waiver of such plan, who receive services in institutions for mental diseases through such organizations and plans.

(3) The range of and average number of months, and the length of stay during such months, that such individuals are receiving such services in such institutions.

(4) How such organizations or plans determine when to provide for the furnishing of such services through an institution for mental diseases in lieu of other benefits (including the full range of community-based services) under their contract with the State agency administering the State plan under such title XIX, or a waiver of such plan, to address psychiatric or substance use disorder treatment.

(5) The extent to which the provision of services within such institutions has affected the capitated payments for such organizations or plans.

(b) REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a).

SEC. 12003. GUIDANCE ON OPPORTUNITIES FOR INNOVATION.

Not later than 1 year after the date of the enactment of this Act, the Administrator of the Centers for Medicare & Medicaid Services shall issue a State Medicaid Director letter regarding opportunities to design innovative service delivery systems, including systems for providing

community-based services, for adults with a serious mental illness or children with a serious emotional disturbance who are receiving medical assistance under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.). The letter shall include opportunities for demonstration projects under section 1115 of such Act (42 U.S.C. 1315) to improve care for such adults and children.

SEC. 12004. STUDY AND REPORT ON MEDICAID EMERGENCY PSYCHIATRIC DEMONSTRATION PROJECT.

(a) **COLLECTION OF INFORMATION.**—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall, to the extent practical and data is available, with respect to each State that has participated in the demonstration project established under section 2707 of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note), collect from each such State information on the following:

(1) The number of institutions for mental diseases (as defined in section 1905(i) of the Social Security Act (42 U.S.C. 1396d(i))) and beds in such institutions that received payment for the provision of services to individuals who receive medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) through the demonstration project in each such State as compared to the total number of institutions for mental diseases and beds in the State.

(2) The extent to which there is a reduction in expenditures under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) or other spending on the full continuum of physical or mental health care for individuals who receive treatment in an institution for mental diseases under the demonstration project, including outpatient, inpatient, emergency, and ambulatory care, that is attributable to such individuals receiving treatment in institutions for mental diseases under the demonstration project.

(3) The number of forensic psychiatric hospitals, the number of beds in such hospitals, and the number of forensic psychiatric beds in other hospitals in such State, based on the most recent data available, to the extent practical, as determined by such Administrator.

(4) The amount of any disproportionate share hospital payments under section 1923 of the Social Security Act (42 U.S.C. 1396r-4) that institutions for mental diseases in the State received during the period beginning on July 1, 2012, and ending on June 30, 2015, and the extent to which the demonstration project reduced the amount of such payments.

(5) The most recent data regarding all facilities or sites in the State in which any adults with a serious mental illness who are receiving medical assistance under a State plan under the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan) are treated during the period referred to in paragraph (4), to the extent practical, as determined by the Administrator, including—

(A) the types of such facilities or sites (such as an institution for mental diseases, a hospital emergency department, or other inpatient hospital);

(B) the average length of stay in such a facility or site by such an individual, disaggregated by facility type; and

(C) the payment rate under the State plan (or a waiver of such plan) for services furnished to such an individual for that treatment, disaggregated by facility type, during the period in which the demonstration project is in operation.

(6) The extent to which the utilization of hospital emergency departments during the period in which the demonstration project was in operation differed, with respect to individuals who are receiving medical assistance under a State plan under the Medicaid program under title

XIX of the Social Security Act (42 U.S.C. 1396 et seq.) (or under a waiver of such plan), between—

(A) those individuals who received treatment in an institution for mental diseases under the demonstration project;

(B) those individuals who met the eligibility requirements for the demonstration project but who did not receive treatment in an institution for mental diseases under the demonstration project; and

(C) those adults with a serious mental illness who did not meet such eligibility requirements and did not receive treatment for such illness in an institution for mental diseases.

(b) **REPORT.**—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that summarizes and analyzes the information collected under subsection (a). Such report may be submitted as part of the report required under section 2707(f) of the Patient Protection and Affordable Care Act (42 U.S.C. 1396a note) or separately.

SEC. 12005. PROVIDING EPSDT SERVICES TO CHILDREN IN IMDS.

(a) **IN GENERAL.**—Section 1905(a)(16) of the Social Security Act (42 U.S.C. 1396d(a)(16)) is amended—

(1) by striking “effective January 1, 1973” and inserting “(A) effective January 1, 1973”; and

(2) by inserting before the semicolon at the end the following: “, and, (B) for individuals receiving services described in subparagraph (A), early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)), whether or not such screening, diagnostic, and treatment services are furnished by the provider of the services described in such subparagraph”.

(b) **EFFECTIVE DATE.**—The amendments made by subsection (a) shall apply with respect to items and services furnished in calendar quarters beginning on or after January 1, 2019.

SEC. 12006. ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED FOR PERSONAL CARE SERVICES AND HOME HEALTH CARE SERVICES UNDER MEDICAID.

(a) **IN GENERAL.**—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by inserting after subsection (k) the following new subsection:

“(1)(I) Subject to paragraphs (3) and (4), with respect to any amount expended for personal care services or home health care services requiring an in-home visit by a provider that are provided under a State plan under this title (or under a waiver of the plan) and furnished in a calendar quarter beginning on or after January 1, 2019 (or, in the case of home health care services, on or after January 1, 2023), unless a State requires the use of an electronic visit verification system for such services furnished in such quarter under the plan or such waiver, the Federal medical assistance percentage shall be reduced—

“(A) in the case of personal care services—

“(i) for calendar quarters in 2019 and 2020, by .25 percentage points;

“(ii) for calendar quarters in 2021, by .5 percentage points;

“(iii) for calendar quarters in 2022, by .75 percentage points; and

“(iv) for calendar quarters in 2023 and each year thereafter, by 1 percentage point; and

“(B) in the case of home health care services—

“(i) for calendar quarters in 2023 and 2024, by .25 percentage points;

“(ii) for calendar quarters in 2025, by .5 percentage points;

“(iii) for calendar quarters in 2026, by .75 percentage points; and

“(iv) for calendar quarters in 2027 and each year thereafter, by 1 percentage point.

“(2) Subject to paragraphs (3) and (4), in implementing the requirement for the use of an electronic visit verification system under paragraph (1), a State shall—

“(A) consult with agencies and entities that provide personal care services, home health care

services, or both under the State plan (or under a waiver of the plan) to ensure that such system—

“(i) is minimally burdensome;

“(ii) takes into account existing best practices and electronic visit verification systems in use in the State; and

“(iii) is conducted in accordance with the requirements of HIPAA privacy and security law (as defined in section 3009 of the Public Health Service Act);

“(B) take into account a stakeholder process that includes input from beneficiaries, family caregivers, individuals who furnish personal care services or home health care services, and other stakeholders, as determined by the State in accordance with guidance from the Secretary; and

“(C) ensure that individuals who furnish personal care services, home health care services, or both under the State plan (or under a waiver of the plan) are provided the opportunity for training on the use of such system.

“(3) Paragraphs (1) and (2) shall not apply in the case of a State that, as of the date of the enactment of this subsection, requires the use of any system for the electronic verification of visits conducted as part of both personal care services and home health care services, so long as the State continues to require the use of such system with respect to the electronic verification of such visits.

“(4)(A) In the case of a State described in subparagraph (B), the reduction under paragraph (1) shall not apply—

“(i) in the case of personal care services, for calendar quarters in 2019; and

“(ii) in the case of home health care services, for calendar quarters in 2023.

“(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that demonstrates to the Secretary that the State—

“(i) has made a good faith effort to comply with the requirements of paragraphs (1) and (2) (including by taking steps to adopt the technology used for an electronic visit verification system); and

“(ii) in implementing such a system, has encountered unavoidable system delays.

“(5) In this subsection:

“(A) The term ‘electronic visit verification system’ means, with respect to personal care services or home health care services, a system under which visits conducted as part of such services are electronically verified with respect to—

“(i) the type of service performed;

“(ii) the individual receiving the service;

“(iii) the date of the service;

“(iv) the location of service delivery;

“(v) the individual providing the service; and

“(vi) the time the service begins and ends.

“(B) The term ‘home health care services’ means services described in section 1905(a)(7) provided under a State plan under this title (or under a waiver of the plan).

“(C) The term ‘personal care services’ means personal care services provided under a State plan under this title (or under a waiver of the plan), including services provided under section 1905(a)(24), 1915(c), 1915(i), 1915(j), or 1915(k) or under a waiver under section 1115.

“(6)(A) In the case in which a State requires personal care service and home health care service providers to utilize an electronic visit verification system operated by the State or a contractor on behalf of the State, the Secretary shall pay to the State, for each quarter, an amount equal to 90 per centum of so much of the sums expended during such quarter as are attributable to the design, development, or installation of such system, and 75 per centum of so much of the sums for the operation and maintenance of such system.

“(B) Subparagraph (A) shall not apply in the case in which a State requires personal care service and home health care service providers

to utilize an electronic visit verification system that is not operated by the State or a contractor on behalf of the State.”.

(b) **COLLECTION AND DISSEMINATION OF BEST PRACTICES.**—Not later than January 1, 2018, the Secretary of Health and Human Services shall, with respect to electronic visit verification systems (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), collect and disseminate best practices to State Medicaid Directors with respect to—

(1) training individuals who furnish personal care services, home health care services, or both under the State plan under title XIX of such Act (or under a waiver of the plan) on such systems and the operation of such systems and the prevention of fraud with respect to the provision of personal care services or home health care services (as defined in such subsection (l)(5)); and

(2) the provision of notice and educational materials to family caregivers and beneficiaries with respect to the use of such electronic visit verification systems and other means to prevent such fraud.

(c) **RULES OF CONSTRUCTION.**—

(1) **NO EMPLOYER-EMPLOYEE RELATIONSHIP ESTABLISHED.**—Nothing in the amendment made by this section may be construed as establishing an employer-employee relationship between the agency or entity that provides for personal care services or home health care services and the individuals who, under a contract with such an agency or entity, furnish such services for purposes of part 552 of title 29, Code of Federal Regulations (or any successor regulations).

(2) **NO PARTICULAR OR UNIFORM ELECTRONIC VISIT VERIFICATION SYSTEM REQUIRED.**—Nothing in the amendment made by this section shall be construed to require the use of a particular or uniform electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)) by all agencies or entities that provide personal care services or home health care under a State plan under title XIX of the Social Security Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.).

(3) **NO LIMITS ON PROVISION OF CARE.**—Nothing in the amendment made by this section may be construed to limit, with respect to personal care services or home health care services provided under a State plan under title XIX of the Social Security Act (or under a waiver of the plan) (42 U.S.C. 1396 et seq.), provider selection, constrain beneficiaries' selection of a caregiver, or impede the manner in which care is delivered.

(4) **NO PROHIBITION ON STATE QUALITY MEASURES REQUIREMENTS.**—Nothing in the amendment made by this section shall be construed as prohibiting a State, in implementing an electronic visit verification system (as defined in subsection (l)(5) of section 1903 of the Social Security Act (42 U.S.C. 1396b), as inserted by subsection (a)), from establishing requirements related to quality measures for such system.

TITLE XIII—MENTAL HEALTH PARITY

SEC. 13001. ENHANCED COMPLIANCE WITH MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE REQUIREMENTS.

(a) **COMPLIANCE PROGRAM GUIDANCE DOCUMENT.**—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg-26(a)) is amended by adding at the end the following:

“(6) **COMPLIANCE PROGRAM GUIDANCE DOCUMENT.**—

“(A) **IN GENERAL.**—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treas-

ury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled ‘Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance’.

“(B) **EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.**—

“(i) **IN GENERAL.**—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

“(1) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

“(II) descriptions of the violations uncovered during the course of such investigations.

“(ii) **NONQUANTITATIVE TREATMENT LIMITATIONS.**—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

“(iii) **ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.**—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

“(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

“(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

“(C) **RECOMMENDATIONS.**—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

“(D) **UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.**—The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of

Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.”.

(b) **ADDITIONAL GUIDANCE.**—Section 2726(a) of the Public Health Service Act (42 U.S.C. 300gg-26(a)), as amended by subsection (a), is further amended by adding at the end the following:

“(7) **ADDITIONAL GUIDANCE.**—

“(A) **IN GENERAL.**—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

“(B) **DISCLOSURE.**—

“(i) **GUIDANCE FOR PLANS AND ISSUERS.**—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

“(ii) **DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.**—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

“(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

“(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

“(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

“(C) **NONQUANTITATIVE TREATMENT LIMITATIONS.**—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812

of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

“(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

“(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

“(II) limitations with respect to prescription drug formulary design; and

“(III) use of fail-first or step therapy protocols;

“(ii) examples of methods of determining—

“(I) network admission standards (such as credentialing); and

“(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

“(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

“(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

“(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

“(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

“(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

“(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

“(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

“(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.”

(c) AVAILABILITY OF PLAN INFORMATION.—

(1) SOLICITATION OF PUBLIC FEEDBACK.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall solicit feedback from the public on how the disclosure request process for documents containing information that health plans or health insurance issuers are required under Federal or State law to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with existing mental health parity and addiction equity requirements can be improved while continuing to ensure consumers' rights to access all information required by Federal or State law to be disclosed.

(2) PUBLIC AVAILABILITY.—Not later than 12 months after the date of the enactment of this

Act, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall make such feedback publicly available.

(3) NAIC.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall share feedback obtained pursuant to paragraph (1) directly with the National Association of Insurance Commissioners to the extent such feedback includes recommendations for the development of simplified information disclosure tools to provide consistent information for consumers. Such feedback may be taken into consideration by the National Association of Insurance Commissioners and other appropriate entities for the voluntary development and voluntary use of common templates and other sample standardized forms to improve consumer access to plan information.

(d) IMPROVING COMPLIANCE.—

(1) IN GENERAL.—In the case that the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury determines that a group health plan or health insurance issuer offering group or individual health insurance coverage has violated, at least 5 times, section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), or section 9812 of the Internal Revenue Code of 1986, respectively, the appropriate Secretary shall audit plan documents for such health plan or issuer in the plan year following the Secretary's determination in order to help improve compliance with such section.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority, as in effect on the day before the date of enactment of this Act, of the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury to audit documents of health plans or health insurance issuers.

SEC. 13002. ACTION PLAN FOR ENHANCED ENFORCEMENT OF MENTAL HEALTH AND SUBSTANCE USE DISORDER COVERAGE.

(a) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting of stakeholders described in paragraph (2) to produce an action plan for improved Federal and State coordination related to the enforcement of section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, and any comparable provisions of State law (in this section such sections and provisions are collectively referred to as “mental health parity and addiction equity requirements”).

(2) STAKEHOLDERS.—The stakeholders described in this paragraph shall include each of the following:

(A) The Federal Government, including representatives from—

(i) the Department of Health and Human Services;

(ii) the Department of the Treasury;

(iii) the Department of Labor; and

(iv) the Department of Justice.

(B) State governments, including—

(i) State health insurance commissioners;

(ii) appropriate State agencies, including agencies on public health or mental health; and

(iii) State attorneys general or other representatives of State entities involved in the enforcement of mental health parity and addiction equity requirements.

(C) Representatives from key stakeholder groups, including—

(i) the National Association of Insurance Commissioners;

(ii) health insurance issuers;

(iii) providers of mental health and substance use disorder treatment;

(iv) employers; and

(v) patients or their advocates.

(b) ACTION PLAN.—Not later than 6 months after the conclusion of the public meeting under subsection (a), the Secretary of Health and Human Services shall finalize the action plan described in such subsection and make it plainly available on the Internet website of the Department of Health and Human Services.

(c) CONTENT.—The action plan under this section shall—

(1) take into consideration the recommendations of the Mental Health and Substance Use Disorder Parity Task Force in its final report issued in October of 2016, and any subsequent Federal and State actions in relation to such recommendations;

(2) reflect the input of the stakeholders participating in the public meeting under subsection (a);

(3) identify specific strategic objectives regarding how the various Federal and State agencies charged with enforcement of mental health parity and addiction equity requirements will collaborate to improve enforcement of such requirements;

(4) provide a timeline for implementing the action plan; and

(5) provide specific examples of how such objectives may be met, which may include—

(A) providing common educational information and documents, such as the Consumer Guide to Disclosure Rights, to patients about their rights under mental health parity and addiction equity requirements;

(B) facilitating the centralized collection of, monitoring of, and response to patient complaints or inquiries relating to mental health parity and addiction equity requirements, which may be through the development and administration of—

(i) a single, toll-free telephone number; and

(ii) a new parity website—

(I) to help consumers find the appropriate Federal or State agency to assist with their parity complaints, appeals, and other actions; and

(II) that takes into consideration, but is not duplicative of, the parity beta site being tested, and released for public comment, by the Department of Health and Human Services as of the date of the enactment of this Act;

(C) Federal and State law enforcement agencies entering into memoranda of understanding to better coordinate enforcement responsibilities and information sharing—

(i) including whether such agencies should make the results of enforcement actions related to mental health parity and addiction equity requirements publicly available; and

(ii) which may include State Policy Academies on Parity Implementation for State Officials and other forums to bring together national experts to provide technical assistance to teams of State officials on strategies to advance compliance with mental health parity and addiction equity requirements in both the commercial market, and in the Medicaid program under title XIX of the Social Security Act and the State Children's Health Insurance Program under title XXI of such Act; and

(D) recommendations to the Congress regarding the need for additional legal authority to improve enforcement of mental health parity and addiction equity requirements, including the need for additional legal authority to ensure that nonquantitative treatment limitations are applied, and the extent and frequency of the applications of such limitations, both to medical and surgical benefits and to mental health and substance use disorder benefits in a comparable manner.

SEC. 13003. REPORT ON INVESTIGATIONS REGARDING PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and annually

thereafter for the subsequent 5 years, the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services and the Secretary of the Treasury, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report summarizing the results of all closed Federal investigations completed during the preceding 12-month period with findings of any serious violation regarding compliance with mental health and substance use disorder coverage requirements under section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

(b) CONTENTS.—Subject to subsection (c), a report under subsection (a) shall, with respect to investigations described in such subsection, include each of the following:

(1) The number of closed Federal investigations conducted during the covered reporting period.

(2) Each benefit classification examined by any such investigation conducted during the covered reporting period.

(3) Each subject matter, including compliance with requirements for quantitative and non-quantitative treatment limitations, of any such investigation conducted during the covered reporting period.

(4) A summary of the basis of the final decision rendered for each closed investigation conducted during the covered reporting period that resulted in a finding of a serious violation.

(c) LIMITATION.—Any individually identifiable information shall be excluded from reports under subsection (a) consistent with protections under the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note).

SEC. 13004. GAO STUDY ON PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the extent to which group health plans or health insurance issuers offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, medicaid managed care organizations with a contract under section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)), and health plans provided under the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) comply with section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986, including—

(1) how nonquantitative treatment limitations, including medical necessity criteria, of such plans or issuers comply with such sections;

(2) how the responsible Federal departments and agencies ensure that such plans or issuers comply with such sections, including an assessment of how the Secretary of Health and Human Services has used its authority to conduct audits of such plans to ensure compliance;

(3) a review of how the various Federal and State agencies responsible for enforcing mental health parity requirements have improved enforcement of such requirements in accordance with the objectives and timeline described in the action plan under section 13002; and

(4) recommendations for how additional enforcement, education, and coordination activities by responsible Federal and State departments and agencies could better ensure compliance with such sections, including recommendations regarding the need for additional legal authority.

SEC. 13005. INFORMATION AND AWARENESS ON EATING DISORDERS.

(a) INFORMATION.—The Secretary of Health and Human Services, acting through the Director of the Office on Women's Health, may—

(1) update information, related fact sheets, and resource lists related to eating disorders that are available on the public Internet website of the National Women's Health Information Center sponsored by the Office on Women's Health, to include—

(A) updated findings and current research related to eating disorders, as appropriate; and

(B) information about eating disorders, including information related to males and females;

(2) incorporate, as appropriate, and in coordination with the Secretary of Education, information from publicly available resources into appropriate obesity prevention programs developed by the Office on Women's Health; and

(3) make publicly available (through a public Internet website or other method) information, related fact sheets, and resource lists, as updated under paragraph (1), and the information incorporated into appropriate obesity prevention programs under paragraph (2).

(b) AWARENESS.—The Secretary of Health and Human Services may advance public awareness on—

(1) the types of eating disorders;

(2) the seriousness of eating disorders, including prevalence, comorbidities, and physical and mental health consequences;

(3) methods to identify, intervene, refer for treatment, and prevent behaviors that may lead to the development of eating disorders;

(4) discrimination and bullying based on body size;

(5) the effects of media on self-esteem and body image; and

(6) the signs and symptoms of eating disorders.

SEC. 13006. EDUCATION AND TRAINING ON EATING DISORDERS.

The Secretary of Health and Human Services may facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to—

(1) identify individuals with eating disorders;

(2) provide early intervention services for individuals with eating disorders;

(3) refer patients with eating disorders for appropriate treatment;

(4) prevent the development of eating disorders; and

(5) provide appropriate treatment services for individuals with eating disorders.

SEC. 13007. CLARIFICATION OF EXISTING PARITY RULES.

If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of section 2726 of the Public Health Service Act (42 U.S.C. 300gg-26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986.

TITLE XIV—MENTAL HEALTH AND SAFE COMMUNITIES

Subtitle A—Mental Health and Safe Communities

SEC. 14001. LAW ENFORCEMENT GRANTS FOR CRISIS INTERVENTION TEAMS, MENTAL HEALTH PURPOSES.

(a) EDWARD BYRNE MEMORIAL JUSTICE ASSISTANCE GRANT PROGRAM.—Section 501(a)(1) of

title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3751(a)(1)) is amended by adding at the end the following:

“(H) Mental health programs and related law enforcement and corrections programs, including behavioral programs and crisis intervention teams.”.

(b) COMMUNITY ORIENTED POLICING SERVICES PROGRAM.—Section 1701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796dd(b)) is amended—

(1) in paragraph (17), by striking “and” at the end;

(2) by redesignating paragraph (18) as paragraph (22);

(3) by inserting after paragraph (17) the following:

“(18) to provide specialized training to law enforcement officers to—

“(A) recognize individuals who have a mental illness; and

“(B) properly interact with individuals who have a mental illness, including strategies for verbal de-escalation of crises;

“(19) to establish collaborative programs that enhance the ability of law enforcement agencies to address the mental health, behavioral, and substance abuse problems of individuals encountered by law enforcement officers in the line of duty;

“(20) to provide specialized training to corrections officers to recognize individuals who have a mental illness;

“(21) to enhance the ability of corrections officers to address the mental health of individuals under the care and custody of jails and prisons, including specialized training and strategies for verbal de-escalation of crises; and”;

(4) in paragraph (22), as redesignated, by striking “through (17)” and inserting “through (21)”.

(c) MODIFICATIONS TO THE STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANTS.—Section 34(a)(1)(B) of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229a(a)(1)(B)) is amended by inserting before the period at the end the following: “and to provide specialized training to paramedics, emergency medical services workers, and other first responders to recognize individuals who have mental illness and how to properly intervene with individuals with mental illness, including strategies for verbal de-escalation of crises”.

SEC. 14002. ASSISTED OUTPATIENT TREATMENT PROGRAMS.

(a) IN GENERAL.—Section 2201 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii) is amended in paragraph (2)(B), by inserting before the semicolon the following: “, or court-ordered assisted outpatient treatment when the court has determined such treatment to be necessary”.

(b) DEFINITIONS.—Section 2202 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ii-1) is amended—

(1) in paragraph (1), by striking “and” at the end;

(2) in paragraph (2), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

“(3) the term ‘court-ordered assisted outpatient treatment’ means a program through which a court may order a treatment plan for an eligible patient that—

“(A) requires such patient to obtain outpatient mental health treatment while the patient is not currently residing in a correctional facility or inpatient treatment facility; and

“(B) is designed to improve access and adherence by such patient to intensive behavioral health services in order to—

“(i) avert relapse, repeated hospitalizations, arrest, incarceration, suicide, property destruction, and violent behavior; and

“(ii) provide such patient with the opportunity to live in a less restrictive alternative to incarceration or involuntary hospitalization; and

“(4) the term ‘eligible patient’ means an adult, mentally ill person who, as determined by a court—

“(A) has a history of violence, incarceration, or medically unnecessary hospitalizations;

“(B) without supervision and treatment, may be a danger to self or others in the community;

“(C) is substantially unlikely to voluntarily participate in treatment;

“(D) may be unable, for reasons other than indigence, to provide for any of his or her basic needs, such as food, clothing, shelter, health, or safety;

“(E) has a history of mental illness or a condition that is likely to substantially deteriorate if the person is not provided with timely treatment; or

“(F) due to mental illness, lacks capacity to fully understand or lacks judgment to make informed decisions regarding his or her need for treatment, care, or supervision.”.

SEC. 14003. FEDERAL DRUG AND MENTAL HEALTH COURTS.

(a) DEFINITIONS.—In this section—

(1) the term “eligible offender” means a person who—

(A)(i) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders; or

(ii) manifests obvious signs of mental illness, mental retardation, or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court;

(B) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code; and

(C) is determined by a judge to be eligible; and

(2) the term “mental illness” means a diagnosable mental, behavioral, or emotional disorder—

(A) of sufficient duration to meet diagnostic criteria within the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association; and

(B) that has resulted in functional impairment that substantially interferes with or limits 1 or more major life activities.

(b) ESTABLISHMENT OF PROGRAM.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall establish a pilot program to determine the effectiveness of diverting eligible offenders from Federal prosecution, Federal probation, or a Bureau of Prisons facility, and placing such eligible offenders in drug or mental health courts.

(c) PROGRAM SPECIFICATIONS.—The pilot program established under subsection (b) shall involve—

(1) continuing judicial supervision, including periodic review, of program participants who have a substance abuse problem or mental illness; and

(2) the integrated administration of services and sanctions, which shall include—

(A) mandatory periodic testing, as appropriate, for the use of controlled substances or other addictive substances during any period of supervised release or probation for each program participant;

(B) substance abuse treatment for each program participant who requires such services;

(C) diversion, probation, or other supervised release with the possibility of prosecution, confinement, or incarceration based on noncompliance with program requirements or failure to show satisfactory progress toward completing program requirements;

(D) programmatic offender management, including case management, and aftercare serv-

ices, such as relapse prevention, health care, education, vocational training, job placement, housing placement, and child care or other family support services for each program participant who requires such services;

(E) outpatient or inpatient mental health treatment, as ordered by the court, that carries with it the possibility of dismissal of charges or reduced sentencing upon successful completion of such treatment;

(F) centralized case management, including—

(i) the consolidation of all cases, including violations of probations, of the program participant; and

(ii) coordination of all mental health treatment plans and social services, including life skills and vocational training, housing and job placement, education, health care, and relapse prevention for each program participant who requires such services; and

(G) continuing supervision of treatment plan compliance by the program participant for a term not to exceed the maximum allowable sentence or probation period for the charged or relevant offense and, to the extent practicable, continuity of psychiatric care at the end of the supervised period.

(d) IMPLEMENTATION; DURATION.—The pilot program established under subsection (b) shall be conducted—

(1) in not less than 1 United States judicial district, designated by the Attorney General in consultation with the Director of the Administrative Office of the United States Courts, as appropriate for the pilot program; and

(2) during fiscal year 2017 through fiscal year 2021.

(e) CRITERIA FOR DESIGNATION.—Before making a designation under subsection (d)(1), the Attorney General shall—

(1) obtain the approval, in writing, of the United States Attorney for the United States judicial district being designated;

(2) obtain the approval, in writing, of the chief judge for the United States judicial district being designated; and

(3) determine that the United States judicial district being designated has adequate behavioral health systems for treatment, including substance abuse and mental health treatment.

(f) ASSISTANCE FROM OTHER FEDERAL ENTITIES.—The Administrative Office of the United States Courts and the United States Probation Offices shall provide such assistance and carry out such functions as the Attorney General may request in monitoring, supervising, providing services to, and evaluating eligible offenders placed in a drug or mental health court under this section.

(g) REPORTS.—The Attorney General, in consultation with the Director of the Administrative Office of the United States Courts, shall monitor the drug and mental health courts under this section, and shall submit a report to Congress on the outcomes of the program at the end of the period described in subsection (d)(2).

SEC. 14004. MENTAL HEALTH IN THE JUDICIAL SYSTEM.

Part V of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796i et seq.) is amended by inserting at the end the following:

“SEC. 2209. MENTAL HEALTH RESPONSES IN THE JUDICIAL SYSTEM.

“(a) PRETRIAL SCREENING AND SUPERVISION.—

“(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand pretrial services programs to improve the identification and outcomes of individuals with mental illness.

“(2) ALLOWABLE USES.—Grants awarded under this subsection may be used for—

“(A) behavioral health needs and risk screening of defendants, including verification of interview information, mental health evaluation, and criminal history screening;

“(B) assessment of risk of pretrial misconduct through objective, statistically validated means, and presentation to the court of recommendations based on such assessment, including services that will reduce the risk of pre-trial misconduct;

“(C) followup review of defendants unable to meet the conditions of pretrial release;

“(D) evaluation of process and results of pre-trial service programs;

“(E) supervision of defendants who are on pretrial release, including reminders to defendants of scheduled court dates;

“(F) reporting on process and results of pre-trial services programs to relevant public and private mental health stakeholders; and

“(G) data collection and analysis necessary to make available information required for assessment of risk.

“(b) BEHAVIORAL HEALTH ASSESSMENTS AND INTERVENTION.—

“(1) IN GENERAL.—The Attorney General may award grants to States, units of local government, territories, Indian Tribes, nonprofit agencies, or any combination thereof, to develop, implement, or expand a behavioral health screening and assessment program framework for State or local criminal justice systems.

“(2) ALLOWABLE USES.—Grants awarded under this subsection may be used for—

“(A) promotion of the use of validated assessment tools to gauge the criminogenic risk, substance abuse needs, and mental health needs of individuals;

“(B) initiatives to match the risk factors and needs of individuals to programs and practices associated with research-based, positive outcomes;

“(C) implementing methods for identifying and treating individuals who are most likely to benefit from coordinated supervision and treatment strategies, and identifying individuals who can do well with fewer interventions; and

“(D) collaborative decision-making among the heads of criminal justice agencies, mental health systems, judicial systems, substance abuse systems, and other relevant systems or agencies for determining how treatment and intensive supervision services should be allocated in order to maximize benefits, and developing and utilizing capacity accordingly.

“(c) USE OF GRANT FUNDS.—A State, unit of local government, territory, Indian Tribe, or nonprofit agency that receives a grant under this section shall, in accordance with subsection (b)(2), use grant funds for the expenses of a treatment program, including—

“(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including costs relating to enforcement;

“(2) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to program participants, including aftercare supervision, vocational training, education, and job placement; and

“(3) payments to public and nonprofit private entities that are approved by the State or Indian Tribe and licensed, if necessary, to provide alcohol and drug addiction treatment to offenders participating in the program.

“(d) SUPPLEMENT OF NON-FEDERAL FUNDS.—

“(1) IN GENERAL.—Grants awarded under this section shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this section.

“(2) FEDERAL SHARE.—The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (e).

“(e) APPLICATIONS.—To request a grant under this section, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.

“(f) **GEOGRAPHIC DISTRIBUTION.**—The Attorney General shall ensure that, to the extent practicable, the distribution of grants under this section is equitable and includes—

“(1) each State; and

“(2) a unit of local government, territory, Indian Tribe, or nonprofit agency—

“(A) in each State; and

“(B) in rural, suburban, Tribal, and urban jurisdictions.

“(g) **REPORTS AND EVALUATIONS.**—For each fiscal year, each grantee under this section during that fiscal year shall submit to the Attorney General a report on the effectiveness of activities carried out using such grant. Each report shall include an evaluation in such form and containing such information as the Attorney General may reasonably require. The Attorney General shall specify the dates on which such reports shall be submitted.

“(h) **ACCOUNTABILITY.**—Grants awarded under this section shall be subject to the following accountability provisions:

“(1) **AUDIT REQUIREMENT.**—

“(A) **DEFINITION.**—In this paragraph, the term ‘unresolved audit finding’ means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which final audit report is issued.

“(B) **AUDITS.**—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

“(C) **FINAL AUDIT REPORT.**—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

“(D) **MANDATORY EXCLUSION.**—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

“(E) **PRIORITY.**—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

“(F) **REIMBURSEMENT.**—If an entity receives a grant under this section during the 2-fiscal-year period during which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

“(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

“(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

“(2) **NONPROFIT AGENCY REQUIREMENTS.**—

“(A) **DEFINITION.**—For purposes of this paragraph and the grant program under this section, the term ‘nonprofit agency’ means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

“(B) **PROHIBITION.**—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an off-shore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

“(C) **DISCLOSURE.**—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to

create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

“(3) **CONFERENCE EXPENDITURES.**—

“(A) **LIMITATION.**—Not more than \$20,000 of the amounts made available to the Department of Justice to carry out this section may be used by the Attorney General, or by any individual or entity awarded a grant under this section to host, or make any expenditures relating to, a conference unless the Deputy Attorney General provides prior written authorization that the funds may be expended to host the conference or make such expenditure.

“(B) **WRITTEN APPROVAL.**—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

“(C) **REPORT.**—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

“(4) **ANNUAL CERTIFICATION.**—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

“(A) indicating whether—

“(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

“(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

“(iii) any reimbursements required under paragraph (1)(F) have been made; and

“(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

“(i) **PREVENTING DUPLICATIVE GRANTS.**—

“(1) **IN GENERAL.**—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare the possible grant with any other grants awarded to the applicant under this Act to determine whether the grants are for the same purpose.

“(2) **REPORT.**—If the Attorney General awards multiple grants to the same applicant for the same purpose, the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

“(A) a list of all duplicate grants awarded, including the total dollar amount of any such grants awarded; and

“(B) the reason the Attorney General awarded the duplicate grants.”

SEC. 14005. FORENSIC ASSERTIVE COMMUNITY TREATMENT INITIATIVES.

Section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by—

(1) redesignating subsection (j) as subsection (o); and

(2) inserting after subsection (i) the following:

“(j) **FORENSIC ASSERTIVE COMMUNITY TREATMENT (FACT) INITIATIVE PROGRAM.**—

“(1) **IN GENERAL.**—The Attorney General may make grants to States, units of local government, territories, Indian Tribes, nonprofit agen-

cies, or any combination thereof, to develop, implement, or expand Assertive Community Treatment initiatives to develop forensic assertive community treatment (referred to in this subsection as ‘FACT’) programs that provide high intensity services in the community for individuals with mental illness with involvement in the criminal justice system to prevent future incarcerations.

“(2) **ALLOWABLE USES.**—Grant funds awarded under this subsection may be used for—

“(A) multidisciplinary team initiatives for individuals with mental illnesses with criminal justice involvement that address criminal justice involvement as part of treatment protocols;

“(B) FACT programs that involve mental health professionals, criminal justice agencies, chemical dependency specialists, nurses, psychiatrists, vocational specialists, forensic peer specialists, forensic specialists, and dedicated administrative support staff who work together to provide recovery oriented, 24/7 wraparound services;

“(C) services such as integrated evidence-based practices for the treatment of co-occurring mental health and substance-related disorders, assertive outreach and engagement, community-based service provision at participants’ residence or in the community, psychiatric rehabilitation, recovery oriented services, services to address criminogenic risk factors, and community tenure;

“(D) payments for treatment providers that are approved by the State or Indian Tribe and licensed, if necessary, to provide needed treatment to eligible offenders participating in the program, including behavioral health services and aftercare supervision; and

“(E) training for all FACT teams to promote high-fidelity practice principles and technical assistance to support effective and continuing integration with criminal justice agency partners.

“(3) **SUPPLEMENT AND NOT SUPPLANT.**—Grants made under this subsection shall be used to supplement, and not supplant, non-Federal funds that would otherwise be available for programs described in this subsection.

“(4) **APPLICATIONS.**—To request a grant under this subsection, a State, unit of local government, territory, Indian Tribe, or nonprofit agency shall submit an application to the Attorney General in such form and containing such information as the Attorney General may reasonably require.”

SEC. 14006. ASSISTANCE FOR INDIVIDUALS TRANSITIONING OUT OF SYSTEMS.

Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)) is amended—

(1) in paragraph (5), by striking “and” at the end;

(2) in paragraph (6), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

“(7) provide mental health treatment and transitional services for those with mental illnesses or with co-occurring disorders, including housing placement or assistance; and”.

SEC. 14007. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN DRUG COURTS.

Part EE of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797u et seq.) is amended—

(1) in section 2951(a)(1) (42 U.S.C. 3797u(a)(1)), by inserting “, including co-occurring substance abuse and mental health problems,” after “problems”; and

(2) in section 2959(a) (42 U.S.C. 3797u-8(a)), by inserting “, including training for drug court personnel and officials on identifying and addressing co-occurring substance abuse and mental health problems” after “part”.

SEC. 14008. MENTAL HEALTH TRAINING FOR FEDERAL UNIFORMED SERVICES.

(a) **IN GENERAL.**—Not later than 180 days after the date of enactment of this Act, the Secretary of Defense, the Secretary of Homeland

Security, the Secretary of Health and Human Services, and the Secretary of Commerce shall provide the following to each of the uniformed services (as that term is defined in section 101 of title 10, United States Code) under their direction:

(1) **TRAINING PROGRAMS.**—Programs that offer specialized and comprehensive training in procedures to identify and respond appropriately to incidents in which the unique needs of individuals with mental illnesses are involved.

(2) **IMPROVED TECHNOLOGY.**—Computerized information systems or technological improvements to provide timely information to Federal law enforcement personnel, other branches of the uniformed services, and criminal justice system personnel to improve the Federal response to mentally ill individuals.

(3) **COOPERATIVE PROGRAMS.**—The establishment and expansion of cooperative efforts to promote public safety through the use of effective intervention with respect to mentally ill individuals encountered by members of the uniformed services.

SEC. 14009. ADVANCING MENTAL HEALTH AS PART OF OFFENDER REENTRY.

(a) **REENTRY DEMONSTRATION PROJECTS.**—Section 2976(f) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797w(f)), as amended by section 14006, is amended—

(1) in paragraph (3)(C), by inserting “mental health services,” before “drug treatment”; and

(2) by adding at the end the following:

“(B) target offenders with histories of homelessness, substance abuse, or mental illness, including a prerelease assessment of the housing status of the offender and behavioral health needs of the offender with clear coordination with mental health, substance abuse, and homelessness services systems to achieve stable and permanent housing outcomes with appropriate support service.”.

(b) **MENTORING GRANTS.**—Section 211(b)(2) of the Second Chance Act of 2007 (42 U.S.C. 17531(b)(2)) is amended by inserting “, including mental health care” after “community”.

SEC. 14010. SCHOOL MENTAL HEALTH CRISIS INTERVENTION TEAMS.

Section 2701(b) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797a(b)) is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(2) by inserting after paragraph (3) the following:

“(4) The development and operation of crisis intervention teams that may include coordination with law enforcement agencies and specialized training for school officials in responding to mental health crises.”.

SEC. 14011. ACTIVE-SHOOTER TRAINING FOR LAW ENFORCEMENT.

The Attorney General, as part of the Preventing Violence Against Law Enforcement and Ensuring Officer Resilience and Survivability Initiative (VALOR) of the Department of Justice, may provide safety training and technical assistance to local law enforcement agencies, including active-shooter response training.

SEC. 14012. CO-OCCURRING SUBSTANCE ABUSE AND MENTAL HEALTH CHALLENGES IN RESIDENTIAL SUBSTANCE ABUSE TREATMENT PROGRAMS.

Section 1901(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796ff(a)) is amended—

(1) in paragraph (1), by striking “and” at the end;

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

(3) by adding at the end the following:

“(3) developing and implementing specialized residential substance abuse treatment programs that identify and provide appropriate treatment to inmates with co-occurring mental health and substance abuse disorders or challenges.”.

SEC. 14013. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS.

Title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3711 et seq.) is amended by striking part CC and inserting the following:

“PART CC—MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS

“SEC. 2901. MENTAL HEALTH AND DRUG TREATMENT ALTERNATIVES TO INCARCERATION PROGRAMS.

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

“(1) the term ‘eligible entity’ means a State, unit of local government, Indian tribe, or non-profit organization; and

“(2) the term ‘eligible participant’ means an individual who—

“(A) comes into contact with the criminal justice system or is arrested or charged with an offense that is not—

“(i) a crime of violence, as defined under applicable State law or in section 3156 of title 18, United States Code; or

“(ii) a serious drug offense, as defined in section 924(e)(2)(A) of title 18, United States Code;

“(B) has a history of, or a current—

“(i) substance use disorder;

“(ii) mental illness; or

“(iii) co-occurring mental illness and substance use disorder; and

“(C) has been approved for participation in a program funded under this section by the relevant law enforcement agency, prosecuting attorney, defense attorney, probation official, corrections official, judge, representative of a mental health agency, or representative of a substance abuse agency, as required by law.

“(b) **PROGRAM AUTHORIZED.**—The Attorney General may make grants to eligible entities to develop, implement, or expand a treatment alternative to incarceration program for eligible participants, including—

“(1) pre-booking treatment alternative to incarceration programs, including—

“(A) law enforcement training on substance use disorders, mental illness, and co-occurring mental illness and substance use disorders;

“(B) receiving centers as alternatives to incarceration of eligible participants;

“(C) specialized response units for calls related to substance use disorders, mental illness, or co-occurring mental illness and substance use disorders; and

“(D) other arrest and pre-booking treatment alternatives to incarceration models; or

“(2) post-booking treatment alternative to incarceration programs, including—

“(A) specialized clinical case management;

“(B) pre-trial services related to substances use disorders, mental illness, and co-occurring mental illness and substance use disorders;

“(C) prosecutor and defender based programs;

“(D) specialized probation;

“(E) treatment and rehabilitation programs; and

“(F) problem-solving courts, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts.

“(c) **APPLICATION.**—

“(1) **IN GENERAL.**—An eligible entity desiring a grant under this section shall submit an application to the Attorney General—

“(A) that meets the criteria under paragraph (2); and

“(B) at such time, in such manner, and accompanied by such information as the Attorney General may require.

“(2) **CRITERIA.**—An eligible entity, in submitting an application under paragraph (1), shall—

“(A) provide extensive evidence of collaboration with State and local government agencies overseeing health, community corrections, courts, prosecution, substance abuse, mental health, victims services, and employment services, and with local law enforcement agencies;

“(B) demonstrate consultation with the Single State Authority for Substance Abuse of the State (as that term is defined in section 201(e) of the Second Chance Act of 2007);

“(C) demonstrate that evidence-based treatment practices will be utilized; and

“(D) demonstrate that evidence-based screening and assessment tools will be used to place participants in the treatment alternative to incarceration program.

“(d) **REQUIREMENTS.**—Each eligible entity awarded a grant for a treatment alternative to incarceration program under this section shall—

“(1) determine the terms and conditions of participation in the program by eligible participants, taking into consideration the collateral consequences of an arrest, prosecution or criminal conviction;

“(2) ensure that each substance abuse and mental health treatment component is licensed and qualified by the relevant jurisdiction;

“(3) for programs described in subsection (b)(2), organize an enforcement unit comprised of appropriately trained law enforcement professionals under the supervision of the State, Tribal, or local criminal justice agency involved, the duties of which shall include—

“(A) the verification of addresses and other contact information of each eligible participant who participates or desires to participate in the program; and

“(B) if necessary, the location, apprehension, arrest, and return to custody of an eligible participant in the program who has absconded from the facility of a treatment provider or has otherwise significantly violated the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

“(4) notify the relevant criminal justice entity if any eligible participant in the program absconds from the facility of the treatment provider or otherwise violates the terms and conditions of the program, consistent with Federal and State confidentiality requirements;

“(5) submit periodic reports on the progress of treatment or other measured outcomes from participation in the program of each eligible participant in the program to the relevant State, Tribal, or local criminal justice agency, including mental health courts, drug courts, co-occurring mental health and substance abuse courts, DWI courts, and veterans treatment courts;

“(6) describe the evidence-based methodology and outcome measurements that will be used to evaluate the program, and specifically explain how such measurements will provide valid measures of the impact of the program; and

“(7) describe how the program could be broadly replicated if demonstrated to be effective.

“(e) **USE OF FUNDS.**—An eligible entity shall use a grant received under this section for expenses of a treatment alternative to incarceration program, including—

“(1) salaries, personnel costs, equipment costs, and other costs directly related to the operation of the program, including the enforcement unit;

“(2) payments for treatment providers that are approved by the relevant State or Tribal jurisdiction and licensed, if necessary, to provide needed treatment to eligible offenders participating in the program, including aftercare supervision, vocational training, education, and job placement; and

“(3) payments to public and nonprofit private entities that are approved by the State or Tribal jurisdiction and licensed, if necessary, to provide alcohol and drug addiction treatment to eligible offenders participating in the program.

“(f) **SUPPLEMENT NOT SUPPLANT.**—An eligible entity shall use Federal funds received under this section only to supplement the funds that would, in the absence of those Federal funds, be made available from other Federal and non-Federal sources for the activities described in this section, and not to supplant those funds. The Federal share of a grant made under this section may not exceed 50 percent of the total costs of the program described in an application under subsection (d).

“(g) GEOGRAPHIC DISTRIBUTION.—The Attorney General shall ensure that, to the extent practicable, the geographical distribution of grants under this section is equitable and includes a grant to an eligible entity in—

“(1) each State;

“(2) rural, suburban, and urban areas; and

“(3) Tribal jurisdictions.

“(h) REPORTS AND EVALUATIONS.—Each fiscal year, each recipient of a grant under this section during that fiscal year shall submit to the Attorney General a report on the outcomes of activities carried out using that grant in such form, containing such information, and on such dates as the Attorney General shall specify.

“(i) ACCOUNTABILITY.—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

“(1) AUDIT REQUIREMENT.—

“(A) DEFINITION.—In this paragraph, the term ‘unresolved audit finding’ means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date on which the final audit report is issued.

“(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

“(C) MANDATORY EXCLUSION.—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

“(D) PRIORITY.—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

“(E) REIMBURSEMENT.—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

“(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

“(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

“(2) NONPROFIT ORGANIZATION REQUIREMENTS.—

“(A) DEFINITION.—For purposes of this paragraph and the grant programs under this part, the term ‘nonprofit organization’ means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

“(B) PROHIBITION.—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

“(C) DISCLOSURE.—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such

compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

“(3) CONFERENCE EXPENDITURES.—

“(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than \$20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

“(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

“(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

“(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

“(A) indicating whether—

“(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

“(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

“(iii) all reimbursements required under paragraph (1)(E) have been made; and

“(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

“(5) PREVENTING DUPLICATIVE GRANTS.—

“(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

“(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

“(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

“(ii) the reason the Attorney General awarded the duplicate grants.”

SEC. 14014. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE.

Part HH of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa et seq.) is amended by adding at the end the following:

“SEC. 2992. NATIONAL CRIMINAL JUSTICE AND MENTAL HEALTH TRAINING AND TECHNICAL ASSISTANCE.

“(a) AUTHORITY.—The Attorney General may make grants to eligible organizations to provide for the establishment of a National Criminal Justice and Mental Health Training and Technical Assistance Center.

“(b) ELIGIBLE ORGANIZATION.—For purposes of subsection (a), the term ‘eligible organization’

means a national nonprofit organization that provides technical assistance and training to, and has special expertise and broad, national-level experience in, mental health, crisis intervention, criminal justice systems, law enforcement, translating evidence into practice, training, and research, and education and support of people with mental illness and the families of such individuals.

“(c) USE OF FUNDS.—Any organization that receives a grant under subsection (a) shall collaborate with other grant recipients to establish and operate a National Criminal Justice and Mental Health Training and Technical Assistance Center to—

“(1) provide law enforcement officer training regarding mental health and working with individuals with mental illnesses, with an emphasis on de-escalation of encounters between law enforcement officers and those with mental disorders or in crisis, which shall include support the development of in-person and technical information exchanges between systems and the individuals working in those systems in support of the concepts identified in the training;

“(2) provide education, training, and technical assistance for States, Indian tribes, territories, units of local government, service providers, nonprofit organizations, probation or parole officers, prosecutors, defense attorneys, emergency response providers, and corrections institutions to advance practice and knowledge relating to mental health crisis and approaches to mental health and criminal justice across systems;

“(3) provide training and best practices to mental health providers and criminal justice agencies relating to diversion initiatives, jail and prison strategies, reentry of individuals with mental illnesses into the community, and dispatch protocols and triage capabilities, including the establishment of learning sites;

“(4) develop suicide prevention and crisis intervention training and technical assistance for criminal justice agencies;

“(5) develop a receiving center system and pilot strategy that provides, for a jurisdiction, a single point of entry into the mental health and substance abuse system for assessments and appropriate placement of individuals experiencing a crisis;

“(6) collect data and best practices in mental health and criminal health and criminal justice initiatives and policies from grantees under this part, other recipients of grants under this section, Federal, State, and local agencies involved in the provision of mental health services, and nongovernmental organizations involved in the provision of mental health services;

“(7) develop and disseminate to mental health providers and criminal justice agencies evaluation tools, mechanisms, and measures to better assess and document performance measures and outcomes relating to the provision of mental health services;

“(8) disseminate information to States, units of local government, criminal justice agencies, law enforcement agencies, and other relevant entities about best practices, policy standards, and research findings relating to the provision of mental health services; and

“(9) provide education and support to individuals with mental illness involved with, or at risk of involvement with, the criminal justice system, including the families of such individuals.

“(d) ACCOUNTABILITY.—Grants awarded under this section shall be subject to the following accountability provisions:

“(1) AUDIT REQUIREMENT.—

“(A) DEFINITION.—In this paragraph, the term ‘unresolved audit finding’ means a finding in the final audit report of the Inspector General of the Department of Justice under subparagraph (C) that the audited grantee has used grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 1 year after the date on which the final audit report is issued.

“(B) AUDITS.—Beginning in the first fiscal year beginning after the date of enactment of this section, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of grantees under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

“(C) FINAL AUDIT REPORT.—The Inspector General of the Department of Justice shall submit to the Attorney General a final report on each audit conducted under subparagraph (B).

“(D) MANDATORY EXCLUSION.—Grantees under this section about which there is an unresolved audit finding shall not be eligible to receive a grant under this section during the 2 fiscal years beginning after the end of the 1-year period described in subparagraph (A).

“(E) PRIORITY.—In making grants under this section, the Attorney General shall give priority to applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

“(F) REIMBURSEMENT.—If an entity receives a grant under this section during the 2-fiscal-year period during which the entity is prohibited from receiving grants under subparagraph (D), the Attorney General shall—

“(i) deposit an amount equal to the amount of the grant that was improperly awarded to the grantee into the General Fund of the Treasury; and

“(ii) seek to recoup the costs of the repayment under clause (i) from the grantee that was erroneously awarded grant funds.

“(2) NONPROFIT AGENCY REQUIREMENTS.—

“(A) DEFINITION.—For purposes of this paragraph and the grant program under this section, the term ‘nonprofit agency’ means an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986 (26 U.S.C. 501(a)).

“(B) PROHIBITION.—The Attorney General may not award a grant under this section to a nonprofit agency that holds money in an offshore account for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986 (26 U.S.C. 511(a)).

“(C) DISCLOSURE.—Each nonprofit agency that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

“(3) CONFERENCE EXPENDITURES.—

“(A) LIMITATION.—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than \$20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

“(B) WRITTEN APPROVAL.—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

“(C) REPORT.—The Deputy Attorney General shall submit an annual report to the Committee

on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

“(4) ANNUAL CERTIFICATION.—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives an annual certification—

“(A) indicating whether—

“(i) all final audit reports issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

“(ii) all mandatory exclusions required under paragraph (1)(D) have been issued; and

“(iii) any reimbursements required under paragraph (1)(F) have been made; and

“(B) that includes a list of any grantees excluded under paragraph (1)(D) from the previous year.

“(5) PREVENTING DUPLICATIVE GRANTS.—

“(A) IN GENERAL.—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

“(B) REPORT.—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

“(i) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

“(ii) the reason the Attorney General awarded the duplicate grants.”

SEC. 14015. IMPROVING DEPARTMENT OF JUSTICE DATA COLLECTION ON MENTAL ILLNESS INVOLVED IN CRIME.

(a) IN GENERAL.—Notwithstanding any other provision of law, on or after the date that is 90 days after the date on which the Attorney General promulgates regulations under subsection (b), any data prepared by, or submitted to, the Attorney General or the Director of the Federal Bureau of Investigation with respect to the incidences of homicides, law enforcement officers killed, seriously injured, and assaulted, or individuals killed or seriously injured by law enforcement officers shall include data with respect to the involvement of mental illness in such incidences, if any.

(b) REGULATIONS.—Not later than 90 days after the date of the enactment of this Act, the Attorney General shall promulgate or revise regulations as necessary to carry out subsection (a).

SEC. 14016. REPORTS ON THE NUMBER OF MENTALLY ILL OFFENDERS IN PRISON.

(a) REPORT ON THE COST OF TREATING THE MENTALLY ILL IN THE CRIMINAL JUSTICE SYSTEM.—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report detailing the cost of imprisonment for individuals who have serious mental illness by the Federal Government or a State or unit of local government, which shall include—

(1) the number and type of crimes committed by individuals with serious mental illness each year; and

(2) detail strategies or ideas for preventing crimes by those individuals with serious mental illness from occurring.

(b) DEFINITION.—For purposes of this section, the Attorney General, in consultation with the Assistant Secretary of Mental Health and Substance Use Disorders, shall define “serious mental illness” based on the “Health Care Reform for Americans with Severe Mental Illnesses: Report” of the National Advisory Mental Health

Council, *American Journal of Psychiatry* 1993; 150:1447–1465.

SEC. 14017. CODIFICATION OF DUE PROCESS FOR DETERMINATIONS BY SECRETARY OF VETERANS AFFAIRS OF MENTAL CAPACITY OF BENEFICIARIES.

(a) IN GENERAL.—Chapter 55 of title 38, United States Code, is amended by inserting after section 5501 the following new section:

“§5501A. Beneficiaries’ rights in mental competence determinations

“The Secretary may not make an adverse determination concerning the mental capacity of a beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title unless such beneficiary has been provided all of the following, subject to the procedures and timelines prescribed by the Secretary for determinations of incompetency:

“(1) Notice of the proposed adverse determination and the supporting evidence.

“(2) An opportunity to request a hearing.

“(3) An opportunity to present evidence, including an opinion from a medical professional or other person, on the capacity of the beneficiary to manage monetary benefits paid to or for the beneficiary by the Secretary under this title.

“(4) An opportunity to be represented at no expense to the Government (including by counsel) at any such hearing and to bring a medical professional or other person to provide relevant testimony at any such hearing.”

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter 55 is amended by inserting after the item relating to section 5501 the following new item:

“5501A. Beneficiaries’ rights in mental competence determinations”.

(c) EFFECTIVE DATE.—Section 5501A of title 38, United States Code, as added by subsection (a), shall apply to determinations made by the Secretary of Veterans Affairs on or after the date of the enactment of this Act.

SEC. 14018. REAUTHORIZATION OF APPROPRIATIONS.

Subsection (o) of section 2991 of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as redesignated by section 14006, is amended—

(1) in paragraph (1)(C), by striking “2009 through 2014” and inserting “2017 through 2021”; and

(2) by adding at the end the following:

“(3) LIMITATION.—Not more than 20 percent of the funds authorized to be appropriated under this section may be used for purposes described in subsection (i) (relating to veterans).”

Subtitle B—Comprehensive Justice and Mental Health

SEC. 14021. SEQUENTIAL INTERCEPT MODEL.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa), as amended by section 14005, is amended by inserting after subsection (j), the following:

“(k) SEQUENTIAL INTERCEPT GRANTS.—

“(1) DEFINITION.—In this subsection, the term ‘eligible entity’ means a State, unit of local government, Indian tribe, or tribal organization.

“(2) AUTHORIZATION.—The Attorney General may make grants under this subsection to an eligible entity for sequential intercept mapping and implementation in accordance with paragraph (3).

“(3) SEQUENTIAL INTERCEPT MAPPING; IMPLEMENTATION.—An eligible entity that receives a grant under this subsection may use funds for—

“(A) sequential intercept mapping, which—

“(i) shall consist of—

“(I) convening mental health and criminal justice stakeholders to—

“(aa) develop a shared understanding of the flow of justice-involved individuals with mental illnesses through the criminal justice system; and

“(bb) identify opportunities for improved collaborative responses to the risks and needs of individuals described in item (aa); and

“(II) developing strategies to address gaps in services and bring innovative and effective programs to scale along multiple intercepts, including—

“(aa) emergency and crisis services;
“(bb) specialized police-based responses;
“(cc) court hearings and disposition alternatives;

“(dd) reentry from jails and prisons; and
“(ee) community supervision, treatment and support services; and

“(ii) may serve as a starting point for the development of strategic plans to achieve positive public health and safety outcomes; and

“(B) implementation, which shall—
“(i) be derived from the strategic plans described in subparagraph (A)(ii); and

“(ii) consist of—
“(I) hiring and training personnel;
“(II) identifying the eligible entity’s target population;

“(III) providing services and supports to reduce unnecessary penetration into the criminal justice system;

“(IV) reducing recidivism;
“(V) evaluating the impact of the eligible entity’s approach; and

“(VI) planning for the sustainability of effective interventions.”

SEC. 14022. PRISON AND JAILS.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (k), as added by section 14021, the following:

“(I) CORRECTIONAL FACILITIES.—

“(1) DEFINITIONS.—
“(A) CORRECTIONAL FACILITY.—The term ‘correctional facility’ means a jail, prison, or other detention facility used to house people who have been arrested, detained, held, or convicted by a criminal justice agency or a court.
“(B) ELIGIBLE INMATE.—The term ‘eligible inmate’ means an individual who—

“(i) is being held, detained, or incarcerated in a correctional facility; and

“(ii) manifests obvious signs of a mental illness or has been diagnosed by a qualified mental health professional as having a mental illness.

“(2) CORRECTIONAL FACILITY GRANTS.—The Attorney General may award grants to applicants to enhance the capabilities of a correctional facility—

“(A) to identify and screen for eligible inmates;

“(B) to plan and provide—
“(i) initial and periodic assessments of the clinical, medical, and social needs of inmates; and

“(ii) appropriate treatment and services that address the mental health and substance abuse needs of inmates;

“(C) to develop, implement, and enhance—
“(i) post-release transition plans for eligible inmates that, in a comprehensive manner, coordinate health, housing, medical, employment, and other appropriate services and public benefits;

“(ii) the availability of mental health care services and substance abuse treatment services; and

“(iii) alternatives to solitary confinement and segregated housing and mental health screening and treatment for inmates placed in solitary confinement or segregated housing; and

“(D) to train each employee of the correctional facility to identify and appropriately respond to incidents involving inmates with mental health or co-occurring mental health and substance abuse disorders.”

SEC. 14023. ALLOWABLE USES.

Section 2991(b)(5)(I) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(b)(5)(I)) is amended by adding at the end the following:

“(v) TEAMS ADDRESSING FREQUENT USERS OF CRISIS SERVICES.—Multidisciplinary teams that—

“(I) coordinate, implement, and administer community-based crisis responses and long-term plans for frequent users of crisis services;

“(II) provide training on how to respond appropriately to the unique issues involving frequent users of crisis services for public service personnel, including criminal justice, mental health, substance abuse, emergency room, healthcare, law enforcement, corrections, and housing personnel;

“(III) develop or support alternatives to hospital and jail admissions for frequent users of crisis services that provide treatment, stabilization, and other appropriate supports in the least restrictive, yet appropriate, environment; and

“(IV) develop protocols and systems among law enforcement, mental health, substance abuse, housing, corrections, and emergency medical service operations to provide coordinated assistance to frequent users of crisis services.”

SEC. 14024. LAW ENFORCEMENT TRAINING.

Section 2991(h) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(h)) is amended—

(1) in paragraph (1), by adding at the end the following:

“(F) ACADEMY TRAINING.—To provide support for academy curricula, law enforcement officer orientation programs, continuing education training, and other programs that teach law enforcement personnel how to identify and respond to incidents involving persons with mental health disorders or co-occurring mental health and substance abuse disorders.”; and

(2) by adding at the end the following:

“(4) PRIORITY CONSIDERATION.—The Attorney General, in awarding grants under this subsection, shall give priority to programs that law enforcement personnel and members of the mental health and substance abuse professions develop and administer cooperatively.”

SEC. 14025. FEDERAL LAW ENFORCEMENT TRAINING.

Not later than 1 year after the date of enactment of this Act, the Attorney General shall provide direction and guidance for the following:

(1) TRAINING PROGRAMS.—Programs that offer specialized and comprehensive training, in procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to first responders and tactical units of—

(A) Federal law enforcement agencies; and
(B) other Federal criminal justice agencies such as the Bureau of Prisons, the Administrative Office of the United States Courts, and other agencies that the Attorney General determines appropriate.

(2) IMPROVED TECHNOLOGY.—The establishment of, or improvement of existing, computerized information systems to provide timely information to employees of Federal law enforcement agencies, and Federal criminal justice agencies to improve the response of such employees to situations involving individuals who have a mental illness.

SEC. 14026. GAO REPORT.

Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in coordination with the Attorney General, shall submit to Congress a report on—

(1) the practices that Federal first responders, tactical units, and corrections officers are trained to use in responding to individuals with mental illness;

(2) procedures to identify and appropriately respond to incidents in which the unique needs of individuals who have a mental illness are involved, to Federal first responders and tactical units;

(3) the application of evidence-based practices in criminal justice settings to better address individuals with mental illnesses; and

(4) recommendations on how the Department of Justice can expand and improve information sharing and dissemination of best practices.

SEC. 14027. EVIDENCE BASED PRACTICES.

Section 2991(c) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(c)) is amended—

(1) in paragraph (3), by striking “or” at the end;

(2) by redesignating paragraph (4) as paragraph (6); and

(3) by inserting after paragraph (3), the following:

“(4) propose interventions that have been shown by empirical evidence to reduce recidivism;

“(5) when appropriate, use validated assessment tools to target preliminarily qualified offenders with a moderate or high risk of recidivism and a need for treatment and services; or”.

SEC. 14028. TRANSPARENCY, PROGRAM ACCOUNTABILITY, AND ENHANCEMENT OF LOCAL AUTHORITY.

(a) IN GENERAL.—Section 2991(a) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(a)) is amended—

(1) in paragraph (7)—

(A) in the heading, by striking “MENTAL ILLNESS” and inserting “MENTAL ILLNESS; MENTAL HEALTH DISORDER”; and

(B) by striking “term ‘mental illness’ means” and inserting “terms ‘mental illness’ and ‘mental health disorder’ mean”; and

(2) by striking paragraph (9) and inserting the following:

“(9) PRELIMINARILY QUALIFIED OFFENDER.—

“(A) IN GENERAL.—The term ‘preliminarily qualified offender’ means an adult or juvenile accused of an offense who—

“(i)(I) previously or currently has been diagnosed by a qualified mental health professional as having a mental illness or co-occurring mental illness and substance abuse disorders;

“(II) manifests obvious signs of mental illness or co-occurring mental illness and substance abuse disorders during arrest or confinement or before any court; or

“(III) in the case of a veterans treatment court provided under subsection (i), has been diagnosed with, or manifests obvious signs of, mental illness or a substance abuse disorder or co-occurring mental illness and substance abuse disorder;

“(ii) has been unanimously approved for participation in a program funded under this section by, when appropriate—

“(I) the relevant—

“(aa) prosecuting attorney;

“(bb) defense attorney;

“(cc) probation or corrections official; and

“(dd) judge; and

“(II) a representative from the relevant mental health agency described in subsection (b)(5)(B)(i);

“(iii) has been determined, by each person described in clause (ii) who is involved in approving the adult or juvenile for participation in a program funded under this section, to not pose a risk of violence to any person in the program, or the public, if selected to participate in the program; and

“(iv) has not been charged with or convicted of—

“(I) any sex offense (as defined in section 111 of the Sex Offender Registration and Notification Act (42 U.S.C. 16911)) or any offense relating to the sexual exploitation of children; or

“(II) murder or assault with intent to commit murder.

“(B) DETERMINATION.—In determining whether to designate a defendant as a preliminarily qualified offender, the relevant prosecuting attorney, defense attorney, probation or corrections official, judge, and mental health or substance abuse agency representative shall take into account—

“(i) whether the participation of the defendant in the program would pose a substantial risk of violence to the community;

“(ii) the criminal history of the defendant and the nature and severity of the offense for which the defendant is charged;

“(iii) the views of any relevant victims to the offense;

“(iv) the extent to which the defendant would benefit from participation in the program;

“(v) the extent to which the community would realize cost savings because of the defendant’s participation in the program; and

“(vi) whether the defendant satisfies the eligibility criteria for program participation unanimously established by the relevant prosecuting attorney, defense attorney, probation or corrections official, judge and mental health or substance abuse agency representative.”.

(b) **TECHNICAL AND CONFORMING AMENDMENT.**—Section 2927(2) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797s–6(2)) is amended by striking “has the meaning given that term in section 2991(a).” and inserting “means an offense that—

“(A) does not have as an element the use, attempted use, or threatened use of physical force against the person or property of another; or

“(B) is not a felony that by its nature involves a substantial risk that physical force against the person or property of another may be used in the course of committing the offense.”.

SEC. 14029. GRANT ACCOUNTABILITY.

Section 2991 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa) is amended by inserting after subsection (l), as added by section 14022, the following:

“(m) **ACCOUNTABILITY.**—All grants awarded by the Attorney General under this section shall be subject to the following accountability provisions:

“(1) **AUDIT REQUIREMENT.**—

“(A) **DEFINITION.**—In this paragraph, the term ‘unresolved audit finding’ means a finding in the final audit report of the Inspector General of the Department of Justice that the audited grantee has utilized grant funds for an unauthorized expenditure or otherwise unallowable cost that is not closed or resolved within 12 months from the date when the final audit report is issued.

“(B) **AUDITS.**—Beginning in the first fiscal year beginning after the date of enactment of this subsection, and in each fiscal year thereafter, the Inspector General of the Department of Justice shall conduct audits of recipients of grants under this section to prevent waste, fraud, and abuse of funds by grantees. The Inspector General shall determine the appropriate number of grantees to be audited each year.

“(C) **MANDATORY EXCLUSION.**—A recipient of grant funds under this section that is found to have an unresolved audit finding shall not be eligible to receive grant funds under this section during the first 2 fiscal years beginning after the end of the 12-month period described in subparagraph (A).

“(D) **PRIORITY.**—In awarding grants under this section, the Attorney General shall give priority to eligible applicants that did not have an unresolved audit finding during the 3 fiscal years before submitting an application for a grant under this section.

“(E) **REIMBURSEMENT.**—If an entity is awarded grant funds under this section during the 2-fiscal-year period during which the entity is barred from receiving grants under subparagraph (C), the Attorney General shall—

“(i) deposit an amount equal to the amount of the grant funds that were improperly awarded to the grantee into the General Fund of the Treasury; and

“(ii) seek to recoup the costs of the repayment to the fund from the grant recipient that was erroneously awarded grant funds.

“(2) **NONPROFIT ORGANIZATION REQUIREMENTS.**—

“(A) **DEFINITION.**—For purposes of this paragraph and the grant programs under this part, the term ‘nonprofit organization’ means an or-

ganization that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Code.

“(B) **PROHIBITION.**—The Attorney General may not award a grant under this part to a nonprofit organization that holds money in offshore accounts for the purpose of avoiding paying the tax described in section 511(a) of the Internal Revenue Code of 1986.

“(C) **DISCLOSURE.**—Each nonprofit organization that is awarded a grant under this section and uses the procedures prescribed in regulations to create a rebuttable presumption of reasonableness for the compensation of its officers, directors, trustees, and key employees, shall disclose to the Attorney General, in the application for the grant, the process for determining such compensation, including the independent persons involved in reviewing and approving such compensation, the comparability data used, and contemporaneous substantiation of the deliberation and decision. Upon request, the Attorney General shall make the information disclosed under this subparagraph available for public inspection.

“(3) **CONFERENCE EXPENDITURES.**—

“(A) **LIMITATION.**—No amounts made available to the Department of Justice under this section may be used by the Attorney General, or by any individual or entity awarded discretionary funds through a cooperative agreement under this section, to host or support any expenditure for conferences that uses more than \$20,000 in funds made available by the Department of Justice, unless the head of the relevant agency or department, provides prior written authorization that the funds may be expended to host the conference.

“(B) **WRITTEN APPROVAL.**—Written approval under subparagraph (A) shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

“(C) **REPORT.**—The Deputy Attorney General shall submit an annual report to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives on all conference expenditures approved under this paragraph.

“(4) **ANNUAL CERTIFICATION.**—Beginning in the first fiscal year beginning after the date of enactment of this subsection, the Attorney General shall submit, to the Committee on the Judiciary and the Committee on Appropriations of the Senate and the Committee on the Judiciary and the Committee on Appropriations of the House of Representatives, an annual certification—

“(A) indicating whether—

“(i) all audits issued by the Office of the Inspector General under paragraph (1) have been completed and reviewed by the appropriate Assistant Attorney General or Director;

“(ii) all mandatory exclusions required under paragraph (1)(C) have been issued; and

“(iii) all reimbursements required under paragraph (1)(E) have been made; and

“(B) that includes a list of any grant recipients excluded under paragraph (1) from the previous year.

“(n) **PREVENTING DUPLICATIVE GRANTS.**—

“(1) **IN GENERAL.**—Before the Attorney General awards a grant to an applicant under this section, the Attorney General shall compare potential grant awards with other grants awarded under this Act to determine if duplicate grant awards are awarded for the same purpose.

“(2) **REPORT.**—If the Attorney General awards duplicate grants to the same applicant for the same purpose the Attorney General shall submit to the Committee on the Judiciary of the Senate and the Committee on the Judiciary of the House of Representatives a report that includes—

“(A) a list of all duplicate grants awarded, including the total dollar amount of any duplicate grants awarded; and

“(B) the reason the Attorney General awarded the duplicate grants.”.

DIVISION C—INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

SEC. 15000. SHORT TITLE.

This division may be cited as the “Increasing Choice, Access, and Quality in Health Care for Americans Act”.

TITLE XV—PROVISIONS RELATING TO MEDICARE PART A

SEC. 15001. DEVELOPMENT OF HCPCS VERSION OF MS-DRG CODES FOR SIMILAR HOSPITAL SERVICES.

Section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended by adding at the end the following new subsection:

“(t) **RELATING SIMILAR INPATIENT AND OUTPATIENT HOSPITAL SERVICES.**—

“(1) **DEVELOPMENT OF HCPCS VERSION OF MS-DRG CODES.**—Not later than January 1, 2018, the Secretary shall develop HCPCS versions for MS-DRGs that are similar to the ICD-10-PCS for such MS-DRGs such that, to the extent possible, the MS-DRG assignment shall be similar for a claim coded with the HCPCS version as an identical claim coded with a ICD-10-PCS code.

“(2) **COVERAGE OF SURGICAL MS-DRGS.**—In carrying out paragraph (1), the Secretary shall develop HCPCS versions of MS-DRG codes for not fewer than 10 surgical MS-DRGs.

“(3) **PUBLICATION AND DISSEMINATION OF THE HCPCS VERSIONS OF MS-DRGS.**—

“(A) **IN GENERAL.**—The Secretary shall develop a HCPCS MS-DRG definitions manual and software that is similar to the definitions manual and software for ICD-10-PCS codes for such MS-DRGs. The Secretary shall post the HCPCS MS-DRG definitions manual and software on the Internet website of the Centers for Medicare & Medicaid Services. The HCPCS MS-DRG definitions manual and software shall be in the public domain and available for use and redistribution without charge.

“(B) **USE OF PREVIOUS ANALYSIS DONE BY MEDPAC.**—In developing the HCPCS MS-DRG definitions manual and software under subparagraph (A), the Secretary shall consult with the Medicare Payment Advisory Commission and shall consider the analysis done by such Commission in translating outpatient surgical claims into inpatient surgical MS-DRGs in preparing chapter 7 (relating to hospital short-stay policy issues) of its ‘Medicare and the Health Care Delivery System’ report submitted to Congress in June 2015.

“(4) **DEFINITION AND REFERENCE.**—In this subsection:

“(A) **HCPCS.**—The term ‘HCPCS’ means, with respect to hospital items and services, the code under the Healthcare Common Procedure Coding System (HCPCS) (or a successor code) for such items and services.

“(B) **ICD-10-PCS.**—The term ‘ICD-10-PCS’ means the International Classification of Diseases, 10th Revision, Procedure Coding System, and includes any subsequent revision of such International Classification of Diseases, Procedure Coding System.”.

SEC. 15002. ESTABLISHING BENEFICIARY EQUITY IN THE MEDICARE HOSPITAL READMISSION PROGRAM.

(a) **TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLE POPULATION.**—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)) is amended—

(1) in subparagraph (A), by inserting “subject to subparagraph (D),” after “purposes of paragraph (1),”; and

(2) by adding at the end the following new subparagraph:

“(D) **TRANSITIONAL ADJUSTMENT FOR DUAL ELIGIBLES.**—

“(i) **IN GENERAL.**—In determining a hospital’s adjustment factor under this paragraph for purposes of making payments for discharges occurring during and after fiscal year 2019, and before the application of clause (i) of subparagraph (E), the Secretary shall assign hospitals

to groups (as defined by the Secretary under clause (ii)) and apply the applicable provisions of this subsection using a methodology in a manner that allows for separate comparison of hospitals within each such group, as determined by the Secretary.

“(ii) **DEFINING GROUPS.**—For purposes of this subparagraph, the Secretary shall define groups of hospitals, based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under part A, and who are full-benefit dual eligible individuals (as defined in section 1935(c)(6)). In defining groups, the Secretary shall consult the Medicare Payment Advisory Commission and may consider the analysis done by such Commission in preparing the portion of its report submitted to Congress in June 2013 relating to readmissions.

“(iii) **MINIMIZING REPORTING BURDEN ON HOSPITALS.**—In carrying out this subparagraph, the Secretary shall not impose any additional reporting requirements on hospitals.

“(iv) **BUDGET NEUTRAL DESIGN METHODOLOGY.**—The Secretary shall design the methodology to implement this subparagraph so that the estimated total amount of reductions in payments under this subsection equals the estimated total amount of reductions in payments that would otherwise occur under this subsection if this subparagraph did not apply.”

(b) **CHANGES IN RISK ADJUSTMENT.**—Section 1886(q)(3) of the Social Security Act (42 U.S.C. 1395ww(q)(3)), as amended by subsection (a), is further amended by adding at the end the following new subparagraph:

“(E) **RISK ADJUSTMENT.**—

“(i) **CONSIDERATION OF RECOMMENDATIONS IN IMPACT REPORTS.**—The Secretary may take into account the studies conducted and the recommendations made by the Secretary under section 2(d)(1) of the IMPACT Act of 2014 (Public Law 113-185; 42 U.S.C. 1395lll note) with respect to the application under this subsection of risk adjustment methodologies. Nothing in this clause shall be construed as precluding consideration of the use of groupings of hospitals.

“(ii) **CONSIDERATION OF EXCLUSION OF PATIENT CASES BASED ON V OR OTHER APPROPRIATE CODES.**—In promulgating regulations to carry out this subsection with respect to discharges occurring after fiscal year 2018, the Secretary may consider the use of V or other ICD-related codes for removal of a readmission. The Secretary may consider modifying measures under this subsection to incorporate V or other ICD-related codes at the same time as other changes are being made under this subparagraph.

“(iii) **REMOVAL OF CERTAIN READMISSIONS.**—In promulgating regulations to carry out this subsection, with respect to discharges occurring after fiscal year 2018, the Secretary may consider removal as a readmission of an admission that is classified within one or more of the following: transplants, end-stage renal disease, burns, trauma, psychosis, or substance abuse. The Secretary may consider modifying measures under this subsection to remove readmissions at the same time as other changes are being made under this subparagraph.”

(c) **MEDPAC STUDY ON READMISSIONS PROGRAM.**—The Medicare Payment Advisory Commission shall conduct a study to review overall hospital readmissions described in section 1886(q)(5)(E) of the Social Security Act (42 U.S.C. 1395ww(q)(5)(E)) and whether such readmissions are related to any changes in inpatient and emergency services furnished. The Commission shall submit to Congress a report on such study in its report to Congress in June 2018.

SEC. 15003. FIVE-YEAR EXTENSION OF THE RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.

(a) **EXTENSION.**—Section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173; 42 U.S.C. 1395ww note) is amended—

(1) in subsection (a)(5), by striking “5-year extension period” and inserting “10-year extension period”; and

(2) in subsection (g)—

(A) in the subsection heading, by striking “FIVE-YEAR” and inserting “TEN-YEAR”;

(B) in paragraph (1), by striking “additional 5-year” and inserting “additional 10-year”;

(C) by striking “5-year extension period” and inserting “10-year extension period” each place it appears;

(D) in paragraph (4)(B)—

(i) in the matter preceding clause (i), by inserting “each 5-year period in” after “hospital during”; and

(ii) in clause (i), by inserting “each applicable 5-year period in” after “the first day of”; and

(E) by adding at the end the following new paragraphs:

“(5) **OTHER HOSPITALS IN DEMONSTRATION PROGRAM.**—During the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of paragraph (4) to rural community hospitals that are not described in paragraph (4) but are participating in the demonstration program under this section as of December 30, 2014, in a similar manner as such provisions apply to rural community hospitals described in paragraph (4).

“(6) **EXPANSION OF DEMONSTRATION PROGRAM TO RURAL AREAS IN ANY STATE.**—

“(A) **IN GENERAL.**—The Secretary shall, notwithstanding subsection (a)(2) or paragraph (2) of this subsection, not later than 120 days after the date of the enactment of this paragraph, issue a solicitation for applications to select up to the maximum number of additional rural community hospitals located in any State to participate in the demonstration program under this section for the second 5 years of the 10-year extension period without exceeding the limitation under paragraph (3) of this subsection.

“(B) **PRIORITY.**—In determining which rural community hospitals that submitted an application pursuant to the solicitation under subparagraph (A) to select for participation in the demonstration program, the Secretary—

“(i) shall give priority to rural community hospitals located in one of the 20 States with the lowest population densities (as determined by the Secretary using the 2015 Statistical Abstract of the United States); and

“(ii) may consider—

“(I) closures of hospitals located in rural areas in the State in which the rural community hospital is located during the 5-year period immediately preceding the date of the enactment of this paragraph; and

“(II) the population density of the State in which the rural community hospital is located.”

(b) **CHANGE IN TIMING FOR REPORT.**—Subsection (e) of such section 410A is amended—

(1) by striking “Not later than 6 months after the completion of the demonstration program under this section” and inserting “Not later than August 1, 2018”; and

(2) by striking “such program” and inserting “the demonstration program under this section”.

SEC. 15004. REGULATORY RELIEF FOR LTCHS.

(a) **TECHNICAL CHANGE TO THE MEDICARE LONG-TERM CARE HOSPITAL MORATORIUM EXCEPTION.**—

(1) **IN GENERAL.**—Section 114(d)(7) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by sections 3106(b) and 10312(b) of Public Law 111-148, section 1206(b)(2) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67), and section 112 of the Protecting Access to Medicare Act of 2014 (Public Law 113-93), is amended by striking “The moratorium under paragraph (1)(A)” and inserting “Any moratorium under paragraph (1)”.

(2) **EFFECTIVE DATE.**—The amendment made by paragraph (1) shall take effect as if included

in the enactment of section 112 of the Protecting Access to Medicare Act of 2014.

(b) **MODIFICATION TO MEDICARE LONG-TERM CARE HOSPITAL HIGH COST OUTLIER PAYMENTS.**—Section 1886(m) of the Social Security Act (42 U.S.C. 1395ww(m)) is amended by adding at the end the following new paragraph:

“(7) **TREATMENT OF HIGH COST OUTLIER PAYMENTS.**—

“(A) **ADJUSTMENT TO THE STANDARD FEDERAL PAYMENT RATE FOR ESTIMATED HIGH COST OUTLIER PAYMENTS.**—Under the system described in paragraph (1), for fiscal years beginning on or after October 1, 2017, the Secretary shall reduce the standard Federal payment rate as if the estimated aggregate amount of high cost outlier payments for standard Federal payment rate discharges for each such fiscal year would be equal to 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

“(B) **LIMITATION ON HIGH COST OUTLIER PAYMENT AMOUNTS.**—Notwithstanding subparagraph (A), the Secretary shall set the fixed loss amount for high cost outlier payments such that the estimated aggregate amount of high cost outlier payments made for standard Federal payment rate discharges for fiscal years beginning on or after October 1, 2017, shall be equal to 99.6875 percent of 8 percent of estimated aggregate payments for standard Federal payment rate discharges for each such fiscal year.

“(C) **WAIVER OF BUDGET NEUTRALITY.**—Any reduction in payments resulting from the application of subparagraph (B) shall not be taken into account in applying any budget neutrality provision under such system.

“(D) **NO EFFECT ON SITE NEUTRAL HIGH COST OUTLIER PAYMENT RATE.**—This paragraph shall not apply with respect to the computation of the applicable site neutral payment rate under paragraph (6).”

SEC. 15005. SAVINGS FROM IPSS MACRA PAY-FOR-THROUGH NOT APPLYING DOCUMENTATION AND CODING ADJUSTMENTS.

Section 7(b)(1)(B) of the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (Public Law 110-90), as amended by section 631(b) of the American Taxpayer Relief Act of 2012 (Public Law 112-240) and section 414(1)(B)(iii) of the Medicare Access and CHIP Reauthorization Act of 2015 (Public Law 114-10), is amended in clause (iii) by striking “an increase of 0.5 percentage points for discharges occurring during each of fiscal years 2018 through 2023” and inserting “an increase of 0.4588 percentage points for discharges occurring during fiscal year 2018 and 0.5 percentage points for discharges occurring during each of fiscal years 2019 through 2023”.

SEC. 15006. EXTENSION OF CERTAIN LTCH MEDICARE PAYMENT RULES.

(a) **25-PERCENT PATIENT THRESHOLD PAYMENT ADJUSTMENT.**—Section 114(c)(1)(A) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111-5), sections 3106(a) and 10312(a) of Public Law 111-148, and section 1206(b)(1)(B) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67), is amended by striking “for a 9-year period” and inserting “through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017”.

(b) **PAYMENT FOR HOSPITALS-WITHIN-HOSPITALS.**—Section 114(c)(2) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (42 U.S.C. 1395ww note), as amended by section 4302(a) of division B of the American Recovery and Reinvestment Act (Public Law 111-5), sections 3106(a) and 10312(a) of Public Law 111-148, and section 1206(b)(1)(A) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67), is amended—

(1) in subparagraph (A), by inserting “or any similar provision,” after “Regulations.”;

(2) in subparagraph (B)—

(A) in clause (i), by inserting “or any similar provision,” after “Regulations.”; and

(B) in clause (ii), by inserting “, or any similar provision,” after “Regulations.”; and

(3) in subparagraph (C), by striking “for a 9-year period” and inserting “through June 30, 2016, and for discharges occurring on or after October 1, 2016, and before October 1, 2017”.

SEC. 15007. APPLICATION OF RULES ON THE CALCULATION OF HOSPITAL LENGTH OF STAY TO ALL LTCHS.

(a) IN GENERAL.—Section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67; 42 U.S.C. 1395ww note) is amended—

(1) by striking subparagraph (B);

(2) by striking “SITE NEUTRAL BASIS.—” and all that follows through “For discharges occurring” and inserting “SITE NEUTRAL BASIS.—For discharges occurring”;

(3) by striking “subject to subparagraph (B).”; and

(4) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and moving each of such subparagraphs (as so redesignated) 2 ems to the left.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall be effective as if included in the enactment of section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (division B of Public Law 113-67; 42 U.S.C. 1395ww note).

SEC. 15008. CHANGE IN MEDICARE CLASSIFICATION FOR CERTAIN HOSPITALS.

(a) IN GENERAL.—Section (d)(1)(B)(iv) of section 1886 of the Social Security Act (42 U.S.C. 1395ww) is amended—

(1) in subclause (I), by striking “or” at the end;

(2) in subclause (II)—

(A) by striking “, or” at the end and inserting a semicolon;

(B) by redesignating such subclause as clause (vi) and by moving it to immediately follow clause (v); and

(C) in clause (v), by striking the semicolon at the end and inserting “, or”; and

(3) by striking “(iv)(I) a hospital” and inserting “(iv) a hospital”.

(b) CONFORMING PAYMENT REFERENCES.—The second sentence of subsection (d)(1)(B) of such section is amended—

(1) by inserting “(as in effect as of such date)” after “clause (iv)”;

(2) by inserting “(or, in the case of a hospital described in clause (iv)(II), as so in effect, shall be classified under clause (vi) on and after the effective date of such clause (vi) and for cost reporting periods beginning on or after January 1, 2015, shall not be subject to subsection (m) as of the date of such classification)” after “so classified”.

(c) APPLICATION.—

(1) IN GENERAL.—For cost reporting periods beginning on or after January 1, 2015, in the case of an applicable hospital (as defined in paragraph (3)), the following shall apply:

(A) Payment for inpatient operating costs shall be made on a reasonable cost basis in the manner provided in section 412.526(c)(3) of title 42, Code of Federal Regulations (as in effect on January 1, 2015) and in any subsequent modifications.

(B) Payment for capital costs shall be made in the manner provided by section 412.526(c)(4) of title 42, Code of Federal Regulations (as in effect on such date).

(C) Claims for payment for Medicare beneficiaries who are discharged on or after January 1, 2017, shall be processed as claims which are paid on a reasonable cost basis as described in section 412.526(c) of title 42, Code of Federal Regulations (as in effect on such date).

(2) APPLICABLE HOSPITAL DEFINED.—In this subsection, the term “applicable hospital” means a hospital that is classified under clause (iv)(II) of section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) on the

day before the date of the enactment of this Act and which is classified under clause (vi) of such section, as redesignated and moved by subsection (a), on or after such date of enactment.

(d) CONFORMING TECHNICAL AMENDMENTS.—

(1) Section 1899B(a)(2)(A)(iv) of the Social Security Act (42 U.S.C. 1395ll(a)(2)(A)(iv)) is amended by striking “1886(d)(1)(B)(iv)(II)” and inserting “1886(d)(1)(B)(vi)”.

(2) Section 1886(m)(5)(F) of such Act (42 U.S.C. 1395ww(m)(5)(F)) is amended in each of clauses (i) and (ii) by striking “(d)(1)(B)(iv)(II)” and inserting “(d)(1)(B)(vi)”.

SEC. 15009. TEMPORARY EXCEPTION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.

(a) EXCEPTION.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)) is amended—

(1) in subparagraph (A)(i), by striking “and (E)” and inserting “, (E), and (F)”;

(2) by adding at the end the following new subparagraph:

“(F) TEMPORARY EXCEPTION FOR CERTAIN SPINAL CORD SPECIALTY HOSPITALS.—For discharges in cost reporting periods beginning during fiscal years 2018 and 2019, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge is from a long-term care hospital that meets each of the following requirements:

“(i) NOT-FOR-PROFIT.—The long-term care hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data.

“(ii) PRIMARILY PROVIDING TREATMENT FOR CATASTROPHIC SPINAL CORD OR ACQUIRED BRAIN INJURIES OR OTHER PARALYZING NEUROMUSCULAR CONDITIONS.—Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under this section, at least 50 percent were classified under MS-LTCH-DRGs 28, 29, 52, 57, 551, 573, and 963.

“(iii) SIGNIFICANT OUT-OF-STATE ADMISSIONS.—

“(I) IN GENERAL.—The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under this title and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States, determined by the States of residency of such inpatients and based on such data submitted by the hospital to the Secretary as the Secretary may require.

“(II) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement subclause (I) by program instruction or otherwise.

“(III) NON-APPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to data collected under this clause.”.

(b) STUDY AND REPORT ON THE STATUS AND VIABILITY OF CERTAIN SPINAL CORD SPECIALTY LONG-TERM CARE HOSPITALS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on long-term care hospitals described in section 1886(m)(6)(F) of the Social Security Act, as added by subsection (a). Such report shall include an analysis of the following:

(A) The impact on such hospitals of the classification and facility licensure by State agencies of such hospitals.

(B) The Medicare payment rates for such hospitals.

(C) Data on the number and health care needs of Medicare beneficiaries who have been diagnosed with catastrophic spinal cord or acquired brain injuries or other paralyzing neuromuscular conditions (as described within the discharge classifications specified in clause (ii) of such section) who are receiving services from such hospitals.

(2) REPORT.—Not later than October 1, 2018, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 15010. TEMPORARY EXTENSION TO THE APPLICATION OF THE MEDICARE LTCH SITE NEUTRAL PROVISIONS FOR CERTAIN DISCHARGES WITH SEVERE WOUNDS.

(a) IN GENERAL.—Section 1886(m)(6) of the Social Security Act (42 U.S.C. 1395ww(m)(6)), as amended by section 15009, is further amended—

(1) in subparagraph (A)(i) by striking “and (F)” and inserting “(F), and (G)”;

(2) in subparagraph (E)(i)(I)(aa), by striking “the amendment made” and all that follows before the semicolon and inserting “the last sentence of subsection (d)(1)(B)”;

(3) by adding at the end the following new subparagraph:

“(G) ADDITIONAL TEMPORARY EXCEPTION FOR CERTAIN SEVERE WOUND DISCHARGES FROM CERTAIN LONG-TERM CARE HOSPITALS.—

“(i) IN GENERAL.—For a discharge occurring in a cost reporting period beginning during fiscal year 2018, subparagraph (A)(i) shall not apply (and payment shall be made to a long-term care hospital without regard to this paragraph) if such discharge—

“(I) is from a long-term care hospital identified by the last sentence of subsection (d)(1)(B);

“(II) is classified under MS-LTCH-DRG 602, 603, 539, or 540; and

“(III) is with respect to an individual treated by a long-term care hospital for a severe wound.

“(ii) SEVERE WOUND DEFINED.—In this subparagraph, the term ‘severe wound’ means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, or fistula as identified in the claim from the long-term care hospital.

“(iii) WOUND DEFINED.—In this subparagraph, the term ‘wound’ means an injury involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.”.

(c) STUDY AND REPORT TO CONGRESS.—

(1) STUDY.—The Comptroller General of the United States shall, in consultation with relevant stakeholders, conduct a study on the treatment needs of individuals entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title who require specialized wound care, and the cost, for such individuals and the Medicare program under such title, of treating severe wounds in rural and urban areas. Such study shall include an assessment of—

(A) access of such individuals to appropriate levels of care for such cases;

(B) the potential impact that section 1886(m)(6)(A)(i) of such Act (42 U.S.C. 1395ww(m)(6)(A)(i)) will have on the access, quality, and cost of care for such individuals; and

(C) how to appropriately pay for such care under the Medicare program under such title.

(2) REPORT.—Not later than October 1, 2020, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1), including recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

TITLE XVI—PROVISIONS RELATING TO MEDICARE PART B

SEC. 16001. CONTINUING MEDICARE PAYMENT UNDER HOPD PROSPECTIVE PAYMENT SYSTEM FOR SERVICES FURNISHED BY MID-BUILD OFF-CAMPUS OUTPATIENT DEPARTMENTS OF PROVIDERS.

(a) IN GENERAL.—Section 1833(t)(21) of the Social Security Act (42 U.S.C. 1395l(t)(21)) is amended—

(1) in subparagraph (B)—

(A) in clause (i), by striking “clause (ii)” and inserting “the subsequent provisions of this subparagraph”; and

(B) by adding at the end the following new clauses:

“(iii) DEEMED TREATMENT FOR 2017.—For purposes of applying clause (ii) with respect to applicable items and services furnished during 2017, a department of a provider (as so defined) not described in such clause is deemed to be billing under this subsection with respect to covered OPD services furnished prior to November 2, 2015, if the Secretary received from the provider prior to December 2, 2015, an attestation (pursuant to section 413.65(b)(3) of title 42 of the Code of Federal Regulations) that such department was a department of a provider (as so defined).”

“(iv) ALTERNATIVE EXCEPTION BEGINNING WITH 2018.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2018 or a subsequent year, the term ‘off-campus outpatient department of a provider’ also shall not include a department of a provider (as so defined) that is not described in clause (ii) if—

“(I) the Secretary receives from the provider an attestation (pursuant to such section 413.65(b)(3)) not later than December 31, 2016 (or, if later, 60 days after the date of the enactment of this clause), that such department met the requirements of a department of a provider specified in section 413.65 of title 42 of the Code of Federal Regulations;

“(II) the provider includes such department as part of the provider on its enrollment form in accordance with the enrollment process under section 1866(i); and

“(III) the department met the mid-build requirement of clause (v) and the Secretary receives, not later than 60 days after the date of the enactment of this clause, from the chief executive officer or chief operating officer of the provider a written certification that the department met such requirement.

“(v) MID-BUILD REQUIREMENT DESCRIBED.—The mid-build requirement of this clause is, with respect to a department of a provider, that before November 2, 2015, the provider had a binding written agreement with an outside unrelated party for the actual construction of such department.

“(vi) AUDIT.—Not later than December 31, 2018, the Secretary shall audit the compliance with requirements of clause (iv) with respect to each department of a provider to which such clause applies. If the Secretary finds as a result of an audit under this clause that the applicable requirements were not met with respect to such department, the department shall not be excluded from the term ‘off-campus outpatient department of a provider’ under such clause.

“(vii) IMPLEMENTATION.—For purposes of implementing clauses (iii) through (vii):

“(I) Notwithstanding any other provision of law, the Secretary may implement such clauses by program instruction or otherwise.

“(II) Subchapter I of chapter 35 of title 44, United States Code, shall not apply.

“(III) For purposes of carrying out this subparagraph with respect to clauses (iii) and (iv) (and clause (vii) insofar as it relates to clause (iv)), \$10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until December 31, 2018.”; and

(2) in subparagraph (E), by adding at the end the following new clause:

“(iv) The determination of an audit under subparagraph (B)(vii).”

(b) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114-74).

SEC. 16002. TREATMENT OF CANCER HOSPITALS IN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER POLICY.

(a) IN GENERAL.—Section 1833(t)(21)(B) of the Social Security Act (42 U.S.C. 1395l(t)(21)(B)), as amended by section 16001(a), is amended—

(1) by inserting after clause (v) the following new clause:

“(vi) EXCLUSION FOR CERTAIN CANCER HOSPITALS.—For purposes of paragraph (1)(B)(v) and this paragraph with respect to applicable items and services furnished during 2017 or a subsequent year, the term ‘off-campus outpatient department of a provider’ also shall not include a department of a provider (as so defined) that is not described in clause (ii) if the provider is a hospital described in section 1886(d)(1)(B)(v) and—

“(I) in the case of a department that met the requirements of section 413.65 of title 42 of the Code of Federal Regulations after November 1, 2015, and before the date of the enactment of this clause, the Secretary receives from the provider an attestation that such department met such requirements not later than 60 days after such date of enactment; or

“(II) in the case of a department that meets such requirements after such date of enactment, the Secretary receives from the provider an attestation that such department meets such requirements not later than 60 days after the date such requirements are first met with respect to such department.”;

(2) in clause (vii), by inserting after the first sentence the following: “Not later than 2 years after the date the Secretary receives an attestation under clause (vi) relating to compliance of a department of a provider with requirements referred to in such clause, the Secretary shall audit the compliance with such requirements with respect to the department.”; and

(3) in clause (viii)(III), by adding at the end the following: “For purposes of carrying out this subparagraph with respect to clause (vi) (and clause (vii) insofar as it relates to such clause), \$2,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841, to remain available until expended.”

(b) OFFSETTING SAVINGS.—Section 1833(t)(18) of the Social Security Act (42 U.S.C. 1395l(t)(18)) is amended—

(1) in subparagraph (B), by inserting “, subject to subparagraph (C),” after “shall”; and

(2) by adding at the end the following new subparagraph:

“(C) TARGET PCR ADJUSTMENT.—In applying section 419.43(i) of title 42 of the Code of Federal Regulations to implement the appropriate adjustment under this paragraph for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage points less than the target PCR that would otherwise apply. In addition to the percentage point reduction under the previous sentence, the Secretary may consider making an additional percentage point reduction to such target PCR that takes into account payment rates for applicable items and services described in paragraph (21)(C) other than for services furnished by hospitals described in section 1886(d)(1)(B)(v). In making any budget neutrality adjustments under this subsection for 2018 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.”

(c) EFFECTIVE DATE.—The amendments made by this section shall be effective as if included in the enactment of section 603 of the Bipartisan Budget Act of 2015 (Public Law 114-74).

SEC. 16003. TREATMENT OF ELIGIBLE PROFESSIONALS IN AMBULATORY SURGICAL CENTERS FOR MEANINGFUL USE AND MIPS.

Section 1848(a)(7)(D) of the Social Security Act (42 U.S.C. 1395w-4(a)(7)(D)) is amended—

(1) by striking “HOSPITAL-BASED ELIGIBLE PROFESSIONALS” and all that follows through “No payment” and inserting the following: “HOSPITAL-BASED AND AMBULATORY SURGICAL CENTER-BASED ELIGIBLE PROFESSIONALS.—

“(i) HOSPITAL-BASED.—No payment”; and

(2) by adding at the end the following new clauses:

“(ii) AMBULATORY SURGICAL CENTER-BASED.—Subject to clause (iv), no payment adjustment

may be made under subparagraph (A) for 2017 and 2018 in the case of an eligible professional with respect to whom substantially all of the covered professional services furnished by such professional are furnished in an ambulatory surgical center.

“(iii) DETERMINATION.—The determination of whether an eligible professional is an eligible professional described in clause (ii) may be made on the basis of—

“(I) the site of service (as defined by the Secretary); or

“(II) an attestation submitted by the eligible professional.

Determinations made under subclauses (I) and (II) shall be made without regard to any employment or billing arrangement between the eligible professional and any other supplier or provider of services.

“(iv) SUNSET.—Clause (ii) shall no longer apply as of the first year that begins more than 3 years after the date on which the Secretary determines, through notice and comment rule-making, that certified EHR technology applicable to the ambulatory surgical center setting is available.”

SEC. 16004. CONTINUING ACCESS TO HOSPITALS ACT OF 2016.

(a) EXTENSION OF ENFORCEMENT INSTRUCTION ON SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL HOSPITALS THROUGH 2016.—Section 1 of Public Law 113-198, as amended by section 1 of Public Law 114-112, is amended—

(1) in the heading, by striking “2014 AND 2015” and inserting “2016”; and

(2) by striking “and 2015” and inserting “, 2015, and 2016”.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission (established under section 1805 of the Social Security Act (42 U.S.C. 1395b-6)) shall submit to Congress a report analyzing the effect of the extension of the enforcement instruction under section 1 of Public Law 113-198, as amended by section 1 of Public Law 114-112 and subsection (a) of this section, on the access to health care by Medicare beneficiaries, on the economic impact and the impact upon hospital staffing needs, and on the quality of health care furnished to such beneficiaries.

SEC. 16005. DELAY OF IMPLEMENTATION OF MEDICARE FEE SCHEDULE ADJUSTMENTS FOR WHEELCHAIR ACCESSORIES AND SEATING SYSTEMS WHEN USED IN CONJUNCTION WITH COMPLEX REHABILITATION TECHNOLOGY (CRT) WHEELCHAIRS.

Section 2(a) of the Patient Access and Medicare Protection Act (42 U.S.C. 1305 note) is amended by striking “January 1, 2017” and inserting “July 1, 2017”.

SEC. 16006. ALLOWING PHYSICAL THERAPISTS TO UTILIZE LOCUM TENENS ARRANGEMENTS UNDER MEDICARE.

(a) IN GENERAL.—The first sentence of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as amended by section 5012, is further amended—

(1) by striking “and” before “(I)”; and

(2) by inserting before the period at the end the following: “, and (J) in the case of outpatient physical therapy services furnished by physical therapists in a health professional shortage area (as defined in section 332(a)(1)(A) of the Public Health Service Act), a medically underserved area (as designated pursuant to section 330(b)(3)(A) of such Act), or a rural area (as defined in section 1886(d)(2)(D)), subparagraph (D) of this sentence shall apply to such services and therapists in the same manner as such subparagraph applies to physicians’ services furnished by physicians”.

(b) EFFECTIVE DATE; IMPLEMENTATION.—

(1) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to services furnished beginning not later than six months after the date of the enactment of this Act.

(2) **IMPLEMENTATION.**—The Secretary of Health and Human Services may implement subparagraph (J) of section 1842(b)(6) of the Social Security Act (42 U.S.C. 1395u(b)(6)), as added by subsection (a)(2), by program instruction or otherwise.

SEC. 16007. EXTENSION OF THE TRANSITION TO NEW PAYMENT RATES FOR DURABLE MEDICAL EQUIPMENT UNDER THE MEDICARE PROGRAM.

(a) **IN GENERAL.**—The Secretary of Health and Human Services shall extend the transition period described in clause (i) of section 414.210(g)(9) of title 42, Code of Federal Regulations, from June 30, 2016, to December 31, 2016 (with the full implementation described in clause (ii) of such section applying to items and services furnished with dates of service on or after January 1, 2017).

(b) **STUDY AND REPORT.**—

(1) **STUDY.**—

(A) **IN GENERAL.**—The Secretary of Health and Human Services shall conduct a study that examines the impact of applicable payment adjustments upon—

(i) the number of suppliers of durable medical equipment that, on a date that is not before January 1, 2016, and not later than December 31, 2016, ceased to conduct business as such suppliers; and

(ii) the availability of durable medical equipment, during the period beginning on January 1, 2016, and ending on December 31, 2016, to individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or enrolled under part B of such title.

(B) **DEFINITIONS.**—For purposes of this subsection, the following definitions apply:

(i) **SUPPLIER; DURABLE MEDICAL EQUIPMENT.**—The terms “supplier” and “durable medical equipment” have the meanings given such terms by section 1861 of the Social Security Act (42 U.S.C. 1395x).

(ii) **APPLICABLE PAYMENT ADJUSTMENT.**—The term “applicable payment adjustment” means a payment adjustment described in section 414.210(g) of title 42, Code of Federal Regulations, that is phased in by paragraph (9)(i) of such section. For purposes of the preceding sentence, a payment adjustment that is phased in pursuant to the extension under subsection (a) shall be considered a payment adjustment that is phased in by such paragraph (9)(i).

(2) **REPORT.**—The Secretary of Health and Human Services shall, not later than January 12, 2017, submit to the Committees on Ways and Means and on Energy and Commerce of the House of Representatives, and to the Committee on Finance of the Senate, a report on the findings of the study conducted under paragraph (1).

SEC. 16008. REQUIREMENTS IN DETERMINING ADJUSTMENTS USING INFORMATION FROM COMPETITIVE BIDDING PROGRAMS.

(a) **IN GENERAL.**—Section 1834(a)(1)(G) of the Social Security Act (42 U.S.C. 1395m(a)(1)(G)) is amended by adding at the end the following new sentence: “In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), under subsection (h)(1)(H)(ii), or under section 1842(s)(3)(B), the Secretary shall—

“(i) solicit and take into account stakeholder input; and

“(ii) take into account the highest amount bid by a winning supplier in a competitive acquisition area and a comparison of each of the following with respect to non-competitive acquisition areas and competitive acquisition areas:

“(I) The average travel distance and cost associated with furnishing items and services in the area.

“(II) The average volume of items and services furnished by suppliers in the area.

“(III) The number of suppliers in the area.”.

(b) **CONFORMING AMENDMENTS.**—(1) Section 1834(h)(1)(H)(ii) of the Social Security Act (42

U.S.C. 1395m(h)(1)(H)(ii)) is amended by striking “the Secretary” and inserting “subject to subsection (a)(1)(G), the Secretary”.

(2) Section 1842(s)(3)(B) of the Social Security Act (42 U.S.C. 1395m(s)(3)(B)) is amended by striking “the Secretary” and inserting “subject to section 1834(a)(1)(G), the Secretary”.

TITLE XVII—OTHER MEDICARE PROVISIONS

SEC. 17001. DELAY IN AUTHORITY TO TERMINATE CONTRACTS FOR MEDICARE ADVANTAGE PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.

(a) **FINDINGS.**—Consistent with the studies provided under the IMPACT Act of 2014 (Public Law 113–185), it is the intent of Congress—

(1) to continue to study and request input on the effects of socioeconomic status and dual-eligible populations on the Medicare Advantage STARS rating system before reforming such system with the input of stakeholders; and

(2) pending the results of such studies and input, to provide for a temporary delay in authority of the Centers for Medicare & Medicaid Services (CMS) to terminate Medicare Advantage plan contracts solely on the basis of performance of plans under the STARS rating system.

(b) **DELAY IN MA CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS.**—Section 1857(h) of the Social Security Act (42 U.S.C. 1395w–27(h)) is amended by adding at the end the following new paragraph:

“(3) **DELAY IN CONTRACT TERMINATION AUTHORITY FOR PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATING.**—During the period beginning on the date of the enactment of this paragraph and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1853(o)(4).”.

SEC. 17002. REQUIREMENT FOR ENROLLMENT DATA REPORTING FOR MEDICARE.

Section 1874 of the Social Security Act (42 U.S.C. 1395kk) is amended by adding at the end the following new subsection:

“(g) **REQUIREMENT FOR ENROLLMENT DATA REPORTING.**—

“(1) **IN GENERAL.**—Each year (beginning with 2016), the Secretary shall submit to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on Medicare enrollment data (and, in the case of part A, on data on individuals receiving benefits under such part) as of a date in such year specified by the Secretary. Such data shall be presented—

“(A) by Congressional district and State; and

“(B) in a manner that provides for such data based on—

“(i) fee-for-service enrollment (as defined in paragraph (2));

“(ii) enrollment under part C (including separate for aggregate enrollment in MA–PD plans and aggregate enrollment in MA plans that are not MA–PD plans); and

“(iii) enrollment under part D.

“(2) **FEE-FOR-SERVICE ENROLLMENT DEFINED.**—For purpose of paragraph (1)(B)(i), the term “fee-for-service enrollment” means aggregate enrollment (including receipt of benefits other than through enrollment) under—

“(A) part A only;

“(B) part B only; and

“(C) both part A and part B.”.

SEC. 17003. UPDATING THE WELCOME TO MEDICARE PACKAGE.

(a) **IN GENERAL.**—Not later than 12 months after the last day of the period for the request of information described in subsection (b), the Secretary of Health and Human Services shall, taking into consideration information collected

pursuant to subsection (b), update the information included in the Welcome to Medicare package to include information, presented in a clear and simple manner, about options for receiving benefits under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including through the original Medicare fee-for-service program under parts A and B of such title (42 U.S.C. 1395c et seq., 42 U.S.C. 1395j et seq.), Medicare Advantage plans under part C of such title (42 U.S.C. 1395w–21 et seq.), and prescription drug plans under part D of such title (42 U.S.C. 1395w–101 et seq.). The Secretary shall make subsequent updates to the information included in the Welcome to Medicare package as appropriate.

(b) **REQUEST FOR INFORMATION.**—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall request information, including recommendations, from stakeholders (including patient advocates, issuers, and employers) on information included in the Welcome to Medicare package, including pertinent data and information regarding enrollment and coverage for Medicare eligible individuals.

SEC. 17004. NO PAYMENT FOR ITEMS AND SERVICES FURNISHED BY NEWLY ENROLLED PROVIDERS OR SUPPLIERS WITHIN A TEMPORARY MORATORIUM AREA.

(a) **MEDICARE.**—Section 1866(j)(7) of the Social Security Act (42 U.S.C. 1395cc(j)(7)) is amended—

(1) in the paragraph heading, by inserting “; NONPAYMENT” before the period; and

(2) by adding at the end the following new subparagraph:

“(C) **NONPAYMENT.**—

“(i) **IN GENERAL.**—No payment may be made under this title or under a program described in subparagraph (A) with respect to an item or service described in clause (ii) furnished on or after October 1, 2017.

“(ii) **ITEM OR SERVICE DESCRIBED.**—An item or service described in this clause is an item or service furnished—

“(I) within a geographic area with respect to which a temporary moratorium imposed under subparagraph (A) is in effect; and

“(II) by a provider of services or supplier that meets the requirements of clause (iii).

“(iii) **REQUIREMENTS.**—For purposes of clause (ii), the requirements of this clause are that a provider of services or supplier—

“(I) enrolls under this title on or after the effective date of such temporary moratorium; and

“(II) is within a category of providers of services and suppliers (as described in subparagraph (A)) subject to such temporary moratorium.

“(iv) **PROHIBITION ON CHARGES FOR SPECIFIED ITEMS OR SERVICES.**—In no case shall a provider of services or supplier described in clause (ii)(I) charge an individual or other person for an item or service described in clause (ii) furnished on or after October 1, 2017, to an individual entitled to benefits under part A or enrolled under part B or an individual under a program specified in subparagraph (A).”.

(b) **CONFORMING AMENDMENTS.**—

(1) **MEDICAID.**—

(A) **IN GENERAL.**—Section 1903(i)(2) of the Social Security Act (42 U.S.C. 1396b(i)(2)), as amended by section 5005(a)(4), is further amended—

(i) in subparagraph (C), by striking “or” at the end; and

(ii) by adding at the end the following new subparagraph:

“(E) with respect to any amount expended for such an item or service furnished during calendar quarters beginning on or after October 1, 2017, subject to section 1902(kk)(4)(A)(ii)(II), within a geographic area that is subject to a moratorium imposed under section 1866(j)(7) by a provider or supplier that meets the requirements specified in subparagraph (C)(iii) of such section, during the period of such moratorium; or”.

(B) EXCEPTION WITH RESPECT TO ACCESS.—Section 1902(kk)(4)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)(ii)) is amended to read as follows:

“(i) EXCEPTIONS.—

“(I) COMPLIANCE WITH MORATORIUM.—A State shall not be required to comply with a temporary moratorium described in clause (i) if the State determines that the imposition of such temporary moratorium would adversely impact beneficiaries’ access to medical assistance.

“(II) FFP AVAILABLE.—Notwithstanding section 1903(i)(2)(E), payment may be made to a State under this title with respect to amounts expended for items and services described in such section if the Secretary, in consultation with the State agency administering the State plan under this title (or a waiver of the plan), determines that denying payment to the State pursuant to such section would adversely impact beneficiaries’ access to medical assistance.”

(C) STATE PLAN REQUIREMENT WITH RESPECT TO LIMITATION ON CHARGES TO BENEFICIARIES.—Section 1902(kk)(4)(A) of the Social Security Act (42 U.S.C. 1396a(kk)(4)(A)) is amended by adding at the end the following new clause:

“(iii) LIMITATION ON CHARGES TO BENEFICIARIES.—With respect to any amount expended for items or services furnished during calendar quarters beginning on or after October 1, 2017, the State prohibits, during the period of a temporary moratorium described in clause (i), a provider meeting the requirements specified in subparagraph (C)(iii) of section 1866(j)(7) from charging an individual or other person eligible to receive medical assistance under the State plan under this title (or a waiver of the plan) for an item or service described in section 1903(i)(2)(E) furnished to such an individual.”

(2) CORRECTING AMENDMENTS TO RELATED PROVISIONS.—

(A) SECTION 1866(J).—Section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) is amended—

(i) in paragraph (1)(A)—

(I) by striking “paragraph (4)” and inserting “paragraph (5)”;

(II) by striking “moratoria in accordance with paragraph (5)” and inserting “moratoria in accordance with paragraph (7)”;

(III) by striking “paragraph (6)” and inserting “paragraph (9)”;

(ii) by redesignating the second paragraph (8) (redesignated by section 1304(1) of Public Law 111–152) as paragraph (9).

(B) SECTION 1902(KK).—Section 1902(kk) of such Act (42 U.S.C. 1396a(kk)) is amended—

(i) in paragraph (1), by striking “section 1866(j)(2)” and inserting “section 1866(j)(2)”;

(ii) in paragraph (2), by striking “section 1866(j)(3)” and inserting “section 1866(j)(3)”;

(iii) in paragraph (3), by striking “section 1866(j)(4)” and inserting “section 1866(j)(5)”;

(iv) in paragraph (4)(A), by striking “section 1866(j)(6)” and inserting “section 1866(j)(7)”.

SEC. 17005. PRESERVATION OF MEDICARE BENEFICIARY CHOICE UNDER MEDICARE ADVANTAGE.

Section 1851(e)(2) of the Social Security Act (42 U.S.C. 1395w–21(e)(2)) is amended—

(1) in subparagraph (C)—

(A) in the heading, by inserting “FROM 2011 THROUGH 2018” after “45-DAY PERIOD”; and

(B) by inserting “and ending with 2018” after “beginning with 2011”; and

(2) by adding at the end the following new subparagraph:

“(G) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN 2016 AND SUBSEQUENT YEARS.—

“(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D)—

“(I) in the case of an MA eligible individual who is enrolled in an MA plan, at any time during the first 3 months of a year (beginning with 2019); or

“(II) in the case of an individual who first becomes an MA eligible individual during a year (beginning with 2019) and enrolls in an MA plan, during the first 3 months during such year in which the individual is an MA eligible individual;

such MA eligible individual may change the election under subsection (a)(1).

“(ii) LIMITATION OF ONE CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR.—An individual may change the election pursuant to clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

“(iii) LIMITED APPLICATION TO PART D.—Clauses (i) and (ii) of this subparagraph shall only apply with respect to changes in enrollment in a prescription drug plan under part D in the case of an individual who, previous to such change in enrollment, is enrolled in a Medicare Advantage plan.

“(iv) LIMITATIONS ON MARKETING.—Pursuant to subsection (j), no unsolicited marketing or marketing materials may be sent to an individual described in clause (i) during the continuous open enrollment and disenrollment period established for the individual under such clause, notwithstanding marketing guidelines established by the Centers for Medicare & Medicaid Services.”

SEC. 17006. ALLOWING END-STAGE RENAL DISEASE BENEFICIARIES TO CHOOSE A MEDICARE ADVANTAGE PLAN.

(a) REMOVING PROHIBITION.—

(1) IN GENERAL.—Section 1851(a)(3) of the Social Security Act (42 U.S.C. 1395w–21(a)(3)) is amended—

(A) by striking subparagraph (B); and

(B) by striking “ELIGIBLE INDIVIDUAL” and all that follows through “In this title, subject to subparagraph (B),” and inserting “ELIGIBLE INDIVIDUAL.—In this title.”

(2) CONFORMING AMENDMENTS.—

(A) Section 1852(b)(1) of the Social Security Act (42 U.S.C. 1395w–22(b)(1)) is amended—

(i) by striking subparagraph (B); and

(ii) by striking “BENEFICIARIES” and all that follows through “A Medicare+Choice organization” and inserting “BENEFICIARIES.—A Medicare Advantage organization”.

(B) Section 1859(b)(6) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)) is amended, in the last sentence, by striking “may waive” and all that follows through “subparagraph and”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021.

(b) EXCLUDING COSTS FOR KIDNEY ACQUISITIONS FROM MA BENCHMARK.—Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended—

(1) in subsection (k)—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking “paragraphs (2) and (4)” and inserting “paragraphs (2), (4), and (5)”;

(ii) in subparagraph (B)(i), by striking “paragraphs (2) and (4)” and inserting “paragraphs (2), (4), and (5)”;

(B) by adding at the end the following new paragraph:

“(5) EXCLUSION OF COSTS FOR KIDNEY ACQUISITIONS FROM CAPITATION RATES.—After determining the applicable amount for an area for a year under paragraph (1) (beginning with 2021), the Secretary shall adjust such applicable amount to exclude from such applicable amount the Secretary’s estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d)) in the area for the year.”; and

(2) in subsection (n)(2)—

(A) in subparagraph (A)(i), by inserting “and, for 2021 and subsequent years, the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate as described in subsection (k)(5)” before the semicolon at the end;

(B) in subparagraph (E), in the matter preceding clause (i), by striking “subparagraph (F)” and inserting “subparagraphs (F) and (G)”; and

(C) by adding at the end the following new subparagraph:

“(G) APPLICATION OF KIDNEY ACQUISITIONS ADJUSTMENT.—The base payment amount specified in subparagraph (E) for a year (beginning with 2021) shall be adjusted in the same manner under paragraph (5) of subsection (k) as the applicable amount is adjusted under such subsection.”

(c) FFS COVERAGE OF KIDNEY ACQUISITIONS.—

(1) IN GENERAL.—Section 1852(a)(1)(B)(i) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(B)(i)) is amended by inserting “or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)” after “hospice care”.

(2) CONFORMING AMENDMENT.—Section 1851(i) of the Social Security Act (42 U.S.C. 1395w–21(i)) is amended by adding at the end the following new paragraph:

“(3) FFS PAYMENT FOR EXPENSES FOR KIDNEY ACQUISITIONS.—Paragraphs (1) and (2) shall not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i).”

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to plan years beginning on or after January 1, 2021.

(d) EVALUATION OF QUALITY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the “Secretary”) shall conduct an evaluation of whether the 5-star rating system based on the data collected under section 1852(e) of the Social Security Act (42 U.S.C. 1395w–22(e)) should include a quality measure specifically related to care for enrollees in Medicare Advantage plans under part C of title XVIII of such Act determined to have end-stage renal disease.

(2) PUBLIC AVAILABILITY.—Not later than April 1, 2020, the Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services the results of the evaluation under paragraph (1).

(e) REPORT.—Not later than December 31, 2023, the Secretary of Health and Human Services (in this subsection referred to as the “Secretary”) shall submit to Congress a report on the impact of the provisions of, and amendments made by, this section with respect to the following:

(1) Spending under—

(A) the original Medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act; and

(B) the Medicare Advantage program under part C of such title.

(2) The number of enrollees determined to have end-stage renal disease—

(A) in the original Medicare fee-for-service program; and

(B) in the Medicare Advantage program.

(3) The sufficiency of the amount of data under the original Medicare fee-for-service program for individuals determined to have end-stage renal disease for purposes of determining payment rates for end-stage renal disease under the Medicare Advantage program.

(f) IMPROVEMENTS TO RISK ADJUSTMENT UNDER MEDICARE ADVANTAGE.—

(1) IN GENERAL.—Section 1853(a)(1) of the Social Security Act (42 U.S.C. 1395w–23(a)(1)) is amended—

(A) in subparagraph (C)(i), by striking “The Secretary” and inserting “Subject to subparagraph (1), the Secretary”; and

(B) by adding at the end the following new subparagraph:

“(I) IMPROVEMENTS TO RISK ADJUSTMENT FOR 2019 AND SUBSEQUENT YEARS.—

“(i) IN GENERAL.—In order to determine the appropriate adjustment for health status under subparagraph (C)(i), the following shall apply:

“(I) TAKING INTO ACCOUNT TOTAL NUMBER OF DISEASES OR CONDITIONS.—The Secretary shall take into account the total number of diseases or conditions of an individual enrolled in an MA plan. The Secretary shall make an additional adjustment under such subparagraph as the number of diseases or conditions of an individual increases.

“(II) USING AT LEAST 2 YEARS OF DIAGNOSTIC DATA.—The Secretary may use at least 2 years of diagnosis data.

“(III) PROVIDING SEPARATE ADJUSTMENTS FOR DUAL ELIGIBLE INDIVIDUALS.—With respect to individuals who are dually eligible for benefits under this title and title XIX, the Secretary shall make separate adjustments for each of the following:

“(aa) Full-benefit dual eligible individuals (as defined in section 1935(c)(6)).

“(bb) Such individuals not described in item (aa).

“(IV) EVALUATION OF MENTAL HEALTH AND SUBSTANCE USE DISORDERS.—The Secretary shall evaluate the impact of including additional diagnosis codes related to mental health and substance use disorders in the risk adjustment model.

“(V) EVALUATION OF CHRONIC KIDNEY DISEASE.—The Secretary shall evaluate the impact of including the severity of chronic kidney disease in the risk adjustment model.

“(VI) EVALUATION OF PAYMENT RATES FOR END-STAGE RENAL DISEASE.—The Secretary shall evaluate whether other factors (in addition to those described in subparagraph (H)) should be taken into consideration when computing payment rates under such subparagraph.

“(ii) PHASED-IN IMPLEMENTATION.—The Secretary shall phase-in any changes to risk adjustment payment amounts under subparagraph (C)(i) under this subparagraph over a 3-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years.

“(iii) OPPORTUNITY FOR REVIEW AND PUBLIC COMMENT.—The Secretary shall provide an opportunity for review of the proposed changes to such risk adjustment payment amounts under this subparagraph and a public comment period of not less than 60 days before implementing such changes.”

(2) STUDIES AND REPORTS.—

(A) REPORTS ON THE RISK ADJUSTMENT SYSTEM.—

(i) MEDPAC EVALUATION AND REPORT.—

(I) EVALUATION.—The Medicare Payment Advisory Commission shall conduct an evaluation of the impact of the provisions of, and amendments made by, this section on risk scores for enrollees in Medicare Advantage plans under part C of title XVIII of the Social Security Act and payments to Medicare Advantage plans under such part, including the impact of such provisions and amendments on the overall accuracy of risk scores under the Medicare Advantage program.

(II) REPORT.—Not later than July 1, 2020, the Medicare Payment Advisory Commission shall submit to Congress a report on the evaluation under subclause (I), together with recommendations for such legislation and administrative action as the Commission determines appropriate.

(ii) REPORTS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than December 31, 2018, and every 3 years thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the risk adjustment model and the ESRD risk adjustment model under the Medicare Advantage program under part C of title XVIII of the Social Security Act, including any revisions to either such model since the previous report. Such report shall include information on how such revisions impact the predictive

ratios under either such model for groups of enrollees in Medicare Advantage plans, including very high and very low cost enrollees, and groups defined by the number of chronic conditions of enrollees.

(B) STUDY AND REPORT ON FUNCTIONAL STATUS.—

(i) STUDY.—The Comptroller General of the United States (in this subparagraph referred to as the “Comptroller General”) shall conduct a study on how to most accurately measure the functional status of enrollees in Medicare Advantage plans and whether the use of such functional status would improve the accuracy of risk adjustment payments under the Medicare Advantage program under part C of title XVIII of the Social Security Act. Such study shall include an analysis of the challenges in collecting and reporting functional status information for Medicare Advantage plans under such part, providers of services and suppliers under the Medicare program, and the Centers for Medicare & Medicaid Services.

(ii) REPORT.—Not later than June 30, 2018, the Comptroller General shall submit to Congress a report containing the results of the study under clause (i), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 17007. IMPROVEMENTS TO THE ASSIGNMENT OF BENEFICIARIES UNDER THE MEDICARE SHARED SAVINGS PROGRAM.

Section 1899(c) of the Social Security Act (42 U.S.C. 1395j(j)(c)) is amended—

(1) by striking “utilization of primary” and inserting “utilization of—

“(1) in the case of performance years beginning on or after April 1, 2012, primary”;

(2) in paragraph (1), as added by paragraph (1) of this section, by striking the period at the end and inserting “; and”;

(3) by adding at the end the following new paragraph:

“(2) in the case of performance years beginning on or after January 1, 2019, services provided under this title by a Federally qualified health center or rural health clinic (as those terms are defined in section 1861(aa), as may be determined by the Secretary).”

TITLE XVIII—OTHER PROVISIONS

SEC. 18001. EXCEPTION FROM GROUP HEALTH PLAN REQUIREMENTS FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.

(a) AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986 AND THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.—

(1) IN GENERAL.—Section 9831 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

“(d) EXCEPTION FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

“(1) IN GENERAL.—For purposes of this title (except as provided in section 49801(f)(4) and notwithstanding any other provision of this title), the term ‘group health plan’ shall not include any qualified small employer health reimbursement arrangement.

“(2) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this subsection—

“(A) IN GENERAL.—The term ‘qualified small employer health reimbursement arrangement’ means an arrangement which—

“(i) is described in subparagraph (B), and

“(ii) is provided on the same terms to all eligible employees of the eligible employer.

“(B) ARRANGEMENT DESCRIBED.—An arrangement is described in this subparagraph if—

“(i) such arrangement is funded solely by an eligible employer and no salary reduction contributions may be made under such arrangement,

“(ii) such arrangement provides, after the employee provides proof of coverage, for the payment of, or reimbursement of, an eligible em-

ployee for expenses for medical care (as defined in section 213(d)) incurred by the eligible employee or the eligible employee’s family members (as determined under the terms of the arrangement), and

“(iii) the amount of payments and reimbursements described in clause (ii) for any year do not exceed \$4,950 (\$10,000 in the case of an arrangement that also provides for payments or reimbursements for family members of the employee).

“(C) CERTAIN VARIATION PERMITTED.—For purposes of subparagraph (A)(ii), an arrangement shall not fail to be treated as provided on the same terms to each eligible employee merely because the employee’s permitted benefit under such arrangement varies in accordance with the variation in the price of an insurance policy in the relevant individual health insurance market based on—

“(i) the age of the eligible employee (and, in the case of an arrangement which covers medical expenses of the eligible employee’s family members, the age of such family members), or

“(ii) the number of family members of the eligible employee the medical expenses of which are covered under such arrangement.

The variation permitted under the preceding sentence shall be determined by reference to the same insurance policy with respect to all eligible employees.

“(D) RULES RELATING TO MAXIMUM DOLLAR LIMITATION.—

“(i) AMOUNT PRORATED IN CERTAIN CASES.—In the case of an individual who is not covered by an arrangement for the entire year, the limitation under subparagraph (B)(iii) for such year shall be an amount which bears the same ratio to the amount which would (but for this clause) be in effect for such individual for such year under subparagraph (B)(iii) as the number of months for which such individual is covered by the arrangement for such year bears to 12.

“(ii) INFLATION ADJUSTMENT.—In the case of any year beginning after 2016, each of the dollar amounts in subparagraph (B)(iii) shall be increased by an amount equal to—

“(I) such dollar amount, multiplied by

“(II) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which the taxable year begins, determined by substituting ‘calendar year 2015’ for ‘calendar year 1992’ in subparagraph (B) thereof.

If any dollar amount increased under the preceding sentence is not a multiple of \$50, such dollar amount shall be rounded to the next lowest multiple of \$50.

“(3) OTHER DEFINITIONS.—For purposes of this subsection—

“(A) ELIGIBLE EMPLOYEE.—The term ‘eligible employee’ means any employee of an eligible employer, except that the terms of the arrangement may exclude from consideration employees described in any clause of section 105(h)(3)(B) (applied by substituting ‘90 days’ for ‘3 years’ in clause (i) thereof).

“(B) ELIGIBLE EMPLOYER.—The term ‘eligible employer’ means an employer that—

“(i) is not an applicable large employer as defined in section 4980H(c)(2), and

“(ii) does not offer a group health plan to any of its employees.

“(C) PERMITTED BENEFIT.—The term ‘permitted benefit’ means, with respect to any eligible employee, the maximum dollar amount of payments and reimbursements which may be made under the terms of the qualified small employer health reimbursement arrangement for the year with respect to such employee.

“(4) NOTICE.—

“(A) IN GENERAL.—An employer funding a qualified small employer health reimbursement arrangement for any year shall, not later than 90 days before the beginning of such year (or, in the case of an employee who is not eligible to participate in the arrangement as of the beginning of such year, the date on which such employee is first so eligible), provide a written notice to each eligible employee which includes the information described in subparagraph (B).

“(B) CONTENTS OF NOTICE.—The notice required under subparagraph (A) shall include each of the following:

“(i) A statement of the amount which would be such eligible employee’s permitted benefit under the arrangement for the year.

“(ii) A statement that the eligible employee should provide the information described in clause (i) to any health insurance exchange to which the employee applies for advance payment of the premium assistance tax credit.

“(iii) A statement that if the employee is not covered under minimum essential coverage for any month the employee may be subject to tax under section 5000A for such month and reimbursements under the arrangement may be includible in gross income.”.

(2) LIMITATION ON EXCLUSION FROM GROSS INCOME.—Section 106 of such Code is amended by adding at the end the following:

“(g) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this section and section 105, payments or reimbursements from a qualified small employer health reimbursement arrangement (as defined in section 9831(d)) of an individual for medical care (as defined in section 213(d)) shall not be treated as paid or reimbursed under employer-provided coverage for medical expenses under an accident or health plan if for the month in which such medical care is provided the individual does not have minimum essential coverage (within the meaning of section 5000A(f)).”.

(3) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—Section 36B(c) of such Code is amended by adding at the end the following new paragraph:

“(4) SPECIAL RULES FOR QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—

“(A) IN GENERAL.—The term ‘coverage month’ shall not include any month with respect to an employee (or any spouse or dependent of such employee) if for such month the employee is provided a qualified small employer health reimbursement arrangement which constitutes affordable coverage.

“(B) DENIAL OF DOUBLE BENEFIT.—In the case of any employee who is provided a qualified small employer health reimbursement arrangement for any coverage month (determined without regard to subparagraph (A)), the credit otherwise allowable under subsection (a) to the taxpayer for such month shall be reduced (but not below zero) by the amount described in subparagraph (C)(i)(II) for such month.

“(C) AFFORDABLE COVERAGE.—For purposes of subparagraph (A), a qualified small employer health reimbursement arrangement shall be treated as constituting affordable coverage for a month if—

“(i) the excess of—
“(I) the amount that would be paid by the employee as the premium for such month for self-only coverage under the second lowest cost silver plan offered in the relevant individual health insurance market, over

“(II) $\frac{1}{2}$ of the employee’s permitted benefit (as defined in section 9831(d)(3)(C)) under such arrangement, does not exceed—

“(ii) $\frac{1}{12}$ of 9.5 percent of the employee’s household income.

“(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENT.—For purposes of this paragraph, the term ‘qualified small employer health reimbursement arrangement’ has the meaning given such term by section 9831(d)(2).

“(E) COVERAGE FOR LESS THAN ENTIRE YEAR.—In the case of an employee who is provided a qualified small employer health reimbursement arrangement for less than an entire year, subparagraph (C)(i)(II) shall be applied by substituting ‘the number of months during the year for which such arrangement was provided’ for ‘12’.

“(F) INDEXING.—In the case of plan years beginning in any calendar year after 2014, the

Secretary shall adjust the 9.5 percent amount under subparagraph (C)(ii) in the same manner as the percentages are adjusted under subsection (b)(3)(A)(ii).”.

(4) APPLICATION OF EXCISE TAX ON HIGH COST EMPLOYER-SPONSORED HEALTH COVERAGE.—

(A) IN GENERAL.—Section 49801(f)(4) of such Code is amended by adding at the end the following: “Section 9831(d)(1) shall not apply for purposes of this section.”.

(B) DETERMINATION OF COST OF COVERAGE.—Section 49801(d)(2) of such Code is amended by redesignating subparagraph (D) as subparagraph (E) and by inserting after subparagraph (C) the following new subparagraph:

“(D) QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—In the case of applicable employer-sponsored coverage consisting of coverage under any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)), the cost of coverage shall be equal to the amount described in section 6051(a)(15).”.

(5) ENFORCEMENT OF NOTICE REQUIREMENT.—Section 6652 of such Code is amended by adding at the end the following new subsection:

“(o) FAILURE TO PROVIDE NOTICES WITH RESPECT TO QUALIFIED SMALL EMPLOYER HEALTH REIMBURSEMENT ARRANGEMENTS.—In the case of each failure to provide a written notice as required by section 9831(d)(4), unless it is shown that such failure is due to reasonable cause and not willful neglect, there shall be paid, on notice and demand of the Secretary and in the same manner as tax, by the person failing to provide such written notice, an amount equal to \$50 per employee per incident of failure to provide such notice, but the total amount imposed on such person for all such failures during any calendar year shall not exceed \$2,500.”.

(6) REPORTING.—

(A) W-2 REPORTING.—Section 6051(a) of such Code is amended by striking “and” at the end of paragraph (13), by striking the period at the end of paragraph (14) and inserting “, and”, and by inserting after paragraph (14) the following new paragraph:

“(15) the total amount of permitted benefit (as defined in section 9831(d)(3)(C)) for the year under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2)) with respect to the employee.”.

(B) INFORMATION REQUIRED TO BE PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—Section 1411(b)(3) of the Patient Protection and Affordable Care Act is amended by redesignating subparagraph (B) as subparagraph (C) and by inserting after subparagraph (A) the following new subparagraph:

“(B) CERTAIN INDIVIDUAL HEALTH INSURANCE POLICIES OBTAINED THROUGH SMALL EMPLOYERS.—The amount of the enrollee’s permitted benefit (as defined in section 9831(d)(3)(C) of the Internal Revenue Code of 1986) under a qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of such Code).”.

(7) EFFECTIVE DATES.—

(A) IN GENERAL.—Except as otherwise provided in this paragraph, the amendments made by this subsection shall apply to years beginning after December 31, 2016.

(B) TRANSITION RELIEF.—The relief under Treasury Notice 2015-17 shall be treated as applying to any plan year beginning on or before December 31, 2016.

(C) COORDINATION WITH HEALTH INSURANCE PREMIUM CREDIT.—The amendments made by paragraph (3) shall apply to taxable years beginning after December 31, 2016.

(D) EMPLOYEE NOTICE.—

(i) IN GENERAL.—The amendments made by paragraph (5) shall apply to notices with respect to years beginning after December 31, 2016.

(ii) TRANSITION RELIEF.—For purposes of section 6652(o) of the Internal Revenue Code of 1986 (as added by this Act), a person shall not be treated as failing to provide a written notice

as required by section 9831(d)(4) of such Code if such notice is so provided not later than 90 days after the date of the enactment of this Act.

(E) W-2 REPORTING.—The amendments made by paragraph (6)(A) shall apply to calendar years beginning after December 31, 2016.

(F) INFORMATION PROVIDED BY EXCHANGE SUBSIDY APPLICANTS.—

(i) IN GENERAL.—The amendments made by paragraph (6)(B) shall apply to applications for enrollment made after December 31, 2016.

(ii) VERIFICATION.—Verification under section 1411 of the Patient Protection and Affordable Care Act of information provided under section 1411(b)(3)(B) of such Act shall apply with respect to months beginning after October 2016.

(iii) TRANSITIONAL RELIEF.—In the case of an application for enrollment under section 1411(b) of the Patient Protection and Affordable Care Act made before April 1, 2017, the requirement of section 1411(b)(3)(B) of such Act shall be treated as met if the information described therein is provided not later than 30 days after the date on which the applicant receives the notice described in section 9831(d)(4) of the Internal Revenue Code of 1986.

(8) SUBSTANTIATION REQUIREMENTS.—The Secretary of the Treasury (or his designee) may issue substantiation requirements as necessary to carry out this subsection.

(b) AMENDMENTS TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Section 733(a)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(a)(1)) is amended by adding at the end the following: “Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).”.

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS, ETC.—Section 607(1) of such Act (29 U.S.C. 1167(1)) is amended by adding at the end the following: “Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.

(c) AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.—

(1) IN GENERAL.—Section 2791(a)(1) of the Public Health Service Act (42 U.S.C. 300gg-91(a)(1)) is amended by adding at the end the following: “Except for purposes of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.), such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).”.

(2) EXCEPTION FROM CONTINUATION COVERAGE REQUIREMENTS.—Section 2208(1) of the Public Health Service Act (42 U.S.C. 300bb-8(1)) is amended by adding at the end the following: “Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code of 1986).”.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2016.

TITLE XIX—INVESTING IN PREVENTION AND FAMILY SERVICES

SEC. 19001. PURPOSE.

The purpose of this title is to enable States to use Federal funds available under parts B and E of title IV of the Social Security Act to provide enhanced support to children and families and prevent foster care placements through the provision of mental health and substance abuse prevention and treatment services, in-home parent skill-based programs, and kinship navigator services.

Subtitle A—Prevention Activities Under Title IV—E

SEC. 19011. FOSTER CARE PREVENTION SERVICES AND PROGRAMS.

(a) STATE OPTION.—Section 471 of the Social Security Act (42 U.S.C. 671) is amended—

(1) in subsection (a)(1), by striking “and” and all that follows through the semicolon and inserting “, adoption assistance in accordance with section 473, and, at the option of the State, services or programs specified in subsection (e)(1) of this section for children who are candidates for foster care or who are pregnant or parenting foster youth and the parents or kin caregivers of the children, in accordance with the requirements of that subsection;” and

(2) by adding at the end the following:

“(e) PREVENTION AND FAMILY SERVICES AND PROGRAMS.—

“(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary may make a payment to a State for providing the following services or programs for a child described in paragraph (2) and the parents or kin caregivers of the child when the need of the child, such a parent, or such a caregiver for the services or programs are directly related to the safety, permanence, or well-being of the child or to preventing the child from entering foster care:

“(A) MENTAL HEALTH AND SUBSTANCE ABUSE PREVENTION AND TREATMENT SERVICES.—Mental health and substance abuse prevention and treatment services provided by a qualified clinician for not more than a 12-month period that begins on any date described in paragraph (3) with respect to the child.

“(B) IN-HOME PARENT SKILL-BASED PROGRAMS.—In-home parent skill-based programs for not more than a 12-month period that begins on any date described in paragraph (3) with respect to the child and that include parenting skills training, parent education, and individual and family counseling.

“(2) CHILD DESCRIBED.—For purposes of paragraph (1), a child described in this paragraph is the following:

“(A) A child who is a candidate for foster care (as defined in section 475(13)) but can remain safely at home or in a kinship placement with receipt of services or programs specified in paragraph (1).

“(B) A child in foster care who is a pregnant or parenting foster youth.

“(3) DATE DESCRIBED.—For purposes of paragraph (1), the dates described in this paragraph are the following:

“(A) The date on which a child is identified in a prevention plan maintained under paragraph (4) as a child who is a candidate for foster care (as defined in section 475(13)).

“(B) The date on which a child is identified in a prevention plan maintained under paragraph (4) as a pregnant or parenting foster youth in need of services or programs specified in paragraph (1).

“(4) REQUIREMENTS RELATED TO PROVIDING SERVICES AND PROGRAMS.—Services and programs specified in paragraph (1) may be provided under this subsection only if specified in advance in the child’s prevention plan described in subparagraph (A) and the requirements in subparagraphs (B) through (E) are met:

“(A) PREVENTION PLAN.—The State maintains a written prevention plan for the child that meets the following requirements (as applicable):

“(i) CANDIDATES.—In the case of a child who is a candidate for foster care described in paragraph (2)(A), the prevention plan shall—

“(I) identify the foster care prevention strategy for the child so that the child may remain safely at home, live temporarily with a kin caregiver until reunification can be safely achieved, or live permanently with a kin caregiver;

“(II) list the services or programs to be provided to or on behalf of the child to ensure the success of that prevention strategy; and

“(III) comply with such other requirements as the Secretary shall establish.

“(ii) PREGNANT OR PARENTING FOSTER YOUTH.—In the case of a child who is a pregnant or parenting foster youth described in paragraph (2)(B), the prevention plan shall—

“(I) be included in the child’s case plan required under section 475(1);

“(II) list the services or programs to be provided to or on behalf of the youth to ensure that the youth is prepared (in the case of a pregnant foster youth) or able (in the case of a parenting foster youth) to be a parent;

“(III) describe the foster care prevention strategy for any child born to the youth; and

“(IV) comply with such other requirements as the Secretary shall establish.

“(B) TRAUMA-INFORMED.—The services or programs to be provided to or on behalf of a child are provided under an organizational structure and treatment framework that involves understanding, recognizing, and responding to the effects of all types of trauma and in accordance with recognized principles of a trauma-informed approach and trauma-specific interventions to address trauma’s consequences and facilitate healing.

“(C) ONLY SERVICES AND PROGRAMS PROVIDED IN ACCORDANCE WITH PROMISING, SUPPORTED, OR WELL-SUPPORTED PRACTICES PERMITTED.—

“(i) IN GENERAL.—Only State expenditures for services or programs specified in subparagraph (A) or (B) of paragraph (1) that are provided in accordance with practices that meet the requirements specified in clause (ii) of this subparagraph and that meet the requirements specified in clause (iii), (iv), or (v), respectively, for being a promising, supported, or well-supported practice, shall be eligible for a Federal matching payment under section 474(a)(6)(A).

“(ii) GENERAL PRACTICE REQUIREMENTS.—The general practice requirements specified in this clause are the following:

“(I) The practice has a book, manual, or other available writings that specify the components of the practice protocol and describe how to administer the practice.

“(II) There is no empirical basis suggesting that, compared to its likely benefits, the practice constitutes a risk of harm to those receiving it.

“(III) If multiple outcome studies have been conducted, the overall weight of evidence supports the benefits of the practice.

“(IV) Outcome measures are reliable and valid, and are administered consistently and accurately across all those receiving the practice.

“(V) There is no case data suggesting a risk of harm that was probably caused by the treatment and that was severe or frequent.

“(iii) PROMISING PRACTICE.—A practice shall be considered to be a ‘promising practice’ if the practice is superior to an appropriate comparison practice using conventional standards of statistical significance (in terms of demonstrated meaningful improvements in validated measures of important child and parent outcomes, such as mental health, substance abuse, and child safety and well-being), as established by the results or outcomes of at least one study that—

“(I) was rated by an independent systematic review for the quality of the study design and execution and determined to be well-designed and well-executed; and

“(II) utilized some form of control (such as an untreated group, a placebo group, or a wait list study).

“(iv) SUPPORTED PRACTICE.—A practice shall be considered to be a ‘supported practice’ if—

“(I) the practice is superior to an appropriate comparison practice using conventional standards of statistical significance (in terms of demonstrated meaningful improvements in validated measures of important child and parent outcomes, such as mental health, substance abuse, and child safety and well-being), as established by the results or outcomes of at least one study that—

“(aa) was rated by an independent systematic review for the quality of the study design and

execution and determined to be well-designed and well-executed;

“(bb) was a rigorous random-controlled trial (or, if not available, a study using a rigorous quasi-experimental research design); and

“(cc) was carried out in a usual care or practice setting; and

“(II) the study described in subclause (I) established that the practice has a sustained effect (when compared to a control group) for at least 6 months beyond the end of the treatment.

“(v) WELL-SUPPORTED PRACTICE.—A practice shall be considered to be a ‘well-supported practice’ if—

“(I) the practice is superior to an appropriate comparison practice using conventional standards of statistical significance (in terms of demonstrated meaningful improvements in validated measures of important child and parent outcomes, such as mental health, substance abuse, and child safety and well-being), as established by the results or outcomes of at least two studies that—

“(aa) were rated by an independent systematic review for the quality of the study design and execution and determined to be well-designed and well-executed;

“(bb) were rigorous random-controlled trials (or, if not available, studies using a rigorous quasi-experimental research design); and

“(cc) were carried out in a usual care or practice setting; and

“(II) at least one of the studies described in subclause (I) established that the practice has a sustained effect (when compared to a control group) for at least 1 year beyond the end of treatment.

“(D) GUIDANCE ON PRACTICES CRITERIA AND PRE-APPROVED SERVICES AND PROGRAMS.—

“(i) IN GENERAL.—Not later than October 1, 2018, the Secretary shall issue guidance to States regarding the practices criteria required for services or programs to satisfy the requirements of subparagraph (C). The guidance shall include a pre-approved list of services and programs that satisfy the requirements.

“(ii) UPDATES.—The Secretary shall issue updates to the guidance required by clause (i) as often as the Secretary determines necessary.

“(E) OUTCOME ASSESSMENT AND REPORTING.—The State shall collect and report to the Secretary the following information with respect to each child for whom, or on whose behalf mental health and substance abuse prevention and treatment services or in-home parent skill-based programs are provided during a 12-month period beginning on the date the child is determined by the State to be a child described in paragraph (2):

“(i) The specific services or programs provided and the total expenditures for each of the services or programs.

“(ii) The duration of the services or programs provided.

“(iii) In the case of a child described in paragraph (2)(A), the child’s placement status at the beginning, and at the end, of the 1-year period, respectively, and whether the child entered foster care within 2 years after being determined a candidate for foster care.

“(5) STATE PLAN COMPONENT.—

“(A) IN GENERAL.—A State electing to provide services or programs specified in paragraph (1) shall submit as part of the State plan required by subsection (a) a prevention services and programs plan component that meets the requirements of subparagraph (B).

“(B) PREVENTION SERVICES AND PROGRAMS PLAN COMPONENT.—In order to meet the requirements of this subparagraph, a prevention services and programs plan component, with respect to each 5-year period for which the plan component is in operation in the State, shall include the following:

“(i) How providing services and programs specified in paragraph (1) is expected to improve specific outcomes for children and families.

“(ii) How the State will monitor and oversee the safety of children who receive services and

programs specified in paragraph (1), including through periodic risk assessments throughout the period in which the services and programs are provided on behalf of a child and reexamination of the prevention plan maintained for the child under paragraph (4) for the provision of the services or programs if the State determines the risk of the child entering foster care remains high despite the provision of the services or programs.

“(iii) With respect to the services and programs specified in subparagraphs (A) and (B) of paragraph (1), information on the specific promising, supported, or well-supported practices the State plans to use to provide the services or programs, including a description of—

“(I) the services or programs and whether the practices used are promising, supported, or well-supported;

“(II) how the State plans to implement the services or programs, including how implementation of the services or programs will be continuously monitored to ensure fidelity to the practice model and to determine outcomes achieved and how information learned from the monitoring will be used to refine and improve practices;

“(III) how the State selected the services or programs;

“(IV) the target population for the services or programs; and

“(V) how each service or program provided will be evaluated through a well-designed and rigorous process, which may consist of an ongoing, cross-site evaluation approved by the Secretary.

“(iv) A description of the consultation that the State agencies responsible for administering the State plans under this part and part B engage in with other State agencies responsible for administering health programs, including mental health and substance abuse prevention and treatment services, and with other public and private agencies with experience in administering child and family services, including community-based organizations, in order to foster a continuum of care for children described in paragraph (2) and their parents or kin caregivers.

“(v) A description of how the State shall assess children and their parents or kin caregivers to determine eligibility for services or programs specified in paragraph (1).

“(vi) A description of how the services or programs specified in paragraph (1) that are provided for or on behalf of a child and the parents or kin caregivers of the child will be coordinated with other child and family services provided to the child and the parents or kin caregivers of the child under the State plan under part B.

“(vii) Descriptions of steps the State is taking to support and enhance a competent, skilled, and professional child welfare workforce to deliver trauma-informed and evidence-based services, including—

“(I) ensuring that staff is qualified to provide services or programs that are consistent with the promising, supported, or well-supported practice models selected; and

“(II) developing appropriate prevention plans, and conducting the risk assessments required under clause (iii).

“(viii) A description of how the State will provide training and support for caseworkers in assessing what children and their families need, connecting to the families served, knowing how to access and deliver the needed trauma-informed and evidence-based services, and overseeing and evaluating the continuing appropriateness of the services.

“(ix) A description of how caseload size and type for prevention caseworkers will be determined, managed, and overseen.

“(x) An assurance that the State will report to the Secretary such information and data as the Secretary may require with respect to the provision of services and programs specified in paragraph (1), including information and data nec-

essary to determine the performance measures for the State under paragraph (6) and compliance with paragraph (7).

“(C) REIMBURSEMENT FOR SERVICES UNDER THE PREVENTION PLAN COMPONENT.—

“(i) LIMITATION.—Except as provided in subclause (ii), a State may not receive a Federal payment under this part for a given promising, supported, or well-supported practice unless (in accordance with subparagraph (B)(iii)(V)) the plan includes a well-designed and rigorous evaluation strategy for that practice.

“(ii) WAIVER OF LIMITATION.—The Secretary may waive the requirement for a well-designed and rigorous evaluation of any well-supported practice if the Secretary deems the evidence of the effectiveness of the practice to be compelling and the State meets the continuous quality improvement requirements included in subparagraph (B)(iii)(II) with regard to the practice.

“(6) PREVENTION SERVICES MEASURES.—

“(A) ESTABLISHMENT; ANNUAL UPDATES.—Beginning with fiscal year 2021, and annually thereafter, the Secretary shall establish the following prevention services measures based on information and data reported by States that elect to provide services and programs specified in paragraph (1):

“(i) PERCENTAGE OF CANDIDATES FOR FOSTER CARE WHO DO NOT ENTER FOSTER CARE.—The percentage of candidates for foster care for whom, or on whose behalf, the services or programs are provided who do not enter foster care, including those placed with a kin caregiver outside of foster care, during the 12-month period in which the services or programs are provided and through the end of the succeeding 12-month-period.

“(ii) PER-CHILD SPENDING.—The total amount of expenditures made for mental health and substance abuse prevention and treatment services or in-home parent skill-based programs, respectively, for, or on behalf of, each child described in paragraph (2).

“(B) DATA.—The Secretary shall establish and annually update the prevention services measures—

“(i) based on the median State values of the information reported under each clause of subparagraph (A) for the 3 then most recent years; and

“(ii) taking into account State differences in the price levels of consumption goods and services using the most recent regional price parities published by the Bureau of Economic Analysis of the Department of Commerce or such other data as the Secretary determines appropriate.

“(C) PUBLICATION OF STATE PREVENTION SERVICES MEASURES.—The Secretary shall annually make available to the public the prevention services measures of each State.

“(7) MAINTENANCE OF EFFORT FOR STATE FOSTER CARE PREVENTION EXPENDITURES.—

“(A) IN GENERAL.—If a State elects to provide services and programs specified in paragraph (1) for a fiscal year, the State foster care prevention expenditures for the fiscal year shall not be less than the amount of the expenditures for fiscal year 2014 (or, at the option of a State described in subparagraph (E), fiscal year 2015 or fiscal year 2016 (whichever the State elects)).

“(B) STATE FOSTER CARE PREVENTION EXPENDITURES.—The term ‘State foster care prevention expenditures’ means the following:

“(i) TANF; IV-B; SSBG.—State expenditures for foster care prevention services and activities under the State program funded under part A (including from amounts made available by the Federal Government), under the State plan developed under part B (including any such amounts), or under the Social Services Block Grant Programs under subtitle A of title XX (including any such amounts).

“(ii) OTHER STATE PROGRAMS.—State expenditures for foster care prevention services and activities under any State program that is not described in clause (i) (other than any State expenditures for foster care prevention services

and activities under the State program under this part (including under a waiver of the program)).

“(C) STATE EXPENDITURES.—The term ‘State expenditures’ means all State or local funds that are expended by the State or a local agency including State or local funds that are matched or reimbursed by the Federal Government and State or local funds that are not matched or reimbursed by the Federal Government.

“(D) DETERMINATION OF PREVENTION SERVICES AND ACTIVITIES.—The Secretary shall require each State that elects to provide services and programs specified in paragraph (1) to report the expenditures specified in subparagraph (B) for fiscal year 2014 and for such fiscal years thereafter as are necessary to determine whether the State is complying with the maintenance of effort requirement in subparagraph (A). The Secretary shall specify the specific services and activities under each program referred to in subparagraph (B) that are ‘prevention services and activities’ for purposes of the reports.

“(E) STATE DESCRIBED.—For purposes of subparagraph (A), a State is described in this subparagraph if the population of children in the State in 2014 was less than 200,000 (as determined by the Bureau of the Census).

“(B) PROHIBITION AGAINST USE OF STATE FOSTER CARE PREVENTION EXPENDITURES AND FEDERAL IV-E PREVENTION FUNDS FOR MATCHING OR EXPENDITURE REQUIREMENT.—A State that elects to provide services and programs specified in paragraph (1) shall not use any State foster care prevention expenditures for a fiscal year for the State share of expenditures under section 474(a)(6) for a fiscal year.

“(9) ADMINISTRATIVE COSTS.—Expenditures described in section 474(a)(6)(B)—

“(A) shall not be eligible for payment under subparagraph (A), (B), or (E) of section 474(a)(3); and

“(B) shall be eligible for payment under section 474(a)(6)(B) without regard to whether the expenditures are incurred on behalf of a child who is, or is potentially, eligible for foster care maintenance payments under this part.

“(10) APPLICATION.—

“(A) IN GENERAL.—The provision of services or programs under this subsection to or on behalf of a child described in paragraph (2) shall not be considered to be receipt of aid or assistance under the State plan under this part for purposes of eligibility for any other program established under this Act.

“(B) CANDIDATES IN KINSHIP CARE.—A child described in paragraph (2) for whom such services or programs under this subsection are provided for more than 6 months while in the home of a kin caregiver, and who would satisfy the AFDC eligibility requirement of section 472(a)(3)(A)(i)(II) but for residing in the home of the caregiver for more than 6 months, is deemed to satisfy that requirement for purposes of determining whether the child is eligible for foster care maintenance payments under section 472.”

(b) DEFINITION.—Section 475 of such Act (42 U.S.C. 675) is amended by adding at the end the following:

“(13) The term ‘child who is a candidate for foster care’ means, a child who is identified in a prevention plan under section 471(e)(4)(A) as being at imminent risk of entering foster care (without regard to whether the child would be eligible for foster care maintenance payments under section 472 or is or would be eligible for adoption assistance or kinship guardianship assistance payments under section 473) but who can remain safely in the child’s home or in a kinship placement as long as services or programs specified in section 471(e)(1) that are necessary to prevent the entry of the child into foster care are provided. The term includes a child whose adoption or guardianship arrangement is at risk of a disruption or dissolution that would result in a foster care placement.”

(c) PAYMENTS UNDER TITLE IV—E.—Section 474(a) of such Act (42 U.S.C. 674(a)) is amended—

(1) in paragraph (5), by striking the period at the end and inserting “; plus”; and

(2) by adding at the end the following:

“(6) subject to section 471(e)—

“(A) for each quarter—

“(i) subject to clause (ii)—

“(I) beginning after September 30, 2019, and before October 1, 2025, an amount equal to 50 percent of the total amount expended during the quarter for the provision of services or programs specified in subparagraph (A) or (B) of section 471(e)(1) that are provided in accordance with promising, supported, or well-supported practices that meet the applicable criteria specified for the practices in section 471(e)(4)(C); and

“(II) beginning after September 30, 2025, an amount equal to the Federal medical assistance percentage (which shall be as defined in section 1905(b), in the case of a State other than the District of Columbia, or 70 percent, in the case of the District of Columbia) of the total amount expended during the quarter for the provision of services or programs specified in subparagraph (A) or (B) of section 471(e)(1) that are provided in accordance with promising, supported, or well-supported practices that meet the applicable criteria specified for the practices in section 471(e)(4)(C) (or, with respect to the payments made during the quarter under a cooperative agreement or contract entered into by the State and an Indian tribe, tribal organization, or tribal consortium for the administration or payment of funds under this part, an amount equal to the Federal medical assistance percentage that would apply under section 479B(d) (in this paragraph referred to as the ‘tribal FMAP’) if the Indian tribe, tribal organization, or tribal consortium made the payments under a program operated under that section, unless the tribal FMAP is less than the Federal medical assistance percentage that applies to the State); except that

“(ii) not less than 50 percent of the total amount payable to a State under clause (i) for a fiscal year shall be for the provision of services or programs specified in subparagraph (A) or (B) of section 471(e)(1) that are provided in accordance with well-supported practices; plus

“(B) for each quarter specified in subparagraph (A), an amount equal to the sum of the following proportions of the total amount expended during the quarter:

“(i) 50 percent of so much of the expenditures as are found necessary by the Secretary for the proper and efficient administration of the State plan for the provision of services or programs specified in section 471(e)(1), including expenditures for activities approved by the Secretary that promote the development of necessary processes and procedures to establish and implement the provision of the services and programs for individuals who are eligible for the services and programs and expenditures attributable to data collection and reporting; and

“(ii) 50 percent of so much of the expenditures with respect to the provision of services and programs specified in section 471(e)(1) as are for training of personnel employed or preparing for employment by the State agency or by the local agency administering the plan in the political subdivision and of the members of the staff of State-licensed or State-approved child welfare agencies providing services to children described in section 471(e)(2) and their parents or kin caregivers, including on how to determine who are individuals eligible for the services or programs, how to identify and provide appropriate services and programs, and how to oversee and evaluate the ongoing appropriateness of the services and programs.”.

(d) TECHNICAL ASSISTANCE AND BEST PRACTICES, CLEARINGHOUSE, AND DATA COLLECTION AND EVALUATIONS.—Section 476 of such Act (42 U.S.C. 676) is amended by adding at the end the following:

“(d) TECHNICAL ASSISTANCE AND BEST PRACTICES, CLEARINGHOUSE, DATA COLLECTION, AND EVALUATIONS RELATING TO PREVENTION SERVICES AND PROGRAMS.—

“(1) TECHNICAL ASSISTANCE AND BEST PRACTICES.—The Secretary shall provide to States and, as applicable, to Indian tribes, tribal organizations, and tribal consortia, technical assistance regarding the provision of services and programs described in section 471(e)(1) and shall disseminate best practices with respect to the provision of the services and programs, including how to plan and implement a well-designed and rigorous evaluation of a promising, supported, or well-supported practice.

“(2) CLEARINGHOUSE OF PROMISING, SUPPORTED, AND WELL-SUPPORTED PRACTICES.—The Secretary shall, directly or through grants, contracts, or interagency agreements, evaluate research on the practices specified in clauses (iii), (iv), and (v), respectively, of section 471(e)(4)(C), and programs that meet the requirements described in section 427(a)(1), including culturally specific, or location- or population-based adaptations of the practices, to identify and establish a public clearinghouse of the practices that satisfy each category described by such clauses. In addition, the clearinghouse shall include information on the specific outcomes associated with each practice, including whether the practice has been shown to prevent child abuse and neglect and reduce the likelihood of foster care placement by supporting birth families and kinship families and improving targeted supports for pregnant and parenting youth and their children.

“(3) DATA COLLECTION AND EVALUATIONS.—The Secretary, directly or through grants, contracts, or interagency agreements, may collect data and conduct evaluations with respect to the provision of services and programs described in section 471(e)(1) for purposes of assessing the extent to which the provision of the services and programs—

“(A) reduces the likelihood of foster care placement;

“(B) increases use of kinship care arrangements; or

“(C) improves child well-being.

“(4) REPORTS TO CONGRESS.—

“(A) IN GENERAL.—The Secretary shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives periodic reports based on the provision of services and programs described in section 471(e)(1) and the activities carried out under this subsection.

“(B) PUBLIC AVAILABILITY.—The Secretary shall make the reports to Congress submitted under this paragraph publicly available.

“(5) APPROPRIATION.—Out of any money in the Treasury of the United States not otherwise appropriated, there is appropriated to the Secretary \$1,000,000 for fiscal year 2017 and each fiscal year thereafter to carry out this subsection.”.

(e) APPLICATION TO PROGRAMS OPERATED BY INDIAN TRIBAL ORGANIZATIONS.—

(1) IN GENERAL.—Section 479B of such Act (42 U.S.C. 679c) is amended—

(A) in subsection (c)(1)—

(i) in subparagraph (C)(i)—

(I) in subclause (II), by striking “and” after the semicolon;

(II) in subclause (III), by striking the period at the end and inserting “; and”; and

(III) by adding at the end the following:

“(IV) at the option of the tribe, organization, or consortium, services and programs specified in section 471(e)(1) to children described in section 471(e)(2) and their parents or kin caregivers, in accordance with section 471(e) and subparagraph (E).”; and

(ii) by adding at the end the following:

“(E) PREVENTION SERVICES AND PROGRAMS FOR CHILDREN AND THEIR PARENTS AND KIN CAREGIVERS.—

“(i) IN GENERAL.—In the case of a tribe, organization, or consortium that elects to provide

services and programs specified in section 471(e)(1) to children described in section 471(e)(2) and their parents or kin caregivers under the plan, the Secretary shall specify the requirements applicable to the provision of the services and programs. The requirements shall, to the greatest extent practicable, be consistent with the requirements applicable to States under section 471(e) and shall permit the provision of the services and programs in the form of services and programs that are adapted to the culture and context of the tribal communities served.

“(ii) PERFORMANCE MEASURES.—The Secretary shall establish specific performance measures for each tribe, organization, or consortium that elects to provide services and programs specified in section 471(e)(1). The performance measures shall, to the greatest extent practicable, be consistent with the prevention services measures required for States under section 471(e)(6) but shall allow for consideration of factors unique to the provision of the services by tribes, organizations, or consortia.”; and

(B) in subsection (d)(1), by striking “and (5)” and inserting “(5), and (6)(A)”.’.

(2) CONFORMING AMENDMENT.—The heading for subsection (d) of section 479B of such Act (42 U.S.C. 679c) is amended by striking “FOR FOSTER CARE MAINTENANCE AND ADOPTION ASSISTANCE PAYMENTS”.

(f) APPLICATION TO PROGRAMS OPERATED BY TERRITORIES.—Section 1108(a)(2) of the Social Security Act (42 U.S.C. 1308(a)(2)) is amended by striking “or 413(f)” and inserting “413(f), or 474(a)(6)”.

SEC. 19012. FOSTER CARE MAINTENANCE PAYMENTS FOR CHILDREN WITH PARENTS IN A LICENSED RESIDENTIAL FAMILY-BASED TREATMENT FACILITY FOR SUBSTANCE ABUSE.

(a) IN GENERAL.—Section 472 of the Social Security Act (42 U.S.C. 672) is amended—

(1) in subsection (a)(2)(C), by striking “or” and inserting “, with a parent residing in a licensed residential family-based treatment facility, but only to the extent permitted under subsection (j), or in a”; and

(2) by adding at the end the following:

“(j) CHILDREN PLACED WITH A PARENT RESIDING IN A LICENSED RESIDENTIAL FAMILY-BASED TREATMENT FACILITY FOR SUBSTANCE ABUSE.—

“(1) IN GENERAL.—Notwithstanding the preceding provisions of this section, a child who is eligible for foster care maintenance payments under this section, or who would be eligible for the payments if the eligibility were determined without regard to paragraphs (1)(B) and (3) of subsection (a), shall be eligible for the payments for a period of not more than 12 months during which the child is placed with a parent who is in a licensed residential family-based treatment facility for substance abuse, but only if—

“(A) the recommendation for the placement is specified in the child’s case plan before the placement;

“(B) the treatment facility provides, as part of the treatment for substance abuse, parenting skills training, parent education, and individual and family counseling; and

“(C) the substance abuse treatment, parenting skills training, parent education, and individual and family counseling is provided under an organizational structure and treatment framework that involves understanding, recognizing, and responding to the effects of all types of trauma and in accordance with recognized principles of a trauma-informed approach and trauma-specific interventions to address the consequences of trauma and facilitate healing.

“(2) APPLICATION.—With respect to children for whom foster care maintenance payments are made under paragraph (1), only the children who satisfy the requirements of paragraphs (1)(B) and (3) of subsection (a) shall be considered to be children with respect to whom foster care maintenance payments are made under this section for purposes of subsection (h) or section 473(b)(3)(B).”.

(b) CONFORMING AMENDMENT.—Section 474(a)(1) of such Act (42 U.S.C. 674(a)(1)) is amended by inserting “subject to section 472(j),” before “an amount equal to the Federal” the first place it appears.

SEC. 19013. TITLE IV-E PAYMENTS FOR EVIDENCE-BASED KINSHIP NAVIGATOR PROGRAMS.

Section 474(a) of the Social Security Act (42 U.S.C. 674(a)), as amended by section 19011(c), is amended—

(1) in paragraph (6), by striking the period at the end and inserting “; plus”; and

(2) by adding at the end the following:

“(7) an amount equal to 50 percent of the amounts expended by the State during the quarter as the Secretary determines are for kinship navigator programs that meet the requirements described in section 427(a)(1) and that the Secretary determines are operated in accordance with promising, supported, or well-supported practices that meet the applicable criteria specified for the practices in section 471(e)(4)(C), without regard to whether the expenditures are incurred on behalf of children who are, or are potentially, eligible for foster care maintenance payments under this part.”.

Subtitle B—Enhanced Support Under Title IV-B

SEC. 19021. ELIMINATION OF TIME LIMIT FOR FAMILY REUNIFICATION SERVICES WHILE IN FOSTER CARE AND PERMITTING TIME-LIMITED FAMILY REUNIFICATION SERVICES WHEN A CHILD RETURNS HOME FROM FOSTER CARE.

(a) IN GENERAL.—Section 431(a)(7) of the Social Security Act (42 U.S.C. 629a(a)(7)) is amended—

(1) in the paragraph heading, by striking “TIME-LIMITED FAMILY” and inserting “FAMILY”; and

(2) in subparagraph (A)—

(A) by striking “time-limited family” and inserting “family”; and

(B) by inserting “or a child who has been returned home” after “child care institution”; and

(C) by striking “, but only during the 15-month period that begins on the date that the child, pursuant to section 475(5)(F), is considered to have entered foster care” and inserting “and to ensure the strength and stability of the reunification. In the case of a child who has been returned home, the services and activities shall only be provided during the 15-month period that begins on the date that the child returns home”.

(b) CONFORMING AMENDMENTS.—

(1) Section 430 of such Act (42 U.S.C. 629) is amended in the matter preceding paragraph (1), by striking “time-limited”.

(2) Subsections (a)(4), (a)(5)(A), and (b)(1) of section 432 of such Act (42 U.S.C. 629b) are amended by striking “time-limited” each place it appears.

SEC. 19022. REDUCING BUREAUCRACY AND UNNECESSARY DELAYS WHEN PLACING CHILDREN IN HOMES ACROSS STATE LINES.

(a) STATE PLAN REQUIREMENT.—Section 471(a)(25) of the Social Security Act (42 U.S.C. 671(a)(25)) is amended—

(1) by striking “provide” and insert “provides”; and

(2) by inserting “, which, not later than October 1, 2026, shall include the use of an electronic interstate case-processing system” before the first semicolon.

(b) GRANTS FOR THE DEVELOPMENT OF AN ELECTRONIC INTERSTATE CASE-PROCESSING SYSTEM TO EXPEDITE THE INTERSTATE PLACEMENT OF CHILDREN IN FOSTER CARE OR GUARDIANSHIP, OR FOR ADOPTION.—Section 437 of such Act (42 U.S.C. 629g) is amended by adding at the end the following:

“(g) GRANTS FOR THE DEVELOPMENT OF AN ELECTRONIC INTERSTATE CASE-PROCESSING SYS-

TEM TO EXPEDITE THE INTERSTATE PLACEMENT OF CHILDREN IN FOSTER CARE OR GUARDIANSHIP, OR FOR ADOPTION.—

“(1) PURPOSE.—The purpose of this subsection is to facilitate the development of an electronic interstate case-processing system for the exchange of data and documents to expedite the placements of children in foster, guardianship, or adoptive homes across State lines.

“(2) APPLICATION REQUIREMENTS.—A State that desires a grant under this subsection shall submit to the Secretary an application containing the following:

“(A) A description of the goals and outcomes to be achieved during the period for which grant funds are sought, which goals and outcomes must result in—

“(i) reducing the time it takes for a child to be provided with a safe and appropriate permanent living arrangement across State lines;

“(ii) improving administrative processes and reducing costs in the foster care system; and

“(iii) the secure exchange of relevant case files and other necessary materials in real time, and timely communications and placement decisions regarding interstate placements of children.

“(B) A description of the activities to be funded in whole or in part with the grant funds, including the sequencing of the activities.

“(C) A description of the strategies for integrating programs and services for children who are placed across State lines.

“(D) Such other information as the Secretary may require.

“(3) GRANT AUTHORITY.—The Secretary may make a grant to a State that complies with paragraph (2).

“(4) USE OF FUNDS.—A State to which a grant is made under this subsection shall use the grant to support the State in connecting with the electronic interstate case-processing system described in paragraph (1).

“(5) EVALUATIONS.—Not later than 1 year after the final year in which grants are awarded under this subsection, the Secretary shall submit to the Congress, and make available to the general public by posting on a website, a report that contains the following information:

“(A) How using the electronic interstate case-processing system developed pursuant to paragraph (4) has changed the time it takes for children to be placed across State lines.

“(B) The number of cases subject to the Interstate Compact on the Placement of Children that were processed through the electronic interstate case-processing system, and the number of interstate child placement cases that were processed outside the electronic interstate case-processing system, by each State in each year.

“(C) The progress made by States in implementing the electronic interstate case-processing system.

“(D) How using the electronic interstate case-processing system has affected various metrics related to child safety and well-being, including the time it takes for children to be placed across State lines.

“(E) How using the electronic interstate case-processing system has affected administrative costs and caseworker time spent on placing children across State lines.

“(6) DATA INTEGRATION.—The Secretary, in consultation with the Secretariat for the Interstate Compact on the Placement of Children and the States, shall assess how the electronic interstate case-processing system developed pursuant to paragraph (4) could be used to better serve and protect children that come to the attention of the child welfare system, by—

“(A) connecting the system with other data systems (such as systems operated by State law enforcement and judicial agencies, systems operated by the Federal Bureau of Investigation for the purposes of the Innocence Lost National Initiative, and other systems);

“(B) simplifying and improving reporting related to paragraphs (34) and (35) of section

471(a) regarding children or youth who have been identified as being a sex trafficking victim or children missing from foster care; and

“(C) improving the ability of States to quickly comply with background check requirements of section 471(a)(20), including checks of child abuse and neglect registries as required by section 471(a)(20)(B).”.

(c) RESERVATION OF FUNDS TO IMPROVE THE INTERSTATE PLACEMENT OF CHILDREN.—Section 437(b) of such Act (42 U.S.C. 629g(b)) is amended by adding at the end the following:

“(4) IMPROVING THE INTERSTATE PLACEMENT OF CHILDREN.—The Secretary shall reserve \$5,000,000 of the amount made available for fiscal year 2017 for grants under subsection (g), and the amount so reserved shall remain available through fiscal year 2021.”.

SEC. 19023. ENHANCEMENTS TO GRANTS TO IMPROVE WELL-BEING OF FAMILIES AFFECTED BY SUBSTANCE ABUSE.

Section 437(f) of the Social Security Act (42 U.S.C. 629g(f)) is amended—

(1) in the subsection heading, by striking “INCREASE THE WELL-BEING OF, AND TO IMPROVE THE PERMANENCY OUTCOMES FOR, CHILDREN AFFECTED BY” and inserting “IMPLEMENT IV-E PREVENTION SERVICES, AND IMPROVE THE WELL-BEING OF, AND IMPROVE PERMANENCY OUTCOMES FOR, CHILDREN AND FAMILIES AFFECTED BY HEROIN, OPIOIDS, AND OTHER”;

(2) by striking paragraph (2) and inserting the following:

“(2) REGIONAL PARTNERSHIP DEFINED.—In this subsection, the term ‘regional partnership’ means a collaborative agreement (which may be established on an interstate, State, or intrastate basis) entered into by the following:

“(A) MANDATORY PARTNERS FOR ALL PARTNERSHIP GRANTS.—

“(i) The State child welfare agency that is responsible for the administration of the State plan under this part and part E.

“(ii) The State agency responsible for administering the substance abuse prevention and treatment block grant provided under subpart II of part B of title XIX of the Public Health Service Act.

“(B) MANDATORY PARTNERS FOR PARTNERSHIP GRANTS PROPOSING TO SERVE CHILDREN IN OUT-OF-HOME PLACEMENTS.—If the partnership proposes to serve children in out-of-home placements, the Juvenile Court or Administrative Office of the Court that is most appropriate to oversee the administration of court programs in the region to address the population of families who come to the attention of the court due to child abuse or neglect.

“(C) OPTIONAL PARTNERS.—At the option of the partnership, any of the following:

“(i) An Indian tribe or tribal consortium.

“(ii) Nonprofit child welfare service providers.

“(iii) For-profit child welfare service providers.

“(iv) Community health service providers, including substance abuse treatment providers.

“(v) Community mental health providers.

“(vi) Local law enforcement agencies.

“(vii) School personnel.

“(viii) Tribal child welfare agencies (or a consortia of the agencies).

“(ix) Any other providers, agencies, personnel, officials, or entities that are related to the provision of child and family services under a State plan approved under this subpart.

(D) EXCEPTION FOR REGIONAL PARTNERSHIPS WHERE THE LEAD APPLICANT IS AN INDIAN TRIBE OR TRIBAL CONSORTIA.—If an Indian tribe or tribal consortium enters into a regional partnership for purposes of this subsection, the Indian tribe or tribal consortium—

“(i) may (but is not required to) include the State child welfare agency as a partner in the collaborative agreement;

“(ii) may not enter into a collaborative agreement only with tribal child welfare agencies (or a consortium of the agencies); and

“(iii) if the condition described in paragraph (2)(B) applies, may include tribal court organizations in lieu of other judicial partners.”;

(3) in paragraph (3)—
 (A) in subparagraph (A)—
 (i) by striking “2012 through 2016” and inserting “2017 through 2021”; and
 (ii) by striking “\$500,000 and not more than \$1,000,000” and inserting “\$250,000 and not more than \$1,000,000”;

(B) in subparagraph (B)—
 (i) in the subparagraph heading, by inserting “; PLANNING” after “APPROVAL”;

(ii) in clause (i), by striking “clause (ii)” and inserting “clauses (ii) and (iii)”; and
 (iii) by adding at the end the following:
 “(iii) SUFFICIENT PLANNING.—A grant awarded under this subsection shall be disbursed in two phases: a planning phase (not to exceed 2 years); and an implementation phase. The total disbursement to a grantee for the planning phase may not exceed \$250,000, and may not exceed the total anticipated funding for the implementation phase.”; and

(C) by adding at the end the following:
 “(D) LIMITATION ON PAYMENT FOR A FISCAL YEAR.—No payment shall be made under subparagraph (A) or (C) for a fiscal year until the Secretary determines that the eligible partnership has made sufficient progress in meeting the goals of the grant and that the members of the eligible partnership are coordinating to a reasonable degree with the other members of the eligible partnership.”;

(4) in paragraph (4)—
 (A) in subparagraph (B)—
 (i) in clause (i), by inserting “, parents, and families” after “children”;

(ii) in clause (ii), by striking “safety and permanence for such children; and” and inserting “safe, permanent caregiving relationships for the children;”;

(iii) in clause (iii), by striking “or” and inserting “increase reunification rates for children who have been placed in out of home care, or decrease”;

(iv) by redesignating clause (iii) as clause (v) and inserting after clause (ii) the following:
 “(iii) improve the substance abuse treatment outcomes for parents including retention in treatment and successful completion of treatment;

“(iv) facilitate the implementation, delivery, and effectiveness of prevention services and programs under section 471(e); and”;

(B) in subparagraph (D), by striking “where appropriate,”; and

(C) by striking subparagraphs (E) and (F) and inserting the following:
 “(E) A description of a plan for sustaining the services provided by or activities funded under the grant after the conclusion of the grant period, including through the use of prevention services and programs under section 471(e) and other funds provided to the State for child welfare and substance abuse prevention and treatment services.

“(F) Additional information needed by the Secretary to determine that the proposed activities and implementation will be consistent with research or evaluations showing which practices and approaches are most effective.”;

(5) in paragraph (5)(A), by striking “abuse treatment” and inserting “use disorder treatment including medication assisted treatment and in-home substance abuse disorder treatment and recovery”;

(6) in paragraph (7)—
 (A) by striking “and” at the end of subparagraph (C); and
 (B) by redesignating subparagraph (D) as subparagraph (E) and inserting after subparagraph (C) the following:
 “(D) demonstrate a track record of successful collaboration among child welfare, substance abuse disorder treatment and mental health agencies; and”;

(7) in paragraph (8)—
 (A) in subparagraph (A)—
 (i) by striking “establish indicators that will be” and inserting “review indicators that are”;

(ii) by striking “in using funds made available under such grants to achieve the purpose of this subsection” and inserting “and establish a set of core indicators related to child safety, parental recovery, parenting capacity, and family well-being. In developing the core indicators, to the extent possible, indicators shall be made consistent with the outcome measures described in section 471(e)(6)”;

(B) in subparagraph (B)—
 (i) in the matter preceding clause (i), by inserting “base the performance measures on lessons learned from prior rounds of regional partnership grants under this subsection, and” before “consult”;

(ii) by striking clauses (iii) and (iv) and inserting the following:
 “(iii) Other stakeholders or constituencies as determined by the Secretary.”;

(8) in paragraph (9)(A), by striking clause (i) and inserting the following:
 “(i) SEMIANNUAL REPORTS.—Not later than September 30 of each fiscal year in which a recipient of a grant under this subsection is paid funds under the grant, and every 6 months thereafter, the grant recipient shall submit to the Secretary a report on the services provided and activities carried out during the reporting period, progress made in achieving the goals of the program, the number of children, adults, and families receiving services, and such additional information as the Secretary determines is necessary. The report due not later than September 30 of the last such fiscal year shall include, at a minimum, data on each of the performance indicators included in the evaluation of the regional partnership.”;

(9) in paragraph (10), by striking “2012 through 2016” and inserting “2017 through 2021”.

Subtitle C—Miscellaneous

SEC. 19031. REVIEWING AND IMPROVING LICENSING STANDARDS FOR PLACEMENT IN A RELATIVE FOSTER FAMILY HOME.

(a) IDENTIFICATION OF REPUTABLE MODEL LICENSING STANDARDS.—Not later than October 1, 2017, the Secretary of Health and Human Services shall identify reputable model licensing standards with respect to the licensing of foster family homes (as defined in section 472(c)(1) of the Social Security Act).

(b) STATE PLAN REQUIREMENT.—Section 471(a) of the Social Security Act (42 U.S.C. 671(a)) is amended—

(1) in paragraph (34)(B), by striking “and” after the semicolon;

(2) in paragraph (35)(B), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

“(36) provides that, not later than April 1, 2018, the State shall submit to the Secretary information addressing—

“(A) whether the State licensing standards are in accord with model standards identified by the Secretary, and if not, the reason for the specific deviation and a description as to why having a standard that is reasonably in accord with the corresponding national model standards is not appropriate for the State;

“(B) whether the State has elected to waive standards established in 471(a)(10)(A) for relative foster family homes (pursuant to waiver authority provided by 471(a)(10)(D)), a description of which standards the State most commonly waives, and if the State has not elected to waive the standards, the reason for not waiving these standards;

“(C) if the State has elected to waive standards specified in subparagraph (B), how caseworkers are trained to use the waiver authority and whether the State has developed a process or provided tools to assist caseworkers in waiving nonsafety standards per the authority provided in 471(a)(10)(D) to quickly place children with relatives; and

“(D) a description of the steps the State is taking to improve caseworker training or the process, if any; and”.

SEC. 19032. DEVELOPMENT OF A STATEWIDE PLAN TO PREVENT CHILD ABUSE AND NEGLECT FATALITIES.

Section 422(b)(19) of the Social Security Act (42 U.S.C. 622(b)(19)) is amended to read as follows:

“(19) document steps taken to track and prevent child maltreatment deaths by including—

“(A) a description of the steps the State is taking to compile complete and accurate information on the deaths required by Federal law to be reported by the State agency referred to in paragraph (1), including gathering relevant information on the deaths from the relevant organizations in the State including entities such as State vital statistics department, child death review teams, law enforcement agencies, offices of medical examiners or coroners; and

“(B) a description of the steps the state is taking to develop and implement of a comprehensive, statewide plan to prevent the fatalities that involves and engages relevant public and private agency partners, including those in public health, law enforcement, and the courts.”.

SEC. 19033. MODERNIZING THE TITLE AND PURPOSE OF TITLE IV-E.

(a) PART HEADING.—The heading for part E of title IV of the Social Security Act (42 U.S.C. 670 et seq.) is amended to read as follows:

“PART E—FEDERAL PAYMENTS FOR FOSTER CARE, PREVENTION, AND PERMANENCY”.

(b) PURPOSE.—The first sentence of section 470 of such Act (42 U.S.C. 670) is amended—

(1) by striking “1995) and” and inserting “1995),”;

(2) by inserting “kinship guardianship assistance, and prevention services or programs specified in section 471(e)(1),” after “needs,”; and

(3) by striking “(commencing with the fiscal year which begins October 1, 1980)”.

SEC. 19034. EFFECTIVE DATES.

(a) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), subject to subsection (b), the amendments made by this title shall take effect on January 1, 2017.

(2) EXCEPTIONS.—The amendments made by sections 19031 and 19033 shall take effect on the date of enactment of this Act.

(b) TRANSITION RULE.—

(1) IN GENERAL.—In the case of a State plan under part B or E of title IV of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by this title, the State plan shall not be regarded as failing to comply with the requirements of such part solely on the basis of the failure of the plan to meet such additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be deemed to be a separate regular session of the State legislature.

(2) APPLICATION TO PROGRAMS OPERATED BY INDIAN TRIBAL ORGANIZATIONS.—In the case of an Indian tribe, tribal organization, or tribal consortium which the Secretary of Health and Human Services determines requires time to take action necessary to comply with the additional requirements imposed by the amendments made by this title (whether the tribe, organization, or tribal consortium has a plan under section 479B of the Social Security Act or a cooperative agreement or contract entered into with a State), the Secretary shall provide the tribe, organization, or tribal consortium with such additional time as the Secretary determines is necessary for the tribe, organization, or tribal consortium to take the action to comply with the

additional requirements before being regarded as failing to comply with the requirements.

TITLE XX—ENSURING THE NECESSITY OF A PLACEMENT THAT IS NOT IN A FOSTER FAMILY HOME

SEC. 20001. LIMITATION ON FEDERAL FINANCIAL PARTICIPATION FOR PLACEMENTS THAT ARE NOT IN FOSTER FAMILY HOMES.

(a) LIMITATION ON FEDERAL FINANCIAL PARTICIPATION.—

(1) IN GENERAL.—Section 472 of the Social Security Act (42 U.S.C. 672), as amended by section 19012, is amended—

(A) in subsection (a)(2)(C), by inserting “, but only to the extent permitted under subsection (k)” after “institution”; and

(B) by adding at the end the following:

“(k) LIMITATION ON FEDERAL FINANCIAL PARTICIPATION.—

“(1) IN GENERAL.—Beginning with the third week for which foster care maintenance payments are made under this section on behalf of a child placed in a child-care institution, no Federal payment shall be made to the State under section 474(a)(1) for amounts expended for foster care maintenance payments on behalf of the child unless—

“(A) the child is placed in a child-care institution that is a setting specified in paragraph (2) (or is placed in a licensed residential family-based treatment facility consistent with subsection (j)); and

“(B) in the case of a child placed in a qualified residential treatment program (as defined in paragraph (3) and section 475A(c)) are met.

“(2) SPECIFIED SETTINGS FOR PLACEMENT.—The settings for placement specified in this paragraph are the following:

“(A) A qualified residential treatment program (as defined in paragraph (4)).

“(B) A setting specializing in providing prenatal, post-partum, or parenting supports for youth.

“(C) In the case of a child who has attained 18 years of age, a supervised setting in which the child is living independently.

“(D) A setting providing high-quality residential care and supportive services to children and youth who have been found to be, or are at risk of becoming, sex trafficking victims, in accordance with section 471(a)(9)(C).

“(3) ASSESSMENT TO DETERMINE APPROPRIATENESS OF PLACEMENT IN A QUALIFIED RESIDENTIAL TREATMENT PROGRAM.—

“(A) DEADLINE FOR ASSESSMENT.—In the case of a child who is placed in a qualified residential treatment program, if the assessment required under section 475A(c)(1) is not completed within 30 days after the placement is made, no Federal payment shall be made to the State under section 474(a)(1) for any amounts expended for foster care maintenance payments on behalf of the child during the placement.

“(B) DEADLINE FOR TRANSITION OUT OF PLACEMENT.—If the assessment required under section 475A(c)(1) determines that the placement of a child in a qualified residential treatment program is not appropriate, a court disapproves such a placement under section 475A(c)(2), or a child who has been in an approved placement in a qualified residential treatment program is going to return home or be placed with a fit and willing relative, a legal guardian, or an adoptive parent, or in a foster family home, Federal payments shall be made to the State under section 474(a)(1) for amounts expended for foster care maintenance payments on behalf of the child while the child remains in the qualified residential treatment program only during the period necessary for the child to transition home or to such a placement. In no event shall a State receive Federal payments under section 474(a)(1) for amounts expended for foster care maintenance payments on behalf of a child who remains placed in a qualified residential treatment

program after the end of the 30-day period that begins on the date a determination is made that the placement is no longer the recommended or approved placement for the child.

“(4) QUALIFIED RESIDENTIAL TREATMENT PROGRAM.—For purposes of this part, the term ‘qualified residential treatment program’ means a program that—

“(A) has a trauma-informed treatment model that is designed to address the needs, including clinical needs as appropriate, of children with serious emotional or behavioral disorders or disturbances and, with respect to a child, is able to implement the treatment identified for the child by the assessment of the child required under section 475A(c);

“(B) subject to paragraph (5), has registered or licensed nursing staff and other licensed clinical staff who—

“(i) provide care within the scope of their practice as defined by State law;

“(ii) are on-site during business hours; and

“(iii) are available 24 hours a day and 7 days a week;

“(C) to extent appropriate, and in accordance with the child’s best interests, facilitates participation of family members in the child’s treatment program;

“(D) facilitates outreach to the family members of the child, including siblings, documents how the outreach is made (including contact information), and maintains contact information for any known biological family and fictive kin of the child;

“(E) documents how family members are integrated into the treatment process for the child, including post-discharge, and how sibling connections are maintained;

“(F) provides discharge planning and family-based aftercare support for at least 6 months post-discharge; and

“(G) is licensed in accordance with section 471(a)(10) and is accredited by any of the following independent, not-for-profit organizations:

“(i) The Commission on Accreditation of Rehabilitation Facilities (CARF).

“(ii) The Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

“(iii) The Council on Accreditation (COA).

“(iv) Any other independent, not-for-profit accrediting organization approved by the Secretary.

“(5) FLEXIBILITY IN STAFFING REQUIREMENTS FOR QUALIFIED RESIDENTIAL TREATMENT PROGRAMS.—

“(A) IN GENERAL.—In the case of any State that the Secretary determines is described in subparagraph (B) and satisfies the requirements of subparagraphs (C) and (D), respectively, the State may elect to satisfy the requirement of paragraph (4)(B) that a qualified residential treatment program have registered or licensed nursing staff and other licensed clinical staff with clinical staff which include staff licensed to monitor medications and physical and behavioral health staff with demonstrated training in child development and trauma, in lieu of with registered or licensed nursing staff and other licensed clinical staff.

“(B) STATE DESCRIBED.—Subject to subparagraph (E), a State is described in this subparagraph if for the most recent fiscal year for which data are available—

“(i) the percentage of children in foster care under the responsibility of the State who have been placed in congregate care settings—

“(I) is at or below 5 percent for the fiscal year; or

“(II) has been reduced by at least 20 percent from the preceding fiscal year; and

“(ii) the average length of stay for children in foster care under the responsibility of the State in congregate care settings is at or below 9 months.

“(C) DEMONSTRATION OF CAPACITY AND NEED.—A State described in subparagraph (B) shall be eligible to use the alternative staffing

model permitted under subparagraph (A) if the State can demonstrate to the satisfaction of the Secretary that the qualified residential treatment programs utilizing the alternative staffing models permitted under subparagraph (A) have the capacity to serve children and youth whose treatment plans—

“(i) indicate a need for increased supervision based on behavioral history, history of juvenile delinquency, or history of sexual offenses; and

“(ii) require a placement that conforms to the alternative staffing model permitted under subparagraph (A).

“(D) EQUITABLE DISTRIBUTION OF CONGREGATE CARE POPULATION.—A State described in subparagraph (B) shall be eligible to use the alternative staffing model permitted under subparagraph (A) if the State annually demonstrates to the satisfaction of the Secretary that the State is reducing the number of children in foster care under the responsibility of the State who are in congregate care placements on a general statewide basis and without wide disparities between rural, suburban, and urban areas in the rates of such children in congregate care placements.

“(E) ANNUAL DETERMINATION OF STATE ELIGIBILITY BASED ON AFCARS AND OTHER DATA.—The Secretary annually shall make the determinations required under subparagraph (B) with respect to a State and a fiscal year, on the basis of data meeting the requirements of the system established pursuant to section 479, as reported by the State and approved by the Secretary, and, to the extent the Secretary determines necessary, on the basis of such other information reported to the Secretary as the Secretary may require to determine that a State is, or continues to be, a State described in subparagraph (B).

“(F) CONGREGATE CARE SETTINGS.—In this paragraph, the term ‘congregate care settings’ includes any settings described as ‘group homes’ or ‘institutions’ for purposes of data reported in accordance with the requirements of the system established pursuant to section 479 or any similar placement settings reported in accordance with such requirements.

“(6) ADMINISTRATIVE COSTS.—The prohibition in paragraph (1) on Federal payments under section 474(a)(1) shall not be construed as prohibiting Federal payments for administrative expenditures incurred on behalf of a child placed in a child-care institution and for which payment is available under section 474(a)(3).”.

(2) CONFORMING AMENDMENT.—Section 474(a)(1) of the Social Security Act (42 U.S.C. 674(a)(1)), as amended by section 19012(b), is amended by striking “section 472(j)” and inserting “subsections (j) and (k) of section 472”.

(b) DEFINITION OF FOSTER FAMILY HOME, CHILD-CARE INSTITUTION.—Section 472(c) of such Act (42 U.S.C. 672(c)(1)) is amended to read as follows:

“(c) DEFINITIONS.—For purposes of this part:

“(1) FOSTER FAMILY HOME.—

“(A) IN GENERAL.—The term ‘foster family home’ means the home of an individual or family—

“(i) that is licensed or approved by the State in which it is situated as a foster family home that meets the standards established for the licensing or approval; and

“(ii) in which a child in foster care has been placed in the care of an individual, who resides with the child and who has been licensed or approved by the State to be a foster parent—

“(I) that the State deems capable of adhering to the reasonable and prudent parent standard;

“(II) that provides 24-hour substitute care for children placed away from their parents or other caretakers; and

“(III) that provides the care for not more than six children in foster care.

“(B) STATE FLEXIBILITY.—The number of foster children that may be cared for in a home under subparagraph (A) may exceed the numerical limitation in subparagraph (A)(ii)(III), at the option of the State, for any of the following reasons:

“(i) To allow a parenting youth in foster care to remain with the child of the parenting youth.

“(ii) To allow siblings to remain together.

“(iii) To allow a child with an established meaningful relationship with the family to remain with the family.

“(iv) To allow a family with special training or skills to provide care to a child who has a severe disability.

“(C) **RULE OF CONSTRUCTION.**—Subparagraph (A) shall not be construed as prohibiting a foster parent from renting the home in which the parent cares for a foster child placed in the parent’s care.

“(2) **CHILD-CARE INSTITUTION.**—

“(A) **IN GENERAL.**—The term ‘child-care institution’ means a private child-care institution, or a public child-care institution which accommodates no more than 25 children, which is licensed by the State in which it is situated or has been approved by the agency of the State responsible for licensing or approval of institutions of this type as meeting the standards established for the licensing.

“(B) **SUPERVISED SETTINGS.**—In the case of a child who has attained 18 years of age, the term shall include a supervised setting in which the individual is living independently, in accordance with such conditions as the Secretary shall establish in regulations.

“(C) **EXCLUSIONS.**—The term shall not include detention facilities, forestry camps, training schools, or any other facility operated primarily for the detention of children who are determined to be delinquent.”

(c) **TRAINING FOR STATE JUDGES, ATTORNEYS, AND OTHER LEGAL PERSONNEL IN CHILD WELFARE CASES.**—Section 438(b)(1) of such Act (42 U.S.C. 629h(b)(1)) is amended in the matter preceding subparagraph (A) by inserting “shall provide for the training of judges, attorneys, and other legal personnel in child welfare cases on Federal child welfare policies and payment limitations with respect to children in foster care who are placed in settings that are not a foster family home,” after “with respect to the child.”

(d) **ASSURANCE OF NONIMPACT ON JUVENILE JUSTICE SYSTEM.**—

(1) **STATE PLAN REQUIREMENT.**—Section 471(a) of such Act (42 U.S.C. 671(a)), as amended by section 19031, is further amended by adding at the end the following:

“(37) includes a certification that, in response to the limitation imposed under section 472(k) with respect to foster care maintenance payments made on behalf of any child who is placed in a setting that is not a foster family home, the State will not enact or advance policies or practices that would result in a significant increase in the population of youth in the State’s juvenile justice system.”

(2) **GAO STUDY AND REPORT.**—The Comptroller General of the United States shall evaluate the impact, if any, on State juvenile justice systems of the limitation imposed under section 472(k) of the Social Security Act (as added by section 19001(a)(1)) on foster care maintenance payments made on behalf of any child who is placed in a setting that is not a foster family home, in accordance with the amendments made by subsections (a) and (b) of this section. In particular, the Comptroller General shall evaluate the extent to which children in foster care who also are subject to the juvenile justice system of the State are placed in a facility under the jurisdiction of the juvenile justice system and whether the lack of available congregate care placements under the jurisdiction of the child welfare systems is a contributing factor to that result. Not later than December 31, 2023, the Comptroller General shall submit to Congress a report on the results of the evaluation.

SEC. 20002. ASSESSMENT AND DOCUMENTATION OF THE NEED FOR PLACEMENT IN A QUALIFIED RESIDENTIAL TREATMENT PROGRAM.

Section 475A of the Social Security Act (42 U.S.C. 675a) is amended by adding at the end the following:

“(c) **ASSESSMENT, DOCUMENTATION, AND JUDICIAL DETERMINATION REQUIREMENTS FOR PLACEMENT IN A QUALIFIED RESIDENTIAL TREATMENT PROGRAM.**—In the case of any child who is placed in a qualified residential treatment program (as defined in section 472(k)(4)), the following requirements shall apply for purposes of approving the case plan for the child and the case system review procedure for the child:

“(1)(A) Within 30 days of the start of each placement in such a setting, a qualified individual (as defined in subparagraph (D)) shall—

“(i) assess the strengths and needs of the child using an age-appropriate, evidence-based, validated, functional assessment tool approved by the Secretary;

“(ii) determine whether the needs of the child can be met with family members or through placement in a foster family home or, if not, which setting from among the settings specified in section 472(k)(2) would provide the most effective and appropriate level of care for the child in the least restrictive environment and be consistent with the short- and long-term goals for the child, as specified in the permanency plan for the child; and

“(iii) develop a list of child-specific short- and long-term mental and behavioral health goals.

“(B)(i) The State shall assemble a family and permanency team for the child in accordance with the requirements of clauses (ii) and (iii). The qualified individual conducting the assessment required under subparagraph (A) shall work in conjunction with the family of, and permanency team for, the child while conducting and making the assessment.

“(ii) The family and permanency team shall consist of all appropriate biological family members, relative, and fictive kin of the child, as well as, as appropriate, professionals who are a resource to the family of the child, such as teachers, medical or mental health providers who have treated the child, or clergy. In the case of a child who has attained age 14, the family and permanency team shall include the members of the permanency planning team for the child that are selected by the child in accordance with section 475(5)(C)(iv).

“(iii) The State shall document in the child’s case plan—

“(I) the reasonable and good faith effort of the State to identify and include all such individuals on the family of, and permanency team for, the child;

“(II) all contact information for members of the family and permanency team, as well as contact information for other family members and fictive kin who are not part of the family and permanency team;

“(III) evidence that meetings of the family and permanency team, including meetings relating to the assessment required under subparagraph (A), are held at a time and place convenient for family;

“(IV) if reunification is the goal, evidence demonstrating that the parent from whom the child was removed provided input on the members of the family and permanency team;

“(V) evidence that the assessment required under subparagraph (A) is determined in conjunction with the family and permanency team; and

“(VI) the placement preferences of the family and permanency team relative to the assessment and, if the placement preferences of the family and permanency team and child are not the placement setting recommended by the qualified individual conducting the assessment under subparagraph (A), the reasons why the preferences of the team and of the child were not recommended.

“(C) In the case of a child who the qualified individual conducting the assessment under subparagraph (A) determines should not be placed in a foster family home, the qualified individual shall specify in writing the reasons why the needs of the child cannot be met by the family of the child or in a foster family home. A shortage or lack of foster family homes shall not be an acceptable reason for determining that a needs of the child cannot be met in a foster family home. The qualified individual also shall specify in writing why the recommended placement in a qualified residential treatment program is the setting that will provide the child with the most effective and appropriate level of care in the least restrictive environment and how that placement is consistent with the short- and long-term goals for the child, as specified in the permanency plan for the child.

“(D)(i) Subject to clause (ii), in this subsection, the term ‘qualified individual’ means a trained professional or licensed clinician who is not an employee of the State agency and who is not connected to, or affiliated with, any placement setting in which children are placed by the State.

“(ii) The Secretary may approve a request of a State to waive any requirement in clause (i) upon a submission by the State, in accordance with criteria established by the Secretary, that certifies that the trained professionals or licensed clinicians with responsibility for performing the assessments described in subparagraph (A) shall maintain objectivity with respect to determining the most effective and appropriate placement for a child.

“(2) Within 60 days of the start of each placement in a qualified residential treatment program, a family or juvenile court or another court (including a tribal court) of competent jurisdiction, or an administrative body appointed or approved by the court, independently, shall—

“(A) consider the assessment, determination, and documentation made by the qualified individual conducting the assessment under paragraph (1);

“(B) determine whether the needs of the child can be met through placement in a foster family home or, if not, whether placement of the child in a qualified residential treatment program provides the most effective and appropriate level of care for the child in the least restrictive environment and whether that placement is consistent with the short- and long-term goals for the child, as specified in the permanency plan for the child; and

“(C) approve or disapprove the placement.

“(3) The written documentation made under paragraph (1)(C) and documentation of the determination and approval or disapproval of the placement in a qualified residential treatment program by a court or administrative body under paragraph (2) shall be included in and made part of the case plan for the child.

“(4) As long as a child remains placed in a qualified residential treatment program, the State agency shall submit evidence at each status review and each permanency hearing held with respect to the child—

“(A) demonstrating that ongoing assessment of the strengths and needs of the child continues to support the determination that the needs of the child cannot be met through placement in a foster family home, that the placement in a qualified residential treatment program provides the most effective and appropriate level of care for the child in the least restrictive environment, and that the placement is consistent with the short- and long-term goals for the child, as specified in the permanency plan for the child;

“(B) documenting the specific treatment or service needs that will be met for the child in the placement and the length of time the child is expected to need the treatment or services; and

“(C) documenting the efforts made by the State agency to prepare the child to return home or to be placed with a fit and willing relative, a legal guardian, or an adoptive parent, or in a foster family home.

“(5) In the case of any child who is placed in a qualified residential treatment program for more than 12 consecutive months or 18 non-consecutive months (or, in the case of a child who has not attained age 13, for more than 6 consecutive or nonconsecutive months), the State agency shall submit to the Secretary—

“(A) the most recent versions of the evidence and documentation specified in paragraph (4); and

“(B) the signed approval of the head of the State agency for the continued placement of the child in that setting.”.

SEC. 20003. PROTOCOLS TO PREVENT INAPPROPRIATE DIAGNOSES.

(a) STATE PLAN REQUIREMENT.—Section 422(b)(15)(A) of the Social Security Act (42 U.S.C. 622(b)(15)(A)) is amended—

(1) in clause (vi), by striking “and” after the semicolon;

(2) by redesignating clause (vii) as clause (viii); and

(3) by inserting after clause (vi) the following:

“(vii) the procedures and protocols the State has established to ensure that children in foster care placements are not inappropriately diagnosed with mental illness, other emotional or behavioral disorders, medically fragile conditions, or developmental disabilities, and placed in settings that are not foster family homes as a result of the inappropriate diagnoses; and”.

(b) EVALUATION.—Section 476 of such Act (42 U.S.C. 676), as previously amended, is further amended by adding at the end the following:

“(e) EVALUATION OF STATE PROCEDURES AND PROTOCOLS TO PREVENT INAPPROPRIATE DIAGNOSES OF MENTAL ILLNESS OR OTHER CONDITIONS.—The Secretary shall conduct an evaluation of the procedures and protocols established by States in accordance with the requirements of section 422(b)(15)(A)(vii). The evaluation shall analyze the extent to which States comply with and enforce the procedures and protocols and the effectiveness of various State procedures and protocols and shall identify best practices. Not later than January 1, 2019, the Secretary shall submit a report on the results of the evaluation to Congress.”.

SEC. 20004. ADDITIONAL DATA AND REPORTS REGARDING CHILDREN PLACED IN A SETTING THAT IS NOT A FOSTER FAMILY HOME.

Section 479A(a)(7)(A) of the Social Security Act (42 U.S.C. 679b(a)(7)(A)) is amended by striking clauses (i) through (vi) and inserting the following:

“(i) with respect to each such placement—

“(I) the type of the placement setting, including whether the placement is shelter care, a group home and if so, the range of the child population in the home, a residential treatment facility, a hospital or institution providing medical, rehabilitative, or psychiatric care, a setting specializing in providing prenatal, post-partum or parenting supports, or some other kind of child-care institution and if so, what kind;

“(II) the number of children in the placement setting and the age, race, ethnicity, and gender of each of the children;

“(III) for each child in the placement setting, the length of the placement of the child in the setting, whether the placement of the child in the setting is the first placement of the child and if not, the number and type of previous placements of the child, and whether the child has special needs or another diagnosed mental or physical illness or condition; and

“(IV) the extent of any specialized education, treatment, counseling, or other services provided in the setting; and

“(ii) separately, the number and ages of children in the placements who have a permanency plan of another planned permanent living arrangement; and”.

SEC. 20005. EFFECTIVE DATES; APPLICATION TO WAIVERS.

(a) EFFECTIVE DATES.—

(1) IN GENERAL.—Subject to paragraph (2) and subsections (b) and (c), the amendments made by this title shall take effect on January 1, 2017.

(2) TRANSITION RULE.—In the case of a State plan under part B or E of title IV of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by this title, the State plan shall not be regarded as failing to comply with the requirements of such part solely on the basis of the failure of the plan to meet the additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be deemed to be a separate regular session of the State legislature.

(b) LIMITATION ON FEDERAL FINANCIAL PARTICIPATION FOR PLACEMENTS THAT ARE NOT IN FOSTER FAMILY HOMES AND RELATED PROVISIONS.—

(1) IN GENERAL.—The amendments made by sections 20001(a), 20001(b), 20001(d), and 20002 shall take effect on October 1, 2019.

(2) STATE OPTION TO DELAY EFFECTIVE DATE FOR NOT MORE THAN 2 YEARS.—At the sole discretion of a State and for not more than 2 years, the Secretary of Health and Human Services shall delay the effective date provided for in paragraph (1) with respect to the State. If the effective date is so delayed for a period with respect to a State under the preceding sentence, then—

(A) notwithstanding section 1904, the date that the amendments made by section 19011(c) take effect with respect to the State shall be delayed for the period; and

(B) in applying section 474(a)(6) of the Social Security Act with respect to the State, “on or after the date this paragraph takes effect with respect to the State” is deemed to be substituted for “after September 30, 2019” in subparagraph (A)(i)(I) of such section.

(c) APPLICATION TO STATES WITH WAIVERS.—In the case of a State that, on the date of enactment of this Act, has in effect a waiver approved under section 1130 of the Social Security Act (42 U.S.C. 1320a–9), the amendments made by this title shall not apply with respect to the State before the expiration (determined without regard to any extensions) of the waiver to the extent the amendments are inconsistent with the terms of the waiver.

TITLE XXI—CONTINUING SUPPORT FOR CHILD AND FAMILY SERVICES

SEC. 21001. SUPPORTING AND RETAINING FOSTER FAMILIES FOR CHILDREN.

(a) SUPPORTING AND RETAINING FOSTER PARENTS AS A FAMILY SUPPORT SERVICE.—Section 431(a)(2)(B) of the Social Security Act (42 U.S.C. 631(a)(2)(B)) is amended by redesignating clauses (iii) through (vi) as clauses (iv) through (vii), respectively, and inserting after clause (ii) the following:

“(iii) To support and retain foster families so they can provide quality family-based settings for children in foster care.”.

(b) SUPPORT FOR FOSTER FAMILY HOMES.—Section 436 of such Act (42 U.S.C. 629f) is amended by adding at the end the following:

“(c) SUPPORT FOR FOSTER FAMILY HOMES.—Out of any money in the Treasury of the United States not otherwise appropriated, there are appropriated to the Secretary for fiscal year 2018, \$8,000,000 for the Secretary to make competitive grants to States, Indian tribes, or tribal consortia to support the recruitment and retention of high-quality foster families to increase their capacity to place more children in family settings, focused on States, Indian tribes, or tribal consortia with the highest percentage of children in non-family settings. The amount appropriated under this subparagraph shall remain available through fiscal year 2022.”.

SEC. 21002. EXTENSION OF CHILD AND FAMILY SERVICES PROGRAMS.

(a) EXTENSION OF STEPHANIE TUBBS JONES CHILD WELFARE SERVICES PROGRAM.—Section 425 of the Social Security Act (42 U.S.C. 625) is amended by striking “2012 through 2016” and inserting “2017 through 2021”.

(b) EXTENSION OF PROMOTING SAFE AND STABLE FAMILIES PROGRAM AUTHORIZATIONS.—

(1) IN GENERAL.—Section 436(a) of such Act (42 U.S.C. 629f(a)) is amended by striking all that follows “\$345,000,000” and inserting “for each of fiscal years 2017 through 2021”.

(2) DISCRETIONARY GRANTS.—Section 437(a) of such Act (42 U.S.C. 629g(a)) is amended by striking “2012 through 2016” and inserting “2017 through 2021”.

(c) EXTENSION OF FUNDING RESERVATIONS FOR MONTHLY CASEWORKER VISITS AND REGIONAL PARTNERSHIP GRANTS.—Section 436(b) of such Act (42 U.S.C. 629f(b)) is amended—

(1) in paragraph (4)(A), by striking “2012 through 2016” and inserting “2017 through 2021”; and

(2) in paragraph (5), by striking “2012 through 2016” and inserting “2017 through 2021”.

(d) REAUTHORIZATION OF FUNDING FOR STATE COURTS.—

(1) EXTENSION OF PROGRAM.—Section 438(c)(1) of such Act (42 U.S.C. 629h(c)(1)) is amended by striking “2012 through 2016” and inserting “2017 through 2021”.

(2) EXTENSION OF FEDERAL SHARE.—Section 438(d) of such Act (42 U.S.C. 629h(d)) is amended by striking “2012 through 2016” and inserting “2017 through 2021”.

(e) REPEAL OF EXPIRED PROVISIONS.—Section 438(e) of such Act (42 U.S.C. 629h(e)) is repealed.

SEC. 21003. IMPROVEMENTS TO THE JOHN H. CHAFEE FOSTER CARE INDEPENDENCE PROGRAM AND RELATED PROVISIONS.

(a) AUTHORITY TO SERVE FORMER FOSTER YOUTH UP TO AGE 23.—Section 477 of the Social Security Act (42 U.S.C. 677) is amended—

(1) in subsection (a)(5), by inserting “(or 23 years of age, in the case of a State with a certification under subsection (b)(3)(A)(ii) to provide assistance and services to youths who have aged out of foster care and have not attained such age, in accordance with such subsection)” after “21 years of age”; and

(2) in subsection (b)(3)(A)—

(A) by inserting “(i)” before “A certification”;

(B) by striking “children who have left foster care” and all that follows through the period and inserting “youths who have aged out of foster care and have not attained 21 years of age.”; and

(C) by adding at the end the following:

“(ii) If the State has elected under section 475(b)(B) to extend eligibility for foster care to all children who have not attained 21 years of age, or if the Secretary determines that the State agency responsible for administering the State plans under this part and part B uses State funds or any other funds not provided under this part to provide services and assistance for youths who have aged out of foster care that are comparable to the services and assistance the youths would receive if the State had made such an election, the certification required under clause (i) may provide that the State will provide assistance and services to youths who have aged out of foster care and have not attained 23 years of age.”; and

(3) in subsection (b)(3)(B), by striking “children who have left foster care” and all that follows through the period and inserting “youths who have aged out of foster care and have not attained 21 years of age (or 23 years of age, in the case of a State with a certification under subparagraph (A)(i) to provide assistance and services to youths who have aged out of foster care and have not attained such age, in accordance with subparagraph (A)(ii)).”.

(b) AUTHORITY TO REDISTRIBUTE UNSPENT FUNDS.—Section 477(d) of such Act (42 U.S.C. 677(d)) is amended—

(1) in paragraph (4), by inserting “or does not expend allocated funds within the time period specified under section 477(d)(3)” after “provided by the Secretary”; and

(2) by adding at the end the following:

“(5) REDISTRIBUTION OF UNEXPENDED AMOUNTS.—

“(A) AVAILABILITY OF AMOUNTS.—To the extent that amounts paid to States under this section in a fiscal year remain unexpended by the States at the end of the succeeding fiscal year, the Secretary may make the amounts available for redistribution in the second succeeding fiscal year among the States that apply for additional funds under this section for that second succeeding fiscal year.

“(B) REDISTRIBUTION.—

“(i) IN GENERAL.—The Secretary shall redistribute the amounts made available under subparagraph (A) for a fiscal year among eligible applicant States. In this subparagraph, the term ‘eligible applicant State’ means a State that has applied for additional funds for the fiscal year under subparagraph (A) if the Secretary determines that the State will use the funds for the purpose for which originally allotted under this section.

“(ii) AMOUNT TO BE REDISTRIBUTED.—The amount to be redistributed to each eligible applicant State shall be the amount so made available multiplied by the State foster care ratio, (as defined in subsection (c)(4), except that, in such subsection, ‘all eligible applicant States (as defined in subsection (d)(5)(B)(i))’ shall be substituted for ‘all States’).

“(iii) TREATMENT OF REDISTRIBUTED AMOUNT.—Any amount made available to a State under this paragraph shall be regarded as part of the allotment of the State under this section for the fiscal year in which the redistribution is made.

“(C) TRIBES.—For purposes of this paragraph, the term ‘State’ includes an Indian tribe, tribal organization, or tribal consortium that receives an allotment under this section.”

(c) EXPANDING AND CLARIFYING THE USE OF EDUCATION AND TRAINING VOUCHERS.—

(1) IN GENERAL.—Section 477(i)(3) of such Act (42 U.S.C. 677(i)(3)) is amended—

(A) by striking “on the date” and all that follows through “23” and inserting “to remain eligible until they attain 26”; and

(B) by inserting “, but in no event may a youth participate in the program for more than 5 years (whether or not consecutive)” before the period.

(2) CONFORMING AMENDMENT.—Section 477(i)(1) of such Act (42 U.S.C. 677(i)(1)) is amended by inserting “who have attained 14 years of age” before the period.

(d) OTHER IMPROVEMENTS.—Section 477 of such Act (42 U.S.C. 677), as amended by subsections (a), (b), and (c), is amended—

(1) in the section heading, by striking “INDEPENDENCE PROGRAM” and inserting “PROGRAM FOR SUCCESSFUL TRANSITION TO ADULTHOOD”;

(2) in subsection (a)—

(A) in paragraph (1)—

(i) by striking “identify children who are likely to remain in foster care until 18 years of age and to help these children make the transition to self-sufficiency by providing services” and inserting “support all youth who have experienced foster care at age 14 or older in their transition to adulthood through transitional services”;

(ii) by inserting “and post-secondary education” after “high school diploma”; and

(iii) by striking “training in daily living skills, training in budgeting and financial management skills” and inserting “training and opportunities to practice daily living skills (such as financial literacy training and driving instruction)”;

(B) in paragraph (2), by striking “who are likely to remain in foster care until 18 years of age receive the education, training, and services necessary to obtain employment” and inserting

“who have experienced foster care at age 14 or older achieve meaningful, permanent connections with a caring adult”;

(C) in paragraph (3), by striking “who are likely to remain in foster care until 18 years of age prepare for and enter postsecondary training and education institutions” and inserting “who have experienced foster care at age 14 or older engage in age or developmentally appropriate activities, positive youth development, and experiential learning that reflects what their peers in intact families experience”; and

(D) by striking paragraph (4) and redesignating paragraphs (5) through (8) as paragraphs (4) through (7);

(3) in subsection (b)—

(A) in paragraph (2)(D), by striking “adolescents” and inserting “youth”; and

(B) in paragraph (3)—

(i) in subparagraph (D)—

(I) by inserting “including training on youth development” after “to provide training”; and

(II) by striking “adolescents preparing for independent living” and all that follows through the period and inserting “youth preparing for a successful transition to adulthood and making a permanent connection with a caring adult.”;

(ii) in subparagraph (H), by striking “adolescents” each place it appears and inserting “youth”; and

(iii) in subparagraph (K)—

(I) by striking “an adolescent” and inserting “a youth”; and

(II) by striking “the adolescent” each place it appears and inserting “the youth”; and

(4) in subsection (f), by striking paragraph (2) and inserting the following:

“(2) REPORT TO CONGRESS.—Not later than October 1, 2017, the Secretary shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report on the National Youth in Transition Database and any other databases in which States report outcome measures relating to children in foster care and children who have aged out of foster care or left foster care for kinship guardianship or adoption. The report shall include the following:

“(A) A description of the reasons for entry into foster care and of the foster care experiences, such as length of stay, number of placement settings, case goal, and discharge reason of 17-year-olds who are surveyed by the National Youth in Transition Database and an analysis of the comparison of that description with the reasons for entry and foster care experiences of children of other ages who exit from foster care before attaining age 17.

“(B) A description of the characteristics of the individuals who report poor outcomes at ages 19 and 21 to the National Youth in Transition Database.

“(C) Benchmarks for determining what constitutes a poor outcome for youth who remain in or have exited from foster care and plans the Executive branch will take to incorporate these benchmarks in efforts to evaluate child welfare agency performance in providing services to children transitioning from foster care.

“(D) An analysis of the association between types of placement, number of overall placements, time spent in foster care, and other factors, and outcomes at ages 19 and 21.

“(E) An analysis of the differences in outcomes for children in and formerly in foster care at age 19 and 21 among States.”

(e) CLARIFYING DOCUMENTATION PROVIDED TO FOSTER YOUTH LEAVING FOSTER CARE.—Section 475(5)(I) of such Act (42 U.S.C. 675(5)(I)) is amended by inserting after “REAL ID Act of 2005” the following: “, and any official documentation necessary to prove that the child was previously in foster care”.

TITLE XXII—CONTINUING INCENTIVES TO STATES TO PROMOTE ADOPTION AND LEGAL GUARDIANSHIP

SEC. 22001. REAUTHORIZING ADOPTION AND LEGAL GUARDIANSHIP INCENTIVE PROGRAMS.

Section 473A of the Social Security Act (42 U.S.C. 673b) is amended—

(1) in subsection (b)(4), by striking “2013 through 2015” and inserting “2016 through 2020”;

(2) in subsection (h)(1)(D), by striking “2016” and inserting “2021”; and

(3) in subsection (h)(2), by striking “2016” and inserting “2021”.

TITLE XXIII—TECHNICAL CORRECTIONS

SEC. 23001. TECHNICAL CORRECTIONS TO DATA EXCHANGE STANDARDS TO IMPROVE PROGRAM COORDINATION.

(a) IN GENERAL.—Section 440 of the Social Security Act (42 U.S.C. 629m) is amended to read as follows:

“SEC. 440. DATA EXCHANGE STANDARDS FOR IMPROVED INTEROPERABILITY.

“(a) DESIGNATION.—The Secretary shall, in consultation with an interagency work group established by the Office of Management and Budget and considering State government perspectives, by rule, designate data exchange standards to govern, under this part and part E—

“(1) necessary categories of information that State agencies operating programs under State plans approved under this part are required under applicable Federal law to electronically exchange with another State agency; and

“(2) Federal reporting and data exchange required under applicable Federal law.

“(b) REQUIREMENTS.—The data exchange standards required by paragraph (1) shall, to the extent practicable—

“(1) incorporate a widely accepted, non-proprietary, searchable, computer-readable format, such as the eXtensible Markup Language;

“(2) contain interoperable standards developed and maintained by intergovernmental partnerships, such as the National Information Exchange Model;

“(3) incorporate interoperable standards developed and maintained by Federal entities with authority over contracting and financial assistance;

“(4) be consistent with and implement applicable accounting principles;

“(5) be implemented in a manner that is cost-effective and improves program efficiency and effectiveness; and

“(6) be capable of being continually upgraded as necessary.

“(c) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require a change to existing data exchange standards found to be effective and efficient.”

(b) EFFECTIVE DATE.—Not later than the date that is 24 months after the date of the enactment of this section, the Secretary of Health and Human Services shall issue a proposed rule that—

(1) identifies federally required data exchanges, include specification and timing of exchanges to be standardized, and address the factors used in determining whether and when to standardize data exchanges; and

(2) specifies State implementation options and describes future milestones.

SEC. 23002. TECHNICAL CORRECTIONS TO STATE REQUIREMENT TO ADDRESS THE DEVELOPMENTAL NEEDS OF YOUNG CHILDREN.

Section 422(b)(18) of the Social Security Act (42 U.S.C. 622(b)(18)) is amended by striking “such children” and inserting “all vulnerable children under 5 years of age”.

TITLE XXIV—ENSURING STATES REINVEST SAVINGS RESULTING FROM INCREASE IN ADOPTION ASSISTANCE

SEC. 24001. DELAY OF ADOPTION ASSISTANCE PHASE-IN.

(a) IN GENERAL.—The table in section 473(e)(1)(B) of the Social Security Act (42 U.S.C. 673(e)(1)(B)) is amended—

(1) by striking “2016” and inserting “2016, 2017, 2018, or 2019”;

(2) by striking “2017” and inserting “2020”;

and

(3) by striking “2018” and inserting “2021”.

(b) SPECIAL RULE.—Section 473(e) of the Social Security Act (42 U.S.C. 673(e)) is amended by adding at the end the following new paragraph:

“(3) ADDITIONAL EXCEPTION.—Notwithstanding paragraph (1) of this subsection, during the period that begins on October 1, 2016, and ends on December 31, 2016, such term shall include a child—

“(A) who satisfies the requirements for being considered an applicable child under paragraph (1) (as in effect during that period);

“(B) who meets the requirements of subsection (a)(2)(A)(ii); and

“(C) on whose behalf an adoption assistance agreement is entered into under this section during that period.”.

(c) EFFECTIVE DATE.—The amendments made by this section take effect on January 1, 2017.

SEC. 24002. GAO STUDY AND REPORT ON STATE REINVESTMENT OF SAVINGS RESULTING FROM INCREASE IN ADOPTION ASSISTANCE.

(a) STUDY.—The Comptroller General of the United States shall study the extent to which States are complying with the requirements of section 473(a)(8) of the Social Security Act relating to the effects of phasing out the AFDC income eligibility requirements for adoption assistance payments under section 473 of the Social Security Act, as enacted by section 402 of the Fostering Connections to Success and Increasing Adoptions Act of 2008 (Public Law 110-351; 122 Stat. 3975) and amended by section 206 of the Preventing Sex Trafficking and Strengthening Families Act (Public Law 113-183; 128 Stat. 1919). In particular, the Comptroller General shall analyze the extent to which States are complying with the following requirements under section 473(a)(8)(D) of the Social Security Act:

(1) The requirement to spend an amount equal to the amount of the savings (if any) in State expenditures under part E of title IV of the Social Security Act resulting from phasing out the AFDC income eligibility requirements for adoption assistance payments under section 473 of such Act to provide to children of families any service that may be provided under part B or E of title IV of such Act.

(2) The requirement that a State shall spend not less than 30 percent of the amount of any savings described in subparagraph (A) on post-adoption services, post-guardianship services, and services to support and sustain positive permanent outcomes for children who otherwise might enter into foster care under the responsibility of the State, with at least 2/3 of the spending by the State to comply with the 30 percent requirement being spent on post-adoption and post-guardianship services.

(b) REPORT.—The Comptroller General of the United States shall submit to the Committee on Finance of the Senate, the Committee on Ways and Means of the House of Representatives, and the Secretary of Health and Human Services a report that contains the results of the study required by subsection (a), including recommendations to ensure compliance with laws referred to in subsection (a).

TITLE XXV—SOCIAL IMPACT PARTNERSHIPS TO PAY FOR RESULTS

SEC. 25001. SHORT TITLE.

This title may be cited as the “Social Impact Partnership to Pay for Results Act”.

SEC. 25002. SOCIAL IMPACT PARTNERSHIPS TO PAY FOR RESULTS.

Section 403 of the Social Security Act (42 U.S.C. 603) is amended by adding at the end the following:

“(c) SOCIAL IMPACT DEMONSTRATION PROJECTS.—

“(1) PURPOSES.—The purposes of this subsection are the following:

“(A) To improve the lives of families and individuals in need in the United States by funding social programs that achieve real results.

“(B) To redirect funds away from programs that, based on objective data, are ineffective, and into programs that achieve demonstrable, measurable results.

“(C) To ensure Federal funds are used effectively on social services to produce positive outcomes for both service recipients and taxpayers.

“(D) To establish the use of social impact partnerships to address some of our Nation’s most pressing problems.

“(E) To facilitate the creation of public-private partnerships that bundle philanthropic or other private resources with existing public spending to scale up effective social interventions already being implemented by private organizations, nonprofits, charitable organizations, and State and local governments across the country.

“(F) To bring pay-for-performance to the social sector, allowing the United States to improve the impact and effectiveness of vital social services programs while redirecting inefficient or duplicative spending.

“(G) To incorporate outcomes measurement and randomized controlled trials or other rigorous methodologies for assessing program impact.

“(2) SOCIAL IMPACT PARTNERSHIP APPLICATION.—

“(A) NOTICE.—Not later than 1 year after the date of the enactment of this subsection, the Secretary of the Treasury, in consultation with the Federal Interagency Council on Social Impact Partnerships, shall publish in the Federal Register a request for proposals from States or local governments for social impact partnership projects in accordance with this paragraph.

“(B) REQUIRED OUTCOMES FOR SOCIAL IMPACT PARTNERSHIP PROJECT.—To qualify as a social impact partnership project under this subsection, a project must produce one or more measurable, clearly defined outcomes that result in social benefit and Federal, State, or local savings through any of the following:

“(i) Increasing work and earnings by individuals in the United States who are unemployed for more than 6 consecutive months.

“(ii) Increasing employment and earnings of individuals who have attained 16 years of age but not 25 years of age.

“(iii) Increasing employment among individuals receiving Federal disability benefits.

“(iv) Reducing the dependence of low-income families on Federal means-tested benefits.

“(v) Improving rates of high school graduation.

“(vi) Reducing teen and unplanned pregnancies.

“(vii) Improving birth outcomes and early childhood health and development among low-income families and individuals.

“(viii) Reducing rates of asthma, diabetes, or other preventable diseases among low-income families and individuals to reduce the utilization of emergency and other high-cost care.

“(ix) Increasing the proportion of children living in two-parent families.

“(x) Reducing incidences and adverse consequences of child abuse and neglect.

“(xi) Reducing the number of youth in foster care by increasing adoptions, permanent guardianship arrangements, reunifications, or placements with a fit and willing relative, or by avoiding placing children in foster care by ensuring they can be cared for safely in their own homes.

“(xii) Reducing the number of children and youth in foster care residing in group homes, child care institutions, agency-operated foster homes, or other non-family foster homes, unless it is determined that it is in the interest of the child’s long-term health, safety, or psychological well-being to not be placed in a family foster home.

“(xiii) Reducing the number of children returning to foster care.

“(xiv) Reducing recidivism among juvenile offenders, individuals released from prison, or other high-risk populations.

“(xv) Reducing the rate of homelessness among our most vulnerable populations.

“(xvi) Improving the health and well-being of those with mental, emotional, and behavioral health needs.

“(xvii) Improving the educational outcomes of special-needs or low-income children.

“(xviii) Improving the employment and well-being of returning United States military members.

“(xix) Increasing the financial stability of low-income families.

“(xx) Increasing the independence and employability of individuals who are physically or mentally disabled.

“(xxi) Other measurable outcomes defined by the State or local government that result in positive social outcomes and Federal savings.

“(C) APPLICATION REQUIRED.—The notice described in subparagraph (A) shall require a State or local government to submit an application for the social impact partnership project that addresses the following:

“(i) The outcome goals of the project.

“(ii) A description of each intervention in the project and anticipated outcomes of the intervention.

“(iii) Rigorous evidence demonstrating that the intervention can be expected to produce the desired outcomes.

“(iv) The target population that will be served by the project.

“(v) The expected social benefits to participants who receive the intervention and others who may be impacted.

“(vi) Projected Federal, State, and local government costs and other costs to conduct the project.

“(vii) Projected Federal, State, and local government savings and other savings, including an estimate of the savings to the Federal Government, on a program-by-program basis and in the aggregate, if the project is implemented and the outcomes are achieved as a result of the intervention.

“(viii) If savings resulting from the successful completion of the project are estimated to accrue to the State or local government, the likelihood of the State or local government to realize those savings.

“(ix) A plan for delivering the intervention through a social impact partnership model.

“(x) A description of the expertise of each service provider that will administer the intervention, including a summary of the experience of the service provider in delivering the proposed intervention or a similar intervention, or demonstrating that the service provider has the expertise necessary to deliver the proposed intervention.

“(xi) An explanation of the experience of the State or local government, the intermediary, or the service provider in raising private and philanthropic capital to fund social service investments.

“(xii) The detailed roles and responsibilities of each entity involved in the project, including any State or local government entity, intermediary, service provider, independent evaluator, investor, or other stakeholder.

“(xiii) A summary of the experience of the service provider in delivering the proposed intervention or a similar intervention, or a summary demonstrating the service provider has the expertise necessary to deliver the proposed intervention.

“(xiv) A summary of the unmet need in the area where the intervention will be delivered or among the target population who will receive the intervention.

“(xv) The proposed payment terms, the methodology used to calculate outcome payments, the payment schedule, and performance thresholds.

“(xvi) The project budget.

“(xvii) The project timeline.

“(xviii) The criteria used to determine the eligibility of an individual for the project, including how selected populations will be identified, how they will be referred to the project, and how they will be enrolled in the project.

“(xix) The evaluation design.

“(xx) The metrics that will be used in the evaluation to determine whether the outcomes have been achieved as a result of the intervention and how the metrics will be measured.

“(xxi) An explanation of how the metrics used in the evaluation to determine whether the outcomes achieved as a result of the intervention are independent, objective indicators of impact and are not subject to manipulation by the service provider, intermediary, or investor.

“(xxii) A summary explaining the independence of the evaluator from the other entities involved in the project and the evaluator’s experience in conducting rigorous evaluations of program effectiveness including, where available, well-implemented randomized controlled trials on the intervention or similar interventions.

“(xxiii) The capacity of the service provider to deliver the intervention to the number of participants the State or local government proposes to serve in the project.

“(xxiv) A description of whether and how the State or local government and service providers plan to sustain the intervention, if it is timely and appropriate to do so, to ensure that successful interventions continue to operate after the period of the social impact partnership.

“(D) PROJECT INTERMEDIARY INFORMATION REQUIRED.—The application described in subparagraph (C) shall also contain the following information about any intermediary for the social impact partnership project (whether an intermediary is a service provider or other entity):

“(i) Experience and capacity for providing or facilitating the provision of the type of intervention proposed.

“(ii) The mission and goals.

“(iii) Information on whether the intermediary is already working with service providers that provide this intervention or an explanation of the capacity of the intermediary to begin working with service providers to provide the intervention.

“(iv) Experience working in a collaborative environment across government and nongovernmental entities.

“(v) Previous experience collaborating with public or private entities to implement evidence-based programs.

“(vi) Ability to raise or provide funding to cover operating costs (if applicable to the project).

“(vii) Capacity and infrastructure to track outcomes and measure results, including—

“(I) capacity to track and analyze program performance and assess program impact; and

“(II) experience with performance-based awards or performance-based contracting and achieving project milestones and targets.

“(viii) Role in delivering the intervention.

“(ix) How the intermediary would monitor program success, including a description of the interim benchmarks and outcome measures.

“(E) FEASIBILITY STUDIES FUNDED THROUGH OTHER SOURCES.—The notice described in subparagraph (A) shall permit a State or local government to submit an application for social impact partnership funding that contains information from a feasibility study developed for purposes other than applying for funding under this subsection.

“(3) AWARDING SOCIAL IMPACT PARTNERSHIP AGREEMENTS.—

“(A) TIMELINE IN AWARDING AGREEMENT.—Not later than 6 months after receiving an application in accordance with paragraph (2), the Secretary, in consultation with the Federal Interagency Council on Social Impact Partnerships, shall determine whether to enter into an agreement for a social impact partnership project with a State or local government.

“(B) CONSIDERATIONS IN AWARDING AGREEMENT.—In determining whether to enter into an agreement for a social impact partnership project (the application for which was submitted under paragraph (2)) the Secretary, in consultation with the Federal Interagency Council on Social Impact Partnerships (established by paragraph (6)) and the head of any Federal agency administering a similar intervention or serving a population similar to that served by the project, shall consider each of the following:

“(i) The recommendations made by the Commission on Social Impact Partnerships.

“(ii) The value to the Federal Government of the outcomes expected to be achieved if the outcomes specified in the agreement are achieved as a result of the intervention.

“(iii) The likelihood, based on evidence provided in the application and other evidence, that the State or local government in collaboration with the intermediary and the service providers will achieve the outcomes.

“(iv) The savings to the Federal Government if the outcomes specified in the agreement are achieved as a result of the intervention.

“(v) The savings to the State and local governments if the outcomes specified in the agreement are achieved as a result of the intervention.

“(vi) The expected quality of the evaluation that would be conducted with respect to the agreement.

“(vii) The capacity and commitment of the State or local government to sustain the intervention, if appropriate and timely and if the intervention is successful, beyond the period of the social impact partnership.

“(C) AGREEMENT AUTHORITY.—

“(i) AGREEMENT REQUIREMENTS.—In accordance with this paragraph, the Secretary, in consultation with the Federal Interagency Council on Social Impact Partnerships and the head of any Federal agency administering a similar intervention or serving a population similar to that served by the project, may enter into an agreement for a social impact partnership project with a State or local government if the Secretary, in consultation with the Federal Interagency Council on Social Impact Partnerships, determines that each of the following requirements are met:

“(I) The State or local government agrees to achieve one or more outcomes as a result of the intervention, as specified in the agreement and validated by independent evaluation, in order to receive payment.

“(II) The Federal payment to the State or local government for each specified outcome achieved as a result of the intervention is less than or equal to the value of the outcome to the Federal Government over a period not to exceed 10 years, as determined by the Secretary, in consultation with the State or local government.

“(III) The duration of the project does not exceed 10 years.

“(IV) The State or local government has demonstrated, through the application submitted under paragraph (2), that, based on prior rigorous experimental evaluations or rigorous quasi-experimental studies, the intervention can be expected to achieve each outcome specified in the agreement.

“(V) The State, local government, intermediary, or service provider has experience raising private or philanthropic capital to fund social service investments (if applicable to the project).

“(VI) The State or local government has shown that each service provider has experience delivering the intervention, a similar interven-

tion, or has otherwise demonstrated the expertise necessary to deliver the intervention.

“(ii) PAYMENT.—The Secretary shall pay the State or local government only if the independent evaluator described in paragraph (5) determines that the social impact partnership project has met the requirements specified in the agreement and achieved an outcome as a result of the intervention, as specified in the agreement and validated by independent evaluation.

“(D) NOTICE OF AGREEMENT AWARD.—Not later than 30 days after entering into an agreement under this paragraph, the Secretary shall publish a notice in the Federal Register that includes, with regard to the agreement, the following:

“(i) The outcome goals of the social impact partnership project.

“(ii) A description of each intervention in the project.

“(iii) The target population that will be served by the project.

“(iv) The expected social benefits to participants who receive the intervention and others who may be impacted.

“(v) The detailed roles, responsibilities, and purposes of each Federal, State, or local government entity, intermediary, service provider, independent evaluator, investor, or other stakeholder.

“(vi) The payment terms, the methodology used to calculate outcome payments, the payment schedule, and performance thresholds.

“(vii) The project budget.

“(viii) The project timeline.

“(ix) The project eligibility criteria.

“(x) The evaluation design.

“(xi) The metrics that will be used in the evaluation to determine whether the outcomes have been achieved as a result of each intervention and how these metrics will be measured.

“(xii) The estimate of the savings to the Federal, State, and local government, on a program-by-program basis and in the aggregate, if the agreement is entered into and implemented and the outcomes are achieved as a result of each intervention.

“(E) AUTHORITY TO TRANSFER ADMINISTRATION OF AGREEMENT.—The Secretary may transfer to the head of another Federal agency the authority to administer (including making payments under) an agreement entered into under subparagraph (C), and any funds necessary to do so.

“(F) REQUIREMENT ON FUNDING USED TO BENEFIT CHILDREN.—Not less than 50 percent of all Federal payments made to carry out agreements under this paragraph shall be used for initiatives that directly benefit children.

“(4) FEASIBILITY STUDY FUNDING.—

“(A) REQUESTS FOR FUNDING FOR FEASIBILITY STUDIES.—The Secretary shall reserve a portion of the amount reserved to carry out this subsection to assist States or local governments in developing feasibility studies to apply for social impact partnership funding under paragraph (2). To be eligible to receive funding to assist with completing a feasibility study, a State or local government shall submit an application for feasibility study funding addressing the following:

“(i) A description of the outcome goals of the social impact partnership project.

“(ii) A description of the intervention, including anticipated program design, target population, an estimate regarding the number of individuals to be served, and setting for the intervention.

“(iii) Evidence to support the likelihood that the intervention will produce the desired outcomes.

“(iv) A description of the potential metrics to be used.

“(v) The expected social benefits to participants who receive the intervention and others who may be impacted.

“(vi) Estimated costs to conduct the project.

“(vii) Estimates of Federal, State, and local government savings and other savings if the

project is implemented and the outcomes are achieved as a result of each intervention.

“(viii) An estimated timeline for implementation and completion of the project, which shall not exceed 10 years.

“(ix) With respect to a project for which the State or local government selects an intermediary to operate the project, any partnerships needed to successfully execute the project and the ability of the intermediary to foster the partnerships.

“(x) The expected resources needed to complete the feasibility study for the State or local government to apply for social impact partnership funding under paragraph (2).

“(B) FEDERAL SELECTION OF APPLICATIONS FOR FEASIBILITY STUDY.—Not later than 6 months after receiving an application for feasibility study funding under subparagraph (A), the Secretary, in consultation with the Federal Interagency Council on Social Impact Partnerships and the head of any Federal agency administering a similar intervention or serving a population similar to that served by the project, shall select State or local government feasibility study proposals for funding based on the following:

“(i) The recommendations made by the Commission on Social Impact Partnerships.

“(ii) The likelihood that the proposal will achieve the desired outcomes.

“(iii) The value of the outcomes expected to be achieved as a result of each intervention.

“(iv) The potential savings to the Federal Government if the social impact partnership project is successful.

“(v) The potential savings to the State and local governments if the project is successful.

“(C) PUBLIC DISCLOSURE.—Not later than 30 days after selecting a State or local government for feasibility study funding under this paragraph, the Secretary shall cause to be published on the website of the Federal Interagency Council on Social Impact Partnerships information explaining why a State or local government was granted feasibility study funding.

“(D) FUNDING RESTRICTION.—

“(i) FEASIBILITY STUDY RESTRICTION.—The Secretary may not provide feasibility study funding under this paragraph for more than 50 percent of the estimated total cost of the feasibility study reported in the State or local government application submitted under subparagraph (A).

“(ii) AGGREGATE RESTRICTION.—Of the total amount reserved to carry out this subsection, the Secretary may not use more than \$10,000,000 to provide feasibility study funding to States or local governments under this paragraph.

“(iii) NO GUARANTEE OF FUNDING.—The Secretary shall have the option to award no funding under this paragraph.

“(E) SUBMISSION OF FEASIBILITY STUDY REQUIRED.—Not later than 9 months after the receipt of feasibility study funding under this paragraph, a State or local government receiving the funding shall complete the feasibility study and submit the study to the Federal Interagency Council on Social Impact Partnerships.

“(F) DELEGATION OF AUTHORITY.—The Secretary may transfer to the head of another Federal agency the authorities provided in this paragraph and any funds necessary to exercise the authorities.

“(G) EVALUATIONS.—

“(A) AUTHORITY TO ENTER INTO AGREEMENTS.—For each State or local government awarded a social impact partnership project approved by the Secretary under this subsection, the head of the relevant agency, as recommended by the Federal Interagency Council on Social Impact Partnerships and determined by the Secretary, shall enter into an agreement with the State or local government to pay for all or part of the independent evaluation to determine whether the State or local government project has achieved a specific outcome as a result of the intervention in order for the State or

local government to receive outcome payments under this subsection.

“(B) EVALUATOR QUALIFICATIONS.—The head of the relevant agency may not enter into an agreement with a State or local government unless the head determines that the evaluator is independent of the other parties to the agreement and has demonstrated substantial experience in conducting rigorous evaluations of program effectiveness including, where available and appropriate, well-implemented randomized controlled trials on the intervention or similar interventions.

“(C) METHODOLOGIES TO BE USED.—The evaluation used to determine whether a State or local government will receive outcome payments under this subsection shall use experimental designs using random assignment or other reliable, evidence-based research methodologies, as certified by the Federal Interagency Council on Social Impact Partnerships, that allow for the strongest possible causal inferences when random assignment is not feasible.

“(D) PROGRESS REPORT.—

“(i) SUBMISSION OF REPORT.—The independent evaluator shall—

“(I) not later than 2 years after a project has been approved by the Secretary and biannually thereafter until the project is concluded, submit to the head of the relevant agency and the Federal Interagency Council on Social Impact Partnerships a written report summarizing the progress that has been made in achieving each outcome specified in the agreement; and

“(II) before the scheduled time of the first outcome payment and before the scheduled time of each subsequent payment, submit to the head of the relevant agency and the Federal Interagency Council on Social Impact Partnerships a written report that includes the results of the evaluation conducted to determine whether an outcome payment should be made along with information on the unique factors that contributed to achieving or failing to achieve the outcome, the challenges faced in attempting to achieve the outcome, and information on the improved future delivery of this or similar interventions.

“(ii) SUBMISSION TO THE SECRETARY AND CONGRESS.—Not later than 30 days after receipt of the written report pursuant to clause (i)(II), the Federal Interagency Council on Social Impact Partnerships shall submit the report to the Secretary and each committee of jurisdiction in the House of Representatives and the Senate.

“(E) FINAL REPORT.—

“(i) SUBMISSION OF REPORT.—Within 6 months after the social impact partnership project is completed, the independent evaluator shall—

“(I) evaluate the effects of the activities undertaken pursuant to the agreement with regard to each outcome specified in the agreement; and

“(II) submit to the head of the relevant agency and the Federal Interagency Council on Social Impact Partnerships a written report that includes the results of the evaluation and the conclusion of the evaluator as to whether the State or local government has fulfilled each obligation of the agreement, along with information on the unique factors that contributed to the success or failure of the project, the challenges faced in attempting to achieve the outcome, and information on the improved future delivery of this or similar interventions.

“(ii) SUBMISSION TO THE SECRETARY AND CONGRESS.—Not later than 30 days after receipt of the written report pursuant to clause (i)(II), the Federal Interagency Council on Social Impact Partnerships shall submit the report to the Secretary and each committee of jurisdiction in the House of Representatives and the Senate.

“(F) LIMITATION ON COST OF EVALUATIONS.—Of the amount reserved under this subsection for social impact partnership projects, the Secretary may not obligate more than 15 percent to evaluate the implementation and outcomes of the projects.

“(G) DELEGATION OF AUTHORITY.—The Secretary may transfer to the head of another Fed-

eral agency the authorities provided in this paragraph and any funds necessary to exercise the authorities.

“(6) FEDERAL INTERAGENCY COUNCIL ON SOCIAL IMPACT PARTNERSHIPS.—

“(A) ESTABLISHMENT.—There is established the Federal Interagency Council on Social Impact Partnerships (in this paragraph referred to as the ‘Council’) to—

“(i) coordinate with the Secretary on the efforts of social impact partnership projects funded under this subsection;

“(ii) advise and assist the Secretary in the development and implementation of the projects;

“(iii) advise the Secretary on specific programmatic and policy matter related to the projects;

“(iv) provide subject-matter expertise to the Secretary with regard to the projects;

“(v) certify to the Secretary that each State or local government that has entered into an agreement with the Secretary for a social impact partnership project under this subsection and each evaluator selected by the head of the relevant agency under paragraph (5) has access to Federal administrative data to assist the State or local government and the evaluator in evaluating the performance and outcomes of the project;

“(vi) address issues that will influence the future of social impact partnership projects in the United States;

“(vii) provide guidance to the executive branch on the future of social impact partnership projects in the United States;

“(viii) prior to approval by the Secretary, certify that each State and local government application for a social impact partnership contains rigorous, independent data and reliable, evidence-based research methodologies to support the conclusion that the project will yield savings to the State or local government or the Federal Government if the project outcomes are achieved;

“(ix) certify to the Secretary, in the case of each approved social impact partnership that is expected to yield savings to the Federal Government, that the project will yield a projected savings to the Federal Government if the project outcomes are achieved, and coordinate with the relevant Federal agency to produce an after-action accounting once the project is complete to determine the actual Federal savings realized, and the extent to which actual savings aligned with projected savings; and

“(x) provide periodic reports to the Secretary and make available reports periodically to Congress and the public on the implementation of this subsection.

“(B) COMPOSITION OF COUNCIL.—The Council shall have 11 members, as follows:

“(i) CHAIR.—The Chair of the Council shall be the Director of the Office of Management and Budget.

“(ii) OTHER MEMBERS.—The head of each of the following entities shall designate one officer or employee of the entity to be a Council member:

“(I) The Department of Labor.

“(II) The Department of Health and Human Services.

“(III) The Social Security Administration.

“(IV) The Department of Agriculture.

“(V) The Department of Justice.

“(VI) The Department of Housing and Urban Development.

“(VII) The Department of Education.

“(VIII) The Department of Veterans Affairs.

“(IX) The Department of the Treasury.

“(X) The Corporation for National and Community Service.

“(7) COMMISSION ON SOCIAL IMPACT PARTNERSHIPS.—

“(A) ESTABLISHMENT.—There is established the Commission on Social Impact Partnerships (in this paragraph referred to as the ‘Commission’).

“(B) DUTIES.—The duties of the Commission shall be to—

“(i) assist the Secretary and the Federal Interagency Council on Social Impact Partnerships in reviewing applications for funding under this subsection;

“(ii) make recommendations to the Secretary and the Federal Interagency Council on Social Impact Partnerships regarding the funding of social impact partnership agreements and feasibility studies; and

“(iii) provide other assistance and information as requested by the Secretary or the Federal Interagency Council on Social Impact Partnerships.

“(C) COMPOSITION.—The Commission shall be composed of nine members, of whom—

“(i) one shall be appointed by the President, who will serve as the Chair of the Commission;

“(ii) one shall be appointed by the Majority Leader of the Senate;

“(iii) one shall be appointed by the Minority Leader of the Senate;

“(iv) one shall be appointed by the Speaker of the House of Representatives;

“(v) one shall be appointed by the Minority Leader of the House of Representatives;

“(vi) one shall be appointed by the Chairman of the Committee on Finance of the Senate;

“(vii) one shall be appointed by the ranking member of the Committee on Finance of the Senate;

“(viii) one member shall be appointed by the Chairman of the Committee on Ways and Means of the House of Representatives; and

“(ix) one shall be appointed by the ranking member of the Committee on Ways and Means of the House of Representatives.

“(D) QUALIFICATIONS OF COMMISSION MEMBERS.—The members of the Commission shall—

“(i) be experienced in finance, economics, pay for performance, or program evaluation;

“(ii) have relevant professional or personal experience in a field related to one or more of the outcomes listed in this subsection; or

“(iii) be qualified to review applications for social impact partnership projects to determine whether the proposed metrics and evaluation methodologies are appropriately rigorous and reliant upon independent data and evidence-based research.

“(E) TIMING OF APPOINTMENTS.—The appointments of the members of the Commission shall be made not later than 120 days after the date of the enactment of this subsection, or, in the event of a vacancy, not later than 90 days after the date the vacancy arises. If a member of Congress fails to appoint a member by that date, the President may select a member of the President's choice on behalf of the member of Congress. Notwithstanding the preceding sentence, if not all appointments have been made to the Commission as of that date, the Commission may operate with no fewer than five members until all appointments have been made.

“(F) TERM OF APPOINTMENTS.—

“(i) IN GENERAL.—The members appointed under subparagraph (C) shall serve as follows:

“(I) Three members shall serve for 2 years.

“(II) Three members shall serve for 3 years.

“(III) Three members (one of which shall be Chair of the Commission appointed by the President) shall serve for 4 years.

“(ii) ASSIGNMENT OF TERMS.—The Commission shall designate the term length that each member appointed under subparagraph (C) shall serve by unanimous agreement. In the event that unanimous agreement cannot be reached, term lengths shall be assigned to the members by a random process.

“(G) VACANCIES.—Subject to subparagraph (E), in the event of a vacancy in the Commission, whether due to the resignation of a member, the expiration of a member's term, or any other reason, the vacancy shall be filled in the manner in which the original appointment was made and shall not affect the powers of the Commission.

“(H) APPOINTMENT POWER.—Members of the Commission appointed under subparagraph (C)

shall not be subject to confirmation by the Senate.

“(8) LIMITATION ON USE OF FUNDS.—Of the amounts reserved to carry out this subsection, the Secretary may not use more than \$2,000,000 in any fiscal year to support the review, approval, and oversight of social impact partnership projects, including activities conducted by—

“(A) the Federal Interagency Council on Social Impact Partnerships; and

“(B) any other agency consulted by the Secretary before approving a social impact partnership project or a feasibility study under paragraph (4).

“(9) NO FEDERAL FUNDING FOR CREDIT ENHANCEMENTS.—No amount reserved to carry out this subsection may be used to provide any insurance, guarantee, or other credit enhancement to a State or local government under which a Federal payment would be made to a State or local government failing to achieve an outcome specified in a contract.

“(10) AVAILABILITY OF FUNDS.—Amounts reserved to carry out this subsection shall remain available until 10 years after the date of the enactment of this subsection.

“(11) WEBSITE.—The Federal Interagency Council on Social Impact Partnerships shall establish and maintain a public website that shall display the following:

“(A) A copy of, or method of accessing, each notice published regarding a social impact partnership project pursuant to this subsection.

“(B) A copy of each feasibility study funded under this subsection.

“(C) For each State or local government that has entered into an agreement with the Secretary for a social impact partnership project, the website shall contain the following information:

“(i) The outcome goals of the project.

“(ii) A description of each intervention in the project.

“(iii) The target population that will be served by the project.

“(iv) The expected social benefits to participants who receive the intervention and others who may be impacted.

“(v) The detailed roles, responsibilities, and purposes of each Federal, State, or local government entity, intermediary, service provider, independent evaluator, investor, or other stakeholder.

“(vi) The payment terms, methodology used to calculate outcome payments, the payment schedule, and performance thresholds.

“(vii) The project budget.

“(viii) The project timeline.

“(ix) The project eligibility criteria.

“(x) The evaluation design.

“(xi) The metrics used to determine whether the proposed outcomes have been achieved and how these metrics are measured.

“(D) A copy of the progress reports and the final reports relating to each social impact partnership project.

“(E) An estimate of the savings to the Federal, State, and local government, on a program-by-program basis and in the aggregate, resulting from the successful completion of the social impact partnership project.

“(12) REGULATIONS.—The Secretary, in consultation with the Federal Interagency Council on Social Impact Partnerships, may issue regulations as necessary to carry out this subsection.

“(13) DEFINITIONS.—In this subsection:

“(A) AGENCY.—The term ‘agency’ has the meaning given that term in section 551 of title 5, United States Code.

“(B) INTERVENTION.—The term ‘intervention’ means a specific service delivered to achieve an impact through a social impact partnership project.

“(C) SECRETARY.—The term ‘Secretary’ means the Secretary of the Treasury.

“(D) SOCIAL IMPACT PARTNERSHIP PROJECT.—The term ‘social impact partnership project’

means a project that finances social services using a social impact partnership model.

“(E) SOCIAL IMPACT PARTNERSHIP MODEL.—The term ‘social impact partnership model’ means a method of financing social services in which—

“(i) Federal funds are awarded to a State or local government only if a State or local government achieves certain outcomes agreed on by the State or local government and the Secretary; and

“(ii) the State or local government coordinates with service providers, investors (if applicable to the project), and (if necessary) an intermediary to identify—

“(I) an intervention expected to produce the outcome;

“(II) a service provider to deliver the intervention to the target population; and

“(III) investors to fund the delivery of the intervention.

“(F) STATE.—The term ‘State’ means each State of the United States, the District of Columbia, each commonwealth, territory or possession of the United States, and each federally recognized Indian tribe.

“(14) FUNDING.—Of the amounts made available to carry out subsection (b) for fiscal year 2017, the Secretary shall reserve \$100,000,000 to carry out this subsection.”

SEC. 25003. EXTENSION OF TANF PROGRAM.

(a) FAMILY ASSISTANCE GRANTS.—Section 403(a)(1) of the Social Security Act (42 U.S.C. 603(a)(1)) is amended in each of subparagraphs (A) and (C), by striking “2012” and inserting “2017”.

(b) HEALTHY MARRIAGE PROMOTION AND RESPONSIBLE FATHERHOOD GRANTS.—Section 403(a)(2)(D) of such Act (42 U.S.C. 603(a)(2)(D)) is amended by striking “2012” each place it appears and inserting “2017”.

(c) TRIBAL GRANTS.—Section 412(a) of such Act (42 U.S.C. 612(a)) is amended in each of paragraphs (1)(A) and (2)(A) by striking “2012” and inserting “2017”.

(d) CHILD CARE ENTITLEMENT.—Section 418(a)(3) of such Act (42 U.S.C. 618(a)(3)) is amended by striking “2012” and inserting “2017”.

(e) GRANTS TO THE TERRITORIES.—Section 1108(b)(2) of such Act (42 U.S.C. 1308(b)(2)) is amended by striking “2012” and inserting “2017”.

SEC. 25004. STRENGTHENING WELFARE RESEARCH AND EVALUATION AND DEVELOPMENT OF A WHAT WORKS CLEARINGHOUSE.

(a) IN GENERAL.—Section 413 of the Social Security Act (42 U.S.C. 613) is amended to read as follows:

“SEC. 413. EVALUATION OF TEMPORARY ASSISTANCE FOR NEEDY FAMILIES AND RELATED PROGRAMS.

“(a) EVALUATION OF THE IMPACTS OF TANF.—The Secretary shall conduct research on the effect of State programs funded under this part and any other State program funded with qualified State expenditures (as defined in section 409(a)(7)(B)(i)) on employment, self-sufficiency, child well-being, unmarried births, marriage, poverty, economic mobility, and other factors as determined by the Secretary.

“(b) EVALUATION OF GRANTS TO IMPROVE CHILD WELL-BEING BY PROMOTING HEALTHY MARRIAGE AND RESPONSIBLE FATHERHOOD.—The Secretary shall conduct research to determine the effects of the grants made under section 403(a)(2) on child well-being, marriage, family stability, economic mobility, poverty, and other factors as determined by the Secretary.

“(c) DISSEMINATION OF INFORMATION.—The Secretary shall, in consultation with States receiving funds provided under this part, develop methods of disseminating information on any research, evaluation, or study conducted under this section, including facilitating the sharing of information and best practices among States and localities.

“(d) STATE-INITIATED EVALUATIONS.—A State shall be eligible to receive funding to evaluate the State program funded under this part or any other State program funded with qualified State expenditures (as defined in section 409(a)(7)(B)(i)) if—

“(1) the State submits to the Secretary a description of the proposed evaluation;

“(2) the Secretary determines that the design and approach of the proposed evaluation is rigorous and is likely to yield information that is credible and will be useful to other States; and

“(3) unless waived by the Secretary, the State contributes to the cost of the evaluation, from non-Federal sources, an amount equal to at least 25 percent of the cost of the proposed evaluation.

“(e) CENSUS BUREAU RESEARCH.—

“(1) The Bureau of the Census shall implement or enhance household surveys of program participation, in consultation with the Secretary and the Bureau of Labor Statistics and made available to interested parties, to allow for the assessment of the outcomes of continued welfare reform on the economic and child well-being of low-income families with children, including those who received assistance or services from a State program funded under this part or any other State program funded with qualified State expenditures (as defined in section 409(a)(7)(B)(i)). The content of the surveys should include such information as may be necessary to examine the issues of unmarried child-bearing, marriage, welfare dependency and compliance with work requirements, the beginning and ending of spells of assistance, work, earnings and employment stability, and the well-being of children.

“(2) To carry out the activities specified in paragraph (1), the Bureau of the Census, the Secretary, and the Bureau of Labor Statistics shall consider ways to improve the surveys and data derived from the surveys to—

“(A) address under reporting of the receipt of means-tested benefits and tax benefits for low-income individuals and families;

“(B) increase understanding of poverty spells and long-term poverty, including by facilitating the matching of information to better understand intergenerational poverty;

“(C) generate a better geographical understanding of poverty such as through State-based estimates and measures of neighborhood poverty;

“(D) increase understanding of the effects of means-tested benefits and tax benefits on the earnings and incomes of low-income families; and

“(E) improve how poverty and economic well-being are measured, including through the use of consumption measures, material deprivation measures, social exclusion measures, and economic and social mobility measures.

“(f) RESEARCH AND EVALUATION CONDUCTED UNDER THIS SECTION.—Research and evaluation conducted under this section designed to determine the effects of a program or policy (other than research conducted under subsection (e)) shall use experimental designs using random assignment or other reliable, evidence-based research methodologies that allow for the strongest possible causal inferences when random assignment is not feasible.

“(g) DEVELOPMENT OF WHAT WORKS CLEARINGHOUSE OF PROVEN AND PROMISING APPROACHES TO MOVE WELFARE RECIPIENTS INTO WORK.—

“(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor, shall develop a database (which shall be referred to as the ‘What Works Clearinghouse of Proven and Promising Projects to Move Welfare Recipients into Work’) of the projects that used a proven approach or a promising approach in moving welfare recipients into work, based on independent, rigorous evaluations of the projects. The database shall include a separate listing of projects that used a developmental approach in

delivering services and a further separate listing of the projects with no or negative effects. The Secretary shall add to the What Works Clearinghouse of Proven and Promising Projects to Move Welfare Recipients into Work data about the projects that, based on an independent, well-conducted experimental evaluation of a program or project, using random assignment or other research methodologies that allow for the strongest possible causal inferences, have shown they are proven, promising, developmental, or ineffective approaches.

“(2) CRITERIA FOR EVIDENCE OF EFFECTIVENESS OF APPROACH.—The Secretary, in consultation with the Secretary of Labor and organizations with experience in evaluating research on the effectiveness of various approaches in delivering services to move welfare recipients into work, shall—

“(A) establish criteria for evidence of effectiveness; and

“(B) ensure that the process for establishing the criteria—

“(i) is transparent;

“(ii) is consistent across agencies;

“(iii) provides opportunity for public comment; and

“(iv) takes into account efforts of Federal agencies to identify and publicize effective interventions, including efforts at the Department of Health and Human Services, the Department of Education, and the Department of Justice.

“(3) DEFINITIONS.—In this subsection:

“(A) APPROACH.—The term ‘approach’ means a process, product, strategy, or practice that is—

“(i) research-based, based on the results of one or more empirical studies, and linked to program-determined outcomes; and

“(ii) evaluated using rigorous research designs.

“(B) PROVEN APPROACH.—The term ‘proven approach’ means an approach that—

“(i) meets the requirements of a promising approach; and

“(ii) has demonstrated significant and substantively important positive outcomes at more than one site in terms of increasing work and earnings of participants, reducing poverty and dependence, improving child well-being, or strengthening families.

“(C) PROMISING APPROACH.—The term ‘promising approach’ means an approach—

“(i) that meets the requirements of subparagraph (D)(i);

“(ii) that has been evaluated using well-designed and rigorous randomized controlled trials (or, if not available, rigorous quasi-experimental research designs);

“(iii) that has demonstrated significant and substantively important positive outcomes at one site in terms of increasing work and earnings of participants, reducing poverty and dependence, improving child well-being, or strengthening families; and

“(iv) under which the benefits of the positive outcomes have exceeded the costs of achieving the outcomes.

“(D) DEVELOPMENTAL APPROACH.—The term ‘developmental approach’ means an approach that—

“(i) is research-based, grounded in relevant empirically-based knowledge, and linked to program-determined outcomes;

“(ii) is evaluated using rigorous research designs; and

“(iii) has yet to demonstrate a significant positive outcome in terms of increasing work and earnings of participants in a cost-effective way.

“(h) APPROPRIATION.—

“(1) IN GENERAL.—Of the amount appropriated by section 403(a)(1) for each fiscal year, 0.33 percent shall be available for research, technical assistance, and evaluation under this section.

“(2) ALLOCATION.—Of the amount made available under paragraph (1) for each fiscal year, the Secretary shall make available \$10,000,000

plus such additional amount as the Secretary deems necessary and appropriate, to carry out subsection (e).”.

(b) CONFORMING AMENDMENT.—Section 403(a)(1)(B) of such Act (42 U.S.C. 603(a)(1)(B)) is amended by inserting “, reduced by the percentage specified in section 413(h) with respect to the fiscal year,” before “as the amount”.

SEC. 25005. TECHNICAL CORRECTIONS TO DATA EXCHANGE STANDARDS TO IMPROVE PROGRAM COORDINATION.

(a) IN GENERAL.—Section 411(d) of the Social Security Act (42 U.S.C. 611(d)) is amended to read as follows:

“(d) DATA EXCHANGE STANDARDS FOR IMPROVED INTEROPERABILITY.—

“(1) DESIGNATION.—The Secretary shall, in consultation with an interagency work group established by the Office of Management and Budget and considering State government perspectives, by rule, designate data exchange standards to govern, under this part—

“(A) necessary categories of information that State agencies operating programs under State plans approved under this part are required under applicable Federal law to electronically exchange with another State agency; and

“(B) Federal reporting and data exchange required under applicable Federal law.

“(2) REQUIREMENTS.—The data exchange standards required by paragraph (1) shall, to the extent practicable—

“(A) incorporate a widely accepted, non-proprietary, searchable, computer-readable format, such as the eXtensible Markup Language;

“(B) contain interoperable standards developed and maintained by intergovernmental partnerships, such as the National Information Exchange Model;

“(C) incorporate interoperable standards developed and maintained by Federal entities with authority over contracting and financial assistance;

“(D) be consistent with and implement applicable accounting principles;

“(E) be implemented in a manner that is cost-effective and improves program efficiency and effectiveness; and

“(F) be capable of being continually upgraded as necessary.

“(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require a change to existing data exchange standards found to be effective and efficient.”.

(b) EFFECTIVE DATE.—Not later than the date that is 24 months after the date of the enactment of this section, the Secretary of Health and Human Services shall issue a proposed rule that—

(1) identifies federally required data exchanges, include specification and timing of exchanges to be standardized, and address the factors used in determining whether and when to standardize data exchanges; and

(2) specifies State implementation options and describes future milestones.

The SPEAKER pro tempore. Pursuant to House Resolution 934, the motion shall be debatable for 80 minutes, with 60 minutes equally divided and controlled by the chair and ranking minority member of the Committee on Energy and Commerce and 20 minutes equally divided and controlled by the chair and ranking minority member of the Committee on Ways and Means.

The gentleman from Michigan (Mr. UPTON) and the gentleman from New Jersey (Mr. PALLONE) each will control 30 minutes. The gentleman from Texas (Mr. BRADY) and the gentleman from Michigan (Mr. LEVIN) each will control 10 minutes.

The Chair recognizes the gentleman from Michigan (Mr. UPTON).

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GENERAL LEAVE

Mr. UPTON. 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 material on H.R. 34.

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

There was no objection.

Mr. UPTON. Mr. Speaker, I yield myself 3 minutes.

Mr. Speaker, there is not a single person in this Chamber or watching at home today who has not been touched by disease in some way. We have all said too many early good-byes to folks that we hold dear—families robbed of a parent who will never get to see their child's milestones, a child born without the gift of a future.

Every day, countless folks living vibrant lives are delivered unexpected diagnoses. It is a cycle that repeats itself over and over in every community. Life changes in an instant, and hope seems out of reach, whether it be Alzheimer's, lupus, MS, cancer, you name it.

No matter where you are from, one thing that binds us all together is that we all want more time with our loved ones. That is why we are here today, because the clock is ticking for patients and their families.

So, Mr. Speaker, this brings us to the 21st Century Cures Act. This bipartisan bill will ensure that our health system can keep pace with the incredible advances in science and technology. In Cures, we have got a medical innovation game-changer that will deliver hope to patients across the country.

We have been here before. In July of 2015, after a series of roundtables, hearings, white papers, and public feedback, the House overwhelmingly voted in support of 21st Century Cures.

Sure, we have encountered a number of detours and obstacles along the path to Cures, but we have taken great inspiration in those patients who have partnered in this effort to persevere, stay positive, and continue forward to get the job done, just like my two little Michigan girls, Brooke and Brielle, who are battling SMA, do every day. Each day, they muster incredible strength and courage, conquering challenges that most folks will never encounter in a lifetime.

So 3 years ago, we had an idea that, yes, we could do better. We needed to do something to transform our health research system to effectively fight disease in this century. Finding cures and boosting research and innovation was absent from any policy to-do list. People didn't seem to care that the gap between biomedical innovation and our regulatory process was widening, or that of the 10,000 known diseases—7,000 of which are rare—there are treatments for only about 500. We needed to change the conversation and restore urgency. And working together, we have.

First, we listened to more than just Brooke and Brielle, but to Barb, Becky,

Lisa, Geno, the Dons, the Betsys, little Max, and our own little Steve LaTourrette who always sat in the corner. Virtually everyone here had a story to tell and for folks here to listen to.

Science and biomedical innovation have made incredible strides over the last two decades: mapping the human genome, new biomarkers, and personal healthcare apps. Each have offered new opportunities to find new treatment and cures. But the way the FDA and the NIH apply these new innovations to our regulatory process, in fact, has lagged behind.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. UPTON. Mr. Speaker, I yield myself an additional 2 minutes.

These agencies and the rules and regs they produce, affecting the discovery, development, and delivery of lifesaving drugs and devices, also need modernization and innovation. They need a game-changer, and now we have it. This legislation breaks down regulatory barriers and expedites the approvals for drugs and devices, coupled with billions more for research.

The former head of the NCI and the FDA, Andy von Eschenbach, has called this the most transformational biomedical legislation in the past 3 years. He is right.

But this package is not just about Cures. No. It also achieves several additional top-line priorities for our Energy and Commerce Committee, including valuable resources to fight the opioid epidemic and delivering landmark mental health reforms spearheaded by Dr. TIM MURPHY to help families in crisis and treat mental illnesses rather than incarceration. This is, without a doubt, the most important and impactful bill that we will enact in this Congress.

Patients aren't interested in debating the timelines. The failure rates, the size and cost of conducting clinical trials, are at an all-time high. They just know that despite the promise of scientific breakthroughs, they can't get the therapy that might save their life. That is why we need this bill.

I want to give a special thanks to my many partners, including especially DIANA DEGETTE, not to mention JOE PITTS, FRANK PALLONE, TIM MURPHY, and LAMAR ALEXANDER, the leadership on both sides of the aisle in both Chambers. I thank my truly brilliant committee and personal staff led by Gary Andres and Joan Hillebrands, Health Counsel Paul Edattel, and, of course, my wife, Amey.

We are on the cusp of something special, a once-in-a-generation opportunity to transform how we treat disease. With this vote, we are taking a giant leap on the path to Cures. Working together, we will deliver Cures now.

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

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from Colorado (Ms. DEGETTE), who is the Democratic sponsor of the bill and who has

worked so hard to make this day a reality.

Ms. DEGETTE. Mr. Speaker, I rise today in strong support of the 21st Century Cures Act, knowing that I am far from alone in supporting this bill. More than 700 groups representing patients, healthcare providers, researchers, and others have voiced support for the bill, as has the White House, which provided its enthusiastic endorsement last night.

This is a watershed moment in this country for biomedical research. With this bill, we bring hope to millions of patients who suffer from cancer, Alzheimer's, diabetes, and a host of other ailments.

As my cosponsor and partner in crime, FRED UPTON, just said, we started working on this measure 3 years ago. We traveled the country together to gather information about much-needed reforms, and we had tremendous participation in the process from patient groups, medical professionals, academia, and Federal and State healthcare authorities, not to mention the entire Democratic and Republican membership of the Energy and Commerce Committee who worked so closely together to make this happen.

All of this led to a bill that was passed in July, 2015, by 344-77. We can barely pass the Journal every day by that amount, Mr. Speaker.

Now, this was in the summer of 2015, and we have worked tirelessly in a bipartisan way since then to improve and expand the bill and to make sure it can pass through the Senate and be signed by the White House.

The result will help to overcome obstacles to medical progress from discovery to development to delivery through investing in innovation, incorporating the patient perspective, and modernizing clinical trials.

Among the key provisions, this consensus version of the bill will provide \$4.8 billion to the National Institutes of Health, including money for Vice President BIDEN's Cancer Moonshot initiative, including money for Precision Medicine and the BRAIN Initiative. It will provide almost \$1 billion in grants to the States to address the urgent opioid crisis in this country.

It removes the silos at the Food and Drug Administration by transitioning it to a disease-centric approach, and it gives \$500 million so the FDA can implement these reforms. It includes all-important mental health legislation that we have also worked on so hard for so long, and it will catalyze cutting-edge research by supporting potentially transformative efforts.

Mr. Speaker, at a time of heightened acrimony in Washington and in the wake of one of the most rancorous elections we have ever had, isn't it wonderful that we can come together to find cures that affect millions of Americans?

Disease doesn't discriminate according to political party. It knows nothing of claims and counterclaims. It responds only to carefully developed

treatments and cures. What we are doing today is we are voting to put vital innovations in biomedical research within reach, potentially saving countless lives. I urge all of our colleagues to think about the millions of Americans who will be heartened by this bill's progress, and I urge you to vote "yes" on the 21st Century Cures Act.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Texas (Mr. BARTON), who is the former chairman and now chairman emeritus of the Energy and Commerce Committee. My friend, the Honorable JOE BARTON, really helped us push this bill every step of the way.

(Mr. BARTON asked and was given permission to revise and extend his remarks.)

Mr. BARTON. Mr. Speaker, the Affordable Care Act failed because it was a one-sided, partisan, and close-looped system. This bill, the 21st Century Cures Act, will succeed because it has been done just the opposite.

Chairman UPTON, DIANA DEGETTE, FRANK PALLONE, and many other people have worked together, as they said, for the last 3 years to find the best pathway forward to get new drugs and new therapies to our citizenship more quickly and efficiently. I want to congratulate both of them plus Chairman BRADY, Dr. MURPHY, and the others that have worked on this.

This bill makes it possible for cures to actually be put into practice without all the red tape and regulatory overkill. Let me give you an example. This bill makes possible the use of what is called regenerative medicine which we call stem cell therapy.

My 11-year-old son, Jack, last week played football with Coach Sam Harrell of Ennis, Texas, who 3 years ago could not get out of bed because of his disease. He had to go out of the country twice to get stem cell therapy. He can now act normally.

This bill makes possible those kinds of cures. I rise in strong support and thank Chairman UPTON for his strong work on this.

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

Mr. Speaker, over the past 2 years, my colleagues and I on the Energy and Commerce Committee have worked to craft the 21st Century Cures Act with the goal of getting new treatments and cures to the people who need them the most. It has been a long journey, and I want to thank my colleagues, Chairman UPTON, Representatives DeGette and GENE GREEN of Texas for their commitment to this important legislation.

This is not a perfect bill, but, after much consideration, I believe the benefits outweigh my concerns, and I fully support its passage. This final bill includes many provisions that my Democratic colleagues and I, as well as the administration, fought hard to have included.

The bill provides new funding for the National Institutes of Health, the

President's Precision Medicine Initiative, and the Vice President's Cancer Moonshot initiative. It also provides new resources for the Food and Drug Administration and grants for States currently battling the opioid abuse crisis.

This final legislation also includes important policy changes that break down the research silos that have existed for years. The bill includes data sharing among NIH-supported scientists and increases the number of racial and ethnic minorities and women that are included in NIH-funded clinical trials.

These important changes will allow the entire scientific community to learn lessons from this critical NIH-funded research and will strengthen research for diverse populations.

I am also pleased, Mr. Speaker, that the bill includes a new FDA grant program to study the process of continuous drug manufacturing. This innovative process will allow for more effective drug production without sacrificing quality. The bill also includes important hiring provisions to help the FDA recruit and retain the best and the brightest and policies to move us closer to ensuring we have interoperable electronic health records, which are critical to reducing costs and improving care.

As I said, this is not a perfect bill, and I have some concerns with the final product. I am disappointed that the bill does not contain guaranteed funding. Instead, we must ensure each year that the Appropriations Committee and the Republican majority lives up to the promises they make today, and we will hold them to these promises. The lack of immediate funding for the FDA is a particular concern given the fact that this bill asks the FDA to take on significantly more responsibilities that we know are extremely resource intensive.

I am also concerned that the bill removes certain categories of medical software from FDA oversight. This makes it difficult for FDA, in the future, to bring software that is used to support or sustain human life back under FDA's jurisdiction.

I am also troubled by the new priority review voucher program which will likely require the FDA to issue significantly more PRVs. This could pose a burden on FDA drug reviewers when redeemed and could prevent the FDA from being able to prioritize its review of drugs based on public health priorities.

The bill includes new language added without full consideration by the House or Senate regarding FDA oversight of regenerative medicine products.

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While most of the harmful language was taken out, I do remain troubled that the bill creates a new designation process under FDA's accelerated approval pathway.

I am pleased, Mr. Speaker, that this package includes the Helping Families in Mental Health Crisis Act. This is a helpful step towards the more substantial reforms our broken mental health system needs.

I am specifically proud that the bill expands an important set of Medicaid benefits to kids receiving inpatient psychiatric treatment. However, let's be clear, the benefits of the mental health bill will be far outweighed by the catastrophic harm caused by individuals with mental illness if the Republicans move forward with their radical plans to repeal the Affordable Care Act or block grants for Medicaid or cut benefits for low-income individuals.

Again, on balance, this is a good bill. I fully support it. I want to thank all of my committee colleagues and their staff for their hard work on this legislation.

I reserve the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 30 seconds to the gentleman from Illinois (Mr. SHIMKUS), one of the senior subcommittee chairmen on the Energy and Commerce Committee, one that helped lead the fight all across the Nation in support of this bill.

(Mr. SHIMKUS asked and was given permission to revise and extend his remarks.)

Mr. SHIMKUS. Mr. Speaker, I thank Chairman UPTON, and I congratulate my friend DIANA DEGETTE. Also, I thank FRANK PALLONE for a good job. I thank him for being supportive, especially today, as we move this forward.

Thank you for including six of my bills that I had involved, one that deals with the lack of antibiotics in the market in the pipeline. So that is helpful. Four other bills help innovation to get lifesaving devices to the market.

I encourage all of my colleagues on both sides of the aisle to support this bill.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from Texas (Mr. GENE GREEN), the ranking member of the Health Subcommittee, who, again, has been critical, particularly in the last 3 months, in putting this bill together.

Mr. GENE GREEN of Texas. Mr. Speaker, I thank my colleague for providing the time.

I rise to express strong support for the 21st Century Cures Act.

Almost 3 years ago, we set out on a mission to do something positive to boost medical research and innovation and accelerate the discovery, development, and delivery of new cures and treatments.

After countless hours devoted to roundtables, white papers, hearings, and drafts, today, Cures has bipartisan support and endorsements from over 700 organizations representing a full spectrum of stakeholders and the strong support of the administration. My Houston area neighbors, Congressmen PETE OLSON and MIKE BURGESS, and I held a roundtable in the Houston area with the great institutions at our

Texas Media Center in the Houston area.

It dedicates \$6.3 billion in new investments to support priorities like the Cancer Moonshot and Precision Medicine Initiative within the National Institutes of Health, and to combat prescription drug abuse. This also provides money for the Food and Drug Administration to advance the agency's mission and implement the policies in the underlying bill. This influx of investment will be put towards solving today's complex scientific problems, getting new treatments from the lab table to the bedside, and improving public health.

In addition to this much-needed funding, there are so many provisions in this package worthy of support. From facilitating the development of new antibiotics to fight against superbugs, to advancing the use of modern clinical trial designs, to fostering the next generation of medical researchers, the 21st Century Cures Act will develop hope and new treatments for Americans in need. While some of these provisions are technical in nature, the real-world impact they will have is not abstract. Patients and families deserve to have their elected officials respond to their needs, and this bill does that.

Eighteen months ago, 344 Members supported Cures when it passed the House of Representatives. Since then, we have responded to feedback and tailored the bill, and it now includes additional priorities like improvements to our mental health system and non-partisan provisions to strengthen Medicare on behalf of beneficiaries.

I want to thank Chairman UPTON, Ranking Member PALLONE, Congresswoman DEGETTE, and Chairman PITTS for their leadership, vision, and determination. I also want to thank our staff, the House Legislative Counsel, and the countless stakeholders without whom we would not be here today.

It was a privilege to be part of this landmark effort. As an original sponsor and coauthor of the 21st Century Cures Act, I urge my colleagues to vote "yes."

Mr. Speaker, the following is my complete statement: I rise to express my strong support for the 21st Century Cures Act.

Almost three years ago, we set out on a mission: do something positive to boost medical research and innovation, and accelerate the discovery, development, and delivery of new cures and treatments.

After countless hours devoted to roundtables, whitepapers, hearings and drafts, today Cures has bipartisan support and endorsements from over 700 organizations representing the full spectrum of stakeholders, and the strong support of the Administration. My Houston area neighbors Congressmen PETE OLSON and MIKE BURGESS held a roundtable with the many great institutions at our Texas Media Center.

It dedicates \$6.3 billion in new investments to support priorities like the Cancer Moonshot and Precision Medicine Initiative within the National Institutes of Health (NIH), and to combat prescription drug abuse.

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From facilitating the development of new antibiotics to fight against superbugs to advancing the use of modern clinical trial designs to the fostering of the next generation of medical researchers, the 21st Century Cures Act will deliver hope and new treatments to Americans in need.

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Patients and families deserve to have their elected officials respond to their needs.

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Eighteen months ago, 344 members supported Cures (H.R. 6) when it passed the House of Representatives.

Since then, we have responded to feedback and tailored the bill, and it now includes additional priorities like improvements to our mental health care system and non-partisan provisions to strengthen Medicare on behalf of beneficiaries.

I want to thank Chairman UPTON, Ranking Member PALLONE, Congresswoman DEGETTE, and Chairman PITTS for their leadership, vision, and determination.

I also want to thank our staff, House Legislative Council, and the countless stakeholders without whom we would not be here today.

I want to particularly thank Tiffany Guarascio, Arielle Woronoff, Rachel Pryor, Kimberlee Trzeciak, Megan Velez, Waverly Gordon, Polly Webster, Kristen O'Neill, Paul Edattel, John Stone, Carly McWilliams, Adriana Simonelli, JP Paluskiewicz, Tim Pataki, Josh Trent and others on the Energy and Commerce Committee staff for all their work.

It was a privilege to be a part of this landmark effort.

As an original sponsor and co-author of the 21st Century Cures Act, I urge my colleagues to vote yes.

Mr. UPTON. Mr. Speaker, I yield 2 minutes to the gentleman from Pennsylvania (Mr. MURPHY), one of the subcommittee chairmen who helped craft the bipartisan Murphy mental health bill, which passed the House 422-2 earlier this year, and is a very valuable member of the committee.

Mr. MURPHY of Pennsylvania. Mr. Speaker, this is a moment of great joy out of a situation of tremendous tragedy.

After the last 4 years, since the time of the terrible tragedy at Sandy Hook Elementary School followed by repeated other ones, our Nation has awoken from a slumber of ignoring the problems of mental illness in America, one that when we closed down our institutions decades ago, we turned our eye to those who lay homeless on the street, who filled our prisons, who filled our cemeteries or lay on a gurney in an emergency room or were sent

back home to a family who felt helpless and hopeless.

We have changed now to a situation where we are coming together on a bill that will save lives. This is a new era of health care and the next generation of hope for Americans that really transcends boundaries.

To all of the families who brought their stories out of the shadows, that dared to share their sorrows, their hopes, their shattered dreams, today is a day of joy. And today is only possible, I say to all of those families, because they dared to step forward. There is not time enough to thank all of those involved, but to those families who have helped, I say thank you.

I also want to make sure I thank Chairman UPTON, Speaker RYAN, EDDIE BERNICE JOHNSON, DIANA DEGETTE, FRANK PALLONE, Senators BILL CASIDY and CHRIS MURPHY, Leader KEVIN MCCARTHY, Whip STEVE SCALISE, and so many others from our committee who have worked so hard to make this happen. And a special shout-out to some of the staff: Scott Dziengelski, Gary Andres, Karen Christian, Paul Edattel, Susan Mosychuk, and so many other staff who worked so hard on this.

We can look back on this moment in history and say today that, although we have much to do and although we didn't get everything we needed, we needed everything that we did get. But this is the moment from this day forward we can say today that we took action to save lives.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Florida (Ms. CASTOR).

Ms. CASTOR of Florida. Mr. Speaker, I rise today in support of the 21st Century Cures Act legislation and the important investment that it will make in medical research across America.

This legislation supports an additional \$4.8 billion for the National Institutes of Health, specifically for President Obama's Precision Medicine Initiative and the BRAIN Initiative so we can tackle the challenge of Alzheimer's. It supports Vice President BIDEN's Cancer Moonshot initiative. Hopefully, it will keep the young scientists on the job at institutions like the Moffitt Cancer Center and the University of South Florida's Alzheimer's Research Institute back home in Tampa.

While additional support for NIH is vital and this is a move in the right direction, I would have much preferred that we put this in the mandatory category as we voted on in H.R. 6 earlier in the year. I know many of you agree with that, that medical research in America today shouldn't be subject to the whims of congressional budget battles or political fights. I will continue to advocate for mandatory funding for NIH so that we can remain on the cutting edge of medical innovation and boost higher wage jobs back home. These initiatives save lives and provide investments that we need to make sure that we are developing the cures of tomorrow.

I am very pleased that legislation I introduced with my colleague Representative HERRERA BEUTLER was included in this package. The Safe Medications for Moms and Babies Act ensures that expectant mothers and doctors have accurate information about medications used during pregnancy and when nursing to facilitate the best health outcomes. Representative HERRERA BEUTLER has been a champion for families, and I am grateful to her for leading this effort to improve the quality of data and information on medication used during pregnancy and breastfeeding.

I also applaud the inclusion of language to improve our mental health system, the \$1 billion to address the opioid epidemic. This is very positive. I would like to thank Chairman FRED UPTON for his devotion to the issue, to Congresswoman DEGETTE, and to all of my colleagues on the Energy and Commerce Committee.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. PALLONE. I yield the gentleman an additional 30 seconds.

Ms. CASTOR of Florida. This is the way legislation is supposed to be developed: in a bipartisan way, through studies, through asking, reaching out, and working with experts all across the country, because all of the answers do not emanate from a congressional committee in Washington. It is very important that we tap the expertise all across the country to get something done.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Tennessee (Mrs. BLACKBURN), the vice chairman of the Energy and Commerce Committee, who, again, helped so much with the medical community to rally around and provide us the input necessary to move this bill to where it is today.

Mrs. BLACKBURN. Mr. Speaker, I congratulate Chairman UPTON and all of our colleagues on the Energy and Commerce Committee for a job well done, and done in the appropriate manner. It really has, as Ms. DEGETTE said, been so interesting to work across the country and work with patients, with physicians, with researchers, with those who are innovating new concepts, who are delving into delivery systems that are necessary for precision medicine which underpins 21st century health care.

There are three components that I want to bring attention to. First of all, section 3060 is there addressing medical technology and software. This is so important that we get the FDA on the right track and move components of this away so that it does not face FDA approval processes that will slow down access to the marketplace for patients.

Also, section 2038, the Children's Count Act—Mrs. CAPPS and I worked on this—allowing children access to clinical trials, and section 3076, the reauthorization of the Reagan-Udall language.

I congratulate my colleagues.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from Oregon (Mr. SCHRADER).

Mr. SCHRADER. Mr. Speaker, I rise today in strong support of the 21st Century Cures Act and to thank Chairman UPTON and my friends, Mr. PALLONE, Ms. DEGETTE, and Mr. GREEN, for their leadership and willingness to work across the aisle to produce this quality piece of legislation.

For too long, Congress has been shirking its responsibility when it comes to funding the critical research that will lead to cures and treatments at the NIH. Our scientists, physicians, and medical institutions are getting closer every day to medical breakthroughs that will help families and save lives. In my State alone, the NIH is funding research into new therapeutic avenues to combat cancer, heart disease, and illness born by pollution. It is time to streamline the path for critically needed medical devices and pharmaceuticals for vulnerable populations that can't afford to wait.

This bill takes a giant step forward to help fix the mental health infrastructure of our country. Currently, as a result of the mental health system's inadequacy, our emergency rooms, our prisons, and our homeless shelters are full of people who are having trouble getting the care they need. The status quo is not okay.

This bill moves us in the right direction through innovation and integration of mental health services for the overall healthcare system. The Cures Act enhances the capabilities of our law enforcement and first responders, strengthens our crisis intervention programs, and ensures that our Medicaid program does not deny access to beneficiaries seeking mental health care. It also includes a number of Medicare provisions to make sure seniors aren't left behind by bureaucratic red tape.

Getting to this point wasn't easy. Democrats and Republicans didn't always agree on every provision of this bill, but we were able to work together and find common ground and produce a bill that takes great strides toward producing better healthcare outcomes for Americans.

I hope the President-elect and Members of this body are taking note of this achievement today as we move forward instead of pushing through divisive harmful policies that will reduce access to quality health care. Let's work together and produce better results for all Americans.

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Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Kentucky (Mr. GUTHRIE), a member of the committee and a leader in pushing this bill forward.

Mr. GUTHRIE. I thank the chairman for yielding.

Mr. Speaker, all of us have families who come to our offices, and they are advocating for research or for cures for

diseases to which they have lost a parent or a child, or they have their children with them who have the diseases, and they are just hoping for a move forward.

In being on the Health Subcommittee, at least weekly and sometimes daily, innovators and entrepreneurs come to my office, and they talk about a new procedure or a new product—something that is innovative, that will change the lives of these families—but they are having trouble getting them through the system and getting them approved.

It hurts families, though, like a family in Elizabethtown, who has someone with a degenerative disease. This family is trying to beat the clock because they think there is some kind of help out there. I have a friend of mine from Bowling Green whose son went through a diabetes trial. The first time they said they got any sleep through the night was when their kid was in this trial. Then they called me, crying, saying they were out of the trial and that it may be another year before they get in. So, in taking our entrepreneurs and our innovators and putting together these cures, it is not just about getting these products to market—it is about changing the dynamics of these families who are suffering.

Our chairman and Ms. DEGETTE from Colorado put together this effort to move forward, and I urge support for this bill because it will change families' lives.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from Tennessee (Mr. COHEN).

Mr. COHEN. I thank the gentleman.

Mr. Speaker, I think everybody has been thanked who should be thanked, but I certainly want to thank Mr. UPTON for all of his work and Mr. PALLONE for his time and his work and Ms. DEGETTE. I also want to thank Senator ROGER WICKER, who worked on a bill that is incorporated into this bill that Congressman DUNCAN and I sponsored, called the EUREKA Act, which will incentivize and reward research on diseases for which there is not great public-private partnerships but for which there is a great handicap and problem for the American public because of the particular disease. It will reward successful treatments through a competition, which I think is a great way to go about encouraging research and then paying for it. ROGER WICKER, I think, came up with the idea, and I sponsored it with JOHN DUNCAN, and it is included in the bill. It was originally aimed at Alzheimer's. It is now for other diseases, but Alzheimer's is one of them.

Alzheimer's is a disease that is going to have a particularly crippling effect on our country economically in the future. Beyond that, it will affect many of us, and it will affect our pocketbooks; so it is important that this bill goes after Alzheimer's and that it deals with the opioid crisis, which is great in my State and across the country. It

works against all diseases and it encourages moneys in the National Institutes of Health.

I have long said, while we need to have a strong Defense Department, that my Secretary of Defense is Francis Collins, the head of the NIH, because the true enemy of each and every one of us isn't somebody in South Korea or somebody in Iran or ISIS or one of those folk—it is cancer; it is Alzheimer's; it is AIDS; it is diabetes; it is heart disease; it is Parkinson's. It is all of those diseases—the dreadful, awful, awful diseases for which the NIH is looking for cures. That is our Secretary of Defense, and that is what we need to invest our moneys in. I don't think there is enough money that we can put into the NIH, because it is important and it affects all Americans independent of political party, race, sexual orientation—you name it.

I thank the Members for their work on this, and I am proud to vote for it.

Mr. UPTON. Mr. Speaker, I yield 2 minutes to the gentleman from Florida (Mr. BILIRAKIS), a valuable member of the Health Subcommittee and whose father once chaired that subcommittee.

Mr. BILIRAKIS. I thank the chairman for all of his hard work on this great bill.

Mr. Speaker, I rise to talk about the incredible impact the 21st Century Cures Act would have on so many Americans.

Deadly diseases like cancer, Alzheimer's, ALS, and more affect each and every one of us. Within Cures, one will find the voices of patients, doctors, advocacy groups, and families I have met with from throughout Florida's 12th Congressional District. I am proud to say that a lot of their input is reflected in this final bill.

Samantha Lindsay, from Lutz, Florida, has Alpha-1, which is a rare genetic condition that results in serious lung problems. When we met, she talked about the need to use biomarkers for the faster approval of drugs for rare diseases. We did that. We have a framework for biomarker qualifications in this legislation.

Wayne Taylor, from Hudson, Florida, was a leukemia patient. He talked about the difficulty of participating in the clinical trials that eventually saved his life. This bill has reforms to make clinical trials more patient-focused and input-driven.

Dr. David Morgan, the CEO of the Health Byrd Alzheimer's Institute at the University of South Florida, talked about the need for stable funding for Alzheimer's and about reforming institutional review boards.

This bill invests in the NIH, and it reforms the IRB system. Cures also includes my provisions to reform the FDA's Office of Combination Products in order to streamline the approval of these products; to establish a new Medicare Web site to help seniors price shop; and to allow physical therapists to enter into locum tenens arrange-

ments so they can take maternity leave or sick time without having to turn away patients.

For many families, including my own, the potential impact of 21st Century Cures could change their lives. Let's get this meaningful bill across the finish line.

Mr. PALLONE. Mr. Speaker, I have a few additional speakers on their way; so I reserve the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Ohio (Mr. JOHNSON), a valuable member of our committee who has worked so hard to get this bill to where it is today.

Mr. JOHNSON of Ohio. I thank the chairman.

Mr. Speaker, I rise in support of the 21st Century Cures Act and add my voice to the steady stream of acclaim this legislation has already received.

American families and communities are suffering from rare diseases, and this innovative legislation works to align Federal incentives and regulations with the science and technology that make treatments and cures possible and attainable. I am proud to have supported this bill all along the way.

This package includes mental health reform—work that I am grateful to have been a part of during my time on the Oversight and Investigations Subcommittee with Chairman MURPHY. His tireless efforts will benefit many individuals and families who struggle with mental illness and substance abuse. This bill also includes \$1 billion for grants to States to fight opioid abuse. A recent report shows that my home State of Ohio leads the Nation in opioid overdose deaths. This funding is sorely needed to address the issue head on.

I ask my colleagues to support the Cures bill today.

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

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentlewoman from North Carolina (Mrs. ELLMERS), a member of the important Health Subcommittee and a real proponent of this legislation from day one.

Mrs. ELLMERS of North Carolina. I thank Chairman UPTON; Ranking Member PALLONE; Ms. DEGETTE, my good friend; TIM MURPHY from Pennsylvania, who worked so hard on the mental health reforms; and Chairman PITTS, the Health Subcommittee's chairman.

Mr. Speaker, there has been a great deal of effort put into this great piece of legislation, which basically has the goal of bringing our healthcare innovation infrastructure into the 21st Century Cures so that real hope for patients and loved ones can be achieved.

From removing barriers in the mental health system, to ensuring collaboration, to modernizing the clinical trial pathways, to boosting modern medical interventions, 21st Century Cures is a win for everyone. It will accelerate the discovery, development,

and delivery of lifesaving therapies in a safe and effective way. It will also empower families to support their loved ones.

In closing, Cures will change lives. I, personally, as a nurse, would like to say that this is one of the most important pieces of legislation we will pass here in the House.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentleman from Massachusetts (Mr. KENNEDY), who has been such a strong advocate on mental health issues.

Mr. KENNEDY. I thank the ranking member for yielding. I also thank him, as well as Chairman UPTON and Congresswoman DEGETTE, for being tireless throughout the entire process in their advocacy of trying to get this bill as a bipartisan compromise and for creating an environment that allows for our committee's members to raise their voices and shape this legislation.

Mr. Speaker, when we first passed the version of this bill last year, it was as a result of strong, bipartisan compromise and sacrifice. It certainly was not easy, but the legislative process is not intended to be.

While I am disappointed that the funding levels for the NIH were cut even further and that the investment is no longer mandatory, I take my Republican colleagues at their word that it will be appropriated in the years ahead. I am also pleased that this legislation includes language to remove obstacles for children who are covered by Medicaid; but my real concerns with the legislation lie with the mental health reform proposals, which don't go nearly far enough. Mental health parity is already the law, thanks to the Mental Health Parity and Addiction Equity Act and the Affordable Care Act; but each study we read, Mr. Speaker, and each story we hear proves that insurance companies are skirting those rules.

Instead of further guidance or meetings or studies carried out years down the road, we need enforcement and transparency today. We need random audits before there have been violations, not after. We need insurers to publicly disclose the rates and reasons for denials in a way that patients and their families can understand, not in a way that mental health advocates can't even obtain. We need to increase Medicaid reimbursements in order to expand access to care, not to reduce them or roll back expansion; and we need to appreciate the difference the ACA has made for mental health patients, especially for the most vulnerable among us. Until we do, we cannot consider these proposals comprehensive, and we certainly can't pretend that they are nearly enough.

This is an important compromise forged from an awful lot of hard work. I am happy and pleased to support this proposal, and I thank my colleagues on both sides of the aisle for getting it here today.

Mr. UPTON. Mr. Speaker, I yield myself 15 seconds.

I appreciate the gentleman from Massachusetts' statement. He is a very valuable player as we move this legislation on all fronts forward. I look very forward to working with the gentleman and with every Member of this body to make sure that the funding is there as we have laid out in this bill and to work with our colleagues in the Senate to make sure that it happens.

Mr. Speaker, how much time remains on both sides?

The SPEAKER pro tempore. The gentleman from Michigan has 15¼ minutes remaining, and the gentleman from New Jersey has 12 minutes remaining.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from New Jersey (Mr. LANCE), another valuable member of the Health Subcommittee and someone who pursued this legislation from the very get-go.

Mr. LANCE. Mr. Speaker, I rise in strong support of the 21st Century Cures legislation.

This bill provides significant investments to accelerate the discovery, development, and delivery of new cures and treatments for millions of Americans. The passage of this legislation will protect and create American jobs and will ensure that the United States remains the global leader in biomedical innovation and discovery. The measure reforms and strengthens the country's mental health system and makes mental health a strong national priority. The legislation includes critical funding for States to prevent opioid abuse and provide the needed treatment for those suffering from this public health crisis.

Reducing bureaucratic redtape, advancing lifesaving research, reforming our broken mental health system, and tackling opioid abuse in our communities will reduce healthcare costs and give many Americans new opportunities to live long, healthy, and productive lives.

I thank Chairman UPTON for his unparalleled leadership on this issue. It is an honor to have worked with him and all of our colleagues on the Energy and Commerce Committee to have crafted this landmark legislation.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Ohio (Ms. KAPTUR).

Ms. KAPTUR. I thank Ranking Member PALLONE for yielding me the time.

Mr. Speaker, I rise in strong support of the bipartisan 21st Century Cures Act, which dedicates more than \$6 billion to implement key health priorities, such as combating the heroin and prescription opioid epidemic across this country and the Vice President's Cancer Moonshot. It also takes steps to improve mental health, including provisions that build on the work of the President's Mental Health and Substance Use Disorder Parity Task Force and policies to further modernize the drug approval process. This will mean so much to the researchers across this country who are trying to unlock the mysteries of the human brain and heal

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The legislation includes \$1 billion over 2 years, including \$500 million in fiscal year 2017, to combat the prescription opioid and heroin epidemic as well. The legislation dedicates support for other key research initiatives with the goal of helping researchers find new ways to treat, cure, and prevent brain disorders, such as Alzheimer's disease, epilepsy, and traumatic brain injury.

This legislation includes a much-needed renewed emphasis on evidence-based strategies for treating serious mental illness, improved coordination between primary care and behavioral health services, reauthorization of important programs focused on suicide prevention and other prevention services, and mental health and substance use disorder parity provisions.

I would like to thank Dr. Joseph Calabrese at Case Western Reserve University in Cleveland and my good friend, Representative TIM MURPHY, who came to Ohio and hosted a roundtable on mental health that can be added to this major bill in order to move America forward.

I thank Chairman FRED UPTON, knowing the deep commitment that he has to so many Americans who desperately need the help that this bill will provide. Again, to Congressman FRANK PALLONE of New Jersey, I want to compliment both men for working together to do something great for this country for so many Americans who are desperate to find answers for those who are ill. I want to thank Congresswoman DIANA DEGETTE of Colorado who has shepherded this to this point.

Although not perfect or complete, this legislation offers advances in health that greatly outweigh any concerns we might have. I am proud to add my strong support for 21st Century Cures Act.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Indiana (Mr. BUCSHON), who again hosted a number of roundtables and discussions throughout the country and a very valuable member of the committee.

Mr. BUCSHON. Mr. Speaker, I urge my colleagues to support the Senate amendment to H.R. 34, the 21st Century Cures Act.

Over our country's history, American innovators have proven among the best in the world, especially in the field of drug and device research.

21st Century Cures streamlines the process for American innovators to see their research and development reach patients faster than ever, while maintaining a safe and effective review process.

It also invests in the areas we need it the most, to advance research and testing on the most complex and devastating diseases in our country. It also gives young scientists the support they need to bring new ideas to the scientific community.

The mental health and opioid abuse provisions in this legislation are also

critical. As a physician who has relied on medical innovation to care for patients, working to pass the 21st Century Cures Act and ensuring America remains on the forefront of cutting edge research has been one of the highlights of my time in Congress.

I thank Chairman UPTON and Representative DEGETTE for their leadership and commitment to this legislation.

Mr. PALLONE. Mr. Speaker, I yield 2 minutes to the gentlewoman from Connecticut (Ms. DELAURO).

Ms. DELAURO. Mr. Speaker, I rise in opposition to this bill. The 21st Century Cures bill aims to promote biomedical innovation and mental health, noble goals that I share. Unfortunately, this bill sets a dangerous precedent and has the potential to do more harm than good for millions of Americans.

In its attempt to speed up the drug and device approval process, this legislation neglects the very people whom clinical trials are meant to help, that is, the patients. Rather than protect those who rely on the healthcare system, it reduces the already weak regulation on medical devices, allows drugs to be approved with only limited evidence of the drug's safety and efficacy, and rushes the use of new and unproven antibiotics.

An example, 13 models of the St. Jude's defibrillators are currently being recalled for sudden battery failure that has been linked to at least two deaths, 10 people fainting, and 37 people feeling dizzy.

When the cost of our prescription drugs is skyrocketing, this bill does nothing to combat excessive prices.

Finally, this bill strips away funding from the public health and prevention fund. While the bill authorizes \$4.8 billion to the NIH over the next 10 years—on average, a mere \$480 million a year—this is barely a quarter per year of what the House passed last year. Let us not forget that we would need to provide \$7 billion a year to keep up where we were in 2003.

There is also no guarantee that the appropriators will follow through and provide funding each year, as we have seen with the public health prevention fund, which has been used to fill appropriations shortfalls.

Illness touches us all. We owe it to the patients who depend on the standards that we set. Unfortunately, I believe the standards in this bill are both weak and dangerous. This legislation is the wrong path forward, and I strongly oppose it.

Mr. UPTON. Mr. Speaker, I yield 2 minutes to the gentleman from New York (Mr. COLLINS), whose personal knowledge of the maze of the regulatory approval process made him a very valuable member of the Health Subcommittee in pushing this legislation forward.

Mr. COLLINS of New York. Mr. Speaker, I thank all the people who worked tirelessly to make this legislation a reality.

Simply stated, the goal of this legislation is to incentivize innovation to defeat disease. Today, the 21st Century Cures Act will do that and much more for patients suffering from currently incurable diseases.

This legislation provides substantial funding to the National Institutes of Health, including \$1.8 billion to speed up cancer research, \$1.5 billion to improve our understanding of debilitating diseases such as Alzheimer's, and another \$1.5 billion to assist in genetic and other individual specific research efforts.

This bill provides funding to fight the opioid addiction crisis, which has been particularly devastating to western New York, and it includes mental health legislation to improve those services nationwide.

I am excited that this final bill contains a few provisions I authored and worked on over the past 2 years. Section 3021 encourages the broader application of innovative clinical trial designs to enhance and accelerate effective clinical trials.

Section 3071 will expedite and improve drug approval processes by increasing the allowable number of senior biomedical researchers the FDA is allowed to hire and making their salary more competitive with the private industry.

Section 9023, which I worked on with Representative JOE COURTNEY, incentivizes child and adolescent psychiatrists to begin their practices in underserved areas like those in rural western New York.

Lastly, Section 5006, which I worked on with Congressman PAUL TONKO, includes the House-passed Medicaid DOC Act, which requires States to publish an online directory of physicians who have billed Medicaid in the past year and indicate whether those physicians are accepting new patients.

None of this would have been possible without the tireless work of Chairman FRED UPTON and the entire staff on Energy and Commerce. I thank them for their tremendous effort and look forward to seeing innovation defeat disease because of this game-changing legislation.

Mr. PALLONE. Mr. Speaker, how much time remains on both sides?

The SPEAKER pro tempore. The gentleman from New Jersey has 8 minutes remaining, and the gentleman from Michigan has 11¼ minutes remaining.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from New Mexico (Mr. BEN RAY LUJÁN).

Mr. BEN RAY LUJÁN of New Mexico. Mr. Speaker, I begin by thanking Chairman UPTON and Ranking Member PALLONE of the Energy and Commerce Committee, as well as Congresswoman DEGETTE, for their bipartisan cooperation during this long legislative process.

This is a good, if imperfect, bill that will provide vital funding to the National Institutes of Health and the Vice President's Cancer Moonshot while

taking steps to strengthen our mental health system. I want to focus my remarks on the critical investments this bill promises to combat the opioid epidemic.

In communities across our country, families are struggling with the pain of addiction to opioids. Earlier this year, Congress took an important step against substance abuse by passing the Comprehensive Addiction and Recovery Act, or CARA.

Unfortunately, congressional Republicans did not support including the necessary funding to CARA's success. This was a missed opportunity. In the months since Congress passed CARA, we have lost parents, siblings, children, and friends—129 people every day.

When I talk to New Mexicans on the front lines of this crisis, the most urgent need is for more resources. That is why I introduced the Opioid and Heroin Abuse Crisis Investment Act. This bill, cosponsored by nearly 100 of my colleagues, sought to advance the President's proposal to combat this epidemic.

This legislation we are considering today—like my bill—promises \$1 billion for the opioid crisis. Though we cannot bring back those that we have lost, we owe it to them and their families to pass this bill. This funding will make a real difference in people's lives.

While I am relieved that we will soon be able to get the resources to our communities, I am fearful that some of my colleagues will see this as a mission accomplished instead of what it must be, which is only a first step toward healing our communities.

I can't help but ask my Republican colleagues, who support the advances we are making today for mental health: Why are they preparing to roll back the most important advances we made for mental health in the past 8 years by promising to repeal the Affordable Care Act?

The 21st Century Cures Act shows what we can do and what can happen when we work across the aisle, and I hope we will truly continue to work together to strengthen our Nation's health system.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentlewoman from California (Mrs. MIMI WALTERS), an original cosponsor of our bill and great proponent from day one.

Mrs. MIMI WALTERS of California. Mr. Speaker, over the last 2 years, I have worked with organizations in my district, including the Children's Hospital of Orange County, the Juvenile Diabetes Research Foundation, and Alzheimer's Orange County.

During my visits with these groups, I have met with constituents who are suffering from incurable diseases. I have met with parents of children suffering from prescription drug addiction and families struggling to find adequate mental health care for their loved ones.

All of these people have one thing in common. The 21st Century Cures Act

would directly improve the care they receive. This innovative legislation will provide them with faster and better cures and treatment.

In passing this legislation, we have the opportunity to accelerate the discovery, development, and delivery of lifesaving and life-improving therapies.

I urge my colleagues to join me in supporting the 21st Century Cures Act. It is time for cures now.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentlewoman from Colorado (Ms. DEGETTE).

Ms. DEGETTE. Mr. Speaker, I thank Mr. PALLONE for yielding me the time and for being an unerring partner on this quest that we have had.

I just want to take a few minutes to talk about the extraordinary journey that we have had here. When Representative FRED UPTON came up to me on the floor about 3 years ago and asked if I would help him work on a bill to help modernize and update the way we do biomedical research in this country, little did I realize the road that lay ahead. There have been a lot of twists and turns in that road. There have been some very interesting sightings along that road, and it has been an extraordinary effort for all of us. It has really brought the Energy and Commerce Committee together in a bipartisan way, and I am hoping that we can continue those efforts in the next Congress.

So many of my colleagues are right. We still have a lot that we have to do in the area of mental health, in the area of biomedical research, and so much more.

I want to thank a number of people because they really all deserve to be thanked: Of course, Energy and Commerce Committee Chairman UPTON and Ranking Member PALLONE, and Subcommittee on Health Ranking Member GENE GREEN and Chairman JOE PITTS. I want to thank the entire committee, as I said.

I want to thank the patient advocacy community who have been with us unerringly throughout this process. I want to thank the researchers. I want to thank the entrepreneurs who came and talked to us about what they needed. I want to thank the agencies themselves, specifically the FDA and the NIH, for technical assistance, and the entire executive branch.

I want to thank a number of people. First of all, I want to thank Lisa Cohen, my chief of staff, who has been with me for 20 years through thick and thin. I want to thank Polly Webster, my health policy director, who took the bar exam, got married, and actually helped pass this bill all during this process. I want to thank Lynne Weil, my communications director, and Eleanor Bastian, my legislative director. I want to thank Rachel Stauffer, my former health policy director who started this, and Matt Inzeo, who is Lynne's predecessor.

From the Upton staff, I want to thank Gary Andres, Joan Hillebrand,

Paul Edattel, John Stone, Carly McWilliams, Adrianna Simonelli, and J.P. Paluskiewicz. All of you guys have worked together as a team with my team.

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I want to thank Kristen O'Neill from Mr. GREEN's staff. I don't think I thanked Mr. GREEN. I want to thank Mr. GREEN, who has done such an extraordinary job and who has really been my wingman. I want to thank Wendell Primus, who is Leader PELOSI's senior adviser; and Charlene MacDonald, who is Mr. HOYER's adviser. Finally, I want to thank the entire Pallone team, who has worked as our committee staff tirelessly: Jeff Carroll, Tiffany, Kim, Arielle, Waverly, and Megan. They have been fabulous. We haven't always agreed on everything, but in the end we have all worked together. It really is a great team. I hope we can use this in the next Congress to get to even greater heights.

I urge the House to pass this bill on a strong bipartisan basis, and I urge the other body to take it up.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Georgia (Mr. CARTER), the only pharmacist in the Congress.

Mr. CARTER of Georgia. Mr. Speaker, I rise today in support of H.R. 34, the 21st Century Cures Act. This long-awaited legislation promotes medical innovation by streamlining the discovery, development, and delivery of critical medicines. This bill also helps reform our Nation's deteriorating mental health system to ensure that millions of Americans receive the care they need. Such reforms include the reduction of regulatory red tape that slows prescription drugs' entry to the market, the breaking down of barriers that restrict data sharing, and expediting the review of potentially breakthrough devices.

While some may believe that the resources needed to develop new cures or new devices are too costly and time consuming, the potential savings to the broader healthcare system will be significant. By modernizing the governance surrounding the development of new medicines and treatment, we ensure that the lives of millions—not only here in the U.S., but across the world—will improve.

I want to thank Chairman UPTON and Chairman MURPHY for their unrelenting determination to bring this negotiated piece of legislation to the floor for a vote. I urge my colleagues to support H.R. 34.

Mr. PALLONE. Mr. Speaker, I have no additional speakers other than myself to close, so I am going to continue to reserve the balance of my time.

Mr. UPTON. Mr. Speaker, we have a good number of speakers left, and we will use all of our time.

I yield 1 minute to the gentleman from Pennsylvania (Mr. ROTHFUS).

Mr. ROTHFUS. Mr. Speaker, I rise today in strong support of this impor-

tant legislation that provides significant investments and reforms to accelerate the discovery of new treatments and cures for Americans. I also applaud the inclusion of a provision I authored that is crucial for our seniors. It would restore the open enrollment period for Medicare Advantage beneficiaries, who until 2011 had the ability to change Medicare Advantage plans during the first 3 months of the year.

Unfortunately, those 3 months of flexibility have been replaced with an annual Medicare Advantage disenrollment period during the first 45 days of the year. Given Medicare Advantage's popularity and history of success, seniors should be given the choice of changing to a plan that addresses their needs. Restoring this 90-day open enrollment window will allow seniors who find that their plan is not working for them to make the change that does work for them.

This bill also contains very important legislation authored by my colleague from Pennsylvania, Representative MURPHY, to help families dealing with a mental health crisis by significantly reforming our mental healthcare system. These reforms are crucial for families, veterans, and all individuals dealing with a mental health crisis and the drug addictions that can often accompany such illnesses.

I commend Chairman UPTON's work in bringing this critical legislation to the floor. I urge its passage.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from New Jersey (Mr. SMITH), my dear friend who I have served with all my years here in Congress.

Mr. SMITH of New Jersey. I thank the gentleman for yielding and for his extraordinary leadership on this legislation.

Mr. Speaker, in 1992, 24 years ago, I met—along with a great advocate, Pat Smith—with top officials of NIH and CDC on Federal guidelines that precluded the existence of chronic Lyme disease. Subsequently, every Congress, I would introduce legislation trying to get a diversity of viewpoints so that clinicians, patients, and other advocates could be heard.

Today, CDC estimates there are about 380,000 cases of Lyme disease; and a provision in this bill, an important, game-changing provision, insisted upon by Majority Leader KEVIN MCCARTHY and Chairman UPTON requires that a new working group on tickborne disease includes members with a diversity of viewpoints, including patients, clinicians, and researchers. This working group will make a difference. Those patients—and there are tens of thousands of them—have been told chronic Lyme disease doesn't exist, what you are feeling can be attributable to some other disease, and they don't get better.

I thank the chairman for doing this. Also, as cofounder and co-chairman of both the Alzheimer's Caucus 16 years

ago and the Autism Caucus 16 years ago, I am thankful for the great work that this will do for those patients as well.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentlewoman from Washington (Ms. HERRERA BEUTLER).

Ms. HERRERA BEUTLER. Mr. Speaker, I am really excited about this bill, and I am excited about an inclusion in the 21st Century bill that we are voting today that is going to help moms and babies. Nearly all of the 400 million women who give birth each year in the U.S. and the 3 million women who breast-feed will take medications or receive a vaccine during their pregnancy or while they are nursing.

This bill that we are voting on, that we hope is going to pass and be signed into law, contains a provision that will reduce the health risks faced by these moms. Here is where the risk lies. Pregnant women are often not included in clinical trials on medications, so we really don't know what the effects are of drugs on a woman and on her pregnancy.

Without reliable information, women and doctors are really just playing a guessing game, trying to figure out the impacts of medication, and that could be on medication that is a prescription for a chronic disease: hypertension, diabetes, or severe depression.

The other undesirable choice for moms is whether or not to choose just not to treat their condition. If they don't know what the impact is, maybe they are just going to forgo their therapy altogether.

Moms should be able to safely manage ongoing conditions throughout their pregnancies and while breastfeeding without playing this guessing game. Fortunately, the Safe Medications for Moms and Babies Act is included in the bill that we are voting on. I urge its support.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from Pennsylvania (Mr. COSTELLO), a long-time supporter of this legislation.

Mr. COSTELLO of Pennsylvania. Mr. Speaker, I rise today in support of the 21st Century Cures Act, and I want to thank the chairman and ranking member for their advocacy and leadership to bring this bill to the floor today.

I also congratulate my colleague and neighbor, Congressman JOE PITTS, for his leadership as chairman of the Health Subcommittee. Mr. PITTS and I represent adjoining and very similar districts in Pennsylvania, each including parts of Chester and Berks counties. He has done outstanding work for our constituencies by incorporating the concerns and issues important to southeastern Pennsylvania into the Cures Act.

This bill will make an immediate, long-lasting impact on the families and communities we represent. It supports medical research, helps fight the opioid epidemic, and would improve the delivery of mental health care by putting

patients at the center of the review process. In short, this bill includes major priorities that will make our communities healthier and safer.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentleman from New York (Mr. GIBSON). This may be his last speech on the House floor, as he announced his retirement some time ago. He is a good Member in support of this legislation. He hounded us from the get-go.

Mr. GIBSON. Mr. Speaker, I rise in strong support of 21st Century Cures. I want to thank the chairman, and I want to thank Majority Leader KEVIN MCCARTHY and my colleague CHRIS SMITH for insisting that we restore original language that deals with chronic Lyme and tickborne diseases. This was critically important to my district and to the Nation. I have so many friends and neighbors who are sick, chronically sick, and they are desperate for cures and solutions. Thanks to this bill, they now have a voice and a fighting chance. I am deeply grateful.

Mr. UPTON. Mr. Speaker, I yield 1 minute to the gentlewoman from Arizona (Ms. MCSALLY), my friend who is, again, a strong advocate of this legislation.

Ms. MCSALLY. Mr. Speaker, I rise in strong support of this important legislation. I want to thank Chairman UPTON for his tireless leadership on the 21st Century Cures Act. The bill is the result of years of hard work and brings hope to countless Americans suffering from incurable diseases in all of our districts around this country.

I also want to recognize the work of Congressman TIM MURPHY, who has served as a leader and a champion on the critical issue of mental health and is the author of legislation included in this bill that will overhaul our mental health system for the first time in 50 years.

Additionally, this legislation includes parts of a bill that I introduced with Senator JOHN CORNYN to improve mental health collaboration between Federal, State, and local justice systems to allow better responses to mental health crises. These provisions will also divert low-level offenders from incarceration to treatment programs, help reduce recidivism and provide support to mentally ill offenders reentering the community.

Many diverse groups came together in support of these bipartisan efforts, including mental health advocates and law enforcement organizations. I urge all of my colleagues to vote in favor of this very important bill. I thank the chairman for his leadership.

Mr. UPTON. Mr. Speaker, I have no further speakers. Therefore, I will let Mr. PALLONE use the balance of his time to close, and then I will use the balance of mine.

I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, may I inquire how much time remains on each side?

The SPEAKER pro tempore. The gentleman from New Jersey has 2½ minutes remaining. The gentleman from Michigan (Mr. UPTON) has 3½ minutes remaining.

Mr. PALLONE. I yield myself such time as I may consume.

Mr. Speaker, I would like to conclude by referencing the Statement of Administration Policy because I believe it reflects my position for the most part.

If I could just read some sections—I am not reading the whole thing—it says:

“The Administration strongly supports passage of the bipartisan House Amendment to the Senate Amendment to H.R. 34, the 21st Century Cures Act, which dedicates more than \$6 billion to implement key priorities such as the President’s proposal to combat the heroin and prescription opioid epidemic; the Vice President’s Cancer Moonshot; and the President’s signature biomedical research initiatives, the Precision Medicine and Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiatives. It also takes important steps to improve mental health . . .

“The Administration is committed to taking immediate action to lay the groundwork to ensure that the funds in the bill would be disbursed quickly and effectively so we can begin to address these important public health challenges . . .

“There are . . . provisions in the bill that raise concerns, but that have been modified from previous versions to help address those concerns, such as provisions that allow for the marketing of drugs to payers for off-label uses. In addition, a number of effective dates will be challenging to meet, especially without additional administrative funding . . .

“That said, this legislation offers advances in health that far outweigh these concerns. As such, the Administration strongly supports passage of the House Amendment to the Senate Amendment to H.R. 34, the 21st Century Cures Act.”

Let me just say also in conclusion, I believe that this is an important piece of legislation that we need to pass, and I would hope that the Senate would take it up and pass it, and, obviously, the administration or the President will sign it.

From the very beginning, when we passed the 21st Century Cures Act, I thought that it would make important strides in actually dealing with those diseases for which we have not made a lot of progress in terms of advancing and finding cures, but, at the same time, I am happy that this legislation has now become a little more of a catch-all or a lot more of a catch-all, if you will, because it is addressing funding for opioids. Many of us know we passed an opioid package that the President signed in July, but it is not funded. So there will be funding for that bill now.

As far as the mental health reforms, our committee spent a tremendous

amount of time over the last 2 years trying to address that legislation. We passed a bill here in the House. Again, I am happy that this is included because the kinds of reforms that were in that bill are now in this bill, and I think they are important strides in terms of addressing some of the mental health concerns that we have in this country.

The same is true for Cancer Moonshot. The President spent a lot of time, the Vice President as well, and this will make at least a down payment on that. So, overall, this is a good bill. I support it. I urge my colleagues to support it as well.

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

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

Mr. Speaker, I just want to thank all the people who have been involved in this Chamber, our staff, our Members, the Senate as well. I want to thank all the people outside the Chamber who brought their message to us because one of the things that we wanted to do from the very start was listen. You tell us what we need to do so we can find these cures for you—name the disease. I will confess that some of us had probably never heard of some of the diseases and some of the disease patient advocacy groups that actually came to us.

We are doing the right thing because, yes, we listened; yes, we knew we needed more research; and as fiscal conservatives—and we all care about the deficit, we all do—we want to make sure that we can actually have the resources and a timeline to spend it in a prudent manner, really outlining the priorities that both sides of the aisle share.

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I commend the President. He was personally involved in this issue, not a Johnny-come-lately, coming up this aisle with his last couple of State of the Union Addresses on both Precision Medicine and the Cancer Moonshot. Vice President BIDEN spent weeks of his time and many hours with us helping us draft the legislation that we all care about and is included in this legislation. There are LAMAR ALEXANDER, MITCH MCCONNELL, PATTY MURRAY, CHUCK SCHUMER, and others in the Senate caring about this legislation, knowing its impact on so many millions of people—our researchers, who have devoted their lives, and, again, many of us here.

We traveled to MD Anderson, the Mayo Clinic, Ann Arbor, the Cleveland Clinic, and other great places to do research that actually can save people’s lives. And we learned a lot. We learned a lot that, working together, we can get something done, and that is what this bill does.

But I will tell you why this vote is important when we take it at about 5 p.m. or so. We don’t want to win by a narrow margin. We want to win by a

huge margin. We want to send a message to the Senate that what we did in countless hearings and roundtables has made a difference, that it is a strong bipartisan message, including the mental health legislation, again, which we debated for weeks and months here in the House, not only in the committee, but on the House floor. It is very important. It is important to people like JOE KENNEDY, who spoke on the floor earlier today. The Ways and Means provisions that passed on a voice vote here are included so we can get the job done.

Our leadership on both sides—John Boehner, PAUL RYAN, KEVIN MCCARTHY, STEVE SCALISE, CATHY MCMORRIS RODGERS, NANCY PELOSI, STENY HOYER—have really been outstanding. They knew from the get-go that we needed to get this thing done. Patients can't wait. They cannot wait. We are going to have the cure to get this thing done, and, yes, it will impact millions of lives.

So, in an hour or two, when we vote on this, I would urge all my colleagues on both sides of the aisle to vote "yes" for patients.

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

Mr. BRADY of Texas. Madam Speaker, I yield myself such time as I may consume.

America has always been a leader in developing cutting-edge medical treatments and technologies, breakthroughs that have saved countless lives; but due to outdated and burdensome Federal healthcare policies, medical innovation in our country is failing to keep pace with the 21st century challenges facing doctors and families.

Today, Americans nationwide are being forced to wait for the lifesaving treatments they need while important advancements are held up by unnecessary red tape. Chairman UPTON's 21st Century Cures Act provides an opportunity to put America back at the forefront of medical innovation and the delivery of cutting-edge care.

This legislation will empower America's researchers and doctors with the tools needed to solve the biggest healthcare challenges of our time. It includes many bipartisan solutions that will increase healthcare choice, access, and affordability for the American people.

Thanks to Chairman UPTON's leadership and the hard work of many Members of Congress from multiple committees, the 21st Century Cures Act brings together a variety of solutions that will help Americans throughout the country.

Ten of these patient-focused measures are from the Ways and Means Committee. All 10 are bipartisan. More than 20 of our members crafted and introduced these bills. Many more helped move them forward.

In particular, I would like to recognize the leadership of Congressman PAT TIBERI and JIM McDERMOTT, the chairman and ranking member of our Health Subcommittee.

Ranking Member McDERMOTT, by the way, is retiring at the end of this Congress. I want to take this moment to thank him for his years of service and friendship. I want to thank him and Chairman TIBERI for their efforts in support of the 21st Century Cures Act.

The Ways and Means healthcare provisions in the bill will remove harmful regulations on providers to impede the delivery of care. They will increase healthcare options for job creators and families. They will expand access to high-quality, affordable care for America's most vulnerable patients.

I am also excited that this legislation includes a policy by Representative ENGEL and Chairman TIBERI to ensure patients have access to new home infusion benefits. We look forward to working with the Energy and Commerce Committee next year to quickly implement this solution so that more patients have access to this vital service.

In closing, I want to thank all the Members on both sides of the aisle who helped develop the bill before us today. I again want to thank Chairman UPTON for his leadership. This historic legislation has been years in the making. We would not be here today without Chairman UPTON's dedication, vision, and commitment to bipartisan collaboration.

The 21st Century Cures Act is an incredible opportunity to help Americans from all walks of life for generations to come. I urge all my colleagues to join me in supporting its passage.

Madam Speaker, I reserve the balance of my time.

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

This bill is a typical lameduck bill. It has one provision in it that people really want, and that is a giveaway to the pharmaceutical industry.

Every provision that Mr. BRADY has talked about with respect to the Ways and Means Committee has already been passed out of here, and none of them are harmless, but the issue here is reducing the effect of the FDA in protecting the American public. My colleague, Ms. DELAURO from Connecticut, was absolutely right: the weakening of the FDA in protecting the American public is the central part of this bill.

Now, it is wrapped in \$4 billion worth of inadequate money for NIH. It would take \$7 billion to keep us where we are today. The money that went out of here a few months ago was mandatory, and now it is subject to appropriation. Everybody says: Oh, well, there are commitments made. There are commitments made.

Anybody who believes in the tooth fairy will believe that money is going to go to NIH. But the changes in law in how we push drugs, that is going to be in law.

Now, let me tell you what the problem with that is. If you push drugs out there quickly, there are some side effects and people die and people say,

Well, it is too bad; the FDA approved it. We put the FDA in the position of protecting the American public, and then we cut them out at the knees.

Once we have done these cures, we come up with these great drugs, who can afford them? The other thing that is wrong with this bill and that this House has failed to do is to deal with the cost of pharmaceuticals in this country. There is not one single thing in this bill.

There is a specialty drug called Sovaldi. It is a treatment for hepatitis C. There are actually several million people in this country who need that drug. One pill costs \$1,000. Full treatment costs \$84,000. Who can afford it? Who is going to pay for that? Are you going to be willing to put the money into part D of Medicare to pay for it?

The question here is: What are we doing in giving away to the pharmaceutical companies an open door to push any drug out they want or that they can get through the screen, make the screen big so that it is easy to get them out, and then we pick up the pieces for the American people? That is the reason I oppose this bill. I think there are good things in it.

I come from a university that is the number one recipient of research money in this country. The University of Washington is the number one public university. We have so little money at NIH now that you have to be 40 years old until you get a grant from NIH for a research project. It used to be that 17 percent of all the grants were approved. Now we are down to 6 percent. That is because we have been squeezing the life out of NIH. And this \$4 billion sounds like a lot of money, but it isn't even the \$7 billion to keep us at the present level. That is what is wrong with this bill.

Madam Speaker, I reserve the balance of my time.

Mr. BRADY of Texas. Madam Speaker, I yield 1 minute to the gentleman from Ohio (Mr. TIBERI), the chairman of the Health Subcommittee who shepherded these bills through the House earlier and leads the effort to correct issues so important to our hospitals and cancer hospitals, as well as some new reforms for infusion healthcare patients.

Mr. TIBERI. Madam Speaker, I thank Chairman BRADY for his leadership on this issue.

Madam Speaker, Chairman UPTON unveiled the 21st Century Cures Act back in 2014 to initiate quicker development and pathways to approve treatments and cure diseases. This bipartisan and bicameral bill is another example how the House is delivering on patient-focused solutions for Americans.

I am incredibly pleased that three of my initiatives are included in this final package, the first of which is a bill that provides necessary regulatory relief to providers and fixes a site-neutral policy to hospitals that were in the middle of construction when the policy went into effect.

Second, the 21st Century Cures Act gives relief to long-term care hospitals from the 25 percent rule and common-sense Medicare reforms.

Lastly, the bill includes a provision of a bill I sponsored that provides infusion therapy to Medicare beneficiaries in their home.

I look forward to continuing work on these issues with my colleagues in the next session of Congress. I want to congratulate Chairman UPTON for his incredible work on this. He solicited feedback from stakeholders, Members, patients, and has worked tirelessly to make this bill the best version possible. His accomplishments during his chairmanship are admirable, and I am grateful to call him a close friend.

Let's pass the 21st Century Cures Act on a bipartisan basis, Madam Speaker, and get America back in the driver's seat on medical innovation.

Mr. MCDERMOTT. Madam Speaker, I yield 3 minutes to the gentleman from Texas (Mr. DOGGETT).

Mr. DOGGETT. Madam Speaker, while certainly saluting the many Members who have worked so diligently on this measure, I cannot vote for it.

In a wide and endless desert of support for research funding, even getting a few drops of rain is understandably welcomed by the thirsty. Under Republican rule, we have seen a dreadful drought in research funding. This is a bill that attempts to address that shortfall. I voted for the bill when it was on the floor of the House at a previous time. At that point, it promised the hope, after this long drought of almost \$10 billion in assured, certain funding, for research so that we might find cures for some of these diseases before we get them ourselves—the concern of so many people.

Now, under this new measure, we have only about a fourth of the funding previously approved in the House, and it is no longer certain money; it is maybe money for the future. So there may be bipartisan agreement, but there is not a bipartisan advancement.

At the same time that research dollars are dramatically cut—the very research dollars that were the reason for having this bill in the first place—Big Pharma got some of its wish list approved. And how very appropriate that this measure and so many other moving parts have been packed into what it calls the Tsunami Warning bill.

If there is one thing we can be sure of this past year, it is that those people who rely on lifesaving drugs and who want to be able to have a prescription that the doctor prescribes have been hit by a real tsunami. They have been buried in one wave after another wave after another giant wave of pharmaceutical price gouging. Whether it is the EpiPen for a child who is might have an allergic reaction, whether it is insulin for someone who is diabetic and relies on that insulin, whether it is an oncology drug that costs over \$100,000, it is wave after wave of a tsunami of price gouging.

□ 1515

And what has this Congress done about that?

Absolutely nothing. I must say, the administration has done very little more. They have looked at it. There have been a few speeches about it, but there has not been effective action.

So what we get in this bill are a few things that Big Pharma wants that have been on its wish list for a long time, and consumers, they get nothing to look forward to other than more of those big waves of huge price increases.

I am also concerned that the policy arm that publishes Consumer Reports magazine has expressed deep concerns about additional patient risk as a result of some of the provisions that the pharmaceutical companies and the medical device manufacturers have insisted as the price for getting a little additional research funding.

So I am voting “no,” not because this provides some research dollars. It ought to be providing the level of certain research funding we approved already, but because it fails to address this critical health need.

Mr. BRADY of Texas. Madam Speaker, I yield 1 minute to the gentlewoman from Kansas (Ms. JENKINS), one of our key members of the Health Subcommittee who also focuses on rural hospitals and access to care for rural communities.

Ms. JENKINS of Kansas. Madam Speaker, I rise today to support this legislation. It improves access to health care for rural communities through measures I introduced, such as the Continuing Access to Hospitals Act, which stops unjustified regulations from interfering with rural healthcare providers offering quality services; and the Rural ACO Provider Equity Act, which will ensure the work of PAs and nurse practitioners is recognized so that rural hospitals can join ACOs and afford to remain open and serve our rural communities.

Finally, it will help the 40 million Americans who deal with a mental illness each year through inclusion of my Mental Health First Aid Act. This bipartisan legislation delivers \$15 million every year to train police officers, teachers, veterans' advocates, and others to identify and aid those with a mental illness, building a stronger mental health safety net in America that addresses the needs of millions of Americans.

I urge my colleagues to pass this legislation.

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

Mr. BRADY of Texas. Madam Speaker, I yield 1 minute to the gentleman from Minnesota (Mr. PAULSEN), one of our leaders in medical devices innovation and bringing lifesaving cures to the market sooner.

Mr. PAULSEN. Madam Speaker, I rise in strong support of the bipartisan 21st Century Cures Act.

There are more than 10,000 known diseases in the world, and many of

them are rare diseases. Yet, there are only 500 of them that have an FDA-approved treatment. Millions of Americans today feel powerless because they have a deadly disease and they have no hope of a cure because there aren't enough resources for research or the regulatory barriers are discouraging innovation.

This bipartisan initiative today gives patients new hope. It supports more NIH research; it streamlines the regulatory approval process; and it gives patients more input in the treatment and delivery process.

I am also pleased today, Madam Speaker, that we are providing important reforms to our mental health system. For too long, patients and families, mental healthcare professionals, and law enforcement have been crying for help. This legislative effort represents the most significant improvement to the mental health system that we have seen in over a decade.

Madam Speaker, this is an innovation game-changer. It is a once-in-a-generation, transformational opportunity to change the way we treat disease. It expedites the discovery, the development, and the delivery of new treatments and cures; and it ensures that America will be a leader in the global fight for medical innovation.

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

Mr. BRADY of Texas. Madam Speaker, I yield 1 minute to the gentleman from Ohio (Mr. RENACCI), who has, among many healthcare issues, led the charge to create much smarter measurements in hospital readmissions.

Mr. RENACCI. Madam Speaker, I rise in support of H.R. 34, the 21st Century Cures Act. At its core, this legislation, while not perfect, ensures our country will continue to be at the forefront of medical innovations and breakthroughs.

Also important is what the bill does for States like Ohio that are fighting the opioid epidemic. Just today it was reported that Ohio has seen more opioid overdose deaths than any other State in the Nation. This bill would especially help Ohio reverse this devastating trend.

I also applaud the inclusion of my bill, H.R. 1343, the Establishing Equity in the Hospital Readmission Program. The Hospital Readmission Program was created due to concerns that too few resources were being spent on reducing acute care hospital readmissions. While reducing acute care hospital readmissions is important, my bill ensures that we are not disproportionately penalizing those who see a large number of our most vulnerable patients.

This is one of the many common-sense, bipartisan reforms to improve our healthcare system included in the 21st Century Cures Act, and I urge all Members to support this bill.

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

Mr. BRADY of Texas. Madam Speaker, I yield 1 minute to the gentleman

from Pennsylvania (Mr. MEEHAN), again, another key member of our committee who is focused on health care and, in this case, increasing information to seniors about their Medicare plans in advance, and also improving physical therapy, so critical to so many in health care.

Mr. MEEHAN. Madam Speaker, the 21st Century Cures Act is a historic, bipartisan legislation that will eliminate the barriers standing between us and cures for diseases like Alzheimer's and diabetes, and cancer.

The bill fosters coordination and research related to pediatric diseases and birth defects, and we encourage the NIH and FDA to establish a global pediatric clinical study network with the hope that more collaboration will lead to new treatments, and it will help build our understanding of how treatments geared for adults can help to lead to cures for children.

Just 3 years ago, after a fight with Washington bureaucrats, Sarah Murnaghan, a 10-year-old young woman from my district, received an adult lung transplant. She is now a thriving 14-year-old. And through "Sarah's Heroes," we highlight the stories of other children who are courageously working to overcome challenges presented by cystic fibrosis and lung transplant.

Schizophrenia and mental illness are among other conditions without a cure. The bill improves access to mental health by increasing the number of healthcare professionals trained to treat patients. It also strengthens the requirement that mental health coverage be on par with coverage for physical ailments; many good reasons to continue to support. I urge my colleagues to do so.

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

Mr. BRADY of Texas. Madam Speaker, I yield 1 minute to the gentleman from Illinois (Mr. DOLD), one of our smartest members on the Ways and Means Committee who has really carved out a niche in support of medical innovation, really bringing these breakthroughs to the community and patients quickly.

Mr. DOLD. Madam Speaker, I certainly thank the chairman for his leadership.

I also stand here today in strong support of the 21st Century Cures Act. I want to thank Chairman UPTON for his leadership, and Ranking Member PALONE, Congresswoman DEGETTE, and Congressman MURPHY for their great work on compiling things that are in this bill.

I have been a longtime advocate for both the 21st Century Cures Act and the Helping Families in Mental Health Crisis Act because I believe it is critically important that we modernize how we treat mental health and how we develop lifesaving cures. This package accomplishes both of these important goals and many more.

Over the next 10 years, we will provide an additional \$4.8 billion to the

National Institutes of Health in support of groundbreaking medical research and an additional \$500 million to the FDA to help bring drugs and devices to patients more quickly.

We will also be providing States with \$1 billion in grants over the next 2 years to help combat the opioid epidemic, which is impacting every single community across our Nation.

Finally, we will increase choice, access, and quality in health care by making serious improvements to Medicare.

The SPEAKER pro tempore (Mrs. LUMMIS). The time of the gentleman has expired.

Mr. BRADY of Texas. I yield the gentleman an additional 1½ minutes.

Mr. DOLD. This package is proof that when we are willing to work together, we can improve our healthcare system for all Americans through changes large and small. I encourage all of my colleagues to join me in supporting the 21st Century Cures Act.

I also want to thank, again, Chairman UPTON, Congressman MURPHY, Congresswoman DEGETTE, and all those that helped put this together, and the staff that were so instrumental in making this become a reality today.

Mr. BRADY of Texas. Madam Speaker, I have no further speakers and I am prepared to close if the gentleman would like to close.

I reserve the balance of my time.

Mr. McDERMOTT. Madam Speaker, I yield myself such time as I may consume. I want to thank my colleagues for their interest in children. I hear some of the speakers stand up and say they are really interested in kids, yet they oppose the CHIP program. They talk about cutting back the help to children.

Now, the problem here is that if you are talking about cures, and you are going to create a magnificent cure that costs \$80,000, if you don't provide Medicaid, the children who are poor in this country aren't going to get access to that cure. That is a cure for rich people who could pay it out of their clippings on their bonds and their stock.

The EPSDT program, which is the program that covers kids, the President-elect has put in the charge of that a woman from Indiana who testified against it. This is the benefit that ensures sick kids will get cures.

Now, you are setting in motion something here for pharmaceutical companies to find a way to take as much money out of the system as they can with every drug they can put out there, and you are, at the same time, moving in the direction of making it impossible for poor children to be taken care of in this country.

How many States have the Governors said: We don't believe in Medicaid; we don't believe that the government should give Medicaid; we believe the government should stay out of medicine?

So they deny their own people health care, simple, everyday, ordinary health

care; and we are talking about cures for disease. As somebody said, there were 50 cases in the United States of it last year. One feels for those 50.

I am a physician. I have listened to those people. I know that it is awful, but you have to keep in balance and say to yourself: Are we going to spend all the money there or are we going to spend it dealing with all the Americans?

That is what is wrong with this bill. The pharmaceutical industry has no control on it whatsoever. When you put in that benefit, in part D, you tied the Secretary of Health and Human Services' hands, and he or she cannot negotiate lower prices. You said: Whatever the pharmaceutical company says the cost is, that is what we are going to pay.

Now, the Veterans Administration—veterans are different than ordinary people in this country. They have an administration that has the right to negotiate changes in prices, and their pharmaceutical prices are down 50, 60 percent from what people pay in Medicare.

Now, as long as you have that kind of giveaway going on to the pharmaceutical companies, this bill is just kind of frosting on the cake, and I guess Members will vote for it. In the short run it will seem like, you know, it didn't make any difference, but you are going to pay down the line.

This is going to be a Fram commercial. You either pay now or you are going to pay later, because if you do not screen those drugs carefully and make sure that they are really doing something, and let the pharmaceutical companies add a Chlorine ion or a Boron or whatever, they are simply putting drugs out on the table that cost too much for the Americans to buy.

I urge a "no" vote.

I yield back the balance of my time.

Mr. BRADY of Texas. Madam Speaker, I yield myself the balance of my time.

There are so many Americans who could be watching today who wonder when that lifesaving drug, that new treatment will be made available to them. They know it is in other countries. They read about it in other places, but they can't get it here in America. The Cures Act changes that. It streamlines it, moves things faster; and when you are in that tough situation, it provides options for health care, experimental drugs never before available to them. This is important to patients and it is important to doing it better in America. I urge its support.

I yield back the balance of my time.

Mr. THOMPSON of California. Madam Speaker, I rise in support of this bill.

H.R. 34, the 21st Century Cures Act, is the product of extensive bipartisan, bicameral collaboration between stakeholders and policy makers.

This bill stands to help us make significant progress when it comes to keeping Americans healthy, and keeping America on the forefront of medical innovation.

Included in the bill text are provisions based on legislation I authored, known as the Small Business Healthcare Relief Act.

These provisions would allow small businesses with fewer than 50 employees to offer tax preferred Health Reimbursement Arrangements, or HRAs, to their workforce.

The HRAs can be used to buy health insurance in the individual market, or pay for qualified health expenses if an individual already has coverage.

This targeted bill seeks not to override those long-standing responsibilities between employers and their employees, nor does it seek to override ERISA protections that existed before the Affordable Care Act was enacted, but to provide small employers an option for coverage in a robust individual market.

Given that this bill will be passed late in the year, it's my hope that the incoming Administration acts promptly to ensure a smooth transition for employers, employees, and the current exchange infrastructure.

Small businesses drive job creation and grow our economy. We should be going out of our way to help them support their employees so that they can focus on what they do best: running their business.

I urge my colleagues to support this bill.

Ms. EDDIE BERNICE JOHNSON of Texas. Madam Speaker, I rise in support of H.R. 34, the 21st Century Cures Act which will encourage innovation in biomedical research and development of new treatments.

The bill contains \$6.3 billion in spending over the next ten years. With \$4.8 billion in funding over the next ten years delivered to Innovation Funds within the National Institutes of Health and \$500 million for the Food and Drug Administration over the next five years, it is clear that Congress is committed to investing in health research. Developing a better system of funding towards high-risk high reward research and research by early stage investigators is crucial to finding better health outcomes. With a better focus on infectious disease, precision medicine, and biomarkers, I strongly believe that we will finally address these areas of unmet medical needs, which are often the most pervasive issues in our health system.

The legislation also includes elements of H.R. 2646, the Helping Families in Mental Health Crisis Act, in order to get mental health reforms across the Senate's finish line. I am proud that this legislation will include many of the provisions that Congressman TIM MURPHY (R-PA) and I worked on for several years. The bill establishes an Assistant Secretary for Mental Health and Substance Use within the Substance Abuse and Mental Health Services Administration; reauthorizes Assisted Outpatient Treatment grant programs; and requires the Secretary to clarify HIPAA rules regarding circumstances when a provider can share information. Among other provisions, these aforementioned are just a few that will benefit patients directly and immediately.

While H.R. 34 contains many provisions regarding the biomedical research workforce, clinical trials, FDA improvements, I strongly believe that the Congress has not placed enough importance on scientific research and this is a way to get us back on track. Investing in innovation will yield high rewards for the medical community, especially patients. I am proud to support H.R. 34, the 21st Century Cures Act and urge my Senate colleagues to pass this legislation swiftly.

Ms. JACKSON LEE. Madam Speaker, I rise in support of the House Amendment to the Senate Amendment to H.R. 34, the "21st Century Cures Act," a bipartisan piece of legislation that is vital to the future and health of our Nation's citizens and ecosystem.

This thoughtful legislation is the culmination of the hard work of my dedicated colleagues who have sought out and engaged in public conversations with patients, innovators, providers, regulators and researchers about how to move advances in science and medicine into new therapies.

This outreach has garnered the critical input and support of more than 370 patient and physician groups, state and local organizations, cancer centers, and research and life sciences.

I am proud to be one of the cosponsors of 21st Century Cures Act, which represents a new national effort to find treatment and cures for thousands of unknown and rare diseases.

Looking to the various policies this legislation aims to address, it is important to highlight the commendable objectives and that will not only accelerate the discovery, development and delivery of new treatments and cures for thousands of serious and rare diseases, but it will also open the doors of innovation and the growth of health care system by enhancing and enriching the medical field for all Americans.

The most ambitious action calls for \$6.3 billion in mandatory funding to be delivered over the next ten years to the National Institutes of Health (NIH).

NIH is part of our nation's top ranked educational research institutions in the world.

In order to maintain our global competitiveness in the biomedical field, we must invest in the industries that guarantee economic prosperity for our current and future economies.

It has been estimated that every \$1 of NIH funding generates about \$2.21 in local economic growth, and, in 2012, NIH-funded research supported an estimated 402,000 jobs all across the U.S.

The bill's funding for NIH would provide for an annual 3 percent increase in the NIH budget, which has been stagnant for the past few years and which desperately needs more funding to capitalize on emerging scientific insights.

This increased funding not only aims to continue the sustainability of our economy but it also supports our President's initiative to provide more resources to the biomedical field.

The 21st Century Cures Act supports the President's Precision Medicine Initiative, which would advance a new model of participant-centered research to accelerate biomedical discoveries and provide clinicians with new tools and therapies tailored to individual patients' needs.

The Obama Administration believes we can build on the progress in improving the drug development and approval process made to date by: Incorporating patients' voices into the Food and Drug Administration (FDA) decision-making; encouraging the development and qualification of reliable biomarkers to accelerate work on important new therapies; and reducing barriers to initiating medical device trials.

In furtherance of this initiative, the legislation before us allows, for the creation of an "Innovation Fund" through the National Institute of Health.

This "Innovation Fund" is a welcome effort because it promotes the maintenance of the best biomedical workforce in the world and help to increase the diversity of the biomedical workforce.

In particular, the \$4.8 billion provided for the Innovation Fund, will not only increase the number of the research projects it supports but it also increases the cap for NIH's loan repayment programs.

This would include a repayment program for clinical scientists who do research in health disparities and for clinical scientist from disadvantaged backgrounds, from \$35,000 per year to \$50,000 per year plus a yearly inflation for adjustment.

With the support of H.R. 34, underrepresented communities and those with disadvantaged backgrounds from across the country can undoubtedly provide the future researchers and workers of the biomedical workforce.

The Journal on STEM Education reported in 2011 that only 8.34 percent of the STEM doctorates awarded in 2006 were given to underrepresented minorities, despite making up approximately 28 percent of the U.S. population.

Furthermore, GAO found noted that while the percentage of underrepresented minorities nationwide increased from 13 percent to 19 percent from 1994 to 2003, the total number of STEM doctorates awarded to the same group dropped during this period from 8,335 to 7,310.

In response, the National Institute of General Medical Sciences (NIGMS) created the Minority Opportunities in Research (MORE) Division and similar academic intervention programs.

The MORE programs are comprised of four primary components: research experience, mentoring and advisement, supplemental instruction and workshops, and financial support.

In 2007, NIGMS' annual budget was \$1.9 billion, of which nearly \$126 million was spent on its MORE programs.

This amount includes the Minority Biomedical Research Support-Research Initiative for Scientific Enhancement (MBRS-RISE) program, the Minority Access to Research Careers (MARC), Post-baccalaureate Research Education Program (PREP), and the Bridges to the Baccalaureate and Bridges to the PhD programs.

The amount of funds dedicated to these programs reflects the commitment by the science and research community to the goals of the MORE Division in addressing this problem.

Increased funding set forth in H.R. 34 will only strengthen NIH's focus on diversifying the biomedical workforce by requiring NIH to focus on ensuring participation from scientists from underrepresented communities.

In addition to addressing the needs of underrepresented communities, H.R. 34 also calls for specific action to increase representation of racial minorities.

The 21st Century Cures Act acknowledges that there are disturbing statistics on the low numbers of African Americans, Hispanics and Native Americans pursuing academic qualification and participating in scientific research.

Under H.R. 34, the National Institute on Minority Health and Health Disparities will necessarily include strategies for increasing representation of minority communities in its strategic plan.

I am proud that H.R. 34 incorporates the Jackson Lee Amendment which I offered during the initial consideration of the 21st Century Cures Act by the House which will help ensure that the national goals of finding and bringing more cures and treatments to patients and strengthening the biomedical innovation ecosystem in the United States is aided by an expanding pool of diverse and talented medical researchers.

Specifically, the Jackson Lee Amendment instructed the Secretary of Health and Human Services to conduct outreach to historically Black colleges and universities, Hispanic-serving institutions, Native American colleges, and rural colleges to ensure that health professionals from underrepresented populations are aware of research opportunities under this Act.

Many racial health disparities stem from lack of access to effective test, treatments and cures for illnesses that have devastating consequences for African American, Hispanic and Native American populations.

For example:

1. African-Americans (represent 12 percent of the U.S. population but only 5 percent of clinical trial participants).

2. Hispanics make up 16 percent of the population but only 1 percent of clinical trial participants.

3. Women are under-represented in cardiovascular device trials, which have 67 percent male participation.

The most significant barriers limiting clinical participation are race, age, and sex of participants:

1. Women and minority patients are more difficult to recruit.

2. Women and minority physicians have less experience and are relatively more costly to engage.

3. Minority patients with limited English proficiency can require costly translation services.

Physicians are the gateway to the patient. Increasing diversity of those conducting research will have implications on the types of conditions that are researched and the participants in clinical trials that are seeking answers to illnesses like lupus, triple negative breast cancer, and sickle cell disease that can be difficult to detect, treat and cure.

Certain medical illnesses have been known to have higher prevalence in certain demographic groups, including type II diabetes, lupus, sickle cell anemia, and Triple Negative Breast Cancer for which African Americans are more than twice as likely to be diagnosed on average.

Lupus, triple negative breast cancer and sickle cell disease are of particular concern because they are often difficult to diagnose and disproportionately impact persons of color and especially women.

In particular, Lupus is a chronic, complex and prevalent autoimmune disease that affects more than 1.5 million Americans. Yet, Lupus is one of America's least recognized major diseases.

More than 90 percent of lupus sufferers are women, mostly young women between the ages of 15 to 44, and women of color are two to three times more at risk for lupus than Caucasians.

Triple negative breast cancer also disproportionately impacts younger women, African American women, Hispanic/Latina women, and women with a "BRCA1" genetic mutation, which is prevalent in Jewish women.

More than 30 percent of all breast cancer diagnoses in African American are of the triple negative variety, and African American women are far more susceptible to this dangerous subtype than white or Hispanic women.

Additionally, there are about 2 million people who carry the sickle cell trait and with about 100,000 having the disease. According to the Centers for Disease Control and Prevention, sickle cell trait is common among African Americans and occurs in about 1 in 12, and sickle cell disease occurs in about 1 out of every 500 African-American births, compared to about 1 out of every 36,000 Hispanic-American births.

Treatments for Lupus, triple negative breast cancer and sickle cell disease are not progressing as quickly as desired by patients, researchers, and policy makers. We must support the advancement of legislation that will allow for the remediation and end of health care disparities and the promotion of research parity for diseases such as lupus, triple negative breast cancer, sickle cell disease, and countless other rare and serious diseases.

Race and ethnicity have also been shown to affect the effectiveness of and response to certain drugs, such as anti-hypertensive therapies in the treatment of hypertension in African Americans and anti-depressants in Hispanics.

Increased diversity in research trials could help researchers find better, more precise ways to fight diseases that disproportionately impact certain populations, and may be important for the safe and effective use of new therapies. As one of the most diverse cities in the country, Houston is the 4th largest city in the United States and the 5th most populated metropolitan area in the nation. Houston is home to the largest medical complex in the world—the Texas Medical Center, which provides clinical health care, research and education at its 54 institutions.

The University of Houston, ranked number three out of all other colleges and universities in Texas, is an example of a premier institution that can produce students with advanced STEM degrees who would be able to join a progressing biomedical field.

Another important requirement of H.R. 34 is that it would require National Institute of Health to publically report the number of children by race and gender who participate in NIH funded clinical trials.

This legislation would help ensure that children of all races are adequately represented in clinical trials and that we can determine the safety and effectiveness of drugs on children of all demographic backgrounds.

With 10,000 known diseases, 7,000 of which are rare, and treatments for only 500 of them—clear there is much work to do. Medical research saves lives and improves the quality of life for millions of Americans because the government provides a steady and reliable commitment to basic research into cures for debilitating and deadly diseases.

Given the array of commendable initiatives, H.R. 34 is a necessary piece of legislation that will accelerate the discovery, development, and delivery of promising new treatments and cures for all patients while investing in our nation's ability to maintain the best and most diverse biomedical workforce in the world.

Madam Speaker, I call for the support of all of my colleagues in ensuring the passage of the important legislation.

The SPEAKER pro tempore. All time for debate has expired.

Pursuant to House Resolution 934, the previous question is ordered on the motion to concur.

The question is on the motion to concur offered by the gentleman from Michigan (Mr. UPTON).

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. McDERMOTT, Madam Speaker, I demand a recorded vote.

A recorded vote was ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, and the order of the House of today, further proceedings on this question will be postponed.

□ 1530

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (Mr. DOLD). Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote incurs objection under clause 6 of rule XX.

Record votes on postponed questions will be taken later.

OVERTIME PAY FOR SECRET SERVICE AGENTS ACT OF 2016

Mr. CHAFFETZ. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6302) to provide an increase in premium pay for United States Secret Service agents performing protective services during 2016, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6302

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 "Overtime Pay for Secret Service Agents Act of 2016".

SEC. 2. PREMIUM PAY EXCEPTION IN 2016 FOR WORK AUTHORIZED UNDER SECTION 3056 OF TITLE 18.

(a) IN GENERAL.—Notwithstanding any other provision of law, including section 5307 of title 5, United States Code, and subject to subsection (b), during calendar year 2016—

(1) section 5547(a) of such title shall not apply to an employee who performs work authorized by section 3056(a) of title 18, United States Code; and

(2) such an employee may be paid premium pay to the extent that the payment of such pay does not cause the total of basic pay and such premium pay for any pay period for such employee to exceed the annual rate of basic pay payable to level II of the Executive Schedule under section 5313 of title 5, United States Code.

(b) TREATMENT OF ADDITIONAL PAY.—To the extent that subsection (a) results in payment of additional premium pay of a type that is normally creditable as basic pay for retirement or any other purpose, such additional pay shall not be considered to be basic pay for any purpose and shall not be used in computing a lump-sum payment for accumulated and accrued annual leave under section 5551 of title 5, United States Code.

(c) DEFINITION.—In this section, the term “employee” means any special agent of the United States Secret Service that is a law enforcement officer, but does not include—

(1) a member of the United States Secret Service Uniformed Division; or

(2) an officer, employee, agent, or law enforcement officer of any other Federal agency.

(d) CONFORMING AMENDMENT.—Section 118 of the Treasury and General Government Appropriations Act, 2001 (Public Law 106-554) is amended by inserting “and except as provided in section 2 of the Overtime Pay for Secret Service Agents Act of 2016,” after “Hereafter,”.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Utah (Mr. CHAFFETZ) and the gentleman from Massachusetts (Mr. LYNCH) each will control 20 minutes.

The Chair recognizes the gentleman from Utah.

GENERAL LEAVE

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

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

There was no objection.

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

Mr. Speaker, I rise today in support of my bill, H.R. 6302, the Overtime Pay for Secret Service Agents Act of 2016.

The United States Secret Service has a zero-fail mission to protect the President and other protectees at all costs. The 2016 Presidential campaign year was an especially busy year for the Secret Service. They have done an exceptional job.

I will give you some metrics of what this agency was dealing with. They staffed more than 2,500 candidate trips, 8,580 total protective travel stops, and 62 foreign travel trips with the President and the Vice President. The most recent Presidential election saw Secret Service agents working record hours to fulfill their mission. Incredibly, this was accomplished despite the Secret Service suffering from historic levels of attrition and low staffing levels.

In our December 2015 bipartisan report, the Committee on Oversight and Government Reform found that the Secret Service was “experiencing a staffing crisis that threatens to jeopardize its critical mission.”

The Secret Service was at a peak staffing level of 7,024 employees in the year 2011. That number has declined every year until the beginning of this year when the agency had 6,289 employees.

The staffing numbers are beginning to improve, now at 6,500. But the problem is the agency hopes to have between 8,000 and 9,000 employees by the next Presidential election in 2020. It is hard and difficult to hire a Secret Service agent, and once they are hired, you can't simply put them out in front of the White House or next to a candidate

or one of the protectees and expect them to simply flip on the switch and do their job.

As a result of the current manpower shortage and the lack of employees, Secret Service agents had to work significant overtime to ensure around-the-clock protection of Presidential candidates. No matter the number of hours worked, Secret Service agents are subject to a title 5 statutory cap on their biweekly pay. As a result, agents were not compensated for overtime hours worked that would have resulted in compensation beyond the cap during any pay period. Within the Secret Service, this became known as a max-out problem.

These so-called max-outs contribute to the agency's low morale and exacerbate attrition. The excessive overtime also negatively impacts protective efforts. The agency needs fresh and energetic agents to fulfill a critical mission, one that they have to be in tune with at every moment while they are on the job. The bill, the Overtime Pay for Secret Service Agents Act of 2016, offers relief for agents who have not received pay due to the so-called max-out problem.

Secret Service agents who worked on the 2016 Presidential campaign would be eligible to receive compensation above normal levels up to the basic pay currently given to members of the Executive Schedule Level II for the calendar year 2016.

Every Secret Service agent with outstanding overtime would receive an additional compensation for 2016 under this bill. This is not a bonus. This is not extra pay. This is simply trying to compensate them for hours that they worked. We heard story after story about Secret Service agents who would literally go weeks on end with no pay and yet continue to do their job.

At the same time, the limitation to the 2016 Presidential election in the bill presents a good balance and encourages Secret Service to fix its current staffing problems instead of relying on excessive and expensive overtime pay in the future.

It is my expectation that the Secret Service meets its staffing goals by the next election cycle and does not have to rely on scheduling excessive overtime. It is also my expectation that the Secret Service will focus its staffing capital away from its increasing non-essential investigative and cyber-related missions which distract from the core mission of protecting the President and other protectees.

There are currently three ongoing studies analyzing the Secret Service's nonessential mission of cyber investigations. By the way, this nonprotective mission usually takes more than half of their time, but certainly during a Presidential election cycle, you can see the demand that was there.

I am very pleased with the bipartisan nature in which the committee came together to make sure that we are supporting the men and women who serve

in the Secret Service. They have done so in a very admirable fashion. They have provided a great service to the Nation. But when you hear stories where people would go 43 days without a single day off, when they would work, literally, 100-plus hours in a week and they would go to work knowing that they weren't going to be compensated for that work, that is inexcusable. This bill would provide relief to them. Again, it is not a bonus; it is not extra pay; but it is some compensation for the work that they did protecting our Nation and protecting those protectees. By all accounts, they did an exceptional job without any major incident in this 2016 election cycle.

I urge the passage of this bill. Again, I appreciate the bipartisan nature in which we are doing this.

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

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

Mr. Speaker, I rise in support of H.R. 6302, the Overtime Pay for Secret Service Agents Act of 2016, which was approved by our committee unanimously by a voice vote. This legislation would authorize an increase in the current pay cap up to Level II of the Executive Schedule so that Secret Service agents are permitted to receive compensation for the hours of overtime they worked in 2016.

As the chairman has indicated, the Presidential campaign of 2016 has been a year of extraordinary challenges and strain on the Secret Service. The Secret Service has provided information to the committee indicating that more than 1,000 Secret Service agents—one-third of the agents on board—have worked so many hours that they maxed out their annual overtime and salary. Some agents started working overtime for free as of early June and are exceeding the pay cap by as many as \$50,000 to \$60,000 per agent. Current law prohibits them from receiving any additional overtime pay, and that is what this bill is intended to fix for calendar year 2016.

These spikes in overtime are a necessary factor in these election campaigns. As we know, there were 16 Republican candidates in the primary, and all received Secret Service protection, as well as several candidates on the Democratic side. There were countless stops across the country over the months of our campaigns, and I don't think there is any way to avoid the need for overtime.

I am glad that this is a bipartisan bill, but every 4 years we have to have agents working without pay. There has got to be a way that we can estimate roughly what the overtime needs will be every 4 years and incorporate something that at least eliminates the need to have Secret Service agents working for free in a very dangerous job. I think we can figure that out.

I had a proposal in committee to make this an every-4-year thing and incorporate that. It did not succeed. But

I am hoping that, in a bipartisan manner with the chairman and my Republican colleagues on the committee, we can solve this.

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

The SPEAKER pro tempore. Without objection, the gentleman from Arizona will control the remainder of the time.

There was no objection.

Mr. GOSAR. Mr. Speaker, I urge adoption of the bill.

I yield back the balance of my time.

Mr. CUMMINGS. Mr. Speaker, I support H.R. 6302, the Overtime Pay for Secret Service Agents Act of 2016. The bill would authorize an increase in the annual salary and overtime limit up to level II of the Executive Schedule so that Secret Service agents would be eligible to receive additional back pay for the considerable hours of overtime they worked in 2016.

Last year, the Committee adopted a bipartisan report concluding that the Secret Service, and I quote, "is experiencing a staffing crisis that threatens to jeopardize its critical mission" due in large part to "significant cuts imposed by the Budget Control Act of 2011." The unanimous report recommended that Congress, quote, "ensure that Secret Service has sufficient funds to restore staffing to required levels." Providing this much-needed relief in the highly demanding 2016 presidential campaign year is a first and essential step towards fulfilling the Committee's recommendation.

I appreciate the efforts that Chairman CHAFFETZ and his staff have made to address this issue, and I believe we are in agreement that we must pay the dedicated men and the women of the Secret Service for the overtime they worked in 2016. However, addressing just this one year retroactively does not go far enough.

The Federal Law Enforcement Officers Association, which represents rank-and-file Secret Service agents, testified before our Committee that there should be a legislative fix to raise the overtime pay cap, and I quote, "at a minimum, during a presidential campaign year." The witness added that although, quote, "this last election season was unprecedented in many respects, we do not believe it will prove to be unique in the years ahead," and he stressed, quote, "the importance of working together to find a permanent solution to the effect that the pay cap has on the USSS."

The demands on Secret Service agents are likely to remain extremely high with the substantial resources needed to provide around-the-clock protective details for all 18 Trump family members—including the First Lady, five children and three of their spouses, and eight grandchildren. The announced plan to split time between the White House and the Trump tower in Manhattan would also add significant challenges and strain the resources of the Secret Service.

That is why all Committee Democrats joined together to introduce H.R. 6318, the Fair Pay for Presidential Protection Act of 2016, to ensure that Secret Service agents are paid not just for the overtime they worked in 2016, but also for the overtime they will work in all future presidential years. Our legislation would also authorize a greater level of overtime compensation than H.R. 6302.

I would also note that the Republican Leadership recently decided to change course and use a continuing resolution to fund the government at last year's spending levels through next March. Passing only this stopgap measure would mean Secret Service agents would not see an additional penny unless Congress includes additional funds in this spending bill. Otherwise, Secret Service agents may have to wait at least another four months without any additional compensation for their work in 2016.

I urge my colleagues to support this bill, but I also hope the Committee will revisit this overtime pay issue next year so that the Secret Service will have a legislative solution in time for the 2020 election season.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Utah (Mr. CHAFFETZ) that the House suspend the rules and pass the bill, H.R. 6302.

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

A motion to reconsider was laid on the table.

POST OFFICE DESIGNATIONS AND ESTABLISHING NEW ZIP CODES

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6303) to designate facilities of the United States Postal Service, to establish new ZIP Codes, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6303

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

SECTION 1. POST OFFICE DESIGNATIONS.

(a) SPECIAL WARFARE OPERATOR MASTER CHIEF PETTY OFFICER (SEAL) LOUIS "LOU" J. LANGLAIS POST OFFICE BUILDING.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 1221 State Street, Suite 12, Santa Barbara, California, shall be known and designated as the "Special Warfare Operator Master Chief Petty Officer (SEAL) Louis 'Lou' J. Langlais Post Office Building".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Special Warfare Operator Master Chief Petty Officer (SEAL) Louis 'Lou' J. Langlais Post Office Building".

(b) RICHARD ALLEN CABLE POST OFFICE.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 23323 Shelby Road in Shelby, Indiana, shall be known and designated as the "Richard Allen Cable Post Office".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Richard Allen Cable Post Office".

(c) LEONARD MONTALTO POST OFFICE BUILDING.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 3031 Veterans Road West in Staten Island, New York, shall be known and designated as the "Leonard Montalto Post Office Building".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other

record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Leonard Montalto Post Office Building".

(d) ARMY FIRST LIEUTENANT DONALD C. CARWILE POST OFFICE BUILDING.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 401 McElroy Drive in Oxford, Mississippi, shall be known and designated as the "Army First Lieutenant Donald C. Carwile Post Office Building".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Army First Lieutenant Donald C. Carwile Post Office Building".

(e) E. MARIE YOUNGBLOOD POST OFFICE.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 14231 TX-150 in Coldspring, Texas, shall be known and designated as the "E. Marie Youngblood Post Office".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "E. Marie Youngblood Post Office".

(f) ZAPATA VETERANS POST OFFICE.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 810 N. U.S. Highway 83 in Zapata, Texas, shall be known and designated as the "Zapata Veterans Post Office".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Zapata Veterans Post Office".

(g) MARINE LANCE CORPORAL SQUIRE "SKIP" WELLS POST OFFICE BUILDING.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 2886 Sandy Plains Road in Marietta, Georgia, shall be known and designated as the "Marine Lance Corporal Squire 'Skip' Wells Post Office Building".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Marine Lance Corporal Squire 'Skip' Wells Post Office Building".

(h) OFFICER JOSEPH P. CALI POST OFFICE BUILDING.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 6300 N. Northwest Highway in Chicago, Illinois, shall be known and designated as the "Officer Joseph P. Cali Post Office Building".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Officer Joseph P. Cali Post Office Building".

(i) SEGUNDO T. SABLAN AND CNMI FALLEN MILITARY HEROES POST OFFICE BUILDING.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 1 Chalan Kanoa VLG in Saipan, Northern Mariana Islands, shall be known and designated as the "Segundo T. Sablan and CNMI Fallen Military Heroes Post Office Building".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Segundo T. Sablan and CNMI Fallen Military Heroes Post Office Building".

(j) ABNER J. MIKVA POST OFFICE BUILDING.—

(1) DESIGNATION.—The facility of the United States Postal Service located at 1101

Davis Street in Evanston, Illinois, shall be known and designated as the "Abner J. Mikva Post Office Building".

(2) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in paragraph (1) shall be deemed to be a reference to the "Abner J. Mikva Post Office Building".

SEC. 2. ESTABLISHING NEW ZIP CODES.

Not later than September 30, 2017, the United States Postal Service shall designate a single, unique ZIP code for, as nearly as practicable, each of the following communities:

- (1) Miami Lakes, Florida.
- (2) Storey County, Nevada.
- (3) Flanders, Northampton, and Riverside in the Town of Southampton, New York.
- (4) Ocoee, Florida.
- (5) Glendale, New York.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentleman from Massachusetts (Mr. LYNCH) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

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

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

There was no objection.

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

Mr. Speaker, I rise today in support of H.R. 6303, introduced by Chairman JASON CHAFFETZ. This straightforward legislation would consolidate 10 postal naming bills and solve important local issues by designating five new ZIP Codes.

The 10 postal naming bills have all been passed by the House already this Congress. The five ZIP Codes designated by the bill will address significant issues faced by those five communities. In each case, the ZIP Code designation is driven by local leaders and strongly supported by the relevant Member of Congress. Local communities are not asking for new postal buildings, and no new construction will be required to accommodate the changes.

In the case of Southampton, New York, Chairman CHAFFETZ personally met with individuals and businesses impacted by delivery problems that could be solved with the addition of a new ZIP Code. I look forward to hearing more about the specifics of that situation from Representative LEE ZELDIN of New York, who is here today.

In another example, the community of Ocoee, Florida, faces a lack of identity due to the six different ZIP Codes serving its citizens. Additionally, some Ocoee residents are forced to pay non-resident rates or are flatly denied services because they are not identified by the correct ZIP Code.

These concerns aren't just limited to mail delivery. Communities without a

unique ZIP Code are at higher risk for extended response times when calling 911 due to confusion and similar street names. ZIP Codes are also used to determine the appropriate distribution of tax revenue and insurance funds to local communities. Without the proper ZIP Code designations, some local communities may not receive their fair cut of local tax revenues.

In many situations, local leaders within the new ZIP Code designations have exhausted all options to obtain the requested changes. Some of these communities, such as Ocoee and Miami Lakes, have even offered to pay the Postal Service for the cost of new ZIP Codes but have been rebuffed. This legislation is the last path forward for these communities.

I urge my colleagues to support H.R. 6303.

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

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

Mr. Speaker, ZIP Codes are used to organize our country to ensure the effective and efficient delivery of the mail to millions of Americans. The Postal Service has the authority to establish ZIP Codes and to adjust their boundaries based on changes in delivery and volume or operational concerns. However, communities, businesses, and other local entities can also voice their concerns about ZIP Code boundaries and petition for corresponding adjustments.

H.R. 6303 would make such adjustments by requiring the Postal Service to establish new ZIP Codes for five communities that have each requested, and subsequently been denied, ZIP Code changes. These communities have based their ZIP Code requests on delays in mail delivery and emergency service response times, the denial or inconsistent application of services to their communities, and other similar community concerns.

□ 1545

These are important issues and they should be addressed accordingly. The Postal Service has worked with affected communities to find solutions, and I commend those efforts by the Postal Service.

The Oversight and Government Reform Committee has also worked to find solutions to these concerns in its proposed postal reform legislation, and, in fact, most of these would receive unique ZIP Codes as part of that bill. That is why I support H.R. 6303 today.

Finally, I want to highlight my strong support for the language in this bill before us today that would name ten post offices after honorable men and women, all of whom made important contributions to our Nation. Individual legislation allowing for the naming of those postal facilities has already passed the House and is simply awaiting action in the Senate.

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

I reserve the balance of my time.

Mr. GOSAR. Mr. Speaker, I yield 2 minutes to the gentleman from New York (Mr. ZELDIN).

Mr. ZELDIN. Mr. Speaker, I rise in support of H.R. 6303, which would create a new, unique ZIP Code for the hamlets of Flanders, Riverside, and Northampton in my district.

These three hamlets currently share the same ZIP Code with the nearby town of Riverhead, and there are at least 18 identical street names and 32 similar street names. This causes a number of issues, including delay of mail and packages, which can hold important goods like medications. Shared street names can also delay the response time of emergency and medical personnel in situations where every second counts.

This could all be avoided by assigning a new and unique ZIP Code to Flanders, Northampton, and Riverside, which is why I have been working closely with Chairman CHAFFETZ, even bringing him to Long Island to speak with those impacted in the community firsthand. I thank Chairman CHAFFETZ for his exceptional help with this issue.

For many years, residents, local elected officials, and community organizations have been aware of this issue and the problems it brings. But despite their previous efforts, the issue still serves to be a burden for those in this area of the First Congressional District of New York.

I would also like to thank Ron Fisher, chairman of the Flanders/Riverside/Northampton Citizen Advisory Council and president of the Flanders, Riverside and Northampton Community Association, and all the members of these organizations for continuing this effort over the years. This has been a priority for them for many years, and it is an honor to be their voice in the House.

I know this legislation also includes a new ZIP Code for the area, including Glendale. I have spoken with my colleague, Ms. MENG, who has been a tireless advocate on behalf of those residents in Glendale. I am real thrilled to see that that is included as well.

I thank Mr. GOSAR for his support and his efforts. To the entire staff of the Oversight and Government Reform Committee, Chairman CHAFFETZ is fortunate to have an amazing team working with him.

Mr. LYNCH. Mr. Speaker, I yield such time as she may consume to the gentlewoman from New York (Ms. MENG), one of the other champions of this legislation.

Ms. MENG. Mr. Speaker, I thank my friend, Mr. LYNCH, for yielding.

Mr. Speaker, I rise in support of H.R. 6303, which includes a section to establish a new ZIP Code for the community of Glendale, New York. This section is identical to legislation I introduced last February, H.R. 657.

I thank Oversight and Government Reform Chairman CHAFFETZ for authoring this legislation, and I thank Ranking Member CUMMINGS for his support.

For almost 30 years, the residents of Glendale, New York, have sought to obtain a unique ZIP Code for their community in Queens. They have experienced mail and service-related problems due to sharing a ZIP Code with the neighboring community of Ridgewood. These problems include medications that were spoiled or not received due to mail processing errors, delays in first responder services to residents in need of care, and inaccuracies with GPS devices.

Roughly one-quarter of Glendale's population is eligible to receive Medicare, or will become eligible in the next decade. Many use a mail-order pharmacy to receive their prescription drugs, and many more will use such services in the years to come. A single, unique ZIP Code for Glendale will ensure that mail delivery will be improved in the future.

Creating a new ZIP Code for Glendale has been an ongoing and bipartisan challenge for Members of Congress who previously represented the area. I commend them for their efforts on behalf of the community, especially my predecessor, Representative Bob Turner.

When I took office in the 113th Congress, the only recourse left to address this matter was through legislation. I am grateful to Chairman CHAFFETZ for including Glendale in this legislation. It has been a long fight for the community of Glendale to receive its own ZIP Code.

Mr. Speaker, before I close, I would like to thank the local elected officials, civic associations, and community activists who have voiced their support for this issue over the years. In particular, I would like to thank Queens Borough President Melinda Katz, New York State Senator Joseph Addabbo, New York State Assemblymen Michael Miller and Andrew Hevesi, and New York City Councilwoman Elizabeth Crowley. I would also like to thank Dori Figliola, the Glendale Property Owners Association, Glendale Civic Association, and Citizens for a Better Ridgewood for their advocacy.

Mr. Speaker, I thank you for allowing this legislation to the floor for a vote today, and I urge all of my colleagues to support this important measure.

Mr. LYNCH. Mr. Speaker, having no further speakers, I yield back the balance of my time.

Mr. GOSAR. Mr. Speaker, I yield 2 minutes to the gentleman from Nevada (Mr. AMODEI).

Mr. AMODEI. Mr. Speaker, I thank my colleague from Arizona and the ranking member. I appreciate the fact that the committee has taken this issue.

As the person who represents the only district west of the Mississippi that was fortunate enough to be considered as deserving in this, I just want to make a couple of points. From the earlier talks too, it is like none of these ZIP Codes were ones where peo-

ple just said: hey, let's go, OGR folks, and create a new one. Without exception, everybody went to the Postal Service and said: here is our stuff. And while the people in my State were good about it, what we got from the folks back here was basically: we kind of don't do that, and if you ask and if you are turned down, you can't ask again for X number of years. It is almost an implied threat for requesting one.

So I can't thank the committee enough for taking a look into the issue. This particular one is actually the largest industrial park in the Nation—the marketing people tell me, so I will assume they are right—and it helps in another area, which is the State tax department that collects sales taxes. When you are building something, there are a lot of sales taxes based on ZIP Codes. So this will make sure that those sales tax dollars are generated and credited to where those materials are actually going.

And I want to also note for the RECORD before I yield back that what you have here, apparently, is the three greatest States in the Nation—New York, Florida, and Nevada—and so the other 47, keep trying.

Mr. GOSAR. Mr. Speaker, I yield 2 minutes to the gentleman from Florida (Mr. DIAZ-BALART).

Mr. DIAZ-BALART. Mr. Speaker, let me first thank the gentleman from Arizona for the time. And I also need to, in particular, thank Chairman CHAFFETZ for introducing this, I think, very important piece of legislation.

We have heard what the issue is. Look, for years now the city of Miami Lakes, which I am privileged to represent, has attempted to receive a unique ZIP Code for all the same reasons that you have already heard. This would help with auto insurance rates, with branding and economic development, and, frankly, would lead to less election and census confusion, Mr. Speaker. So it is a no-brainer.

But, unfortunately, the Postal Service has continued, and continues, to stonewall the city, despite absolutely no opposition from either anyone in Miami Lakes or, frankly, the areas around it. I have had meetings with the mayors from the areas around it, and everybody supports it. This legislation solves the problem and grants Miami Lakes its own ZIP Code.

I really need to, by the way, give credit to then-Vice Mayor, now Mayor-elect of Miami Lakes, Manny Cid. He has made this a priority. He was told “no” time and time again, refused to accept that as an answer, and came to us. It has been a privilege to work with him. Because of his hard work, together, we were able to get the committee, with the chairman and the ranking member and all of the rest of the members of this committee, to get this done through the House.

Again, I want to thank Congressman CHAFFETZ. I want to thank the committee staff. His staff has been great to work with.

Mr. Speaker, I urge the passage of this legislation.

Mr. GOSAR. Mr. Speaker, I urge the adoption of the bill.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 6303.

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

A motion to reconsider was laid on the table.

FEDERAL REGISTER PRINTING SAVINGS ACT OF 2016

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5384) to amend title 44, United States Code, to restrict the distribution of free printed copies of the Federal Register to Members of Congress and other officers and employees of the United States, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5384

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 “Federal Register Printing Savings Act of 2016”.

SEC. 2. RESTRICTIONS ON DISTRIBUTION OF FREE PRINTED COPIES OF FEDERAL REGISTER TO MEMBERS OF CONGRESS AND FEDERAL EMPLOYEES.

(a) RESTRICTIONS.—Section 1506 of title 44, United States Code, is amended—

(1) by striking “The Administrative Committee” and inserting “(a) COMPOSITION; DUTIES.—The Administrative Committee”;

(2) in subsection (a)(4), by striking “the number of copies” and inserting “subject to subsection (b), the number of copies”; and

(3) by adding at the end the following new subsection:

“(b) RESTRICTIONS ON DISTRIBUTION OF FREE PRINTED COPIES TO MEMBERS OF CONGRESS AND OFFICERS AND EMPLOYEES OF THE UNITED STATES.—

“(1) PROHIBITING SUBSCRIPTION TO PRINTED COPIES WITHOUT REQUEST.—Under the regulations prescribed to carry out subsection (a)(4), the Director of the Government Publishing Office may not provide a printed copy of the Federal Register without charge to any Member of Congress or any other office of the United States during a year unless—

“(A) the Member or office requests a printed copy of a specific issue of the Federal Register; or

“(B) during that year or during the previous year, the Member or office requested a subscription to printed copies of the Federal Register for that year, as described in paragraph (2).

“(2) ADMINISTRATION OF SUBSCRIPTIONS.—The regulations prescribed to carry out subsection (a)(4) shall include—

“(A) provisions regarding notifications to offices of Members of Congress and other offices of the United States of the restrictions of paragraph (1);

“(B) provisions describing the process by which Members and other offices may request a specific issue of the Federal Register for purposes of paragraph (1)(A); and

“(C) provisions describing the process by which Members and other offices may request a subscription to the Federal Register

for purposes of paragraph (1)(B), except that such regulations shall limit the period for such a subscription to not longer than one year.”.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect January 1, 2017.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentleman from Massachusetts (Mr. LYNCH) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

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

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

There was no objection.

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

I rise today in support of H.R. 5384, the Federal Register Printing Savings Act of 2016, introduced by my colleague on the Oversight and Government Reform Committee, the gentleman from Oklahoma (Mr. RUSSELL).

This commonsense legislation will help curb government waste.

The Federal Register is aptly described as the official newspaper of the Federal Government. Its daily editions include copies of proposed and final regulations, requests for comment, executive orders, and information concerning other government activities.

Today, virtually every Member of Congress, the White House, and many Federal agencies receive printed copies of the Federal Register. It is important to note that Members of Congress do not proactively request, or pay for this service. However, for the public, an annual subscription costs \$929 annually.

In the days before the Internet, this paper-based service brought great value to Members, agencies, and the White House, allowing them to keep track of activity across the government. Today, though, the full Federal Register is available online in a completely searchable and downloadable format. As a result, offices on Capitol Hill and across the government throw away the paper version every morning, often unopened, resulting in hundreds of thousands of dollars of waste.

This legislation, H.R. 5384, would change this dynamic by banning automatic subscriptions to the Federal Register by the Federal Government. Instead, Members of Congress and offices across the Federal Government who still want to receive printed copies would be required to request individual copies, or an annual subscription.

This is a simple, good government piece of legislation that will save the American taxpayer potentially hundreds of thousands of dollars every year.

I urge my colleagues to support this legislation.

I reserve the balance of my time.

HOUSE OF REPRESENTATIVES, COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,

Washington, DC, November 29, 2016.

Hon. CANDICE S. MILLER,

Chairman, Committee on House Administration, Washington, DC.

DEAR MADAM CHAIRMAN: On November 16, 2016, the Committee on Oversight and Government Reform ordered reported without amendment H.R. 5384, the Federal Register Printing Savings Act of 2016. The bill was referred primarily to the Committee on Oversight and Government Reform, with an additional referral to the Committee on House Administration.

I ask that you allow the Committee on House Administration to be discharged from further consideration of the bill so that it may be scheduled by the Majority Leader. This discharge in no way affects your jurisdiction over the subject matter of the bill, and it will not serve as precedent for future referrals. In addition, should a conference on the bill be necessary, I would support your request to have the Committee on House Administration represented on the conference committee. Finally, I would be pleased to include this letter and any response in the bill report filed by the Committee on Oversight and Government Reform, as well as in the Congressional Record during floor consideration, to memorialize our understanding.

Thank you for your consideration of my request.

Sincerely,

JASON CHAFFETZ,

Chairman.

HOUSE OF REPRESENTATIVES, COMMITTEE ON HOUSE ADMINISTRATION, Washington, DC, November 29, 2016.

Hon. JASON CHAFFETZ,

Chairman, Committee on Oversight and Government Reform, Washington, DC.

DEAR MR. CHAIRMAN: Thank you for your letter regarding H.R. 5384. As you know, the bill was received in the House of Representatives on June 3, 2016, and referred primarily to the Committee on Oversight and Government Reform and in addition to the Committee on the Committee on House Administration. The bill seeks to restrict the distribution of free printed copies of the Federal Register to Members of Congress and other officers and employees of the United States. On November 16, 2016 your Committee ordered H.R. 5384 to be reported without amendment.

I realize that discharging the Committee on House Administration from further consideration of H.R. 5384 will serve in the best interest of the House of Representatives and agree to do so. It is the understanding of the Committee on House Administration that forgoing action on H.R. 5384 will not prejudice the Committee with respect to appointment of conferees or any future jurisdictional claim. I request that your letter and this response be included in the bill report filed by your Committee, as well as in the Congressional Record.

Sincerely,

CANDICE S. MILLER,

Chairman.

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

Mr. Speaker, I rise in support of H.R. 5384, the Federal Register Printing Savings Act of 2016. I agree with the gentleman from Arizona (Mr. GOSAR) that this is a commonsense, good government bill about cutting waste.

This bill would allow the Government Publishing Office to avoid send-

ing printed copies of the Federal Register to Members of Congress and other Federal offices, unless those offices actually want the printed copies. Of course, the Federal Register would continue to be available online.

This bill would be good for the environment and good for taxpayers. The Congressional Budget Office estimates that this bill would save about \$1 million a year.

I urge my colleagues to support H.R. 5384.

I yield back the balance of my time. Mr. GOSAR. Mr. Speaker, I urge the adoption of the bill.

I yield back the balance of my time. The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 5384.

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

A motion to reconsider was laid on the table.

□ 1600

FEDERAL AGENCY MAIL MANAGEMENT ACT OF 2016

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6009) to ensure the effective processing of mail by Federal agencies, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6009

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 “Federal Agency Mail Management Act of 2016”.

SEC. 2. RECORD MANAGEMENT.

(a) AMENDMENTS.—Section 9 of the Presidential and Federal Records Act Amendments of 2014 (44 U.S.C. 101 note) is amended—

(1) in subsection (a), by amending paragraph (3) to read as follows:

“(3) in paragraph (7), by striking ‘the Administrator or the Archivist’ and inserting ‘the Archivist or the Administrator.’”;

(2) in subsection (c)—

(A) by amending paragraph (1) to read as follows:

“(1) by amending subsection (a) to read as follows:

“(a) The Archivist shall provide guidance and assistance to Federal agencies with respect to ensuring—

“(1) economical and effective records management;

“(2) adequate and proper documentation of the policies and transactions of the Federal Government; and

“(3) proper records disposition.”;

(B) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively;

(C) by inserting after paragraph (1), the following new paragraph:

“(2) in subsection (b), by striking ‘effective records management by such agencies’ and inserting ‘effective processing of mail by Federal agencies.’”;

(D) in paragraph (3), as so redesignated—

(i) in subparagraph (A)(ii), by striking “subsections (a) and (b)” and inserting “subsection (a)”;

(ii) in subparagraph (B), by striking “; and” and inserting a semicolon;

(E) in paragraph (4), as so redesignated, by striking the period at the end and inserting “; and”; and

(F) by inserting at the end the following new paragraph:

“(5) by inserting at the end the following new subsection:

“(e) The Administrator, in carrying out subsection (b), shall have the responsibility to promote economy and efficiency in the selection and utilization of space, staff, equipment, and supplies for processing mail at Federal facilities.”

(3) in subsection (d)—

(A) in paragraph (1), by striking “; and” at the end and inserting a semicolon;

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

(C) by inserting at the end the following new paragraph:

“(3) by inserting at the end the following new subsection:

“(c) The Administrator (or the Administrator’s designee) may inspect the mail processing practices and programs of any Federal agency for the purpose of rendering recommendations for the improvement of mail processing practices and programs. Officers and employees of such agencies shall cooperate fully in such inspections of mail processing practices and programs.”

(4) by striking subsection (f); and

(5) by redesignating subsection (g) as subsection (f).

(b) **EFFECTIVE DATE.**—The amendments made by this section shall take effect as if included in the Presidential and Federal Records Act Amendments of 2014 (Public Law 113–187).

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentleman from Massachusetts (Mr. LYNCH) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

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

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

There was no objection.

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

I rise in support of H.R. 6009, the Federal Agency Mail Management Act of 2016, introduced by my colleague on the Oversight and Government Reform Committee, Representative STEVE RUSSELL of Oklahoma.

This legislation is intended to make a bipartisan technical correction to the Presidential and Federal Records Act Amendments of 2014, enacted as Public Law 113–187.

Among the provisions of that bipartisan law was language designed to eliminate outdated references to the General Services Administration, or GSA, relating to records management. These changes updated outdated references from a time period when the National Archives was a part of the GSA. Since the National Archives became independent in 1984, these house-

keeping changes were long overdue. However, after the bill was enacted, the GSA and the Archives realized that the GSA had relied upon the now altered provisions for its oversight and management authority for Federal agency mail processing and management, which is a function that had not previously been transferred to the Archives. It was never the intent of the Congress to transfer this function.

The Archives and the GSA have been working closely together to ensure the law is being appropriately followed, but both agencies support clarification that this responsibility is properly the GSA’s. This legislation provides that exact clarification. Specifically, the bill makes technical corrections to the 2014 law to carve out the responsibility for mailroom management from records management to ensure that the former is properly the GSA’s duty and that the latter is the Archives’.

I believe this is a commonsense, good-government bill, and I am pleased to see that my colleague Representative Gerald Connolly is a cosponsor. I urge my colleagues to support this bill, and I hope it will move quickly through the legislative process so that we can properly resolve any lingering uncertainty that has been created regarding Federal mail management.

I reserve the balance of my time.

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

I support this bipartisan bill, which simply makes a technical correction to clarify that the Administrator of the General Services Administration is responsible for managing mail in the executive branch.

The Administrator of the GSA has historically had this responsibility. When the Federal Records Act was updated in 2014, changes made to the statute made it unclear whether the Administrator’s role had changed. This bill makes clear that Congress never intended to take away the GSA Administrator’s authority to manage the executive mail.

In closing, I would like to especially thank Representative STEVE RUSSELL from Oklahoma and Representative GERRY CONNOLLY from Virginia for their excellent work that they put into this legislation, and I hope that the Senate will take it up before the end of this Congress.

I yield back the balance of my time.

Mr. GOSAR. Mr. Speaker, I urge the adoption of the bill.

I yield back the balance of my time.

The SPEAKER pro tempore (Mr. SIMPSON). The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 6009.

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

A motion to reconsider was laid on the table.

FOLLOW THE RULES ACT

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6186) to amend title 5, United States Code, to extend certain protections against prohibited personnel practices, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6186

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 “Follow the Rules Act”.

SEC. 2. PROHIBITED PERSONNEL ACTION BASED ON ORDERING INDIVIDUAL TO VIOLATE RULE OR REGULATION.

(a) **IN GENERAL.**—Subparagraph (D) of section 2302(b)(9) of title 5, United States Code, is amended by inserting “, rule, or regulation” after “law”.

(b) **TECHNICAL CORRECTION.**—Such subparagraph is further amended by striking “for”.

(c) **APPLICATION.**—The amendment made by subsection (a) shall apply to any personnel action (as that term is defined in section 2302(a)(2)(A) of such title) occurring after the date of enactment of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentleman from Massachusetts (Mr. LYNCH) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

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

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

There was no objection.

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

I rise in support of H.R. 6186, the Follow the Rules Act, introduced by Representative SEAN DUFFY. This legislation reiterates Congress’ intent that whistleblower protections be broadly construed.

Whistleblowers are the best source of information about waste, fraud, and abuse in the Federal Government. We should do all we can to protect them. Under the Whistleblower Protection Act of 1989, a whistleblower is protected for disclosing violations of laws, rules, or regulations; yet a recent opinion by the U.S. Court of Appeals for the Federal Circuit would limit the scope of those protections. The Federal Circuit held that Federal employees are not protected if they refuse to violate a rule or a regulation. This would mean whistleblowers could be ordered to violate the same rule or regulation whose violation they blew the whistle on. If they refuse, they could be retaliated against, such as being demoted or even fired.

In the case heard by the Federal Circuit, Dr. Timothy Allen Rainey, a contracting officer at the Department of

State, was ordered to tell a contractor to rehire a terminated subcontractor. Dr. Rainey refused on the grounds it would violate the Federal Acquisition Regulation—governmentwide contracting standards that have been in place for over 30 years. These contracting standards are exactly the sort of thing the Oversight and Government Reform Committee oversees to ensure compliance. In return for his objections, Dr. Rainey was stripped of his duties as a contracting officer and was given a negative performance rating. The Court of Appeals for the Federal Circuit held that, because Dr. Rainey was refusing to obey an order that would require him to violate a regulation and not a law, he could not be shielded by the Whistleblower Protection Act.

We should protect Federal workers who act in good faith to abide by the rules of their agencies. They shouldn't have to choose between disobeying the order of a supervisor and being disciplined for violating an agency's rules or regulations.

While nearly all Federal laws have implementing regulations, not all regulations have a detailed basis in law. Furthermore, agencies do not always train their employees to know which regulations are based in law. This means Federal workers may have to conduct extensive legal research before deciding on the safest course of action, in this case, whether to apply the very standards their own agencies put into place.

Whether the issue is regulations aimed against whistleblowers or whistleblowers acting to uphold other regulations, the issue is the same: we should incentivize and protect Federal employees for acting as principled civil servants. The Follow the Rules Act would send a clear, consistent message that Federal employees are expected to uphold standards of good government. It would ensure Federal workers are protected if they refuse to obey an order that would require them to violate even just a rule or a regulation.

Mr. Speaker, we are a nation based on the rule of law. We expect agencies to act in a transparent fashion and to be governed by predictable rules. We should provide the same sort of predictability to whistleblowers and protect them when they apply what they have been trained to follow. For that reason, I urge my colleagues to support this legislation.

I reserve the balance of my time.

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

I rise in strong support of H.R. 6186, the Follow the Rules Act.

I appreciate the hard work done by Representative DUFFY of Wisconsin and by Mr. CONNOLLY of Virginia in taking the lead in introducing this legislation and then in working diligently and in a bipartisan manner to achieve its passage.

This bill would clarify that an employee who refuses to obey an order

that would require the employee to violate the law, a rule, or a regulation is protected from retaliation under the Whistleblower Protection Act.

In June 2016, the U.S. Court of Appeals for the Federal Circuit issued a ruling that is contrary to the Whistleblower Protection Act and that is contrary to congressional intent. As Mr. GOSAR of Arizona previously laid out the facts, in *Rainey v. MSPB*, the court ruled that an employee who refuses to obey an order is protected only if the order would violate a statute but that the employee would not be protected if the order would simply violate a rule or a regulation.

This ruling incorrectly interprets congressional intent. Employees should be protected from retaliation if they do the right thing. That includes refusing to obey orders that would violate an agency's rules and regulations, as well as statutes. It is more critical than ever that we send a message to Federal employees that they have the right to do their jobs free from political pressure to bend or to violate the rules.

I urge my colleagues to support the passage of this legislation today.

I reserve the balance of my time.

Mr. GOSAR. Mr. Speaker, I yield 4 minutes to the gentleman from Wisconsin (Mr. DUFFY).

Mr. DUFFY. I thank the gentleman from Arizona for yielding, and I thank my friends across the aisle for their support of this commonsense piece of legislation that, again, rights a wrong perception from the U.S. Court of Appeals.

Mr. Speaker, many of us in this institution do talk about how we are a nation of laws; but, unfortunately, on June 7, when the U.S. Court of Appeals handed down its decision, it ruled that we are a nation of laws but not a nation of rules and regulations, at least as they apply to Federal workers.

We have had a good discussion about the case. Dr. Timothy Rainey, just to summarize again, is a State Department employee who was asked to violate the Federal Acquisition Regulation, and he didn't want to do it; so he denied, and he invoked his right to disobey under the Whistleblower Protection Act. This was brought to the Merit Systems Protection Board, and it ruled against Dr. Rainey. It went to the U.S. Court of Appeals, and it also found against Dr. Rainey. This exposed a glaring inconsistency in the application of the Whistleblower Protection Act, which, again, is inconsistent with the intent of this institution.

So we ask ourselves: What does this mean?

I chair the Financial Services Committee's Subcommittee on Oversight and Investigation. Federal whistleblowers play an important role in exposing the mismanagement at Federal agencies and in supporting the oversight that all of us do in this Congress. Critical to them is the Whistleblower Protection Act, which provides Federal workers with certain safeguards to dis-

close information that an employee reasonably believes evidences gross mismanagement, a waste of funds, an abuse of authority, or a violation of law.

This court ruling will take away those protections when Federal employees stand up against bad actors within our Federal workforce. In effect, this ruling will give permission to supervisors in positions of authority to force Federal workers to violate the rules and regulations that Congress, through law, directs the agencies to implement.

For example, at the Treasury Department, one of the agencies that I have the great privilege of overseeing, this would mean that Federal workers could be forced to violate sanctions against Russia for a violation of Ukraine's territorial integrity. Many of those sanctions are enforced through the Code of Federal Regulations pursuant to laws that are passed by this Congress.

Regardless of one's opinion about rules and regulations—and if that were the conversation today, I am sure one would have a debate that was far more disagreeable, but that is not the issue. No matter what one thinks about rules and regulations, we should not leave exposed Federal workers who simply want to follow those rules and regulations. This bipartisan Follow the Rules Act, which, again, I introduced with my good friend from Virginia (Mr. CONNOLLY), will close the loophole that was created by the court. What we are doing is ensuring that Federal employees aren't just protected under our whistleblower statute for violations of Federal law, but that they are also protected as whistleblowers if there is a violation of a Federal rule or regulation.

This makes sense. It closes a loophole. I think that is why we have seen such bipartisan support from the far right of this institution and the far left of this institution. I think this is a great bill, and I thank my friends for so closely working with me to garner the support.

Mr. LYNCH. Mr. Speaker, I yield such time as he may consume to the gentleman from Virginia (Mr. CONNOLLY), the other champion along with Mr. DUFFY of Wisconsin.

□ 1615

Mr. CONNOLLY. Mr. Speaker, I thank the gentleman from Massachusetts (Mr. LYNCH). I thank the gentleman from Arizona (Mr. GOSAR). I thank the gentleman from Wisconsin (Mr. DUFFY) for his leadership and collaboration on this important bill that he and I have introduced and is on the floor today, the Follow the Rules Act, H.R. 6186.

I appreciate Representative DUFFY's efforts to work to advance this legislation that falls under the umbrella of good government, which the Oversight and Government Reform Committee usually strives to promote on a bipartisan basis.

I welcome consideration of the bill, the Follow the Rules Act, to extend Congress' commitment to whistleblowers. The Follow the Rules Act upholds the committee's obligation to protect whistleblowers and help identify mismanagement at Federal agencies in supporting the oversight work of Congress.

The bill's language was previously adopted by a voice vote as section 1206 of the House-passed Financial Services and General Government Appropriations Act of 2017, H.R. 5482. The bill closes a loophole in the Whistleblower Protection Act created falsely, in my view, by the ruling in *Rainey v. Merit Systems Protection Board*, a precedent-setting case decided on June 7 in the U.S. Court of Appeals for the Federal Circuit.

The Whistleblower Protection Act provides Federal workers with legal safeguards to disclose information that an employee reasonably believes is evidence of gross mismanagement of a contract or a grant, gross waste of funds, abuse of authority regarding a contract or grant, or violation of law or rule regarding a contract or grant. That language ought to be fairly clear, but apparently it wasn't to the appellate court.

In *Rainey*, the right-to-disobey provision of the Whistleblower Protection Act was determined to only provide protection to Federal workers who refuse to obey an order that would require the individual to violate a law, but not to Federal workers who refuse to violate rules and regulations. God knoweth why.

This distinction leaves a gap in protections originally clearly intended for Federal employees by this Congress. In effect, the ruling exposes whistleblowers who refuse to violate the rules and regulations that were promulgated as a result of laws passed by Congress and signed by the President. That is how it flows.

This is a gap in coverage that must be addressed by Congress and clarified in the statute. Though, had the appellate court ruled correctly, it would be unnecessary.

The only way to protect whistleblowers from this court decision is to update the law to ensure that rules and regulations are covered by the right-to-disobey provision of the Whistleblower Protection Act.

I urge my colleagues to continue Congress' longstanding support for whistleblowers and vote in the affirmative for the Follow the Rules Act.

Mr. LYNCH. Mr. Speaker, having no further speakers on our side, I yield back the balance of my time.

Mr. GOSAR. Mr. Speaker, I urge the adoption of the bill.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 6186.

The question was taken; and (two-thirds being in the affirmative) the

rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

ADOLFO "HARPO" CELAYA POST OFFICE

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6304) to designate the facility of the United States Postal Service located at 501 North Main Street in Florence, Arizona, as the "Adolfo 'Harpo' Celaya Post Office".

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6304

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

SECTION 1. ADOLFO "HARPO" CELAYA POST OFFICE.

(a) DESIGNATION.—The facility of the United States Postal Service located at 501 North Main Street in Florence, Arizona, shall be known and designated as the "Adolfo 'Harpo' Celaya Post Office".

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in subsection (a) shall be deemed to be a reference to the "Adolfo 'Harpo' Celaya Post Office".

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentleman from the Virgin Islands (Ms. PLASKETT) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

Mr. GOSAR. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and to include any extraneous material on the bill under consideration.

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

There was no objection.

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

I rise today in support of my bill, H.R. 6304. The bill designates a post office in Florence, Arizona, as the Adolfo "Harpo" Celaya Post Office.

Mr. Speaker, this bill honors a great man and an Arizona hero. He has served his Nation both in combat and with a lifetime of community service. That man is Adolfo "Harpo" Celaya.

The bill being considered here today, H.R. 6304, would designate the United States Postal Service facility in Florence, Arizona, as the Adolfo "Harpo" Celaya Post Office. This is a small gesture to honor a man who has given so much to this Nation and to his community.

By way of background, Harpo Celaya was born in Florence, Arizona, on May 16, 1927. He worked numerous jobs, including picking cotton and working at the local dairy from the time he was only 8 years old. He earned the nickname "Harpo" because he had thick

black curls that reminded his friends of Harpo Marx.

When he was just 17 years old, he read a recruitment poster that boasted "Join the Navy, see the world" and he begged his father to let him join. He was assigned to the USS *Indianapolis*, the flagship of the 5th Fleet.

The Indy saw many battles during World War II, and Harpo was there with the ship at the battle of Iwo Jima and witnessed the historic flag-raising on the island in February of 1945. He was also aboard when the Indy went on a secret mission delivering parts for Little Boy, the atomic bomb that was dropped on Hiroshima.

His experiences on the Indy would change his life forever. On the night of July 30, 1945, the Indy was on its way back to the Philippines after a secret mission delivering the atomic bomb. Harpo and many of his mates were sleeping on the deck because it was too hot to sleep in their bunks below. Despite the heat, Harpo covered himself with a blanket, as had been his habit for many years in trying to ward off mosquitoes in the Arizona desert.

Shortly after midnight, a Japanese submarine hit the Indy with two torpedoes. Fire tore through the deck, burning Harpo and his mates. Harpo credits his blanket, which was essentially vaporized in the heat, for saving him from being burned more severely.

He was en route to retrieve his life-jacket when he ran into his friend, Santos Pena, who told him that the ship was sinking and they needed to abandon it immediately. The USS *Indianapolis* sank within 12 minutes.

The two friends separated after jumping into the water, and 3 days passed before they found each other again. They continued to endure excruciating conditions with their fellow sailors in the choppy open seas, most slowly succumbing to dehydration, exposure, and shark attacks.

The survivors of the Indy were eventually rescued after spending almost 5 harrowing days in the water. Of the 1,196 men aboard, only 317 survived. After this incident, Harpo was medically discharged from the Navy and awarded the Purple Heart.

Still only 17 years of age, he went back to high school in his hometown of Florence, Arizona, and was recruited to play on the Florence Gophers basketball team. Even though none of the players were over 6 feet tall, Harpo led his team to the Arizona State Basketball Championship and was named captain of the first-string all-state team.

Harpo continued his winning streak by playing for and eventually coaching the basketball team at Palo Verde Community College in Blythe, California.

Harpo went on to become a cowboy for a few years and eventually ran his own small business, providing heating and air-conditioning services to his new community of San Jose, California.

Throughout his life, Harpo could often be found coaching or refereeing

games for local youth. He knew firsthand of the value of sports and exercise as a means to keep young boys out of trouble.

Harpo's walls are adorned by many plaques and awards honoring his efforts. He is honored in the Arizona Basketball Hall of Fame at Arizona State University, the Florence High School Athletic Hall of Fame, and served as grand marshal for the Florence Junior Parade in November 2009.

Harpo Celaya is a true hero, beloved by his hometown of Florence.

I would like to thank all of the survivors of the USS *Indianapolis* for their sacrifice. Of the 23 survivors still alive today, Harpo is the only Native American. We are humbled to honor him today.

I would like to thank the town of Florence for their support of this bill and for proposing this great honor for Mr. Celaya. Thank you to the Oversight and Government Reform Committee for their expertise and patience in bringing this bill forward.

I urge Members to support my bill.

I reserve the balance of my time.

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

I rise today in strong support of H.R. 6304, to designate the facility of the United States Postal Service located at 501 North Main Street in Florence, Arizona, as the Adolfo "Harpo" Celaya Post Office.

Born in 1927, Mr. Celaya overcame a childhood of poverty, neglect, and abuse. At age 17, he joined the Navy and was assigned to the USS *Indianapolis* during World War II. Harpo fought in the battles of Iwo Jima and Okinawa and was aboard the USS *Indianapolis* during its secret mission to deliver the ingredients of the atomic bomb Little Boy to the island of Tinian.

As the ship was returning from this mission, it was hit with two torpedoes from a Japanese submarine. Despite being badly burned, Harpo Celaya jumped from a sinking ship into the water, where he remained for 5 days until rescuers arrived.

Of the 1,196 men aboard the ship that day, Harpo was one of only 317 survivors. He received the Purple Heart and returned to high school in his hometown of Florence, Arizona. There, he led the basketball team to the Arizona State Basketball Championship and was named captain of the all-state team in spite of his combat injuries.

Harpo Celaya attended Palo Verde Community College and again led the basketball team to a championship. He was inducted into the Arizona Basketball Hall of Fame in 1972 and the Florence High School Athletic Hall of Fame in 2008.

Outside of basketball, Harpo led a successful career as a cowboy and then as a small-business owner, but always made time to mentor local youth by coaching or refereeing athletic sports.

Mr. Speaker, we should pass this bill to honor Harpo Celaya for both his valiant military service and his ability to

overcome hardship and having a lasting positive impact on his community.

I urge my colleagues to support this bill.

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

Mr. GOSAR. Mr. Speaker, I ask that Members pass this bill.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 6304.

The question was taken.

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

Mr. GOSAR. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

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

The point of no quorum is considered withdrawn.

JONATHAN "J.D." DE GUZMAN POST OFFICE BUILDING

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5948) to designate the facility of the United States Postal Service located at 830 Kuhn Drive in Chula Vista, California, as the "Jonathan 'J.D.' De Guzman Post Office Building".

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 5948

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

SECTION 1. JONATHAN "J.D." DE GUZMAN POST OFFICE BUILDING.

(a) DESIGNATION.—The facility of the United States Postal Service located at 830 Kuhn Drive in Chula Vista, California, shall be known and designated as the "Jonathan 'J.D.' De Guzman Post Office Building".

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in subsection (a) shall be deemed to be a reference to the "Jonathan 'J.D.' De Guzman Post Office Building".

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentleman from the Virgin Islands (Ms. PLASKETT) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

Mr. GOSAR. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and to include any extraneous material on the bill under consideration.

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

There was no objection.

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

I rise today in support of H.R. 5948, introduced by my colleague, Representative SUSAN DAVIS of California. The bill designates a post office in Chula Vista, California, as the Jonathan "J.D." De Guzman Post Office Building.

Jonathan De Guzman was born in the Philippines in 1972. He later traveled to the United States and became an American citizen and served as an officer with the San Diego Police Department. Officer De Guzman received the Purple Heart for bravery from the San Diego Police Department in 2003 after being stabbed in the line of duty. He returned to work, but tragically was killed in the line of duty in July of this year.

I join my colleague, Representative DAVIS of California, in honoring Officer De Guzman.

I urge Members to support the bill.

I reserve the balance of my time.

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

Mr. Speaker, I rise today in strong support of H.R. 5948, a bill to designate the facility of the United States Postal Service located at 830 Kuhn Drive in Chula Vista, California, as the Jonathan "J.D." De Guzman Post Office Building.

Jonathan De Guzman emigrated to the U.S. from the Philippines with a strong desire to become a contributor to his new community. His selflessness led him to join the San Diego Police Department, where he served for 16 years.

Officer De Guzman was awarded the San Diego Police Department's Purple Heart in 2003 after surviving a stabbing while on duty. Officer De Guzman was again attacked while on duty in July of 2016. This time, however, he was shot multiple times at pointblank range and tragically did not survive.

Mr. Speaker, we should pass this bill to honor Officer Jonathan De Guzman's courageous life of public service and ensure that the ultimate sacrifice he made is never forgotten.

I urge my colleagues to support H.R. 5948.

I reserve the balance of my time.

□ 1630

Mr. GOSAR. Mr. Speaker, I have no further speakers. I reserve the balance of my time.

Ms. PLASKETT. Mr. Speaker, I yield such time as she may consume to the gentlewoman from California (Mrs. DAVIS).

Mrs. DAVIS of California. Mr. Speaker, I rise today to ask for support of H.R. 5948 in commemorating the life of a humble role model and a courageous American hero. Officer Jonathan De Guzman, or J.D., as he was better known by family and friends, dedicated his life to protecting and serving the San Diego community that he loved.

Born in the Philippines, J.D. traveled to the United States at the age of 20 with high hopes of achieving the American Dream. Through hard work and

perseverance, he achieved this dream as a San Diego law enforcement officer, serving in many different roles within the San Diego Police Department, including serving on the gang suppression unit.

A devoted public servant, J.D. felt most rewarded by the bonds he created through community engagement. J.D.'s family, his friends, and fellow officers characterized him as a selfless, honorable, and caring warrior. San Diego Police Chief Shelley Zimmerman praised J.D. saying: "He always raised the bar" and "cared deeply for his community."

In 2003, he survived a brutal stabbing from a suspect he had stopped for speeding. A true warrior, indeed, upon recovery, he quickly returned to the force to defend the people of San Diego. In that same year, he was awarded the San Diego Police Department's Purple Heart for bravery in the line of duty. Although he appreciated the gesture, the accolades were not what motivated him to serve. The reactions of the community brought J.D. true fulfillment.

Tragically, on July 28, 2016, Officer De Guzman, a 16-year veteran of the force, was shot multiple times at point-blank range and killed. Prosecutors on the case say the attack happened so quickly that J.D. never had the opportunity to pull his service weapon.

On August 5, thousands—I mean thousands—of lined officers and private citizens lined the streets of San Diego for J.D.'s funeral procession, tossing flowers along the path, holding signs, and waving American flags. I can assure you, it was really a moving experience. The amount of love and admiration I witnessed that day showed just how deeply he touched the lives of everyone he encountered in a life that was cut much too short.

He was only 43 years old. He was a beloved son to his proud parents, a caring husband to his adoring wife, Mary Jane, and a hero to their beautiful children, Amira and Jonathan, Jr. I had the pleasure of meeting with his family and some of his close friends to offer my deepest condolences. I saw the wound that was left behind, a wound that may never truly be healed, but through loving memories of their time together, combined with the support of the community, his strong family will endure the pain.

While nothing will ever fill the void, we can take action today to ensure that his legacy will never be forgotten. J.D. made the ultimate sacrifice in protecting our community, and this bill will mean that future generations will know and understand the commitment that Officer De Guzman made and our law enforcement officers continue to make every day.

I urge you to vote "yes" on H.R. 5948 to designate the facility of the United States Postal Service located at 830 Kuhn Drive in Chula Vista, California, as the Jonathan "J.D." De Guzman Post Office Building. This post office sits right in the Eastlake community

that Officer De Guzman called home and will stand as a lasting remembrance of a true role model and American hero.

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

Mr. GOSAR. Mr. Speaker, I urge the adoption of the bill. I yield back the balance of my time.

Mr. VARGAS. Mr. Speaker, I rise today in support of H.R. 5948—An Act to designate the United States Postal Service facility in Chula Vista as the "Johnathan 'J.D.' De Guzman Post Office Building." This legislation is sponsored by my colleague, the gentlewoman from San Diego, Susan Davis. I urge my colleagues to support this bill, so that we may forever honor the sacrifice that Officer De Guzman made for the San Diego community and our great nation.

San Diego Police Officer Johnathan 'J.D.' De Guzman was a true American hero who was killed in the line of duty. Born in the Philippines on September 17, 1972, Officer De Guzman traveled to the United States at the age of 20 and eventually became an American citizen. He believed deeply in the American Dream and in the importance of public service and community involvement, leading him to join the San Diego Police Department (SDPD) in 2000.

Officer De Guzman was a SDPD 16 year veteran and a member of the department's gang suppression unit. In 2003, he received the SDPD's Purple Heart. Officer De Guzman was characterized as a caring, selfless, honorable, and courageous individual. It wasn't uncommon for him to show up at his children's school and engage students about careers in law enforcement.

Tragically, Officer De Guzman was killed while on patrol on July 28th, 2016. He is survived by his parents, his wife Mary Jane, and his two children Amira and Jonathan De Guzman II.

I urge my colleagues to pass H.R. 5948.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 5948.

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

A motion to reconsider was laid on the table.

U.S. NAVAL CONSTRUCTION BATTALION "SEABEES" FALLEN HEROES POST OFFICE BUILDING

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6138) to designate the facility of the United States Postal Service located at 560 East Pleasant Valley Road, Port Hueneme, California, as the U.S. Naval Construction Battalion "Seabees" Fallen Heroes Post Office Building.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6138

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

SECTION 1. U.S. NAVAL CONSTRUCTION BATTALION "SEABEES" FALLEN HEROES POST OFFICE BUILDING.

(a) DESIGNATION.—The facility of the United States Postal Service located at 560 East Pleasant Valley Road, Port Hueneme, California, shall be known and designated as the "U.S. Naval Construction Battalion 'Seabees' Fallen Heroes Post Office Building".

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in subsection (a) shall be deemed to be a reference to the "U.S. Naval Construction Battalion 'Seabees' Fallen Heroes Post Office Building".

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentlewoman from the Virgin Islands (Ms. PLASKETT) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

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

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

There was no objection.

Mr. GOSAR. I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 6138, introduced by the gentlewoman from California (Ms. BROWNLEY). The bill designates a post office in Port Hueneme, California, as the U.S. Naval Construction Battalion "Seabees" Fallen Heroes Post Office Building.

The Seabees were founded during World War II to help complete construction projects, such as airstrips and bridges necessary to help U.S. servicemen win the war. These brave servicemen and -women have since risked their lives in many conflicts to build bases, roadways, airstrips, and other construction projects, often in combat zones while under fire.

I look forward to hearing more about the achievements of the Seabees from the gentlewoman from California (Ms. BROWNLEY). For now, I urge Members to support the bill.

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

Ms. PLASKETT. I yield myself such time as I may consume.

Mr. Speaker, I rise today in strong support of H.R. 6138, a bill to designate the facility of the United States Postal Service located at 560 East Pleasant Valley Road, Port Hueneme, California, as the U.S. Naval Construction Battalion "Seabees" Fallen Heroes Post Office Building.

For over 70 years, the Seabees have provided critical naval construction capabilities during times of war. They assisted in the Normandy invasion during World War II, cut a mountain in half, and carved through a jungle to build a runway during the Korean war, constructed military facilities during

the Vietnam and gulf wars, and supported combat forces in Iraq. Today they continue to build and maintain bases and infrastructure for coalition forces in the global war on terror.

In addition to their military support, the Seabees have also provided vital humanitarian assistance around the world in times of peace. They have helped rebuild after devastating earthquakes, such as the one in Haiti in 2010, and they have led various construction projects in a number of undeveloped countries.

Mr. Speaker, we should pass this bill to honor the brave men and women who have played such an important role in both our military and humanitarian efforts around the globe. I urge my colleagues to support H.R. 6138.

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

Mr. GOSAR. I reserve the balance of my time.

Ms. PLASKETT. Mr. Speaker, I yield such time as she may consume to the gentlewoman from California (Ms. BROWNLEY).

Ms. BROWNLEY of California. Mr. Speaker, as the very proud representative of Naval Base Ventura County, the West Coast home of the Navy Seabees, I rise today in support of H.R. 6138, which would designate the United States Postal Office in Port Hueneme, California, as the U.S. Naval Construction Battalion "Seabees" Fallen Heroes Post Office Building.

My bill is intended to honor the many brave men and women of the U.S. Naval Construction Battalion, also known as the Seabees, who have made the ultimate sacrifice for our freedom. In their more than 70-year history, the Seabees have diligently and honorably served our great Nation in times of war and peace with their renowned can-do spirit. They say: "The difficult we do immediately. The impossible takes a little longer."

First established in 1942 after the attack on Pearl Harbor, the Seabees were created to meet the demand for capable builders who could also fight. Their motto is "We build, we fight." During World War II, over 250,000 Seabees passed through the Naval Construction Battalion Center at Port Hueneme on their way to or from the Pacific theater.

The Seabees also played vital roles in the Korean war, the Vietnam war, the Persian Gulf war, the Iraq war, and in Afghanistan, moving the immovable and taming the untamable to build bases, roadways, airstrips, and other critical infrastructure necessary for our troops to succeed in their missions.

Although primarily known as builders, many Seabees fought tenaciously throughout these conflicts, side by side with other servicemembers. For instance, Construction Mechanic Third Class Marvin Glenn Shields, who trained at Port Hueneme, battled bravely alongside U.S. Special Forces in the Battle of Dong Xoai in Vietnam despite being badly wounded. Ignoring

his wounds, Marvin helped return a wounded special forces second lieutenant back to safety while destroying a Viet Cong machine gun emplacement. His bravery and heroism cost him his life. For his conspicuous gallantry, Marvin was awarded the Medal of Honor after his death.

My bill would honor the contributions of all of our fallen Seabees to our Nation. I am both honored and proud to lead this effort to recognize the heroism of many brave Seabees like Marvin Shields who have paid so dearly for our freedom. We are forever indebted to them for their immense service to our Nation.

Finally, I would like to thank the chair and ranking member of the Committee on Oversight and Government Reform for supporting my bill, as well as my colleagues from California who are all cosponsors of the bill. I urge my colleagues to support H.R. 6138.

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

Mr. GOSAR. Mr. Speaker, I urge the adoption of the bill. I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 6138.

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

A motion to reconsider was laid on the table.

DR. ROSCOE C. BROWN, JR. POST OFFICE BUILDING

Mr. GOSAR. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6282) to designate the facility of the United States Postal Service located at 2024 Jerome Avenue, in Bronx, New York, as the "Dr. Roscoe C. Brown, Jr. Post Office Building".

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6282

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

SECTION 1. DR. ROSCOE C. BROWN, JR. POST OFFICE BUILDING.

(a) DESIGNATION.—The facility of the United States Postal Service located at 2024 Jerome Avenue, in Bronx, New York, shall be known and designated as the "Dr. Roscoe C. Brown, Jr. Post Office Building".

(b) REFERENCES.—Any reference in a law, map, regulation, document, paper, or other record of the United States to the facility referred to in subsection (a) shall be deemed to be a reference to the "Dr. Roscoe C. Brown, Jr. Post Office Building".

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Arizona (Mr. GOSAR) and the gentlewoman from the Virgin Islands (Ms. PLASKETT) each will control 20 minutes.

The Chair recognizes the gentleman from Arizona.

GENERAL LEAVE

Mr. GOSAR. Mr. Speaker, I ask unanimous consent that all Members may

have 5 legislative days in which to revise and extend their remarks and include extraneous material on the bill under consideration.

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

There was no objection.

Mr. GOSAR. I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 6282, introduced by the gentleman from New York (Mr. SERRANO). The bill designates a post office in the Bronx, New York, as the Dr. Roscoe C. Brown, Jr. Post Office Building.

As a member of the Tuskegee Airmen in World War II, Dr. Brown was the first African American fighter pilot to shoot down a German fighter jet. After serving in World War II, Dr. Brown earned his Ph.D. at New York University, where he later taught, and served as the president of Bronx Community College.

His service to the Nation is admirable, and I look forward to learning more about his extraordinary life from my colleague, the gentleman from New York (Mr. SERRANO).

I urge Members to support the bill.

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

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

Mr. Speaker, I rise today in strong support of H.R. 6282, a bill to designate the facility of the United States Postal Service located at 2024 Jerome Avenue, in the Bronx, New York, as the Dr. Roscoe C. Brown, Jr. Post Office Building.

Born in 1922, Dr. Roscoe Brown, Jr. fell in love with aviation after visiting the Smithsonian Institution. During World War II, Dr. Brown joined the Tuskegee Airmen, conducting 68 missions and becoming the first African American fighter pilot to shoot down a German fighter jet. He earned the Distinguished Flying Cross for his service, and, in 2007, Dr. Brown and his fellow remaining Tuskegee Airmen were awarded the Congressional Gold Medal by President George W. Bush.

Following his honorable military service, Dr. Brown earned his Ph.D. at New York University and served as the president of Bronx Community College for 17 years. He also served as an informal adviser to many political leaders in New York City and founded 100 Black Men, an organization dedicated to improving conditions for African Americans.

Mr. Speaker, we should pass H.R. 6282 to commemorate the selflessness exhibited by Dr. Roscoe Brown, Jr.'s military and community service. I urge my colleagues to support this bill.

I reserve the balance of my time.

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

Ms. PLASKETT. Mr. Speaker, I yield such time as he may consume to the gentleman from New York (Mr. SERRANO).

(Mr. SERRANO asked and was given permission to revise and extend his remarks.)

Mr. SERRANO. I thank the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 6282.

Mr. Speaker, I rise today to urge my colleagues to pass H.R. 6282. This legislation will rename the Morris Heights Post Office in the Bronx, New York, in my district, after a legend. Dr. Roscoe Brown was a giant among men and a revered figure in the Bronx, New York City, and the Nation.

□ 1645

I had the privilege of knowing Dr. Brown for decades and considered him a dear friend. He faced the horrors of segregation early in his life, but he never let that stop him from achieving what he wanted and set out to do.

Dr. Brown was a fearless Tuskegee Airman during World War II, conducting some 68 missions and becoming one of the first fighters to shoot down a German fighter jet. The heroism he displayed paved the way for the desegregation of the Armed Forces and, decades later, earned him and his fellow airmen a Congressional Gold Medal.

After the war, he went on to further his studies at New York University, where he eventually served as a professor and an academic of the highest caliber. For 17 years, Dr. Brown served as president of Bronx Community College, which is located in my district, leading an institution that gave hope of a better life through education to a predominantly minority and nontraditional student population.

Throughout his life, Dr. Brown was a quiet, yet fierce advocate and leader that many turned to during the racial discord that plagued the city of New York in the sixties and seventies. His activism in the civil rights movement led him to start 100 Black Men, a civic organization devoted to improving the treatment of African Americans in New York.

Dr. Brown was also an avid runner and participated in nine New York City Marathons. During his tenure at Bronx Community College, he established the Annual Hall of Fame 5K and 10K races to help benefit the school. His invitation to participate in one of those races inspired me to start running myself, and I have now run that particular race for more than 30 years.

While his accomplishments and contributions are far too numerous to list, it is fair to say that Dr. Brown left the world around him in a much better place than which he found it. He was a unique individual with a great smile, a great sense of humor, and a great sense of history. Above all, he was a coalition builder. No one was too far for him to speak to or to bring close to him.

We will miss him, and I know that he is looking on us today. This is a small but very important tribute for a great man, Dr. Roscoe Brown.

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

Mr. GOSAR. Mr. Speaker, I urge adoption of the bill.

I yield back the balance of my time. The SPEAKER pro tempore. The question is on the motion offered by

the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill, H.R. 6282.

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

A motion to reconsider was laid on the table.

MERCHANT MARINE OF WORLD WAR II CONGRESSIONAL GOLD MEDAL ACT

Mr. HUIZENGA of Michigan. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 2992) to award a Congressional Gold Medal, collectively, to the U.S. Merchant Marine of World War II, in recognition of their dedicated and vital service during World War II.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 2992

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 "Merchant Marine of World War II Congressional Gold Medal Act".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) 2015 marks the 70th anniversary of the Allied victory in World War II and the restoration of peacetime across the European and Pacific theaters.

(2) The United States Merchant Marine was integral in providing the link between domestic production and the fighting forces overseas, providing combat equipment, fuel, food, commodities, and raw materials to troops stationed overseas.

(3) Fleet Admiral Ernest J. King acknowledged the indispensability of the Merchant Marine to the victory in a 1945 letter stating that without their support, "the Navy could not have accomplished its mission".

(4) President and former Supreme Commander of the Allied Forces, Dwight D. Eisenhower, acknowledged that "through the prompt delivery of supplies and equipment to our armed forces overseas, and of cargoes representing economic and military aid to friendly nations, the American Merchant Marine has effectively helped to strengthen the forces of freedom throughout the world".

(5) Military missions and war planning were contingent upon the availability of resources and that the United States Merchant Marine played a vital role in this regard, ensuring the efficient and reliable transoceanic transport of military equipment as well as both military and civilian personnel.

(6) The United States Merchant Marine provided for the successful transport of resources and personnel despite consistent and ongoing exposure to enemy combatants from both the air and the sea, such as enemy bomber squadrons, submarines, and mines.

(7) The efforts of the United States Merchant Marine were not without sacrifices as they bore a higher per capita casualty rate than any other branch of the military during the war.

(8) The United States Merchant Marine proved to be an instrumental asset on untold occasions, participating in every landing operation by the United States Marine Corps from Guadalcanal to Iwo Jima as well as providing, for instance, the bulk tonnage of material necessary for the invasion of Nor-

mandy which "would not have been possible without the Merchant Marine", as a 1944 New York Times article observed.

(9) In also assessing their performance, General Dwight D. Eisenhower stated, "every man in this Allied command is quick to express his admiration for the loyalty, courage, and fortitude of the officers and men of the Merchant Marine. We count upon their efficiency and their utter devotion to duty as we do our own; they have never failed us".

(10) During a September 1944 speech, President Franklin D. Roosevelt stated, the Merchant Marine has "delivered the goods when and where needed in every theater of operations and across every ocean in the biggest, the most difficult, and dangerous transportation job ever undertaken. As time goes on, there will be greater public understanding of our merchant fleet's record during this war."

(11) The feats and accomplishments of the Merchant Marine are deserving of broader public recognition.

(12) The United States will be forever grateful and indebted to the U.S. Merchant Marine for their effective, reliable, and courageous transport of goods and resources in enemy territory throughout theaters of every variety in World War II; that these goods and resources saved thousands of lives and enabled the Allied Powers to claim victory in World War II.

(13) The Congressional Gold Medal will be an appropriate way to shed further light on the service of the Merchant Marine in World War II and the instrumental role they played in winning World War II.

SEC. 3. CONGRESSIONAL GOLD MEDAL.

(a) AWARD AUTHORIZED.—The Speaker of the House of Representatives and the President pro tempore of the Senate shall make appropriate arrangements for the award, on behalf of the Congress, of a single gold medal of appropriate design to the U.S. Merchant Marine of World War II, in recognition of their dedicated and vital service during World War II.

(b) DESIGN AND STRIKING.—For the purposes of the award referred to in subsection (a), the Secretary of the Treasury (hereafter referred to as the "Secretary") shall strike the gold medal with suitable emblems, devices, and inscriptions, to be determined by the Secretary.

(c) AMERICAN MERCHANT MARINE MUSEUM.—

(1) IN GENERAL.—Following the award of the gold medal in honor of the U.S. Merchant Marine, the gold medal shall be given to the American Merchant Marine Museum, where it will be available for display as appropriate and available for research.

SEC. 4. DUPLICATE MEDALS.

Under such regulations as the Secretary may prescribe, the Secretary may strike and sell duplicates in bronze of the gold medal struck under section 3, at a price sufficient to cover the costs of the medals, including labor, materials, dies, use of machinery, and overhead expenses.

SEC. 5. STATUS OF MEDALS.

(a) NATIONAL MEDALS.—Medals struck pursuant to this Act are national medals for purposes of chapter 51 of title 31, United States Code.

(b) NUMISMATIC ITEMS.—For purposes of section 5134 of title 31, United States Code, all medals struck under this Act shall be considered to be numismatic items.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. HUIZENGA) and the gentleman from Illinois (Mr. FOSTER) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan.

GENERAL LEAVE

Mr. HUIZENGA of Michigan. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on the bill.

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

There was no objection.

Mr. HUIZENGA of Michigan. Mr. Speaker, merchant mariners act as an auxiliary to the U.S. Navy and are recognized as an integral link between domestic production and forces overseas, delivering combat equipment, food, fuel, raw materials, and commodities to those stationed abroad.

Military success in World War II hinged on the merchant marine delivering these resources and provisions of transport to military and civilian personnel, sailing while exposed to enemy combatants by both air and by sea. During World War II, these merchant mariners suffered the highest per capita casualty rate of any other branch in the U.S. Armed Forces. It is estimated that hundreds of mariner ships and thousands of mariners were lost to enemy combatants as a result of their service during World War II.

Yet, Mr. Speaker, the merchant marine is rarely mentioned when people list the military branches of service during the war. I rise today to help remedy that oversight by supporting H.R. 2992, the Merchant Marine of World War II Congressional Gold Medal Act, introduced by our colleague, Representative SUSAN BROOKS. This bill, which has 312 House cosponsors, would award a single Congressional Gold Medal to the American Merchant Marine of World War II in the recognition of their dedicated and vital service. After the medal is awarded, it will be given to the American Merchant Marine Museum, which is housed within the United States Merchant Marine Academy at Kings Point, New York.

The Treasury Secretary is authorized to make and offer for sale bronze replicas of the medal at a price that will help defray the design and production costs of the actual medal. A companion bill in the Senate, S. 2989, has been introduced by Senator LISA MURKOWSKI.

Mr. Speaker, the merchant marine has contributed greatly to every war in which this country has been involved, beginning with the Revolutionary War and continuing right up until today. Its efforts during peacetime helped carry millions of tons of cargo and countless passengers, but the merchant marines' efforts in lightly guarded ships on the dangerous waters of the Atlantic and Pacific during the Second World War were invaluable to the overall war effort.

President Franklin Roosevelt summed it up succinctly: they delivered the goods.

Now, Mr. Speaker, it is our turn to deliver the goods for those heroes who

have so often gone unnoticed. I urge immediate passage of this bill.

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

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

Mr. Speaker, I rise in support of H.R. 2992, legislation to honor the dedicated and unwavering service provided by the U.S. Merchant Marine during World War II, a bill that I am proud to co-sponsor. I hope that, upon its passage in the House, the Senate will move quickly to take it up and pass this bill before the 114th Congress adjourns.

While many are familiar with the sacrifices made by those who served in the Armed Forces during World War II, less often do we stop and take time to recognize the members of the U.S. Merchant Marine who played an essential role in supplying our troops overseas with the equipment, food, and materials necessary to sustain the fight against the Axis powers.

Despite the unrelenting threat of attack and the risk to their lives, the U.S. Merchant Marine proved to be an invaluable asset on innumerable occasions, participating in every landing operation by the United States Marine Corps during the war.

In speaking of the brave contributions made by the U.S. Merchant Marine, President Franklin Roosevelt said that the Merchant Marine "delivered the goods when and where needed in every theater of operations and across every ocean in the biggest, the most difficult, and dangerous transportation job ever undertaken." President Roosevelt also said that "as time goes on, there will be greater public understanding of our merchant fleet's record during this war."

In fact, during a recent visit to the National World War II Museum in New Orleans, Louisiana, I was pleased and proud to see the proper and impressive display dedicated to the role of the merchant marine in that war. Indeed, more than 70 years after President Roosevelt spoke those words, the House is taking an important step today to honor and to shed light on the contributions of the merchant marines made during World War II.

To further the public's understanding of the role the merchant marines played in securing the defeat of the Axis powers, the legislation will ensure that the Gold Medal will be given to the American Merchant Marine Museum, where it will be available for viewing by the public.

I urge my colleagues to support this legislation before us.

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

Mr. HUIZENGA of Michigan. Mr. Speaker, I yield such time as she may consume to the gentlewoman from Indiana (Mrs. BROOKS).

Mrs. BROOKS of Indiana. Mr. Speaker, I rise today in support of H.R. 2992, the Merchant Marine of World War II Congressional Gold Medal Act. This measure awards a Congressional Gold

Medal to the merchant mariners who served during World War II in appreciation of their dedicated and vital service to our Nation.

I also want to thank my colleague from across the aisle, Congresswoman JANICE HAHN of California's 44th District, who worked with me and other Members here in the House to secure so many cosponsorships of this bill.

The Congressional Gold Medal is the highest honor Congress can bestow upon an individual or group, and these brave servicemen deserve such an honor. The merchant marine was the linchpin connecting the fighting forces overseas with the production forces at home. In the face of certain peril, these brave mariners provided efficient and reliable transport of combat equipment, fuel, food, commodities, personnel, and raw materials that were pivotal in the allied victory.

Oftentimes forgotten, merchant mariners took part in every invasion from Normandy to Okinawa. Never before had the maritime power of America been so effectively utilized. The total cargo lift transported by the mariners totaled over 300 million tons. They transported the great majority of the thousands of military personnel and civilians who traveled overseas during the war and those returning to America after triumphant victories.

Risking their lives to provide the needed supplies for the war, merchant ships faced danger from submarines, mines, armed raiders and destroyers, aircraft, kamikaze attacks, and the elements from Mother Nature.

With an estimated 9,300 total casualties, the merchant marines bore a higher per capita casualty rate than any other branch in the U.S. Armed Forces during World War II. On top of that, about 11,000 mariners were wounded in action and 663 were taken prisoners of war.

Yet, despite these heroic efforts, they were not recognized as veterans until 1988, and they never received the benefits that other World War II veterans received under the GI bill. They came home from the war without recognition for their service and still, to this day, their service is often overlooked.

Today, there are less than 5,000 surviving World War II mariners, and with nearly 500 World War II veterans dying each day, it is more important than ever to recognize these brave achievements today.

Mr. Speaker, the merchant mariners provided the greatest sealift in history and became the difference between victory and defeat. These loyal and brave men put their lives on the line for the cause of freedom and selflessly answered their Nation's call to duty. It is time we give these courageous mariners the recognition they have earned with the Congressional Gold Medal.

I am proud that 312 of my colleagues agreed and are cosponsors of this bill. Now it is time to get it across the finish line, pay respect to these deserving veterans, and recognize the sacrifices

and contributions of this brave group. I urge passage of the bill.

Mr. FOSTER. Mr. Speaker, I have no further requests for time, and I urge my colleagues to support this bill.

I yield back the balance of my time.

Mr. HUIZENGA of Michigan. Mr. Speaker, I, too, have no further speakers.

I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. HUIZENGA) that the House suspend the rules and pass the bill, H.R. 2992.

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

A motion to reconsider was laid on the table.

FILIPINO VETERANS OF WORLD WAR II CONGRESSIONAL GOLD MEDAL ACT OF 2015

Mr. HUIZENGA of Michigan. Mr. Speaker, I move to suspend the rules and pass the bill (S. 1555) to award a Congressional Gold Medal, collectively, to the Filipino veterans of World War II, in recognition of the dedicated service of the veterans during World War II.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 1555

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 "Filipino Veterans of World War II Congressional Gold Medal Act of 2015".

SEC. 2. FINDINGS.

Congress finds the following:

(1) The First Philippine Republic was founded as a result of the Spanish-American War in which Filipino revolutionaries and the United States Armed Forces fought to overthrow Spanish colonial rule. On June 12, 1898, Filipinos declared the Philippines to be an independent and sovereign nation. The Treaty of Paris negotiated between the United States and Spain ignored this declaration of independence, and the United States paid Spain \$20,000,000 to cede control of the Philippines to the United States. Filipino nationalists who sought independence rather than a change in colonial rulers clashed with forces of the United States in the Islands. The Philippine-American War, which officially lasted for 3 years from 1899 to 1902, led to the establishment of the United States civil government in the Philippines.

(2) In 1901, units of Filipino soldiers who fought for the United States against the nationalist insurrection were formally incorporated into the United States Army as the Philippine Scouts.

(3) In 1934, the Philippine Independence Act (Public Law 73-127; 48 Stat. 456) established a timetable for ending colonial rule of the United States. Between 1934 and Philippine independence in 1946, the United States retained sovereignty over Philippine foreign policy and reserved the right to call Filipinos into the service of the United States Armed Forces.

(4) On December 21 1935, President of the Philippine Commonwealth, Manuel Quezon,

signed the National Defense Act, passed by the Philippine Assembly. General Douglas MacArthur set upon the task of creating an independent army in the Philippines, consisting of a small regular force, the Philippine Constabulary, a police force created during the colonial period of the United States, and reservists. By July 1941, the Philippine army had 130,000 reservists and 6,000 officers.

(5) On July 26, 1941, as tensions with Japan rose in the Pacific, President Franklin D. Roosevelt used his authority vested in the Constitution of the United States and the Philippine Independence Act to "call into service of the United States . . . all of the organized military forces of the Government of the Philippines." On July 27th, 1941, in accordance with a War Department directive received a day earlier, the United States Forces in the Far East (USAFFE) was established, and Manila was designated as the command headquarters. Commander of the USAFFE, General Douglas MacArthur, planned to absorb the entire Philippine army into the USAFFE in phases. The first phase, which began on September 1, 1941, included 25,000 men and 4,000 officers.

(6) Filipinos who served in the USAFFE included—

(A) the Philippine Scouts, who comprised half of the 22,532 soldiers in the Philippine Department, or United States Army garrison stationed in the Islands at the start of the war;

(B) the Philippine Commonwealth Army;

(C) the new Philippine Scouts, or Filipinos who volunteered to serve with the United States Army when the United States Armed Forces returned to the island;

(D) Filipino civilians who volunteered to serve in the United States Armed Forces in 1945 and 1946, and who became "attached" to various units of the United States Army; and

(E) the "Guerrilla Services" who had fought behind enemy lines throughout the war.

(7) Even after hostilities ceased, wartime service of the new Philippine Scouts continued as a matter of law until the end of 1946, and the force gradually disbanded until it was disestablished in 1950.

(8) On December 8th, 1941, not even 24 hours after the bombing of Pearl Harbor, Japanese Imperial forces attacked bases of the United States Army in the Philippines.

(9) In the spring of 1942, the Japanese 14th Army overran the Bataan Peninsula, and, after a heroic but futile defense, more than 78,000 members of the United States Armed Forces were captured, specifically 66,000 Filipinos and 12,000 service members from the United States. The Japanese transferred the captured soldiers from Bataan to Camp O'Donnell, in what is now known as the infamous Bataan Death March. Forced to march the 70-mile distance in 1 week, without adequate food, water, or medicine, nearly 700 members of the United States Armed Forces and an estimated 6,000 to 10,000 Filipinos perished during the journey.

(10) After the fall of the Bataan Peninsula, the Japanese Army turned its sights on Corregidor. The estimated forces in defense of Corregidor totaled 13,000, and were comprised of members of the United States Armed Forces and Filipino troops. Of this number, 800 were killed, 1,000 were wounded, and 11,000 were captured and forced to march through the city of Manila, after which the captured troops were distributed to various POW camps. The rest of the captured troops escaped to organize or join an underground guerrilla army.

(11) Even before the fall of Corregidor, Philippine resistance, in the form of guerrilla armies, began to wage warfare on the

Japanese invaders. Guerrilla armies, from Northern Luzon to Mindanao—

(A) raided Japanese camps, stealing weapons and supplies;

(B) sabotaged and ambushed Japanese troops on the move; and

(C) with little weaponry, and severely outnumbered in numbers, began to extract victories.

(12) Japanese intelligence reports reveal that from the time the Japanese invaded until the return of the United States Armed Forces in the summer of 1944, an estimated 300,000 Filipinos continued to fight against Japanese forces. Filipino resistance against the Japanese was so strong that, in 1942, the Imperial Army formed the Morista Butai, a unit designated to suppress guerrillas.

(13) Because Philippine guerrillas worked to restore communication with United States forces in the Pacific, General MacArthur was able to use the guerrillas in advance of a conventional operation and provided the headquarters of General MacArthur with valuable information. Guerrillas captured and transmitted to the headquarters of General MacArthur Japanese naval plans for the Central Pacific, including defense plans for the Mariana Islands. Intelligence derived from guerrillas relating to aircraft, ship, and troop movements allowed for Allied forces to attack Japanese supply lines and guerrillas and even directed United States submarines where to land agents and cargo on the Philippine coast.

(14) On December 20, 1941, President Roosevelt signed the Selective Training and Service Amendments Act (Public Law 77-360; 55 Stat. 844) which, among other things, allowed Filipinos in the United States to enlist in the United States Armed Forces. In February 1942, President Roosevelt issued the Second War Powers Act (Public Law 77-507; 56 Stat. 176), promising a simplified naturalization process for Filipinos who served in the United States Armed Forces. Subsequently, 16,000 Filipinos in California alone decided to enlist.

(15) The mobilization of forces included the activation and assumption of command of the First Filipino Infantry Battalion on April 1, 1942, at Camp San Luis Obispo, California. Orders were issued to activate the First Filipino Infantry Regiment and Band at Salinas, California, effective July 13, 1942. The activation of the Second Filipino Infantry Regiment occurred at Fort Ord, California, on November 21, 1942. Nearly 9,000 Filipinos and Filipino Americans fought in the United States Army 1st and 2nd Filipino Infantry Regiments.

(16) Soldiers of the 1st and 2nd Infantry Regiments participated in the bloody combat and mop-up operations at New Guinea, Leyte, Samar, Luzon, and the Southern Philippines. In 1943, 800 men were selected from the 1st and 2nd Regiments and shipped to Australia to receive training in intelligence gathering, sabotage, and demolition. Reorganized as part of the 1st Reconnaissance Battalion, this group was sent to the Philippines to coordinate with major guerrilla armies in the Islands. Members of the 1st Regiment were also attached to the United States 6th Army "Alamo Scouts", a reconnaissance group that traveled 30 miles behind enemy lines to free Allied prisoners from the Cabatuan death camp on January 30, 1945. In addition, in 1945, according to the 41st Counter Intelligence Unit of the United States Armed Forces, Philippine guerrillas provided "very important information and sketches of enemy positions and installations" for the liberation of the Santo Tomas prisoner of war camp, an event that made front page news across the United States.

(17) In March 1944, members of the 2nd Filipino Infantry Regiment were selected for

special assignments, including intelligence missions, and reorganized as the 2nd Filipino Infantry Battalion (Separate). The 2nd Filipino Infantry Battalion (Separate) contributed to mop-up operations as a civil affairs unit.

(18) Filipinos participated in the war out of national pride, as well as out of a commitment to the Allied forces struggle against fascism. 57,000 Filipinos in uniform died in the war effort. Estimates of civilian deaths range from 700,000 to upwards of 1,000,000, or between 4.38 to 6.25 percent of the prewar population of 16,000,000.

(19) Because Filipinos who served in the Commonwealth Army of the Philippines were originally considered a part of the Allied struggle, the military order issued by President Roosevelt on July 26, 1941, stated that Filipinos who served in the Commonwealth Army of the Philippines were entitled to full veterans benefits. The guarantee to pay back the service of Filipinos through veterans benefits was reversed by the Rescission Acts of 1946 (Public Laws 79-301 and 79-391; 60 Stat. 6 and 60 Stat. 221), which deemed that the wartime service of the Commonwealth Army of the Philippines and the new Philippine Scouts was not considered active and, therefore, did not qualify for benefits.

(20) The loyal and valiant Filipino Veterans of World War II fought, suffered, and, in many instances, died in the same manner and under the same commander as other members of the United States Armed Forces during World War II.

(21) The Filipino Veterans of World War II fought alongside, and as an integral part of, the United States Armed Forces. The Philippines remained a territory of the United States for the duration of the war and, accordingly, the United States maintained sovereignty over Philippine foreign relations, including Philippine laws enacted by the Philippine Government. Filipinos who fought in the Philippines were not only defending or fighting for the Philippines, but also defending, and ultimately liberating, sovereign territory held by the United States Government.

(22) The United States remains forever indebted to the bravery, valor, and dedication that the Filipino Veterans of World War II displayed. Their commitment and sacrifice demonstrates a highly uncommon and commendable sense of patriotism and honor.

SEC. 3. DEFINITIONS.

In this Act—

(a) the term “Filipino Veterans of World War II” includes any individual who served—

(1) honorably at any time during the period beginning on July 26, 1941, and ending on December 31, 1946;

(2) in an active-duty status under the command of the United States Armed Forces in the Far East; and

(3)(A) within the Philippine Commonwealth Army, the Philippine Scouts, the Philippine Constabulary, Recognized Guerrilla units, the New Philippine Scouts, the First Filipino Infantry Regiment, the Second Filipino Infantry Battalion (Separate), or the First Reconnaissance Battalion; or

(B) commanding or serving in a unit described in paragraph (3)(A) as a United States military officer or enlisted soldier; and

(b) the term “Secretary” means the Secretary of the Treasury.

SEC. 4. CONGRESSIONAL GOLD MEDAL.

(a) AWARD AUTHORIZED.—The President pro tempore of the Senate and the Speaker of the House of Representatives shall make appropriate arrangements for the award, on behalf of Congress, of a single gold medal of appropriate design to the Filipino Veterans of World War II in recognition of the dedicated service of the veterans during World War II.

(b) DESIGN AND STRIKING.—For the purposes of the award referred to in subsection (a), the Secretary shall strike the Gold Medal with suitable emblems, devices, and inscriptions, to be determined by the Secretary.

(c) SMITHSONIAN INSTITUTION.—

(1) IN GENERAL.—Following the award of the gold medal in honor of the Filipino Veterans of World War II, the gold medal shall be given to the Smithsonian Institution, where it will be available for display as appropriate and made available for research.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Smithsonian Institution should make the gold medal received under paragraph (1) available for display elsewhere, particularly at other appropriate locations associated with the Filipino Veterans of World War II.

(d) DUPLICATE MEDALS.—

(1) IN GENERAL.—Under regulations that the Secretary may promulgate, the Secretary may strike and sell duplicates in bronze of the gold medal struck under this Act, at a price sufficient to cover the costs of the medals, including labor, materials, dies, use of machinery, and overhead expenses.

(2) SALE OF DUPLICATE MEDALS.—The amounts received from the sale of duplicate medals under paragraph (1) shall be deposited in the United States Mint Public Enterprise Fund.

SEC. 5. STATUS OF MEDALS.

(a) NATIONAL MEDALS.—Medals struck under this Act are national medals for purposes of chapter 51 of title 31, United States Code.

(b) NUMISMATIC ITEMS.—For purposes of section 5134 of title 31, United States Code, all medals struck under this Act shall be considered to be numismatic items.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. HUIZENGA) and the gentleman from Illinois (Mr. FOSTER) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan.

GENERAL LEAVE

Mr. HUIZENGA of Michigan. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on the bill.

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

There was no objection.

Mr. HUIZENGA of Michigan. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, this is a special one for me, personally. I rise today in support of S. 1555, the Filipino Veterans of World War II Congressional Gold Medal Act of 2015, introduced by Senator HIRONO.

□ 1700

This bill, which was passed in the Senate on July 13, has companion legislation here in the House, H.R. 2737, introduced by our colleague, Representative GABBARD, which has 312 House cosponsors.

The reason why it is a special one to me is I have spent significant time in the Philippines and have many close Filipino friends, and know the dedication of the Philippines collectively,

and those families who paid an ultimate sacrifice during World War II. I have actually visited our World War II cemetery in Manila, and have seen the headstones and gravestones of many Filipinos who were there fighting alongside of us as well. That is why it is a special opportunity for me, as chair of the subcommittee that has jurisdiction over this, to be involved.

So this bill authorizes the striking and awarding of a single Congressional Gold Medal of appropriate design to the Filipino Veterans of World War II in recognition of their heroic and dedicated service. Following the award, the medal will be given to the Smithsonian Institute, where it will be available for display as appropriate, or available for display elsewhere, particularly at other locations associated with the Filipino Veterans of World War II.

The Treasury Secretary is authorized to make and offer for sale bronze replicas of the medal at a price that will help defray the design and production costs of the actual medal.

Mr. Speaker, Japanese Imperial forces attacked the Philippines the day after bombing the U.S. base at Pearl Harbor almost exactly 75 years ago on December 7, 1941. At that point, the Philippines still were a United States colony, though the process that led to its independence in 1946 actually began in 1934.

Fortunately, the Philippines formed its own armed forces. Four months before the Pearl Harbor attack, President Roosevelt brought the 136,000 members of the force into a full state of readiness to defend the U.S. and its territories and colonies.

I will leave it to the House sponsor of the companion bill to describe the heroism of those soldiers and the sacrifices that they made in defense of the United States and their homeland; but suffice it to say that it was a difficult and costly defense that they waged.

I will note that our embassy sits right on the bay in Manila today and overlooks Corregidor and so many other places there in the Philippines that were witness to those battles, including my own uncle who, at the time, served in the Navy and helped deliver goods and services throughout the Pacific and into the Philippines as well.

Mr. Speaker, Congress has authorized Congressional Gold Medals in recognition of the heroic efforts of Japanese Americans, Native Americans, and Puerto Rican soldiers, among others, in defense of this country during World War II and in other conflicts. This recognition of Filipino veterans of World War II is long overdue, and I urge immediate passage of the bill.

I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON HOUSE ADMINISTRATION,
Washington, DC, November 30, 2016.

Hon. JEB HENSARLING,
Chairman, Committee on Financial Services,
Washington, DC.

DEAR MR. CHAIRMAN: I write to you regarding S. 1555. As you know, the bill was received in the House of Representatives on

July 17, 2016 and referred to the Committee on Financial Services and in addition to the Committee on House Administration. The bill seeks to award a Congressional Gold Medal, collectively, to the Filipino veterans of World War II, in recognition of the dedicated service of the veterans during World War II. S. 1555 passed the Senate without amendment by unanimous consent on July 13, 2016.

I realize that discharging the Committee on House Administration from further consideration of S. 1555 will serve in the best interest of the House of Representatives and agree to do so. It is the understanding of the Committee on House Administration that forgoing action on S. 1555 will not prejudice the Committee with respect to appointment of conferees or any future jurisdictional claim. I request that this letter and any response be included in the Congressional Record.

Sincerely,

CANDICE S. MILLER,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON FINANCIAL SERVICES,
Washington, DC, November 30, 2016.

Hon. CANDICE MILLER,
*Chairman, Committee on House Administration,
Washington, DC.*

DEAR CHAIRMAN MILLER: Thank you for your November 30th letter regarding S. 1555, the "Filipino Veterans of World War II Congressional Gold Medal Act of 2015."

I am most appreciative of your decision to forego action on S. 1555 so that it may move expeditiously to the House floor. I acknowledge that although you are waiving action on the bill, the Committee on House Administration is in no way waiving its jurisdictional interest in this or similar legislation. In addition, if a conference is necessary on this legislation, I will support any request that your committee be represented therein.

Finally, I shall be pleased to include your letter and this letter on S. 1555 in the Congressional Record during floor consideration of the same.

Sincerely,

JEB HENSARLING,
Chairman.

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

I rise today in strong support of S. 1555, legislation to award a Congressional Gold Medal collectively to the Filipino Veterans of World War II in recognition of their service and sacrifice and their role in defeating the Imperial Japanese Army.

While we are taking up the Senate-passed version of the Filipino Veterans of World War II Congressional Medal Act today, I want to acknowledge the hard work and dedication of the gentlewoman from Hawaii, Representative TULSI GABBARD, who has led the effort to move this same legislation across the finish line here in the House. Since introducing the legislation, Representative GABBARD has garnered the support of more than 300 House cosponsors, and I am proud to be among them.

In 1934, the United States began a 10-year period of bringing its colonial rule to an end. During that time, the U.S. retained control over Philippine foreign policy and maintained the right to call Filipinos into the service of the United States Armed Forces.

As tensions with Japan began to rise in 1941, President Franklin Roosevelt

invoked his authority to call all organized military forces of the Government of the Philippines into the service of the United States. Responding to his call to arms, more than 200,000 Filipinos fought on behalf of the U.S. as part of the United States Armed Forces in the Far East.

The force included the Philippine Scouts, the Philippine Commonwealth Army, the new Philippine Scouts, Filipino civilians who served on a voluntary basis, and the Guerrilla Services who fought behind enemy lines throughout the war.

Over the course of the war, an estimated 57,000 Filipinos in uniform perished, and many more Filipino civilian lives were lost. Despite this loyalty and tremendous sacrifice, and the U.S. commitment to provide Filipinos who served as part of the Allied struggle with full veterans benefits, this promise was shamefully withdrawn by the Rescission Act of 1946 at the close of the war.

While a number of benefits have since been made available to the Filipino veterans, we must continue to work to ensure that those who risked their lives to defend the United States and the free world are provided with the full benefits, honor, and respect that they deserve.

This legislation has the support of the Veterans of Foreign Wars, the Disabled American Veterans, the American Legion, the National Federation of Filipino American Associations, and many other distinguished organizations.

I urge Members to pass this legislation, which takes a modest but welcome step to recognize the contributions of Filipino veterans of World War II.

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

Mr. HUIZENGA of Michigan. Mr. Speaker, I yield such time as he may consume to the gentleman from California (Mr. ROYCE), the chairman of the Foreign Affairs Committee.

Mr. ROYCE. Mr. Speaker, I rise in strong support here for the Filipino Veterans of World War II Congressional Gold Medal Act, and I am one of the proud cosponsors, along with my colleagues here, of this act.

I have had an opportunity over the last couple of years to travel twice to the Philippines. One of them was right after the cyclone hit Tacloban, and we took a delegation there.

As you travel across the islands of the Philippines, it is a constant reminder of the enormity of the sacrifice as you see those battle sites, the enormity of the sacrifice made by this unsung group of heroes who fought so courageously for the defense of our country, during what is really one of the most perilous moments of American history, and their valor and their patriotism is deserving of this recognition from Congress.

I don't think many Americans understand how quickly the reaction across

the Philippines, in terms of Pearl Harbor, more than 250,000 Filipino soldiers responded to President Roosevelt's call to arms to fit under the American flag.

In addition to that, just in my State of California, we had 16,000 Filipino Americans that went forward and enlisted, where the U.S. Army then formed the 1st and 2nd Filipino American Infantry Regiments. That is where those regiments were organized.

On December 8, 1941—and this was not 24 hours after the bombing of Pearl Harbor—it was at that moment in time that the Japanese Imperial forces attacked the U.S. bases in the Philippines. Filipinos and Filipino Americans fought valiantly in the push to regain the Philippines from Imperial Japanese forces.

Mr. Speaker, 57,000 Filipinos in uniform died in the war effort. More than that, among the casualties of those who struggled against Japan, but 50,000 Filipinos in uniform, and they gave their lives in battles such as Bataan and Corregidor; and their sacrifice was absolutely instrumental in disrupting the enemy's advancement in the Pacific.

As President Harry Truman made clear: "They fought as American nationals under the American flag and under the direction of our military leaders. They fought with gallantry and courage under the most difficult conditions. . . ."

So I am honored to rise today in support of recognizing these great heroes. The contributions of the Filipino World War II veterans are a very important part of American military history, and their accomplishments deserve the recognition of the Congressional Gold Medal.

Mr. FOSTER. Mr. Speaker, I yield 5 minutes to the gentlewoman from Hawaii (Ms. GABBARD), the lead sponsor of the House version of this bill.

Ms. GABBARD. Mr. Speaker, I have the privilege of representing the Second Congressional District in Hawaii, a State that has deep cultural roots and ties to the contributions that Filipino Americans have made to our Nation throughout history, from driving Hawaii's plantation-based economy in the early 20th Century, serving in our Armed Forces, to becoming leaders in every industry and sector in our State and across the country.

It is an honor to stand here today as a voice for the more than 200,000 Filipino and Filipino American soldiers that served our country during World War II. These loyal and courageous soldiers suffered, sacrificed, fought, and gave their lives alongside their American counterparts throughout the war.

We have waited far too long to recognize these heroes, who deserve this honor, in standing alongside units like the Tuskegee Airmen and Hawaii's own 442nd/100th Infantry Battalion with being awarded the Congressional Gold Medal, our Nation's highest civilian honor.

With just 18,000 of these Filipino World War II veterans still alive and

with us today, we cannot afford to wait any longer.

I would like to thank the 312 House Members, Republicans and Democrats, and 71 Senators that cosponsored this bipartisan legislation, representing nearly every State and territory in our country.

I also want to say a special mahalo nui loa to my colleagues, Congressman JOE HECK, who is the Republican lead on this legislation; Congresswoman JUDY CHU; and Congressman MIKE HONDA, for working with me to push this bill through the House; and my colleague, Senator MAZIE HIRONO, who is here today; as well as Senator DEAN HELLER, for championing this bill in the Senate; all of our staff; and both Democrat and Republican leadership for their efforts, commitment, and support to passing this legislation.

I would also like to recognize Major General Antonio Taguba, who joins us today in the gallery, and the Filipino Veterans Recognition and Education Project for their years of commitment to this historic effort and for continuing to fight to ensure we remember and recognize the legacy of our Filipino World War II veterans as a critical part of our American history.

Major General Taguba's father, Staff Sergeant Tomas Taguba, was a soldier in the 45th Infantry Regiment Philippine Division that served alongside the U.S. Army during the war, where he fought in the Battle of Bataan. He survived the Bataan Death March.

This legislation is a testament to Staff Sergeant Tomas Taguba, and the hundreds of thousands of Filipino World War II veterans who deserve a place of recognition amongst our greatest generation. Thank you very much to all of you: "Miraming salamat sa inyong lahat."

I urge my colleagues to join me in voting to pass this long overdue legislation today. Time is of the essence. We must honor these courageous men while they are still among us and recognize their dedicated service to our Nation and our history.

The SPEAKER pro tempore. Members are reminded not to reference guests in the gallery.

Mr. HUIZENGA of Michigan. Mr. Speaker, with that admonishment, I won't say Ma-Bu-Hi and welcome to our Filipino friends in the gallery; but I will yield such time as he may consume to the gentleman from Nevada (Mr. HECK), the lead sponsor on the Republican side.

Mr. HECK of Nevada. Mr. Speaker, during my time here in the House of Representatives, each Congressional Session I have introduced the World War II Filipino Veterans Recognition Act in an attempt to restore the benefits that were promised to these brave soldiers by Franklin Delano Roosevelt when they were incorporated into the United States Armed Forces Far East during World War II, but then had those benefits denied by the Rescission Act of 1946.

These soldiers served side by side with American troops. They served under American officers. They bled, fought, and died to protect their homeland on behalf of the United States.

I have had the honor to get to know six of these gentlemen who lived in southern Nevada: Francisco Cedulla; Romeo Barreras; Silverio Cuaresma; Augusto Opus; Bataan Death March survivor, Jesse Baltazar; and Edilberto Briones. Unfortunately, over the last 6 years, five of them have passed on, never receiving the recognition that they justly deserve. That is why this bill is so important.

While it does not justly compensate these brave soldiers for the service that they gave to this country, this bill, S. 1555, and the companion introduced by my good friend, the gentlewoman from Hawaii (Ms. GABBARD), and of which I am the lead cosponsor, is in some small way a recognition of the service rendered by these brave patriots.

□ 1715

It is for that reason that I rise in strong support and urge all of my colleagues to vote in support of S. 1555, so that we can finally pay some level of recognition to those who served side by side with American soldiers under American command.

Mr. FOSTER. Mr. Speaker, I yield 2 minutes to the gentleman from Virginia (Mr. SCOTT), who is the ranking member of the Committee on Education and the Workforce.

Mr. SCOTT of Virginia. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I rise today in support of S. 1555, the Filipino Veterans of World War II Congressional Gold Medal Act of 2015.

Filipino Americans have contributed to American life and culture in countless ways, and one of the most noble is through military service. Over 200,000 Filipino soldiers and guerrilla fighters served with the United States Armed Forces during World War II. Their invaluable service helped provide the necessary support to defeat the Japanese in the Pacific.

For over 60 years, Filipino veterans and community advocates have fought to obtain benefits and recognition that they were promised. In 2009, Congress created the Filipino Veterans Equity Compensation Fund, where eligible veterans who are U.S. citizens could receive a one-time payment of \$15,000; eligible veterans who are not U.S. citizens could receive a one-time payment of \$9,000. While this fund has allowed many of them to receive some compensation, in Congress we are still working to make sure these families get all of the benefits they earned, they deserved and were promised.

Another way that we can recognize these heroes is by awarding them the Congressional Gold Medal. The Senate unanimously passed the Filipino World War II Congressional Gold Medal Act in July. Mr. Speaker, as a cosponsor of the House version of the bill and co-

chair of the U.S.-Philippines Friendship Caucus, I urge my colleagues to support the legislation so that approximately 18,000 surviving Filipino veterans of World War II may be recognized for their service to our Nation. We are forever indebted to these brave soldiers, and it is important that we appropriately express our gratitude for that service.

Mr. Speaker, I therefore urge my colleagues to support the bill.

Mr. FOSTER. Mr. Speaker, I yield 2 minutes to the gentlewoman from California (Ms. JUDY CHU), who is a member of the Judiciary Committee and the chair of the Congressional Asian Pacific American Caucus.

Ms. JUDY CHU of California. Mr. Speaker, over 70 years ago, more than 200,000 brave Filipino and Filipino American soldiers answered the call to fight alongside American servicemembers during World War II. These soldiers served on the front lines and played a critical role in ultimately helping the United States to achieve victory in the Pacific. It is because of their courage that we were able to protect Americans at home while defending democracy abroad. Many of these veterans are now in their twilight years, and it is long past time that we honor them for their sacrifice and service to our Nation.

While we can never fully repay the debt that we owe these veterans, today we have the opportunity to award them with our Nation's highest civilian honor by passing the Filipino Veterans of World War II Congressional Gold Medal Act. I urge my colleagues to join me in voting to pass this critical legislation to honor our Filipino World War II veterans with the recognition they have earned.

Mr. FOSTER. Mr. Speaker, I yield 4 minutes to the gentleman from California (Mr. HONDA), who is a member of the Appropriations Committee and chair emeritus of the Congressional Asian Pacific American Caucus.

Mr. HONDA. Mr. Speaker, I want to thank my colleague, Mr. FOSTER, and on the other side, Congressman HUIZENGA of Michigan, for bringing this up. It is an issue that has been a long time in coming forward. I thank Mr. HECK of Nevada, also, for the gentleman's comments regarding the Filipino veterans' history in World War II.

Prior to this, we talked about the merchant marines. I think that the merchant marines are a long time past in being recognized for their bravery and their willingness to forge through the oceans to bring materiel and artillery to fight fascism in Europe.

Today we stand here in 2016 to ask for support for the bravery, patriotism, and sacrifice of nearly 250,000 Filipinos and Filipino Americans to whom our Nation owes much. I ask this Chamber to show its commitment to those who have bled for our Nation's principles at a time of great adversity by honoring these brave souls with the Congressional Gold Medal.

The Congressional Gold Medal is a symbol of our recognition of their service, but it does very little to recognize the sacrifice and patience that they had to endure since World War II, when, as it was mentioned earlier, this Congress passed two rescission bills in the Appropriations in 1946 removing the Filipino veterans from veterans' benefits and the kinds of promises that President Roosevelt and MacArthur had given to the Filipino veterans.

The story of these proud veterans begins more than 70 years ago when President Roosevelt did ask Filipino and Filipino American soldiers to serve under U.S. authority during World War II. Under our flag, we drafted them and we asked for volunteers. We got both from them.

The people of the Philippines valiantly stepped up to the challenge and played a vital role in securing a victory for the U.S. and its Allies in the Pacific theater. Historians have long since concluded that these valiant efforts by the Filipino and Filipino American soldiers in Bataan helped keep Midway and the coral islands in America's hands at a crucial time during World War II.

Over 60,000 Filipino soldiers, alongside 15,000 American brothers in arms, were captured and forced to walk over 65 miles to the prison camps, which was called the infamous Bataan March—the infamous Bataan Death March—to the ships that would take them to Japan, where they became POWs.

Several thousand Filipinos and Americans died along the way making the ultimate sacrifice in our mutual struggle against fascism and for the promise of democracy and self-determination. A lot of these Filipinos had interceded during the march to the ships, endangering themselves of being beheaded or losing their arms or their lives because they were going to offer water as sustenance to our POWs who were being marched to the ships. We have forgotten that. Hopefully, today, this Congressional Medal of Honor will help us remember the kinds of things that they have sacrificed.

Congress shamefully passed the Rescission Act of 1946, as was mentioned earlier, betraying the promise of full eligibility of rights to Filipino soldiers turning their backs on these valiant souls. We did this consciously twice. In February of 2009, we were here in Congress and at long last passed legislation that included benefits for Filipino and World War II veterans.

The SPEAKER pro tempore. The time of the gentleman has expired.

Mr. FOSTER. Mr. Speaker, I yield the gentleman an additional 30 seconds.

Mr. HONDA. Mr. Speaker, this bitter-sweet victory comes at the end of a 50-year legislative battle which has seen thousands of veterans lose their lives due to the passage of time. This year we must send a clear message to the surviving 18,000 Filipino and Filipino

American World War II veterans that we are honored by their spirit and moved by the heroism and their patience—the spirit that remained hopeful for many, many years that the American people, through their Representatives in this Congress, would do the right thing.

This is the right thing to do. Join me in honoring all of the Filipino World War II veterans with the Congressional Gold Medal.

Mr. FOSTER. Mr. Speaker, I yield 3 minutes to the gentleman from Hawaii (Ms. HANABUSA), who is a member of the Armed Services Committee.

Ms. HANABUSA. Mr. Speaker, I just returned to the 114th Congress, and I would like to have everyone remember that when I first came here in the 112th Congress is when we gave the Congressional Gold Medals to the Japanese Americans who fought in World War II. I remember how much pride they all had to receive that Gold Medal. That is why I introduced, in a subsequent Congress, the first attempt to get the Gold Medal for the Filipino war veterans.

In 7 days, Mr. Speaker, we will be commemorating, in Hawaii, the attack on Pearl Harbor—the 75th anniversary. Imagine, 75 years, and we have still not kept our promise to the Filipino war veterans. Many of them are in both Congresswoman GABBARD's and my district. I must tell you, all that they have asked for is a recognition by this country that we will keep our promises to them.

Mr. Speaker, I would like to say that it is with such pride that I stand here to see that, across the aisle, we have been able to have this piece of legislation hopefully pass and to also know the hard work of my colleagues, especially Senator HIRONO in the Senate and, of course, Congresswoman GABBARD.

There are two gentlemen that I also want us all to remember, and that is former Senator Daniel K. Inouye and Senator Daniel K. Akaka. The reason why is because they both said that the greatest regret they had was that we could not—they could not—change that act in 1946 and keep their word to the Filipino veterans that they would have full benefits, that they could not reunite them with their families as they had all promised.

But, Mr. Speaker, this act, the act of this Gold Medal, will make things somewhat right. It will at least say that this great country recognizes the promises that we have made and this great country will not forget the sacrifices that they have made for us.

Mr. Speaker, I ask that all my colleagues vote in favor of this bill.

Mr. FOSTER. Mr. Speaker, I have no further requests for time. I urge my colleagues to support this bill.

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

Mr. HUIZENGA of Michigan. Mr. Speaker, I, too, urge passage of this bill by my colleagues and thank the Filipino people for their support and friendship for the many, many years.

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 Michigan (Mr. HUIZENGA) that the House suspend the rules and pass the bill, S. 1555.

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

A motion to reconsider was laid on the table.

OFFICE OF STRATEGIC SERVICES CONGRESSIONAL GOLD MEDAL ACT

Mr. HUIZENGA of Michigan. Mr. Speaker, I move to suspend the rules and pass the bill (S. 2234) to award the Congressional Gold Medal, collectively, to the members of the Office of Strategic Services (OSS) in recognition of their superior service and major contributions during World War II.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 2234

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 "Office of Strategic Services Congressional Gold Medal Act".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) The Office of Strategic Services (OSS) was America's first effort to implement a system of strategic intelligence during World War II and provided the basis for the modern-day American intelligence and special operations communities. The U.S. Special Operations Command and the National Clandestine Service chose the OSS spearhead as their insignias.

(2) OSS founder General William J. Donovan is the only person in American history to receive our Nation's four highest decorations, including the Medal of Honor. Upon learning of his death in 1959, President Eisenhower called General Donovan the "last hero". In addition to founding and leading the OSS, General Donovan was also selected by President Roosevelt, who called him his "secret legs", as an emissary to Great Britain and continental Europe before the United States entered World War II.

(3) All the military branches during World War II contributed personnel to the OSS. The present-day Special Operations Forces trace their lineage to the OSS. Its Maritime Unit was a precursor to the U.S. Navy SEALs. The OSS Operational Groups and Jedburghs were forerunners to U.S. Army Special Forces. The 801st/492nd Bombardment Group ("Carpetbaggers") were progenitors to the Air Force Special Operations Command. The Marines who served in the OSS, including the actor Sterling Hayden (a Silver Star recipient), Col. William Eddy (a Distinguished Service Cross recipient who was described as the "nearest thing the United States has had to a Lawrence of Arabia"), and Col. Peter Ortiz (a two-time Navy Cross recipient), were predecessors to the Marine Special Operations Command. U.S. Coast Guard personnel were recruited for the Maritime Unit and its Operational Swimmer Group.

(4) The OSS organized, trained, supplied, and fought with resistance organizations

throughout Europe and Asia that played an important role in America's victory during World War II. General Eisenhower credited the OSS's covert contribution in France to the equivalent to having an extra military division. General Eisenhower told General Donovan that if it did nothing else, the photographic reconnaissance conducted by the OSS prior to the D-Day Invasion justified its creation.

(5) Four future directors of central intelligence served as OSS officers: William Casey, William Colby, Allen Dulles, and Richard Helms.

(6) Women comprised more than one-third of OSS personnel and played a critical role in the organization. They included Virginia Hall, the only civilian female to receive a Distinguished Service Cross in World War II, and Julia Child.

(7) OSS recruited Fritz Kolbe, a German diplomat who became America's most important spy against the Nazis in World War II.

(8) America's leading scientists and scholars served in the OSS Research and Analysis Branch, including Ralph Bunche, the first African-American to receive the Nobel Peace Prize; Pulitzer Prize-winning historian Arthur Schlesinger, Jr.; Supreme Court Justice Arthur Goldberg; Sherman Kent; John King Fairbank; and Walt Rostow. Its ranks included seven future presidents of the American Historical Association, five of the American Economic Association, and two Nobel laureates.

(9) The U.S. Department of State's Bureau of Intelligence and Research traces its creation to the OSS Research and Analysis Branch.

(10) James Donovan, who was portrayed by Tom Hanks in the Steven Spielberg movie "Bridge of Spies" and negotiated the release of U-2 pilot Francis Gary Powers, served as General Counsel of the OSS.

(11) The OSS invented and employed new technology through its Research and Development Branch, inventing new weapons and revolutionary communications equipment. Dr. Christian Lambertsen invented the first underwater rebreathing apparatus that was first utilized by the OSS and is known today as SCUBA.

(12) OSS Detachment 101 operated in Burma and pioneered the art of unconventional warfare. It was the first United States unit to deploy a large guerrilla army deep in enemy territory. It has been credited with the highest kill/loss ratio for any infantry-type unit in American military history and was awarded a Presidential Unit Citation.

(13) Its X-2 branch pioneered counterintelligence with the British and established the modern counterintelligence community. The network of contacts built by the OSS with foreign intelligence services led to enduring Cold War alliances.

(14) Operation Torch, the Allied invasion of French North Africa in November 1942, was aided by the networks established and information acquired by the OSS to guide Allied landings.

(15) OSS Operation Halyard rescued more than 500 downed airmen trapped behind enemy lines in Yugoslavia, one of the most daring and successful rescue operations of World War II.

(16) OSS "Mercy Missions" at the end of World War II saved the lives of thousands of Allied prisoners of war whom it was feared would be murdered by the Japanese.

(17) The handful of surviving men and women of the OSS whom General Donovan said performed "some of the bravest acts of the war" are members of the "Greatest Generation". They have never been collectively recognized for their heroic and pioneering service in World War II.

SEC. 3. CONGRESSIONAL GOLD MEDAL.

(a) PRESENTATION AUTHORIZED.—The Speaker of the House of Representatives and the President pro tempore of the Senate shall make appropriate arrangements for the presentation, on behalf of the Congress, of a gold medal of appropriate design in commemoration to the members of the Office of Strategic Services (OSS), in recognition of their superior service and major contributions during World War II.

(b) DESIGN AND STRIKING.—For purposes of the presentation referred to in subsection (a), the Secretary of the Treasury (referred to in this Act as the "Secretary") shall strike a gold medal with suitable emblems, devices, and inscriptions, to be determined by the Secretary.

(c) SMITHSONIAN INSTITUTION.—

(1) IN GENERAL.—Following the award of the gold medal in commemoration to the members of the Office of Strategic Services under subsection (a), the gold medal shall be given to the Smithsonian Institution, where it will be displayed as appropriate and made available for research.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Smithsonian Institution should make the gold medal received under paragraph (1) available for display elsewhere, particularly at other appropriate locations associated with the Office of Strategic Services.

SEC. 4. DUPLICATE MEDALS.

The Secretary may strike and sell duplicates in bronze of the gold medal struck pursuant to section 3 under such regulations as the Secretary may prescribe, at a price sufficient to cover the cost thereof, including labor, materials, dies, use of machinery, and overhead expenses, and the cost of the gold medal.

SEC. 5. STATUS OF MEDALS.

(a) NATIONAL MEDALS.—The medals struck pursuant to this Act are national medals for purposes of chapter 51 of title 31, United States Code.

(b) NUMISMATIC ITEMS.—For purposes of section 5134 of title 31, United States Code, all medals struck under this Act shall be considered to be numismatic items.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. HUIZENGA) and the gentleman from Illinois (Mr. FOSTER) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan.

GENERAL LEAVE

Mr. HUIZENGA of Michigan. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on this bill.

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

There was no objection.

Mr. HUIZENGA of Michigan. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, every wartime President of the United States—and probably every wartime leader in history—has had some clandestine help from men and women who risked life and limb to report on and sometimes to disrupt the actions of the enemy. No leader of such clandestine force was as uniformly successful, as visionary, or ultimately had as much impact on both his country's affairs and those of the en-

tire world as Colonel William J. "Wild Bill" Donovan.

□ 1730

President Franklin Roosevelt charged Colonel Donovan with the daunting task of unifying and streamlining the previously ad hoc U.S. efforts at intelligence gathering. The unit he founded, the Office of Strategic Services, was the foundation upon which the postwar government built the Central Intelligence Agency.

Each branch of the armed services contributed members of the OSS, which trained, equipped, and fought with resistance forces in the Atlantic and Pacific theaters. Its various operations were the forerunners of many of today's Special Operations Forces. Four future directors of central intelligence—Allen Dulles, William Casey, William Colby, and Richard Helms—were all OSS operatives, and at least a third of the operatives were women, including the world's first and favorite TV chef, Julia Child, of all people.

Mr. Speaker, I rise today in support of S. 2234, the Office of Strategic Services Congressional Gold Medal Act, introduced by Senator BLUNT of Missouri. The bill, which passed the Senate on February 23, has companion legislation to H.R. 3929, introduced by our Republican colleague, Representative LATTA, which has 320 House cosponsors.

The bill authorizes the striking and awarding of a single gold medal of appropriate design to commemorate the members of the Office of Strategic Services in recognition of their superior service and major contributions during World War II.

After awarding the medal, it will be given to the Smithsonian museum where it will be available for display there or elsewhere, as appropriate. The Treasury secretary is authorized to make and offer for sale bronze replicas of the medal at a price that will help defray the design and production costs of the actual medal.

Mr. Speaker, long after World War II ended, most of the efforts of the OSS remained classified, and we probably still do not know all of the hair-raising tales that might be told. One thing is not secret—we owe those men and women an enormous debt of gratitude, not only for their work during the war but for the groundwork that they laid towards what is clearly the best intelligence service in the world today. We should recognize those contributions by awarding the Congressional Gold Medal to these heroes.

I urge immediate passage of this bill.

I reserve the balance of my time.

HOUSE OF REPRESENTATIVES,

COMMITTEE ON HOUSE ADMINISTRATION,

Washington, DC, November 30, 2016.

Hon. JEB HENSARLING,
Chairman, Committee on Financial Services,
Washington, DC.

DEAR MR. CHAIRMAN: I write to you regarding S. 2234. As you know, the bill was received in the House of Representatives on February 23, 2016 and referred to the Committee on Financial Services and in addition

to the Committee on the Committee on House Administration. The bill seeks to award the Congressional Gold Medal, collectively, to the members of the Office of Strategic Services (OSS) in recognition of their superior service and major contributions during World War II. S. 2234 passed the Senate without amendment by unanimous consent on February 22, 2016.

I realize that discharging the Committee on House Administration from further consideration of S. 2234 will serve in the best interest of the House of Representatives and agree to do so. It is the understanding of the Committee on House Administration that forgoing action on S. 2234 will not prejudice the Committee with respect to appointment of conferees or any future jurisdictional claim. I request that this letter and any response be included in the Congressional Record.

Sincerely,

CANDICE S. MILLER,
Chairman.

HOUSE OF REPRESENTATIVES,
COMMITTEE ON FINANCIAL SERVICES,
Washington, DC, November 30, 2016.

Hon. CANDICE MILLER,
Chairman, Committee on House Administration,
Washington, DC.

DEAR CHAIRMAN MILLER: Thank you for your November 30th letter regarding S. 2234, the "Office of Strategic Services Congressional Gold Medal Act."

I am most appreciative of your decision to forego action on S. 2234 so that it may move expeditiously to the House floor. I acknowledge that although you are waiving action on the bill, the Committee on House Administration is in no way waiving its jurisdictional interest in this or similar legislation. In addition, if a conference is necessary on this legislation, I will support any request that your committee be represented therein.

Finally, I shall be pleased to include your letter and this letter on S. 2234 in the Congressional Record during floor consideration of the same.

Sincerely,

JEB HENSARLING,
Chairman.

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

I rise today in support of S. 2234, legislation to award a Congressional Gold Medal to members of the Office of Strategic Services in recognition of their significant service and contributions against the Axis Powers during World War II.

I am pleased to note that the legislation has already passed the Senate with unanimous consent, and that companion legislation, introduced here in the House, has already received the endorsement of 320 cosponsors. Upon passage here in the House, the legislation will be cleared for the President's signature.

Created at the start of World War II, the Office of Strategic Services was the Nation's first effort to implement a coordinated intelligence system, laying the foundation for our modern-day intelligence and special operations capabilities.

In addition to honoring and recognizing the meaningful and personal sacrifice of the thousands of Americans who served as part of the Office of Strategic Services, the legacy of the OSS offers a number of lessons that continue to hold value to this day. Im-

portantly, the legacy of the OSS serves as a reminder that effective coordination across our Nation's intelligence agencies continues to play a foundational role in promoting our national security interests.

The OSS also serves to remind us of the importance of working strategically and in concert with our long-standing allies to prevail against those who seek to do our Nation harm. Indeed, during World War II, the OSS played a critical role in organizing, training, supplying, and fighting alongside resistance organizations throughout Europe and Asia.

Moreover, throughout the war, the OSS demonstrated that our government is at its best when it brings together a wide range of individuals with diverse backgrounds. At its height in late 1944, the Office of Strategic Services employed nearly 13,000 individuals, nearly a third of whom were women. The service also drew its personnel not only from the military but also from civilians from all walks of life, including economists, psychologists, geographers, and a wide range of other fields.

Upon the dissolution of the Office of Strategic Services at the close of World War II, General William J. Donovan, who headed the OSS, stated that, "We have come to the end of an unusual experiment. That experiment was to determine whether a group of Americans constituting a cross section of racial origins, of abilities, of temperaments, and of talents could meet and risk an encounter with long-established and well-trained enemy organizations."

He went on to conclude that, "You can go with the assurance that you have made a beginning in showing the people of America that only by decisions of national policy based upon accurate information can we have the chance of a peace that will endure."

So I am pleased that we are honoring the thousands of men and women who made the sacrifice to serve as part of the Office of Strategic Services, whose contribution was so critical to America's ultimate triumph over the Axis Powers.

I am also pleased that the legislation will allow future generations to appreciate these contributions to our Nation and the world. By designating the Smithsonian Institution as the custodian of the medal, and by allowing for its display at other locations associated with the Office of Strategic Services, the legislation will ensure that the legacy and the lessons that can be drawn from the contributions made by members of the Office of Strategic Services will not be forgotten.

So as we enter into uncharted waters with the incoming administration, I hope that we will all take pause and heed the lessons of the OSS and remember that America is at its best when we work together with our long-standing allies and when we recruit diverse personnel to serve our government.

I also hope that it serves as a reminder of the importance of taking care of our veterans once their service has ended and they return to civilian life.

I urge adoption of the legislation.

I reserve the balance of my time.

Mr. HUIZENGA of Michigan. Mr. Speaker, I yield such time as he may consume to the gentleman from Ohio (Mr. LATTA), the author of the House bill.

Mr. LATTA. Mr. Speaker, I thank the gentleman for yielding.

Mr. Speaker, I rise today in support of S. 2234, the Office of Strategic Services Congressional Gold Medal Act, companion legislation I introduced earlier this Congress as H.R. 3929 to honor and recognize these brave veterans for their superior service and major contributions made during World War II.

The Office of Strategic Services, the OSS as it is often referred to, was America's first strategic intelligence service during World War II and provided the basis for the modern-day American intelligence and special operations communities.

Under the leadership of OSS founder, General Bill Donovan, the OSS conducted acts of great bravery during the war, and their efforts were another factor to the Allied victory in World War II. Let me name a few. These efforts included:

Organizing, training, supplying, and fighting with resistance organizations throughout Europe and Asia;

Engaging in successful guerrilla warfare deep in enemy territory;

Establishing intelligence networks before the successful Allied invasion of French North Africa, known as Operation Torch;

Rescuing more than 500 downed allied airmen behind enemy lines in Yugoslavia during Operation Halyard, one of the most daring and successful rescue missions of World War II;

Conducting mercy missions at the end of the war that saved thousands of Allied prisoners of war; and

Inventing and utilizing new technology, weapons, and revolutionary communications equipment never before seen.

General Eisenhower said that if it did nothing else, the photographic reconnaissance conducted by the OSS before the D-day invasion in June of 1944 justified its creation.

I am truly proud to be here today to honor these men and women who truly embody the greatest generation. Several members of the OSS came from northwest and west central Ohio, including Arthur Jibilian, who took part in Operation Helyard in Yugoslavia; Captain Stephanie Czech Rader; and another veteran who flew OSS missions in B-24s behind enemy lines into occupied France. They have earned and deserve this recognition. Congress and our Nation are proud of them, and we are grateful for their dedicated service. This Congressional Gold Medal is one way we can extend our gratitude.

Mr. Speaker, I want to thank Speaker RYAN, Leader MCCARTHY, and all of the leadership team, Senators BLUNT and WARNER, Chairman NUNES and Ranking Member SCHIFF, Chairman ED ROYCE, Representative MARCY KAPTUR, and all of my other colleagues, including the 320 Members that cosponsored this legislation, for their time, hard work, and support. I would also be remiss if I did not also thank the OSS Society and all those involved for their time and hard work in keeping the legacy of these OSS veterans forever alive.

Mr. Speaker, I urge my colleagues to join me in supporting passage of S. 2234 and bestow upon the OSS the Congressional Gold Medal.

I thank the gentleman for yielding.

Mr. FOSTER. Mr. Speaker, I yield 4 minutes to the gentlewoman from Ohio (Ms. KAPTUR), a member of the Appropriations Committee.

Ms. KAPTUR. Mr. Speaker, I thank Congressman FOSTER for yielding the time.

I am deeply honored to rise today in an official capacity, but also personally, to pay tribute to the patriotic and fearless soldiers, heroes and heroines, of the OSS. Their worthiness to be awarded this Congressional Gold Medal by our Nation for heroism in battle is long overdue.

Over 13,000 exceptional Americans comprise the Office of Strategic Services formed clandestinely during World War II by President Franklin Roosevelt. Roosevelt aimed to create a corps of specially trained intelligence warriors to help win that harrowing conflict. For these many decades since the end of World War II, the secrecy of the OSS and its member soldiers have been maintained.

I can attest to this. Our family's beloved Uncle Tony, full name Anthony Rogowski, our mother's brother, was selected as one of its members. He was a corporal and his medals include: Army Good Conduct, American Theater Medal, Pacific Theater Medal, World War II Victory Medal, and Distinguished Unit badge; Army Serial Number: 35-33-943.

He is buried in a simple grave at Calvary Cemetery in Toledo, Ohio, with a gravestone marker provided by the U.S. Department of Veterans Affairs.

Yes, there is an Army crest on its facing. But there is nothing there, nor in any other location, that would tell his family, or those who will inherit our Nation in the years ahead, what a brilliant man and brave soldier he was.

After his death, it was my particular privilege to present his precious leather flight jacket to his daughter, RoseAnn Rogowski Koperski, and his son, John Rogowski of Toledo. Uncle Tony was part of the elite OSS, trained rigorously as warfighters. We still do not know where he was trained. We know he was dispatched to the Pacific front, flown over the hump in the China-Burma-India campaign. He parachuted at night behind enemy

lines under fire as he hit the ground to gather intelligence. He drove Jeeps filled with dynamite to the front along the Burma Road, fighting to cut off the supply of oil to the Japanese military.

Our bill recognizes OSS Detachment 101 that operated in Burma and pioneered the art of unconventional warfare. It was the first United States unit to deploy a large guerrilla army deep in enemy territory. It has been credited with the highest kill/loss ratio for any infantry-type unit in American military history and was awarded a Presidential Unit Citation.

Our uncle was knifed in a foxhole in Burma by a soldier from the Imperial Japanese Army, wounded badly, and he suffered throughout his life with terrible malaria bouts and flashbacks contracted in theatre. He passed away in his mid 50s, far too young, of poor health, all due to war injuries.

He was never recognized or acknowledged for his heroism, like the other men and women who valiantly fought as members of the OSS. I loved Uncle Tony. He was a complicated man with a rare and devilish sense of humor and a hearty laugh and grin. You just knew on meeting him there was depth, as well as honor.

He was war wise, sharing gripping stories about the war when I was a child, peppered with his own conclusions about the merit of the conflicts in which he participated.

His letters sent home during the war to our mother, which she kept banded in a special corner of our parents' cedar chest, were unusual. Parts of the letters had been cut out by his superiors; others had lines that were blackened out so as not to reveal his location or any aspect of what he was doing. As a child, that fascinated me, though I did not completely understand what it meant. His family never really knew where he was deployed nor how he arrived where he was sent. He never revealed the specific details of what he actually did.

And now through this legislation, sponsored by my dear friend and colleague, Ohio Congressman BOB LATTA, and 320 other Members, on a bipartisan basis, we now make America's military history more whole and complete. Frankly, it is the highest honor to pay just tribute to the OSS members, though long overdue.

□ 1745

As I participate in the passage of this legislation, I am reminded of how America's greatest strength is the weaving together of intergenerational experience from one era to another within our families and communities and then extended to the American family.

The SPEAKER pro tempore. The time of the gentlewoman has expired.

Mr. FOSTER. I yield the gentlewoman an additional 1 minute.

Ms. KAPTUR. I thank the gentleman.

Today, in the gallery, we have noble veterans of the OSS.

We know our Nation stands on your broad shoulders.

Through their patriotism and sacrifice, America still is a young nation but is growing and is keeping what we have learned close to our hearts. In paying Gold Medal tribute to the members of the OSS, America honors those who bequeathed precious liberty to us, and we must carry that torch forward as it was carried at such a great price by our forebears.

I would like to acknowledge Charles Pinck, whose father served as a member of the OSS, for his commitment to educate the public about this valiant group.

May God bless the members of the OSS, their families and friends. May our efforts here award them the Gold they so nobly, royally, and selflessly earned, and may God continue to bless America.

Mr. HUIZENGA of Michigan. Mr. Speaker, I yield such time as he may consume to the gentleman from Pennsylvania (Mr. ROTHFUS).

Mr. ROTHFUS. Mr. Speaker, I rise in strong support of S. 2234, to award the Congressional Gold Medal to the members of the Office of Strategic Services in recognition of their superior service and major contributions during World War II.

The accomplishments of the OSS are too numerous to mention here. We cannot imagine what the world would look like today had evil forces prevailed over good in World War II, but thanks to the invaluable contribution of the brave servicemembers of the OSS, we do not have to. The OSS organized, trained, supplied, and fought resistance organizations throughout Europe and Asia that played an important role in America's victory during World War II. The men and women of the OSS were pioneers in counterintelligence, technology, and unconventional warfare.

The OSS was the prototype for modern-day American intelligence and special operations communities. The outstanding Americans who serve today as Navy SEALs, U.S. Army Special Forces, Air Force Special Operations Command, Marine Special Operations Command, and more can trace their roots to the OSS.

For these and many other reasons, it is right that we honor the servicemembers of the OSS for their extraordinary contributions to American history and that future generations of Americans learn about the crucial role they played in keeping America safe.

While so many of the OSS servicemembers have already gone to their eternal rest, including my own father-in-law, Edgar Lewis, it is fitting and good that we pass this legislation while we continue to have OSS members among us today.

Mr. FOSTER. Mr. Speaker, I urge my colleagues to support this bill.

I yield back the balance of my time.

Mr. HUIZENGA of Michigan. Mr. Speaker, I appreciated the personal touches and discussions from Representative LATTA and Representative

KAPTUR as they talked about their family members in this very important organization. With that, I urge the bill's passage.

I yield back the balance of my time. The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. HUIZENGA) that the House suspend the rules and pass the bill, S. 2234.

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

A motion to reconsider was laid on the table.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. The Chair would remind persons in the gallery that it is a violation of the rules of the House to show approval or disapproval of the proceedings of the House.

INTELLIGENCE AUTHORIZATION ACT FOR FISCAL YEAR 2017

Mr. NUNES. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6393) to authorize appropriations for fiscal year 2017 for intelligence and intelligence-related activities of the United States Government, the Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes.

The Clerk read the title of the bill. The text of the bill is as follows:

H.R. 6393

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Intelligence Authorization Act for Fiscal Year 2017”.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Definitions.

TITLE I—INTELLIGENCE ACTIVITIES

Sec. 101. Authorization of appropriations.
Sec. 102. Classified Schedule of Authorizations.
Sec. 103. Personnel ceiling adjustments.
Sec. 104. Intelligence Community Management Account.

TITLE II—CENTRAL INTELLIGENCE AGENCY RETIREMENT AND DISABILITY SYSTEM

Sec. 201. Authorization of appropriations.

TITLE III—GENERAL INTELLIGENCE COMMUNITY MATTERS

Sec. 301. Restriction on conduct of intelligence activities.
Sec. 302. Increase in employee compensation and benefits authorized by law.
Sec. 303. Support to nonprofit organizations assisting intelligence community employees.
Sec. 304. Promotion of science, technology, engineering, and math education in the intelligence community.
Sec. 305. Retention of employees of the intelligence community who have science, technology, engineering, or math expertise.

Sec. 306. Modifications to certain requirements for construction of facilities.

Sec. 307. Protections for independent inspectors general of certain elements of the intelligence community.

Sec. 308. Modification of certain whistleblowing procedures.

Sec. 309. Congressional oversight of policy directives and guidance.

Sec. 310. Notification of memoranda of understanding.

Sec. 311. Technical correction to Executive Schedule.

Sec. 312. Maximum amount charged for declassification reviews.

TITLE IV—MATTERS RELATING TO ELEMENTS OF THE INTELLIGENCE COMMUNITY

Subtitle A—Office of the Director of National Intelligence

Sec. 401. Designation of the Director of the National Counterintelligence and Security Center.

Sec. 402. Analyses and impact statements by Director of National Intelligence regarding investment into the United States.

Sec. 403. Assistance for governmental entities and private entities in recognizing online violent extremist content.

Subtitle B—Central Intelligence Agency

Sec. 411. Enhanced death benefits for personnel of the Central Intelligence Agency.

Sec. 412. Pay and retirement authorities of the Inspector General of the Central Intelligence Agency.

Subtitle C—Other Elements

Sec. 421. Clarification of authority, direction, and control over the information assurance directorate of the National Security Agency.

Sec. 422. Enhancing the technical workforce for the Federal Bureau of Investigation.

Sec. 423. Plan on assumption of certain weather missions by the National Reconnaissance Office.

TITLE V—MATTERS RELATING TO FOREIGN COUNTRIES

Sec. 501. Committee to counter active measures by the Russian Federation to exert covert influence over peoples and governments.

Sec. 502. Limitation on travel of accredited diplomats and consulars of the Russian Federation in the United States from their diplomatic post.

Sec. 503. Study and report on enhanced intelligence and information sharing with Open Skies Treaty member states.

TITLE VI—PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD

Sec. 601. Information on activities of the Privacy and Civil Liberties Oversight Board.

Sec. 602. Authorization of appropriations for Privacy and Civil Liberties Oversight Board.

TITLE VII—REPORTS AND OTHER MATTERS

Sec. 701. Declassification review with respect to detainees transferred from United States Naval Station, Guantanamo Bay, Cuba.

Sec. 702. Cyber Center for Education and Innovation Home of the National Cryptologic Museum.

Sec. 703. Oversight of national security systems.

Sec. 704. Joint facilities certification.

Sec. 705. Leadership and management of space activities.

Sec. 706. Advances in life sciences and biotechnology.

Sec. 707. Reports on declassification proposals.

Sec. 708. Improvement in Government classification and declassification.

Sec. 709. Report on implementation of research and development recommendations.

Sec. 710. Report on Intelligence Community Research and Development Corps.

Sec. 711. Report on information relating to academic programs, scholarships, fellowships, and internships sponsored, administered, or used by the intelligence community.

Sec. 712. Report on intelligence community employees detailed to National Security Council.

Sec. 713. Intelligence community reporting to Congress on foreign fighter flows.

Sec. 714. Report on cybersecurity threats to seaports of the United States and maritime shipping.

Sec. 715. Report on counter-messaging activities.

Sec. 716. Report on reprisals against contractors of the intelligence community.

SEC. 2. DEFINITIONS.

In this Act:

(1) CONGRESSIONAL INTELLIGENCE COMMITTEES.—The term “congressional intelligence committees” means—

(A) the Select Committee on Intelligence of the Senate; and

(B) the Permanent Select Committee on Intelligence of the House of Representatives.

(2) INTELLIGENCE COMMUNITY.—The term “intelligence community” has the meaning given that term in section 3(4) of the National Security Act of 1947 (50 U.S.C. 3003(4)).

TITLE I—INTELLIGENCE ACTIVITIES

SEC. 101. AUTHORIZATION OF APPROPRIATIONS.

Funds are hereby authorized to be appropriated for fiscal year 2017 for the conduct of the intelligence and intelligence-related activities of the following elements of the United States Government:

(1) The Office of the Director of National Intelligence.

(2) The Central Intelligence Agency.

(3) The Department of Defense.

(4) The Defense Intelligence Agency.

(5) The National Security Agency.

(6) The Department of the Army, the Department of the Navy, and the Department of the Air Force.

(7) The Coast Guard.

(8) The Department of State.

(9) The Department of the Treasury.

(10) The Department of Energy.

(11) The Department of Justice.

(12) The Federal Bureau of Investigation.

(13) The Drug Enforcement Administration.

(14) The National Reconnaissance Office.

(15) The National Geospatial-Intelligence Agency.

(16) The Department of Homeland Security.

SEC. 102. CLASSIFIED SCHEDULE OF AUTHORIZATIONS.

(a) SPECIFICATIONS OF AMOUNTS.—The amounts authorized to be appropriated under section 101 and, subject to section 103, the authorized personnel ceilings as of September 30, 2017, for the conduct of the intelligence activities of the elements listed in paragraphs (1) through (16) of section 101, are those specified in the classified Schedule of

Authorizations prepared to accompany this Act.

(b) AVAILABILITY OF CLASSIFIED SCHEDULE OF AUTHORIZATIONS.—

(1) **AVAILABILITY.**—The classified Schedule of Authorizations referred to in subsection (a) shall be made available to the Committee on Appropriations of the Senate, the Committee on Appropriations of the House of Representatives, and to the President.

(2) **DISTRIBUTION BY THE PRESIDENT.**—Subject to paragraph (3), the President shall provide for suitable distribution of the classified Schedule of Authorizations referred to in subsection (a), or of appropriate portions of such Schedule, within the executive branch.

(3) **LIMITS ON DISCLOSURE.**—The President shall not publicly disclose the classified Schedule of Authorizations or any portion of such Schedule except—

(A) as provided in section 601(a) of the Implementing Recommendations of the 9/11 Commission Act of 2007 (50 U.S.C. 3306(a));

(B) to the extent necessary to implement the budget; or

(C) as otherwise required by law.

SEC. 103. PERSONNEL CEILING ADJUSTMENTS.

(a) **AUTHORITY FOR INCREASES.**—The Director of National Intelligence may authorize employment of civilian personnel in excess of the number authorized for fiscal year 2017 by the classified Schedule of Authorizations referred to in section 102(a) if the Director of National Intelligence determines that such action is necessary to the performance of important intelligence functions, except that the number of personnel employed in excess of the number authorized under such section may not, for any element of the intelligence community, exceed 3 percent of the number of civilian personnel authorized under such schedule for such element.

(b) **TREATMENT OF CERTAIN PERSONNEL.**—The Director of National Intelligence shall establish guidelines that govern, for each element of the intelligence community, the treatment under the personnel levels authorized under section 102(a), including any exemption from such personnel levels, of employment or assignment in—

(1) a student program, trainee program, or similar program;

(2) a reserve corps or as a reemployed annuitant; or

(3) details, joint duty, or long-term, full-time training.

(c) **NOTICE TO CONGRESSIONAL INTELLIGENCE COMMITTEES.**—The Director of National Intelligence shall notify the congressional intelligence committees in writing at least 15 days prior to each exercise of an authority described in subsection (a).

(d) CONTRACTOR CONVERSIONS.—

(1) **AUTHORITY FOR INCREASES.**—In addition to the authority under subsection (a), the Director of National Intelligence may authorize employment of civilian personnel in an element of the intelligence community in excess of the number authorized for fiscal year 2017 by the classified Schedule of Authorizations referred to in section 102(a), as such number may be increased pursuant to subsection (a), if—

(A) the Director determines that the increase under this paragraph is necessary to convert the performance of any function of the element by contractors to performance by civilian personnel; and

(B) the number of civilian personnel of the element employed in excess of the number authorized under such section 102(a), as such number may be increased pursuant to both subsection (a) and this paragraph, does not exceed 10 percent of the number of civilian personnel authorized under such schedule for the element.

(2) **NOTICE TO CONGRESSIONAL INTELLIGENCE COMMITTEES.**—Not less than 30 days prior to

exercising the authority described in paragraph (1), the Director of National Intelligence shall submit to the congressional intelligence committees, in writing—

(A) notification of exercising such authority;

(B) justification for making the conversion described in subparagraph (A) of such paragraph; and

(C) certification that such conversion is cost effective.

SEC. 104. INTELLIGENCE COMMUNITY MANAGEMENT ACCOUNT.

(a) **AUTHORIZATION OF APPROPRIATIONS.**—There is authorized to be appropriated for the Intelligence Community Management Account of the Director of National Intelligence for fiscal year 2017 the sum of \$559,796,000. Within such amount, funds identified in the classified Schedule of Authorizations referred to in section 102(a) for advanced research and development shall remain available until September 30, 2018.

(b) **AUTHORIZED PERSONNEL LEVELS.**—The elements within the Intelligence Community Management Account of the Director of National Intelligence are authorized 787 positions as of September 30, 2017. Personnel serving in such elements may be permanent employees of the Office of the Director of National Intelligence or personnel detailed from other elements of the United States Government.

(c) CLASSIFIED AUTHORIZATIONS.—

(1) **AUTHORIZATION OF APPROPRIATIONS.**—In addition to amounts authorized to be appropriated for the Intelligence Community Management Account by subsection (a), there are authorized to be appropriated for the Community Management Account for fiscal year 2017 such additional amounts as are specified in the classified Schedule of Authorizations referred to in section 102(a). Such additional amounts for advanced research and development shall remain available until September 30, 2018.

(2) **AUTHORIZATION OF PERSONNEL.**—In addition to the personnel authorized by subsection (b) for elements of the Intelligence Community Management Account as of September 30, 2017, there are authorized such additional personnel for the Community Management Account as of that date as are specified in the classified Schedule of Authorizations referred to in section 102(a).

TITLE II—CENTRAL INTELLIGENCE AGENCY RETIREMENT AND DISABILITY SYSTEM

SEC. 201. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated for the Central Intelligence Agency Retirement and Disability Fund for fiscal year 2017 the sum of \$514,000,000.

TITLE III—GENERAL INTELLIGENCE COMMUNITY MATTERS

SEC. 301. RESTRICTION ON CONDUCT OF INTELLIGENCE ACTIVITIES.

The authorization of appropriations by this Act shall not be deemed to constitute authority for the conduct of any intelligence activity which is not otherwise authorized by the Constitution or the laws of the United States.

SEC. 302. INCREASE IN EMPLOYEE COMPENSATION AND BENEFITS AUTHORIZED BY LAW.

Appropriations authorized by this Act for salary, pay, retirement, and other benefits for Federal employees may be increased by such additional or supplemental amounts as may be necessary for increases in such compensation or benefits authorized by law.

SEC. 303. SUPPORT TO NONPROFIT ORGANIZATIONS ASSISTING INTELLIGENCE COMMUNITY EMPLOYEES.

(a) **DIRECTOR OF NATIONAL INTELLIGENCE.**—Section 102A of the National Security Act of

1947 (50 U.S.C. 3024) is amended by adding at the end the following:

“(y) **FUNDRAISING.**—(1) The Director of National Intelligence may engage in fundraising in an official capacity for the benefit of nonprofit organizations that—

“(A) provide support to surviving family members of a deceased employee of an element of the intelligence community; or

“(B) otherwise provide support for the welfare, education, or recreation of employees of an element of the intelligence community, former employees of an element of the intelligence community, or family members of such employees.

“(2) In this subsection, the term ‘fundraising’ means the raising of funds through the active participation in the promotion, production, or presentation of an event designed to raise funds and does not include the direct solicitation of money by any other means.

“(3) Not later than 7 days after the date the Director engages in fundraising authorized by this subsection or at the time the decision is made to participate in such fundraising, the Director shall notify the congressional intelligence committees of such fundraising.

“(4) The Director, in consultation with the Director of the Office of Government Ethics, shall issue regulations to carry out the authority provided in this subsection. Such regulations shall ensure that such authority is exercised in a manner that is consistent with all relevant ethical constraints and principles, including the avoidance of any prohibited conflict of interest or appearance of impropriety.”

(b) **DIRECTOR OF THE CENTRAL INTELLIGENCE AGENCY.**—Section 12(f) of the Central Intelligence Agency Act of 1949 (50 U.S.C. 3512(f)) is amended by adding at the end the following:

“(3) Not later than the date that is 7 days after the date the Director engages in fundraising authorized by this subsection or at the time the decision is made to participate in such fundraising, the Director shall notify the Select Committee on Intelligence of the Senate and the Permanent Select Committee on Intelligence of the House of Representatives of the fundraising.”

SEC. 304. PROMOTION OF SCIENCE, TECHNOLOGY, ENGINEERING, AND MATH EDUCATION IN THE INTELLIGENCE COMMUNITY.

(a) **REQUIREMENT FOR INVESTMENT STRATEGY FOR STEM RECRUITING AND OUTREACH ACTIVITIES.**—Along with the budget for fiscal year 2018 submitted by the President pursuant to section 1105(a) of title 31, United States Code, the Director of National Intelligence shall submit a five-year investment strategy for outreach and recruiting efforts in the fields of science, technology, engineering, and mathematics (STEM), to include cybersecurity and computer literacy.

(b) **REQUIREMENT FOR INTELLIGENCE COMMUNITY PLANS FOR STEM RECRUITING AND OUTREACH ACTIVITIES.**—For each of the fiscal years 2018 through 2022, the head of each element of the intelligence community shall submit an investment plan along with the materials submitted as justification of the budget request of such element that supports the strategy required by subsection (a).

SEC. 305. RETENTION OF EMPLOYEES OF THE INTELLIGENCE COMMUNITY WHO HAVE SCIENCE, TECHNOLOGY, ENGINEERING, OR MATH EXPERTISE.

(a) **SPECIAL RATES OF PAY FOR CERTAIN OCCUPATIONS IN THE INTELLIGENCE COMMUNITY.**—The National Security Act of 1947 (50 U.S.C. 3001 et seq.) is amended by inserting after section 113A the following:

“SEC. 113B. SPECIAL PAY AUTHORITY FOR SCIENCE, TECHNOLOGY, ENGINEERING, OR MATH POSITIONS.

“(a) **AUTHORITY TO SET SPECIAL RATES OF PAY.**—Notwithstanding part III of title 5, United States Code, the head of each element of the intelligence community may establish higher minimum rates of pay for one or more categories of positions in such element that require expertise in science, technology, engineering, or math (STEM).

“(b) **MAXIMUM SPECIAL RATE OF PAY.**—A minimum rate of pay established for a category of positions under subsection (a) may not exceed the maximum rate of basic pay (excluding any locality-based comparability payment under section 5304 of title 5, United States Code, or similar provision of law) for the position in that category of positions without the authority of subsection (a) by more than 30 percent, and no rate may be established under this section in excess of the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

“(c) **NOTIFICATION OF REMOVAL FROM SPECIAL RATE OF PAY.**—If the head of an element of the intelligence community removes a category of positions from coverage under a rate of pay authorized by subsection (a) after that rate of pay takes effect—

“(1) the head of such element shall provide notice of the loss of coverage of the special rate of pay to each individual in such category; and

“(2) the loss of coverage will take effect on the first day of the first pay period after the date of the notice.

“(d) **REVISION OF SPECIAL RATES OF PAY.**—Subject to the limitations in this section, rates of pay established under this section by the head of the element of the intelligence community may be revised from time to time by the head of such element and the revisions have the force and effect of statute.

“(e) **REGULATIONS.**—The head of each element of the intelligence community shall promulgate regulations to carry out this section with respect to such element, which shall, to the extent practicable, be comparable to the regulations promulgated to carry out section 5305 of title 5, United States Code.

“(f) **REPORTS.**—

“(1) **REQUIREMENT FOR REPORTS.**—Not later than 90 days after the date of the enactment of the Intelligence Authorization Act for Fiscal Year 2017, the head of each element of the intelligence community shall submit to the congressional intelligence committees a report on any rates of pay established for such element under this section.

“(2) **CONTENTS.**—Each report required by paragraph (1) shall contain for each element of the intelligence community—

“(A) a description of any rates of pay established under subsection (a); and

“(B) the number of positions in such element that will be subject to such rates of pay.”

(b) **TABLE OF CONTENTS AMENDMENT.**—The table of contents in the first section of the National Security Act of 1947 is amended by inserting after the item relating to section 113A the following:

“Sec. 113B. Special pay authority for science, technology, engineering, or math positions.”

SEC. 306. MODIFICATIONS TO CERTAIN REQUIREMENTS FOR CONSTRUCTION OF FACILITIES.

(a) **INCLUSION IN BUDGET REQUESTS OF CERTAIN PROJECTS.**—Section 8131 of the Department of Defense Appropriations Act, 1995 (50 U.S.C. 3303) is repealed.

(b) **NOTIFICATION.**—Section 602(a)(2) of the Intelligence Authorization Act for Fiscal Year 1995 (50 U.S.C. 3304(a)(2)) is amended by

striking “improvement project to” and inserting “project for the improvement, repair, or modification of”.

SEC. 307. PROTECTIONS FOR INDEPENDENT INSPECTORS GENERAL OF CERTAIN ELEMENTS OF THE INTELLIGENCE COMMUNITY.

(a) **LIMITATION ON ACTIVITIES OF EMPLOYEES OF AN OFFICE OF INSPECTOR GENERAL.**—

(1) **LIMITATIONS.**—Not later than 180 days after the date of the enactment of this Act, the Director of National Intelligence shall develop and implement a uniform policy for each covered office of an inspector general to better ensure the independence of each such office. Such policy shall include—

(A) provisions to prevent any conflict of interest related to a matter any employee of a covered office of an inspector general personally and substantially participated in during previous employment;

(B) standards to ensure personnel of a covered office of an inspector general are free both in fact and in appearance from personal, external, and organizational impairments to independence;

(C) provisions to permit the head of each covered office of an inspector general to waive the application of the policy with respect to an individual if such head—

(i) prepares a written and signed justification for such waiver that sets out, in detail, the need for such waiver, provided that such a waiver shall not be issued for in fact impairments to independence; and

(ii) submits to the congressional intelligence committees each such justification; and

(D) any other protections the Director determines appropriate.

(2) **COVERED OFFICE OF AN INSPECTOR GENERAL DEFINED.**—The term “covered office of an inspector general” means—

(A) the Office of the Inspector General of the Intelligence Community; and

(B) the office of an inspector general for—

(i) the Office of the Director of National Intelligence;

(ii) the Central Intelligence Agency;

(iii) the National Security Agency;

(iv) the Defense Intelligence Agency;

(v) the National Geospatial-Intelligence Agency; or

(vi) the National Reconnaissance Office.

(3) **BRIEFING TO THE CONGRESSIONAL INTELLIGENCE COMMITTEES.**—Prior to the date that the policy required by paragraph (1) takes effect, the Director of National Intelligence shall provide the congressional intelligence committees a briefing on such policy.

(b) **LIMITATION ON ROTATION OF EMPLOYEES OF AN OFFICE OF INSPECTOR GENERAL.**—Section 102A(1)(3) of the National Security Act of 1947 (50 U.S.C. 3024(1)(3)) is amended by adding at the end the following:

“(D) The mechanisms prescribed under subparagraph (A) and any other policies of the Director—

“(i) may not require an employee of an office of inspector general for an element of the intelligence community, including the Office of the Inspector General of the Intelligence Community, to rotate to a position in an office or organization of such an element over which such office of inspector general exercises jurisdiction; and

“(ii) shall be implemented in a manner that exempts employees of an office of inspector general from a rotation that may impact the independence of such office.”

SEC. 308. MODIFICATION OF CERTAIN WHISTLE-BLOWING PROCEDURES.

(a) **CLARIFICATION OF WHISTLEBLOWING PROCEDURES AVAILABLE TO CERTAIN PERSONNEL.**—Subsection (a)(1)(A) of section 8H of the Inspector General Act of 1978 (5 U.S.C. App.) is amended by inserting after “Security Agency,” the following: “including any

such employee who is assigned or detailed to a combatant command or other element of the Federal Government.”

(b) **CENTRAL INTELLIGENCE AGENCY.**—

(1) **ROLE OF DIRECTOR.**—Section 17(d)(5) of the Central Intelligence Agency Act of 1949 (50 U.S.C. 3517(d)(5)) is amended—

(A) in subparagraph (B)—

(i) by striking clause (ii);

(ii) by striking “(i) Not” and inserting “Not”; and

(iii) by striking “to the Director” and inserting “to the intelligence committees”; and

(B) in subparagraph (D)—

(i) in clause (i), by striking “the Director” and inserting “the intelligence committees”; and

(ii) in clause (ii)—

(I) in subclause (I), by striking “the Director, through the Inspector General,” and inserting “the Inspector General”; and

(II) in subclause (II), by striking “the Director, through the Inspector General,” and inserting “the Inspector General, in consultation with the Director.”

(2) **CONFORMING AMENDMENTS.**—

(A) **IN GENERAL.**—Section 17(d)(5) of such Act is further amended—

(i) by striking subparagraph (C); and

(ii) by redesignating subparagraphs (D) through (H) as subparagraphs (C) through (G), respectively.

(B) **INTELLIGENCE REFORM AND TERRORISM PREVENTION ACT OF 2004.**—Section 3001(j)(1)(C)(ii) of the Intelligence Reform and Terrorism Prevention Act of 2004 (50 U.S.C. 3341(j)(1)(C)(ii)) is amended by striking “subparagraphs (A), (D), and (H)” and inserting “subparagraphs (A), (C), and (G)”.

(c) **OTHER ELEMENTS OF INTELLIGENCE COMMUNITY.**—

(1) **ROLE OF HEADS.**—Section 8H of the Inspector General Act of 1978 (5 U.S.C. App.) is amended—

(A) in subsection (b)—

(i) by striking paragraph (2);

(ii) by striking “(1) Not” and inserting “Not”; and

(iii) by striking “to the head of the establishment” and inserting “to the intelligence committees”; and

(B) in subsection (d)—

(i) in paragraph (1), by striking “the head of the establishment” and inserting “the intelligence committees”; and

(ii) in paragraph (2)—

(I) in subparagraph (A), by striking “the head of the establishment, through the Inspector General,” and inserting “the Inspector General”; and

(II) in subparagraph (B), by striking “the head of the establishment, through the Inspector General, in consultation with the head of the establishment.”

(2) **CONFORMING AMENDMENTS.**—Section 8H of such Act is further amended—

(A) by striking subsection (c);

(B) by redesignating subsections (d) through (i) as subsections (c) through (h), respectively; and

(C) in subsection (e), as so redesignated, by striking “subsections (a) through (e)” and inserting “subsections (a) through (d)”.

(d) **OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE.**—

(1) **IN GENERAL.**—Section 103H(k)(5) of the National Security Act of 1947 (50 U.S.C. 3033(k)(5)) is amended—

(A) in subparagraph (B), by striking “to the Director” and inserting “to the congressional intelligence committees”; and

(B) in subparagraph (D)—

(i) in clause (i), by striking “the Director” and inserting “the congressional intelligence committees”; and

(ii) in clause (ii)—

(I) in subclause (I), by striking “the Director, through the Inspector General,” and inserting “the Inspector General”; and

(II) in subclause (II), by striking “the Director, through the Inspector General,” and inserting “the Inspector General, in consultation with the Director;”.

(2) CONFORMING AMENDMENTS.—Section 103H(k)(5) of such Act is further amended—

(A) by striking subparagraph (C); and

(B) by redesignating subparagraphs (D) through (I) as subparagraphs (C) through (H), respectively.

(e) RULE OF CONSTRUCTION.—None of the amendments made by this section may be construed to prohibit or otherwise affect the authority of an Inspector General of an element of the intelligence community, the Inspector General of the Central Intelligence Agency, or the Inspector General of the Intelligence Community to notify the head of the element of the intelligence community, the Director of the Central Intelligence Agency, or the Director of National Intelligence, as the case may be, of a complaint or information otherwise authorized by law.

SEC. 309. CONGRESSIONAL OVERSIGHT OF POLICY DIRECTIVES AND GUIDANCE.

(a) COVERED POLICY DOCUMENT DEFINED.—In this section, the term “covered policy document” means any classified or unclassified Presidential Policy Directive, Presidential Policy Guidance, or other similar policy document issued by the President, including any annex to such a Directive, Guidance, or other document, that assigns takes, roles, or responsibilities the intelligence community.

(b) SUBMISSIONS TO CONGRESS.—The Director of National Intelligence shall submit to the congressional intelligence committees the following:

(1) Not later than 15 days after the date that a covered policy document is issued, a notice of the issuance and a summary of the subject matter addressed by such covered policy document.

(2) Not later than 15 days after the date that the Director issues any guidance or direction on implementation of a covered policy document or implements a covered policy document, a copy of such guidance or direction or a description of such implementation.

(3) Not later than 15 days after the date of the enactment of this Act, for any covered policy document issued prior to such date that is being implemented by any element of the intelligence community or that is in effect on such date—

(A) a notice that includes the date such covered policy document was issued and a summary of the subject matter addressed by such covered policy document; and

(B) if the Director has issued any guidance or direction on implementation of such covered policy document or is implementing such covered policy document, a copy of the guidance or direction or a description of such implementation.

SEC. 310. NOTIFICATION OF MEMORANDA OF UNDERSTANDING.

(a) IN GENERAL.—The head of each element of the intelligence community shall submit to the congressional intelligence committees a copy of each memorandum of understanding or other agreement regarding significant operational activities or policy between or among such element and any other entity or entities of the United States Government—

(1) for such a memorandum or agreement that is in effect on the date of the enactment of this Act, not later than 60 days after such date; and

(2) for such a memorandum or agreement entered into after such date, in a timely

manner and not more than 60 days after the date such memorandum or other agreement is entered into.

(b) ADMINISTRATIVE MEMORANDUM OR AGREEMENT.—Nothing in this section may be construed to require an element of the intelligence community to submit to the congressional intelligence committees any memorandum or agreement that is solely administrative in nature, including a memorandum or agreement regarding joint duty or other routine personnel assignments.

SEC. 311. TECHNICAL CORRECTION TO EXECUTIVE SCHEDULE.

Section 5313 of title 5, United States Code, is amended by striking the item relating to “Director of the National Counter Proliferation Center.”.

SEC. 312. MAXIMUM AMOUNT CHARGED FOR DECLASSIFICATION REVIEWS.

In reviewing and processing a request by a person for the mandatory declassification of information pursuant to Executive Order No. 13526, a successor executive order, or any other provision of law, the head of an element of the intelligence community—

(1) may not charge the person reproduction fees in excess of the amount of fees that the head would charge the person for reproduction required in the course of processing a request for information under section 552 of title 5, United States Code (commonly referred to as the “Freedom of Information Act”); and

(2) may waive or reduce any processing fees in the same manner as the head waives or reduces fees under such section 552.

TITLE IV—MATTERS RELATING TO ELEMENTS OF THE INTELLIGENCE COMMUNITY

Subtitle A—Office of the Director of National Intelligence

SEC. 401. DESIGNATION OF THE DIRECTOR OF THE NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER.

(a) IN GENERAL.—

(1) IN GENERAL.—Section 902 of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3382) is amended to read as follows:

“SEC. 902. DIRECTOR OF THE NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER.

“(a) ESTABLISHMENT.—There shall be a Director of the National Counterintelligence and Security Center (referred to in this section as the ‘Director’), who shall be appointed by the President, by and with the advice and consent of the Senate.

“(b) MISSION.—The mission of the Director shall be to serve as the head of national counterintelligence for the United States Government.

“(c) DUTIES.—Subject to the direction and control of the Director of National Intelligence, the duties of the Director are as follows:

“(1) To carry out the mission referred to in subsection (b).

“(2) To act as chairperson of the National Counterintelligence Policy Board established under section 811 of the Counterintelligence and Security Enhancements Act of 1994 (50 U.S.C. 3381).

“(3) To act as head of the National Counterintelligence and Security Center established under section 904.

“(4) To participate as an observer on such boards, committees, and entities of the executive branch as the Director of National Intelligence considers appropriate for the discharge of the mission and functions of the Director and the National Counterintelligence and Security Center under section 904.”.

(2) TABLE OF CONTENTS AMENDMENT.—The table of contents in section 1(b) of the Intelligence Authorization Act for Fiscal Year

2003 (Public Law 107-306; 116 Stat. 2383) is amended by striking the item relating to section 902 and inserting the following:

“Sec. 902. Director of the National Counterintelligence and Security Center.”.

(3) TECHNICAL EFFECTIVE DATE.—The amendment made by subsection (a) of section 401 of the Intelligence Authorization Act for Fiscal Year 2016 (division M of Public Law 114-113) shall not take effect, or, if the date of the enactment of this Act is on or after the effective date specified in subsection (b) of such section, such amendment shall be deemed to not have taken effect.

(b) NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER.—

(1) IN GENERAL.—Section 904 of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3383) is amended—

(A) by striking the section heading and inserting “NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER.”; and

(B) by striking subsections (a), (b), and (c) and inserting the following:

“(a) ESTABLISHMENT.—There shall be a National Counterintelligence and Security Center.

“(b) HEAD OF CENTER.—The Director of the National Counterintelligence and Security Center shall be the head of the National Counterintelligence and Security Center.

“(c) LOCATION OF CENTER.—The National Counterintelligence and Security Center shall be located in the Office of the Director of National Intelligence.”.

(2) FUNCTIONS.—Section 904(d) of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3383(d)) is amended—

(A) in the matter preceding paragraph (1), by striking “National Counterintelligence Executive, the functions of the Office of the National Counterintelligence Executive” and inserting “Director of the National Counterintelligence and Security Center, the functions of the National Counterintelligence and Security Center”;

(B) in paragraph (5), in the matter preceding subparagraph (A), by striking “In consultation with” and inserting “At the direction of”; and

(C) in paragraph (6), in the matter preceding subparagraph (A), by striking “Office” and inserting “National Counterintelligence and Security Center”.

(3) PERSONNEL.—Section 904(f) of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3383(f)) is amended—

(A) in paragraph (1), by striking “Office of the National Counterintelligence Executive may consist of personnel employed by the Office” and inserting “National Counterintelligence and Security Center may consist of personnel employed by the Center”; and

(B) in paragraph (2), by striking “National Counterintelligence Executive” and inserting “Director of the National Counterintelligence and Security Center”.

(4) TREATMENT OF ACTIVITIES UNDER CERTAIN ADMINISTRATIVE LAWS.—Section 904(g) of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3383(g)) is amended by striking “Office shall be treated as operational files of the Central Intelligence Agency for purposes of section 701 of the National Security Act of 1947 (50 U.S.C. 431)” and inserting “National Counterintelligence and Security Center shall be treated as operational files of the Central Intelligence Agency for purposes of section 701 of the National Security Act of 1947 (50 U.S.C. 3141)”.

(5) OVERSIGHT BY CONGRESS.—Section 904(h) of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3383(h)) is amended—

(A) in the matter preceding paragraph (1), by striking “Office of the National Counterintelligence Executive” and inserting “National Counterintelligence and Security Center”; and

(B) in paragraphs (1) and (2), by striking “Office” and inserting “Center” both places that term appears.

(6) TABLE OF CONTENTS AMENDMENT.—The table of contents in section 1(b) of the Intelligence Authorization Act for Fiscal Year 2003 (Public Law 107-306; 116 Stat. 2383), as amended by subsection (a)(2), is further amended by striking the item relating to section 904 and inserting the following:

“Sec. 904. National Counterintelligence and Security Center.”.

(C) OVERSIGHT OF NATIONAL INTELLIGENCE CENTERS.—Section 102A(f)(2) of the National Security Act of 1947 (50 U.S.C. 3024(f)(2)) is amended by inserting “, the National Counterproliferation Center, and the National Counterintelligence and Security Center” after “National Counterterrorism Center”.

(D) DIRECTOR OF THE NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER WITHIN THE OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE.—Paragraph (8) of section 103(c) of the National Security Act of 1947 (50 U.S.C. 3025(c)) is amended to read as follows: “(8) The Director of the National Counterintelligence and Security Center.”.

(E) DUTIES OF THE DIRECTOR OF THE NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER.—

(1) IN GENERAL.—Section 103F of the National Security Act of 1947 (50 U.S.C. 3031) is amended—

(A) by striking the section heading and inserting “DIRECTOR OF THE NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER”;

(B) in subsection (a)—

(i) by striking the subsection heading and inserting “DIRECTOR OF THE NATIONAL COUNTERINTELLIGENCE AND SECURITY CENTER.—”; and

(ii) by striking “National Counterintelligence Executive under section 902 of the Counterintelligence Enhancement Act of 2002 (title IX of Public Law 107-306; 50 U.S.C. 402b et seq.)” and inserting “Director of the National Counterintelligence and Security Center appointed under section 902 of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3382)”;

(C) in subsection (b), by striking “National Counterintelligence Executive” and inserting “Director of the National Counterintelligence and Security Center”.

(2) TABLE OF CONTENTS AMENDMENT.—The table of contents in the first section of the National Security Act of 1947 is amended by striking the item relating to section 103F and inserting the following:

“Sec. 103F. Director of the National Counterintelligence and Security Center.”.

(F) COORDINATION OF COUNTERINTELLIGENCE ACTIVITIES.—Section 811 of the Counterintelligence and Security Enhancements Act of 1994 (50 U.S.C. 3381) is amended—

(1) in subsection (b), by striking “National Counterintelligence Executive under section 902 of the Counterintelligence Enhancement Act of 2002” and inserting “Director of the National Counterintelligence and Security Center appointed under section 902 of the Counterintelligence Enhancement Act of 2002 (50 U.S.C. 3382)”;

(2) in subsection (c)(1), by striking “National Counterintelligence Executive.” and inserting “Director of the National Counterintelligence and Security Center.”; and

(3) in subsection (d)(1)(B)(ii)—

(A) by striking “National Counterintelligence Executive” and inserting “Director

of the National Counterintelligence and Security Center”;

(B) by striking “by the Office of the National Counterintelligence Executive under section 904(e)(2) of that Act” and inserting “pursuant to section 904(d)(2) of that Act (50 U.S.C. 3383(d)(2))”.

(G) INTELLIGENCE AND NATIONAL SECURITY ASPECTS OF ESPIONAGE PROSECUTIONS.—Section 341(b) of the Intelligence Authorization Act for Fiscal Year 2004 (Public Law 108-177, 28 U.S.C. 519 note) is amended by striking “Office of the National Counterintelligence Executive,” and inserting “National Counterintelligence and Security Center.”.

SEC. 402. ANALYSES AND IMPACT STATEMENTS BY DIRECTOR OF NATIONAL INTELLIGENCE REGARDING INVESTMENT INTO THE UNITED STATES.

Section 102A of the National Security Act of 1947 (50 U.S.C. 3024) is amended by adding at the end the following new subsection:

“(y) ANALYSES AND IMPACT STATEMENTS REGARDING PROPOSED INVESTMENT INTO THE UNITED STATES.—

“(1) IN GENERAL.—Not later than 20 days after the completion of a review or an investigation of any proposed investment into the United States for which the Director has prepared analytic materials, the Director shall submit to the Select Committee on Intelligence of the Senate and the Permanent Select Committee on Intelligence of the House of Representative copies of such analytic materials, including any supplements or amendments to such analysis made by the Director.

“(2) IMPACT STATEMENTS.—Not later than 60 days after the completion of consideration by the United States Government of any investment described in paragraph (1), the Director shall determine whether such investment will have an operational impact on the intelligence community, and, if so, shall submit a report on such impact to the Select Committee on Intelligence of the Senate and the Permanent Select Committee on Intelligence of the House of Representatives. Each such report shall—

“(A) describe the operational impact of the investment on the intelligence community; and

“(B) describe any actions that have been or will be taken to mitigate such impact.”.

SEC. 403. ASSISTANCE FOR GOVERNMENTAL ENTITIES AND PRIVATE ENTITIES IN RECOGNIZING ONLINE VIOLENT EXTREMIST CONTENT.

(A) ASSISTANCE TO RECOGNIZE ONLINE VIOLENT EXTREMIST CONTENT.—Not later than 180 days after the date of the enactment of this Act, and consistent with the protection of intelligence sources and methods, the Director of National Intelligence shall publish on a publicly available Internet website a list of all logos, symbols, insignia, and other markings commonly associated with, or adopted by, an organization designated by the Secretary of State as a foreign terrorist organization under section 219(a) of the Immigration and Nationality Act (8 U.S.C. 1189(a)).

(B) UPDATES.—The Director shall update the list published under subsection (a) every 180 days or more frequently as needed.

Subtitle B—Central Intelligence Agency

SEC. 411. ENHANCED DEATH BENEFITS FOR PERSONNEL OF THE CENTRAL INTELLIGENCE AGENCY.

Section 11 of the Central Intelligence Agency Act of 1949 (50 U.S.C. 3511) is amended to read as follows:

“BENEFITS AVAILABLE IN EVENT OF THE DEATH OF PERSONNEL

“SEC. 11. (a) AUTHORITY.—The Director may pay death benefits substantially similar to those authorized for members of the For-

eign Service pursuant to the Foreign Service Act of 1980 (22 U.S.C. 3901 et seq.) or any other provision of law. The Director may adjust the eligibility for death benefits as necessary to meet the unique requirements of the mission of the Agency.

“(b) REGULATIONS.—Regulations issued pursuant to this section shall be submitted to the Select Committee on Intelligence of the Senate and the Permanent Select Committee on Intelligence of the House of Representatives before such regulations take effect.”.

SEC. 412. PAY AND RETIREMENT AUTHORITIES OF THE INSPECTOR GENERAL OF THE CENTRAL INTELLIGENCE AGENCY.

(A) IN GENERAL.—Section 17(e)(7) of the Central Intelligence Agency Act of 1949 (50 U.S.C. 3517(e)(7)) is amended by adding at the end the following new subparagraph:

“(C)(i) The Inspector General may designate an officer or employee appointed in accordance with subparagraph (A) as a law enforcement officer solely for purposes of subchapter III of chapter 83 or chapter 84 of title 5, United States Code, if such officer or employee is appointed to a position with responsibility for investigating suspected offenses against the criminal laws of the United States.

“(ii) In carrying out clause (i), the Inspector General shall ensure that any authority under such clause is exercised in a manner consistent with section 3307 of title 5, United States Code, as it relates to law enforcement officers.

“(iii) For purposes of applying sections 3307(d), 8335(b), and 8425(b) of title 5, United States Code, the Inspector General may exercise the functions, powers, and duties of an agency head or appointing authority with respect to the Office.”.

(B) RULE OF CONSTRUCTION.—Subparagraph (C) of section 17(e)(7) of the Central Intelligence Agency Act of 1949 (50 U.S.C. 3517(e)(7)), as added by subsection (a), may not be construed to confer on the Inspector General of the Central Intelligence Agency, or any other officer or employee of the Agency, any police or law enforcement or internal security functions or authorities.

Subtitle C—Other Elements

SEC. 421. CLARIFICATION OF AUTHORITY, DIRECTION, AND CONTROL OVER THE INFORMATION ASSURANCE DIRECTORATE OF THE NATIONAL SECURITY AGENCY.

Section 142(b)(1) of title 10, United States Code, is amended—

(1) in subparagraph (B), by striking the semicolon and inserting “; and”;

(2) in subparagraph (C), by striking “; and” and inserting a period; and

(3) by striking subparagraph (D).

SEC. 422. ENHANCING THE TECHNICAL WORKFORCE FOR THE FEDERAL BUREAU OF INVESTIGATION.

(A) REPORT REQUIRED.—Building on the basic cyber human capital strategic plan provided to the congressional intelligence committees in 2015, not later than 180 days after the date of the enactment of this Act and updated two years thereafter, the Director of the Federal Bureau of Investigation shall submit to the congressional intelligence committees a comprehensive strategic workforce report regarding initiatives to effectively integrate information technology expertise in the investigative process.

(B) ELEMENTS.—The report required by subsection (a) shall include the following:

(1) An assessment, including measurable benchmarks, of progress on initiatives to recruit, train, and retain personnel with the necessary skills and experiences in vital areas, including encryption, cryptography, and big data analytics.

(2) An assessment of whether officers of the Federal Bureau of Investigation who possess such skills are fully integrated into the Bureau's work, including Agent-led investigations.

(3) A description of the quality and quantity of the collaborations between the Bureau and private sector entities on cyber issues, including the status of efforts to benefit from employees with experience transitioning between the public and private sectors.

(4) An assessment of the utility of reinstating, if applicable, and leveraging the Director's Advisory Board, which was originally constituted in 2005, to provide outside advice on how to better integrate technical expertise with the investigative process and on emerging concerns in cyber-related issues.

SEC. 423. PLAN ON ASSUMPTION OF CERTAIN WEATHER MISSIONS BY THE NATIONAL RECONNAISSANCE OFFICE.

(a) PLAN.—

(1) IN GENERAL.—Except as provided in subsection (c), the Director of the National Reconnaissance Office shall develop a plan for the National Reconnaissance Office to address how to carry out covered space-based environmental monitoring missions. Such plan shall include—

(A) a description of the related national security requirements for such missions;

(B) a description of the appropriate manner to meet such requirements; and

(C) the amount of funds that would be necessary to be transferred from the Air Force to the National Reconnaissance Office during fiscal years 2018 through 2022 to carry out such plan.

(2) ACTIVITIES.—In developing the plan under paragraph (1), the Director may conduct pre-acquisition activities, including with respect to requests for information, analyses of alternatives, study contracts, modeling and simulation, and other activities the Director determines necessary to develop such plan.

(3) SUBMISSION.—Not later than July 1, 2017, and except as provided in subsection (c), the Director shall submit to the appropriate congressional committees the plan under paragraph (1).

(b) INDEPENDENT COST ESTIMATE.—The Director of the Cost Assessment Improvement Group of the Office of the Director of National Intelligence, in coordination with the Director of Cost Assessment and Program Evaluation, shall certify to the appropriate congressional committees that the amounts of funds identified under subsection (a)(1)(C) as being necessary to transfer are appropriate and include funding for positions and personnel to support program office costs.

(c) WAIVER BASED ON REPORT AND CERTIFICATION OF AIR FORCE ACQUISITION PROGRAM.—The Director of the National Reconnaissance Office may waive the requirement to develop a plan under subsection (a), if the Under Secretary of Defense for Acquisition Technology, and Logistics and the Chairman of the Joint Chiefs of Staff jointly submit to the appropriate congressional committees a report by not later than July 1, 2017, that contains—

(1) a certification that the Secretary of the Air Force is carrying out a formal acquisition program that has received milestone A approval to address the cloud characterization and theater weather imagery requirements of the Department of Defense; and

(2) an identification of the cost, schedule, requirements, and acquisition strategy of such acquisition program.

(d) DEFINITIONS.—In this section:

(1) The term “appropriate congressional committees” means—

(A) the congressional intelligence committees; and

(B) the congressional defense committees (as defined in section 101(a)(16) of title 10, United States Code).

(2) The term “covered space-based environmental monitoring missions” means the acquisition programs necessary to meet the national security requirements for cloud characterization and theater weather imagery.

TITLE V—MATTERS RELATING TO FOREIGN COUNTRIES

SEC. 501. COMMITTEE TO COUNTER ACTIVE MEASURES BY THE RUSSIAN FEDERATION TO EXERT COVERT INFLUENCE OVER PEOPLES AND GOVERNMENTS.

(a) DEFINITIONS.—In this section:

(1) ACTIVE MEASURES BY RUSSIA TO EXERT COVERT INFLUENCE.—The term “active measures by Russia to exert covert influence” means activities intended to influence a person or government that are carried out in coordination with, or at the behest of, political leaders or the security services of the Russian Federation and the role of the Russian Federation has been hidden or not acknowledged publicly, including the following:

(A) Establishment or funding of a front group.

(B) Covert broadcasting.

(C) Media manipulation.

(D) Disinformation and forgeries.

(E) Funding agents of influence.

(F) Incitement and offensive counterintelligence.

(G) Assassinations.

(H) Terrorist acts.

(2) APPROPRIATE COMMITTEES OF CONGRESS.—The term “appropriate committees of Congress” means—

(A) the congressional intelligence committees;

(B) the Committee on Armed Services and the Committee on Foreign Relations of the Senate; and

(C) the Committee on Armed Services and the Committee on Foreign Affairs of the House of Representatives.

(b) ESTABLISHMENT.—There is established within the executive branch an interagency committee to counter active measures by the Russian Federation to exert covert influence.

(c) MEMBERSHIP.—

(1) IN GENERAL.—

(A) APPOINTMENT.—Each head of an agency or department of the United States Government set out under subparagraph (B) shall appoint one member of the committee established by subsection (b) from among officials of such agency or department who occupy a position that is required to be appointed by the President, with the advice and consent of the Senate.

(B) HEAD OF AN AGENCY OR DEPARTMENT.—The head of an agency or department of the United States Government set out under this subparagraph are the following:

(i) The Director of National Intelligence.

(ii) The Secretary of State.

(iii) The Secretary of Defense.

(iv) The Secretary of the Treasury.

(v) The Attorney General.

(vi) The Secretary of Energy.

(vii) The Director of the Federal Bureau of Investigation.

(viii) The head of any other agency or department of the United States Government designated by the President for purposes of this section.

(d) MEETINGS.—The committee shall meet on a regular basis.

(e) DUTIES.—The duties of the committee established by subsection (b) shall be as follows:

(1) To counter active measures by Russia to exert covert influence, including by exposing falsehoods, agents of influence, corruption, human rights abuses, terrorism, and as-

sassinations carried out by the security services or political elites of the Russian Federation or their proxies.

(2) Such other duties as the President may designate for purposes of this section.

(f) STAFF.—The committee established by subsection (b) may employ such staff as the members of such committee consider appropriate.

(g) BUDGET REQUEST.—A request for funds required for the functioning of the committee established by subsection (b) may be included in each budget for a fiscal year submitted by the President pursuant to section 1105(a) of title 31, United States Code.

(h) ANNUAL REPORT.—

(1) REQUIREMENT.—Not later than 180 days after the date of the enactment of this Act, and annually thereafter, and consistent with the protection of intelligence sources and methods, the committee established by subsection (b) shall submit to the appropriate committees of Congress a report describing steps being taken by the committee to counter active measures by Russia to exert covert influence.

(2) MATTERS INCLUDED.—Each report under paragraph (1) shall include a summary of the following:

(A) Active measures by Russia to exert covert influence during the previous year, including significant incidents and notable trends.

(B) Key initiatives of the committee.

(C) Implementation of the committee's initiatives by the heads of the agencies and departments of the United States Government specified in subsection (c)(1)(B).

(D) Analysis of the success of such initiatives.

(E) Changes to such initiatives from the previous year.

(3) SEPARATE REPORTING REQUIREMENT.—The requirement to submit an annual report under paragraph (1) is in addition to any other reporting requirements with respect to Russia.

SEC. 502. LIMITATION ON TRAVEL OF ACCREDITED DIPLOMATS AND CONSULARS OF THE RUSSIAN FEDERATION IN THE UNITED STATES FROM THEIR DIPLOMATIC POST.

(a) APPROPRIATE COMMITTEES OF CONGRESS DEFINED.—In this section, the term “appropriate committees of Congress” means—

(1) the congressional intelligence committees;

(2) the Committee on Foreign Relations and the Committee on the Judiciary of the Senate; and

(3) the Committee on Foreign Affairs and the Committee on the Judiciary of the House of Representatives.

(b) QUARTERLY LIMITATION ON TRAVEL DISTANCE.—Accredited diplomatic personnel and consulars of the Russian Federation in the United States may not be permitted to travel a distance in excess of 25 miles from their diplomatic post in the United States in a calendar quarter unless, on or before the last day of the preceding calendar quarter, the Director of the Federal Bureau of Investigation has certified in writing to the appropriate committees of Congress that during the preceding calendar quarter the Bureau did not identify any violations by accredited diplomatic personnel and consulars of the Russian Federation of applicable requirements to notify the United States Government in connection with travel by such diplomatic personnel and consulars of a distance in excess of 25 miles from their diplomatic post in the United States.

(c) APPLICABILITY.—Subsection (b) shall apply to each calendar quarter that begins more than 90 days after the date of the enactment of this Act.

(d) WAIVER AUTHORITY.—

(1) IN GENERAL.—The Director of the Federal Bureau of Investigation may waive any travel distance limitation imposed by subsection (b) if the Director determines that such a waiver will further the law enforcement or national security interests of the United States.

(2) NOTIFICATION.—Not later than 15 days after issuing a waiver under paragraph (1), the Director of the Federal Bureau of Investigation shall submit to the appropriate committees of Congress a notification that such waiver has been issued and the justification for the issuance of such waiver.

SEC. 503. STUDY AND REPORT ON ENHANCED INTELLIGENCE AND INFORMATION SHARING WITH OPEN SKIES TREATY MEMBER STATES.

(a) DEFINITIONS.—In this section:

(1) APPROPRIATE COMMITTEES OF CONGRESS.—The term “appropriate committees of Congress” means—

(A) congressional intelligence committees;

(B) the Committee on Armed Services and the Committee on Foreign Relations of the Senate; and

(C) the Committee on Armed Services and the Committee on Foreign Affairs of the House of Representatives.

(2) COVERED STATE PARTY.—The term “covered state party” means a foreign country, that—

(A) was a state party to the Open Skies Treaty on February 22, 2016; and

(B) is not the Russian Federation or the Republic of Belarus.

(3) OPEN SKIES TREATY.—The term “Open Skies Treaty” means the Treaty on Open Skies, done at Helsinki March 24, 1992, and entered into force January 1, 2002.

(b) FEASIBILITY STUDY.—

(1) REQUIREMENT FOR STUDY.—Not later than 180 days after the date of the enactment of this Act, the Director of National Intelligence shall conduct and submit to the appropriate committees of Congress a study to determine the feasibility of creating an intelligence sharing arrangement and database to provide covered state parties with imagery that is comparable, delivered more frequently, and in equal or higher resolution than imagery available through the database established under the Open Skies Treaty.

(2) ELEMENTS.—The study required by paragraph (1) shall include an evaluation of the following:

(A) The methods by which the United States could collect and provide imagery, including commercial satellite imagery, national technical means, and through other intelligence, surveillance, and reconnaissance platforms, under an information sharing arrangement and database referred to in paragraph (1).

(B) The ability of other covered state parties to contribute imagery to the arrangement and database.

(C) Any impediments to the United States and other covered states parties providing such imagery, including any statutory barriers, insufficiencies in the ability to collect the imagery or funding, under such an arrangement.

(D) Whether imagery of Moscow, Chechnya, the international border between Russia and Georgia, Kaliningrad, or the Republic of Belarus could be provided under such an arrangement.

(E) The annual and projected costs associated with the establishment of such an arrangement and database, as compared with costs to the United States and other covered state parties of being parties to the Open Skies Treaty, including Open Skies Treaty plane maintenance, aircraft fuel, crew expenses, mitigation measures necessary associated with Russian Federation overflights over the United States or covered state par-

ties, and new sensor development and acquisition.

(3) SUPPORT FROM OTHER FEDERAL AGENCIES.—Each head of a Federal agency shall provide such support to the Director as may be necessary for the Director to conduct the study required by paragraph (1).

(c) REPORT.—

(1) REQUIREMENT FOR REPORT.—Not later than 180 days after the date of the enactment of this Act, the Director of National Intelligence shall submit to the appropriate committees of Congress the report described in this subsection.

(2) CONTENT OF REPORT.—The report required by paragraph (1) shall include the following:

(A) An intelligence assessment on Russian Federation warfighting doctrine and the extent to which Russian Federation flights under the Open Skies Treaty contribute to such doctrine.

(B) A counterintelligence analysis as to whether the Russian Federation has, could have, or intends to have the capability to exceed the imagery limits set forth in the Open Skies Treaty.

(C) A list of intelligence exchanges with covered state parties that have been updated on the information described in subparagraphs (A) and (B) and the date and form such information was provided.

(d) FORM OF SUBMISSION.—The study required by subsection (b) and the report required by subsection (c) shall be submitted in an unclassified form but may include a classified annex.

TITLE VI—PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD

SEC. 601. INFORMATION ON ACTIVITIES OF THE PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD.

Subsection (e) of section 1061 of the Intelligence Reform and Terrorism Prevention Act of 2004 (42 U.S.C. 2000ee(e)) is amended—

(1) by striking the subsection heading and inserting “REPORTS AND OVERSIGHT ACTIVITIES.—”; and

(2) by adding at the end the following:

“(3) INFORMATION.—

“(A) OVERSIGHT ACTIVITIES.—In addition to the reports submitted under paragraph (1)(B), the Board shall ensure that each official and congressional committee specified in subparagraph (B) is kept fully and currently informed of the oversight activities of the Board, including any significant anticipated oversight activities.

“(B) OFFICIALS AND CONGRESSIONAL COMMITTEES SPECIFIED.—The officials and congressional committees specified in this subparagraph are the following:

“(i) The Director of National Intelligence.

“(ii) The head of any element of the intelligence community (as defined in section 3(4) of the National Security Act of 1947 (50 U.S.C. 3003(4)) the activities of which are, or are anticipated to be, the subject of the Board’s oversight activities.

“(iii) The Select Committee on Intelligence of the Senate and the Permanent Select Committee on Intelligence of the House of Representatives.

“(C) EXEMPTION FOR STATUTORY ADVICE FUNCTION.—This paragraph shall not apply to exercises of the Board’s advice function as set out in subsection (d)(1).

“(D) PRESERVATION OF PRIVILEGE.—Nothing in this paragraph may be construed to abridge or require waiver of any applicable privilege.

“(4) REPORTS ON ADVICE TO ELEMENTS OF THE INTELLIGENCE COMMUNITY.—Whenever an element of the intelligence community acts in contravention of the advice provided by the Board under subsection (d)(1), the Board shall, no less than 30 days after the action in

contravention of the Board’s advice, notify the Select Committee on Intelligence of the Senate and the Permanent Select Committee on Intelligence of the House of Representatives of the provision of advice and of the action by the element of the intelligence community.”.

SEC. 602. AUTHORIZATION OF APPROPRIATIONS FOR PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD.

(a) REQUIREMENT FOR AUTHORIZATIONS.—Subsection (m) of section 1061 of the Intelligence Reform and Terrorism Prevention Act of 2004 (42 U.S.C. 2000ee(m)) is amended to read as follows:

“(m) FUNDING.—

“(1) SPECIFIC AUTHORIZATION REQUIRED.—Appropriated funds available to the Board may be obligated or expended to carry out activities under this section only if such funds were specifically authorized by Congress for use for such activities for such fiscal year.

“(2) DEFINITION.—In this subsection, the term ‘specifically authorized by Congress’ has the meaning given that term in section 504(e) of the National Security Act of 1947 (50 U.S.C. 3094(e)).”.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Privacy and Civil Liberties Oversight Board for fiscal year 2017 the sum of \$10,081,000 to carry out the activities of the Board under section 1061 of the Intelligence Reform and Terrorism Prevention Act of 2004 (42 U.S.C. 2000ee).

TITLE VII—REPORTS AND OTHER MATTERS

SEC. 701. DECLASSIFICATION REVIEW WITH RESPECT TO DETAINEES TRANSFERRED FROM UNITED STATES NAVAL STATION, GUANTANAMO BAY, CUBA.

(a) IN GENERAL.—For each individual detained at United States Naval Station, Guantanamo Bay, Cuba, after September 11, 2001, who was transferred or released from United States Naval Station, Guantanamo Bay, Cuba, the Director of National Intelligence shall—

(1)(A) complete a declassification review of intelligence reports regarding past terrorist activities of that individual prepared by the National Counterterrorism Center for the individual’s Periodic Review Board sessions, transfer, or release; or

(B) if the individual’s transfer or release occurred prior to the date on which the National Counterterrorism Center first began to prepare such reports regarding detainees, such other intelligence report or reports that contain the same or similar information regarding the individual’s past terrorist activities;

(2) make available to the public—

(A) any intelligence reports declassified as a result of the declassification review; and

(B) with respect to each individual transferred or released, for whom intelligence reports are declassified as a result of the declassification review, an unclassified summary which shall be prepared by the President of measures being taken by the country to which the individual was transferred or released to monitor the individual and to prevent the individual from carrying out future terrorist activities; and

(3) submit to the congressional intelligence committees a report setting out the results of the declassification review, including a description of intelligence reports covered by the review that were not declassified.

(b) SCHEDULE.—

(1) TRANSFER OR RELEASE PRIOR TO ENACTMENT.—Not later than 210 days after the date of the enactment of this Act, the Director of National Intelligence shall submit the report

required by subsection (a)(3), which shall include the results of the declassification review completed for each individual detained at United States Naval Station, Guantanamo Bay, Cuba, who was transferred or released from United States Naval Station, Guantanamo Bay, prior to the date of the enactment of this Act.

(2) **TRANSFER OR RELEASE AFTER ENACTMENT.**—Not later than 120 days after the date an individual detained at United States Naval Station, Guantanamo Bay, on or after the date of the enactment of this Act is transferred or released from United States Naval Station, Guantanamo Bay, the Director shall submit the report required by subsection (a)(3) for such individual.

(c) **PAST TERRORIST ACTIVITIES.**—For purposes of this section, the past terrorist activities of an individual shall include all terrorist activities conducted by the individual before the individual's transfer to the detention facility at United States Naval Station, Guantanamo Bay, including, at a minimum, the following:

(1) The terrorist organization, if any, with which affiliated.

(2) The terrorist training, if any, received.

(3) The role in past terrorist attacks against United States interests or allies.

(4) The direct responsibility, if any, for the death of United States citizens or members of the Armed Forces.

(5) Any admission of any matter specified in paragraphs (1) through (4).

SEC. 702. CYBER CENTER FOR EDUCATION AND INNOVATION HOME OF THE NATIONAL CRYPTOLOGIC MUSEUM.

(a) **AUTHORITY TO ESTABLISH AND OPERATE CENTER.**—Chapter 449 of title 10, United States Code, is amended by adding at the end the following new section:

“§ 4781. Cyber Center for Education and Innovation Home of the National Cryptologic Museum

“(a) **ESTABLISHMENT.**—(1) The Secretary of Defense may establish at a publicly accessible location at Fort George G. Meade the ‘Cyber Center for Education and Innovation Home of the National Cryptologic Museum’ (in this section referred to as the ‘Center’).

“(2) The Center may be used for the identification, curation, storage, and public viewing of materials relating to the activities of the National Security Agency, any predecessor or successor organizations of such Agency, and the history of cryptology.

“(3) The Center may contain meeting, conference, and classroom facilities that will be used to support such education, training, public outreach, and other purposes as the Secretary considers appropriate.

“(b) **DESIGN, CONSTRUCTION, AND OPERATION.**—The Secretary may enter into an agreement with the National Cryptologic Museum Foundation (in this section referred to as the ‘Foundation’), a nonprofit organization, for the design, construction, and operation of the Center.

“(c) **ACCEPTANCE AUTHORITY.**—(1) If the Foundation constructs the Center pursuant to an agreement with the Foundation under subsection (b), upon satisfactory completion of the Center's construction or any phase thereof, as determined by the Secretary, and upon full satisfaction by the Foundation of any other obligations pursuant to such agreement, the Secretary may accept the Center (or any phase thereof) from the Foundation, and all right, title, and interest in the Center or such phase shall vest in the United States.

“(2) Notwithstanding section 1342 of title 31, the Secretary may accept services from the Foundation in connection with the design construction, and operation of the Center. For purposes of this section and any

other provision of law, employees or personnel of the Foundation shall not be considered to be employees of the United States.

“(d) **FEES AND USER CHARGES.**—(1) The Secretary may assess fees and user charges to cover the cost of the use of Center facilities and property, including rental, user, content, and concession fees.

“(2) Amounts received under paragraph (1) shall be deposited into the fund established under subsection (e).

“(e) **FUND.**—(1) Upon the Secretary's acceptance of the Center under subsection (c)(1) there is established in the Treasury a fund to be known as the ‘Cyber Center for Education and Innovation-Home of the National Cryptologic Museum Fund’ (in this subsection referred to as the ‘Fund’).

“(2) The Fund shall consist of the following amounts:

“(A) Fees and user charges deposited by the Secretary under subsection (d).

“(B) Any other amounts received by the Secretary which are attributable to the operation of the Center.

“(3) Amounts in the Fund shall be available to the Secretary for the benefit and operation of the Center, including the costs of operation and the acquisition of books, manuscripts, works of art, historical artifacts, drawings, plans, models, and condemned or obsolete combat materiel.”

(b) **CLERICAL AMENDMENT.**—The table of sections at the beginning of chapter 449 of title 10, United States Code, is amended by adding at the end the following new item:

“4781. Cyber Center for Education and Innovation Home of the National Cryptologic Museum.”

SEC. 703. OVERSIGHT OF NATIONAL SECURITY SYSTEMS.

(a) **IN GENERAL.**—Section 3557 of title 44, United States Code, is amended—

(1) by striking “The head” and inserting the following:

“(c) **RESPONSIBILITIES OF AGENCIES.**—The head”; and

(2) by inserting before subsection (c), as designated by paragraph (1), the following:

“(a) **DEFINITIONS.**—In this section:

“(1) **BINDING OPERATIONAL DIRECTIVE.**—Notwithstanding section 3552(b), the term ‘binding operational directive’ means a compulsory direction to an agency that—

“(A) is for purposes of safeguarding national security information and information systems from a known or reasonably suspected information security threat, vulnerability, or risk; and

“(B) shall be in accordance with policies, principles, standards, and guidelines issued by the Committee.

“(2) **COMMITTEE.**—The term ‘Committee’ means the committee established pursuant to National Security Directive 42, signed by the President on July 5, 1990.

“(3) **NATIONAL MANAGER.**—The term ‘National Manager’ means the national manager referred to in National Security Directive 42, signed by the President on July 5, 1990.

“(b) **OVERSIGHT BY NATIONAL MANAGER.**—

“(1) **DESIGNATION.**—The Director of the National Security Agency shall serve as the National Manager.

“(2) **REGISTRATION OF NATIONAL SECURITY SYSTEMS.**—

“(A) **IN GENERAL.**—Each head of an agency that operates or exercises control of a national security system shall register such system and its configuration with the National Manager.

“(B) **LIMITATION.**—The head of an agency operating or exercising control of a national security system may not operate or exercise control of such national security system until such head receives a letter from the National Manager that acknowledges registration of such national security system.

“(3) **AUTHORITY TO INSPECT.**—The National Manager, in consultation with the head of an agency that operates or exercises control of a national security system, may, as the National Manager considers appropriate, inspect such system—

“(A) for adherence to such standards as the Committee may establish for national security systems; and

“(B) to confirm whether the national security system coheres with its configuration registered under paragraph (2).

“(4) **BINDING OPERATIONAL DIRECTIVES.**—

“(A) **IN GENERAL.**—Except as provided in subparagraph (B), the National Manager, in consultation with the Committee, may issue such binding operational directives as the National Manager considers appropriate to ensure the security of a national security system.

“(B) **LIMITATION.**—In any case in which the National Manager issues an operational directive under subparagraph (A) with respect to a national security system operated or controlled by an agency, such operational directive shall not be considered binding if the head of such agency submits to the National Manager a certification that the operational directive would degrade national security.

“(C) **ANNUAL REPORT.**—Not less frequently than once each year, the National Manager shall submit to the Select Committee on Intelligence of the Senate and the Permanent Select Committee on Intelligence of the House of Representatives a report on the certifications submitted to the National Manager under subparagraph (B) in the most recent year preceding the report.”

(b) **CONSIDERATION OF CERTAIN ROUTINE ADMINISTRATIVE AND BUSINESS APPLICATIONS AS NATIONAL SECURITY SYSTEMS.**—

(1) **TITLE 40.**—Section 11103(a) of title 40, United States Code, is amended—

(A) by striking paragraph (2);

(B) in paragraph (1)(E), by striking “subject to paragraph (2),”; and

(C) by striking “DEFINITION.” and all that follows through “In this section” and inserting “NATIONAL SECURITY SYSTEM DEFINED.—In this section”; and

(D) by redesignating subparagraphs (A) through (E) as paragraphs (1) through (5), respectively, and moving such paragraphs 2 ems to the left.

(2) **TITLE 44.**—Section 3552(b)(6) of title 44, United States Code, is amended—

(A) by striking subparagraph (B);

(B) in subparagraph (A), by striking “(A)”; and

(C) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively;

(D) by redesignating subclauses (I) through (V) as clauses (i) through (v), respectively; and

(E) in subparagraph (A)(v), as redesignated, by striking “subject to subparagraph (B).”

SEC. 704. JOINT FACILITIES CERTIFICATION.

(a) **FINDINGS.**—Congress finds the following:

(1) The Director of National Intelligence set a strategic goal to use joint facilities as a means to save costs by consolidating administrative and support functions across multiple elements of the intelligence community.

(2) The use of joint facilities provides more opportunities for operational collaboration and information sharing among elements of the intelligence community.

(b) **CERTIFICATION.**—Before an element of the intelligence community purchases, leases, or constructs a new facility that is 20,000 square feet or larger, the head of that element of the intelligence community shall submit to the Director of National Intelligence—

(1) a certification that, to the best of the knowledge of the head of such element, all

prospective joint facilities in the vicinity have been considered and the element is unable to identify a joint facility that meets the operational requirements of such element; and

(2) a statement listing the reasons for not participating in the prospective joint facilities considered by the element.

SEC. 705. LEADERSHIP AND MANAGEMENT OF SPACE ACTIVITIES.

(a) **APPROPRIATE COMMITTEES OF CONGRESS DEFINED.**—In this section, the term “appropriate committees of Congress” means the congressional intelligence committees, the Committee on Armed Services of the Senate, and the Committee on Armed Services of the House of Representatives.

(b) **UPDATE TO STRATEGY FOR COMPREHENSIVE INTERAGENCY REVIEW OF THE UNITED STATES NATIONAL SECURITY OVERHEAD SATELLITE ARCHITECTURE.**—Not later than 180 days after the date of the enactment of this Act, the Director of National Intelligence, in consultation with the Secretary of Defense and the Chairman of the Joint Chiefs of Staff, shall issue an update to the strategy required by section 312 of the Intelligence Authorization Act for Fiscal Year 2016 (division M of Public Law 114-113; 129 Stat. 2919).

(c) **UNITY OF EFFORT IN SPACE OPERATIONS BETWEEN THE INTELLIGENCE COMMUNITY AND DEPARTMENT OF DEFENSE.**—

(1) **REQUIREMENT FOR PLAN.**—Not later than 90 days after the date of the enactment of this Act, the Director of National Intelligence, in consultation with the Secretary of Defense, shall submit to the appropriate committees of Congress a plan to functionally integrate the governance, operations, analysis, collection, policy, and acquisition activities related to space and counterspace carried out by the intelligence community. The plan shall include analysis of no fewer than 2 alternative constructs to implement this plan, and an assessment of statutory, policy, organizational, programmatic, and resources changes that may be required to implement each alternative construct.

(2) **APPOINTMENT BY THE DIRECTOR OF NATIONAL INTELLIGENCE.**—Not later than 30 days after the date of the enactment of this Act, the Director of National Intelligence, in consultation with the Secretary of Defense, shall appoint a single official to oversee development of the plan required by paragraph (1).

(3) **SCOPE OF PLAN.**—The plan required by paragraph (1) shall include methods to functionally integrate activities carried out by—

- (A) the National Reconnaissance Office;
- (B) the functional managers for signals intelligence and geospatial intelligence;
- (C) the Office of the Director of National Intelligence;
- (D) other Intelligence Community elements with space-related programs;
- (E) joint interagency efforts; and
- (F) other entities as identified by the Director of National Intelligence in coordination with the Secretary of Defense.

(d) **INTELLIGENCE COMMUNITY SPACE WORKFORCE.**—Not later than 90 days after the date of the enactment of this Act, the Director of National Intelligence shall submit to the congressional intelligence committees a workforce plan to recruit, develop, and retain personnel in the intelligence community with skills and experience in space and counterspace operations, analysis, collection, policy, and acquisition.

(e) **JOINT INTERAGENCY COMBINED SPACE OPERATIONS CENTER.**—

(1) **SUBMISSION TO CONGRESS.**—The Director of the National Reconnaissance Office and the Commander of the United States Strategic Command, in consultation with the Director of National Intelligence and Under Secretary of Defense for Intelligence, shall

submit to the appropriate committees of Congress concept of operations and requirements documents for the Joint Interagency Combined Space Operations Center by the date that is the earlier of—

(A) the completion of the experimental phase of such Center; or

(B) 30 days after the date of the enactment of this Act.

(2) **QUARTERLY BRIEFINGS.**—The Director of the National Reconnaissance Office and the Commander of the United States Strategic Command, in coordination with the Director of National Intelligence and Under Secretary of Defense for Intelligence, shall provide to the appropriate committees of Congress briefings providing updates on activities and progress of the Joint Interagency Combined Space Operations Center to begin 30 days after the date of the enactment of this Act. Such briefings shall be quarterly for the first year following enactment, and annually thereafter.

SEC. 706. ADVANCES IN LIFE SCIENCES AND BIOTECHNOLOGY.

(a) **REQUIREMENT FOR PLAN.**—Not later than 180 days after the date of the enactment of this Act, the Director of National Intelligence shall brief the congressional intelligence committees on a proposed plan to monitor advances in life sciences and biotechnology to be carried out by the Director.

(b) **CONTENTS OF PLAN.**—The plan required by subsection (a) shall include—

(1) a description of the approach the elements of the intelligence community will take to make use of organic life science and biotechnology expertise within and outside the intelligence community on a routine and contingency basis;

(2) an assessment of the current collection and analytical posture of the life sciences and biotechnology portfolio as it relates to United States competitiveness and the global bio-economy, the risks and threats evolving with advances in genetic editing technologies, and the implications of such advances on future biodefense requirements; and

(3) an analysis of organizational requirements and responsibilities, including potentially creating new positions.

(c) **REPORT TO CONGRESS.**—Not later than 180 days after the date of the enactment of this Act, the Director of National Intelligence shall submit to the congressional intelligence committees, the Committee on Armed Services of the Senate, and the Committee on Armed Services of the House of Representatives a report and provide a briefing on the role of the intelligence community in the event of a biological attack on the United States, including an assessment of the capabilities and gaps in technical capabilities that exist to address the potential circumstance of a novel unknown pathogen.

SEC. 707. REPORTS ON DECLASSIFICATION PROPOSALS.

(a) **COVERED STUDIES DEFINED.**—In this section, the term “covered studies” means the studies that the Director of National Intelligence requested that the elements of the intelligence community produce in the course of producing the fundamental classification guidance review for fiscal year 2017 required by Executive Order No. 13526 (50 U.S.C. 3161 note), as follows:

(1) A study of the feasibility of reducing the number of original classification authorities in each element of the intelligence community to the minimum number required and any negative impacts that reduction could have on mission capabilities.

(2) A study of the actions required to implement a proactive discretionary declassification program distinct from the systematic, automatic, and mandatory declassification

review programs outlined in part 2001 of title 32, Code of Federal Regulations, including section 2001.35 of such part.

(3) A study of the benefits and drawbacks of implementing a single classification guide that could be used by all elements of the intelligence community in the nonoperational and more common areas of such elements.

(4) A study of whether the classification level of “confidential” could be eliminated within agency-generated classification guides from use by elements of the intelligence community and any negative impacts that elimination could have on mission success.

(b) **REPORTS AND BRIEFINGS TO CONGRESS.**—

(1) **PROGRESS REPORT.**—Not later than 30 days after the date of the enactment of this Act, the Director of National Intelligence shall submit a report to the congressional intelligence committees and provide the congressional intelligence committees a briefing on the progress of the elements of the intelligence community in producing the covered studies.

(2) **FINAL REPORT.**—Not later than the earlier of 120 days after the date of the enactment of this Act or June 30, 2017, the Director of National Intelligence shall submit a report and provide a briefing to the congressional intelligence committees on—

(A) the final versions of the covered studies that have been provided to the Director by the elements of the intelligence community; and

(B) a plan for implementation of each initiative included in each such covered study.

SEC. 708. IMPROVEMENT IN GOVERNMENT CLASSIFICATION AND DECLASSIFICATION.

(a) **REVIEW OF GOVERNMENT CLASSIFICATION AND DECLASSIFICATION.**—Not later than 180 days after the date of the enactment of this Act, the Director of National Intelligence shall—

(1) review the system by which the Government classifies and declassifies information;

(2) develop recommendations—

- (A) to make such system a more effective tool for the protection of information relating to national security;
- (B) to improve the sharing of information with partners and allies of the Government; and

(3) to support the appropriate declassification of information; and

(4) submit to the congressional intelligence committees a report with—

- (A) the findings of the Director with respect to the review conducted under paragraph (1); and
- (B) the recommendations developed under paragraph (2).

(b) **ANNUAL CERTIFICATION OF CONTROLLED ACCESS PROGRAMS.**—

(1) **IN GENERAL.**—Not less frequently than once each year, the Director of National Intelligence shall certify to the congressional intelligence committees whether the creation, validation, or substantial modification, including termination, for all existing and proposed controlled access programs, and the compartments and subcompartments within each, are substantiated and justified based on the information required by paragraph (2).

(2) **INFORMATION REQUIRED.**—Each certification pursuant to paragraph (1) shall include—

- (A) the rationale for the revalidation, validation, or substantial modification, including termination, of each controlled access program, compartment and subcompartment;
- (B) the identification of a control officer for each controlled access program; and
- (C) a statement of protection requirements for each controlled access program.

SEC. 709. REPORT ON IMPLEMENTATION OF RESEARCH AND DEVELOPMENT RECOMMENDATIONS.

Not later than 120 days after the date of the enactment of this Act, the Director of National Intelligence shall submit to the congressional intelligence committees a report that includes the following:

(1) An assessment of the actions each element of the intelligence community has completed to implement the recommendations made by the National Commission for the Review of the Research and Development Programs of the United States Intelligence Community established under section 1002 of the Intelligence Authorization Act for Fiscal Year 2003 (Public Law 107-306; 50 U.S.C. 3001 note).

(2) An analysis of the balance between short-, medium-, and long-term research efforts carried out by each element of the intelligence community.

SEC. 710. REPORT ON INTELLIGENCE COMMUNITY RESEARCH AND DEVELOPMENT CORPS.

Not later than 120 days after the date of the enactment of this Act, the Director of National Intelligence shall submit to the congressional intelligence committees a report and a briefing on a plan, with milestones and benchmarks, to implement an Intelligence Community Research and Development Corps, as recommended in the Report of the National Commission for the Review of the Research and Development Programs of the United States Intelligence Community, including an assessment—

(1) of the funding and modification to existing authorities needed to allow for the implementation of such Corps; and

(2) of additional legislative authorities, if any, necessary to undertake such implementation.

SEC. 711. REPORT ON INFORMATION RELATING TO ACADEMIC PROGRAMS, SCHOLARSHIPS, FELLOWSHIPS, AND INTERNSHIPS SPONSORED, ADMINISTERED, OR USED BY THE INTELLIGENCE COMMUNITY.

(a) REPORT.—Not later than 120 days after the date of the enactment of this Act, the Director of National Intelligence shall submit to the congressional intelligence committees a report by the intelligence community regarding covered academic programs. Such report shall include—

(1) a description of the extent to which the Director and the heads of the elements of the intelligence community independently collect information on covered academic programs, including with respect to—

(A) the number of applicants for such programs;

(B) the number of individuals who have participated in such programs; and

(C) the number of individuals who have participated in such programs and were hired by an element of the intelligence community after completing such program;

(2) to the extent that the Director and the heads independently collect the information described in paragraph (1), a chart, table, or other compilation illustrating such information for each covered academic program and element of the intelligence community, as appropriate, during the three-year period preceding the date of the report; and

(3) to the extent that the Director and the heads do not independently collect the information described in paragraph (1) as of the date of the report—

(A) whether the Director and the heads can begin collecting such information during fiscal year 2017; and

(B) the personnel, tools, and other resources required by the Director and the heads to independently collect such information.

(b) COVERED ACADEMIC PROGRAMS DEFINED.—In this section, the term “covered academic programs” means—

(1) the Federal Cyber Scholarship-for-Service Program under section 302 of the Cybersecurity Enhancement Act of 2014 (15 U.S.C. 7442);

(2) the National Security Education Program under the David L. Boren National Security Education Act of 1991 (50 U.S.C. 1901 et seq.);

(3) the Science, Mathematics, and Research for Transformation Defense Education Program under section 2192a of title 10, United States Code;

(4) the National Centers of Academic Excellence in Information Assurance and Cyber Defense of the National Security Agency and the Department of Homeland Security; and

(5) any other academic program, scholarship program, fellowship program, or internship program sponsored, administered, or used by an element of the intelligence community.

SEC. 712. REPORT ON INTELLIGENCE COMMUNITY EMPLOYEES DETAILED TO NATIONAL SECURITY COUNCIL.

Not later than 60 days after the date of the enactment of this Act, the Director of National Intelligence shall submit to the congressional intelligence committees a report listing, by year, the number of employees of an element of the intelligence community who have been detailed to the National Security Council during the 10-year period preceding the date of the report.

SEC. 713. INTELLIGENCE COMMUNITY REPORTING TO CONGRESS ON FOREIGN FIGHTER FLOWS.

(a) REPORTS REQUIRED.—Not later than 60 days after the date of the enactment of this Act, and every 180 days thereafter, the Director of National Intelligence, consistent with the protection of intelligence sources and methods, shall submit to the appropriate congressional committees a report on foreign fighter flows to and from terrorist safe havens abroad.

(b) CONTENTS.—Each report submitted under subsection (a) shall include, with respect to each terrorist safe haven, the following:

(1) The total number of foreign fighters who have traveled or are suspected of having traveled to the terrorist safe haven since 2011, including the countries of origin of such foreign fighters.

(2) The total number of United States citizens present in the terrorist safe haven.

(3) The total number of foreign fighters who have left the terrorist safe haven or whose whereabouts are unknown.

(c) FORM.—The reports submitted under subsection (a) may be submitted in classified form. If such a report is submitted in classified form, such report shall also include an unclassified summary.

(d) SUNSET.—The requirement to submit reports under subsection (a) shall terminate on the date that is two years after the date of the enactment of this Act.

(e) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.—In this section, the term “appropriate congressional committees” means—

(1) in the Senate—

(A) the Committee on Armed Services;
(B) the Select Committee on Intelligence;
(C) the Committee on the Judiciary;
(D) the Committee on Homeland Security and Governmental Affairs;
(E) the Committee on Banking, Housing, and Urban Affairs;
(F) the Committee on Foreign Relations; and

(G) the Committee on Appropriations; and

(2) in the House of Representatives—

(A) the Committee on Armed Services;

(B) the Permanent Select Committee on Intelligence;

(C) the Committee on the Judiciary;

(D) the Committee on Homeland Security;

(E) the Committee on Financial Services;

(F) the Committee on Foreign Affairs; and

(G) the Committee on Appropriations.

SEC. 714. REPORT ON CYBERSECURITY THREATS TO SEAPORTS OF THE UNITED STATES AND MARITIME SHIPPING.

(a) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Under Secretary of Homeland Security for Intelligence and Analysis, in consultation with the Director of National Intelligence, and consistent with the protection of sources and methods, shall submit to the appropriate congressional committees a report on the cybersecurity threats to, and the cyber vulnerabilities within, the software, communications networks, computer networks, or other systems employed by—

(1) entities conducting significant operations at seaports in the United States;

(2) the maritime shipping concerns of the United States; and

(3) entities conducting significant operations at transshipment points in the United States.

(b) MATTERS INCLUDED.—The report under subsection (a) shall include the following:

(1) A description of any recent and significant cyberattacks or cybersecurity threats directed against software, communications networks, computer networks, or other systems employed by the entities and concerns described in paragraphs (1) through (3) of subsection (a).

(2) An assessment of—

(A) any planned cyberattacks directed against such software, networks, and systems;

(B) any significant vulnerabilities to such software, networks, and systems; and

(C) how such entities and concerns are mitigating such vulnerabilities.

(3) An update on the status of the efforts of the Coast Guard to include cybersecurity concerns in the National Response Framework, Emergency Support Functions, or both, relating to the shipping or ports of the United States.

(c) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.—In this section, the term “appropriate congressional committees” means—

(1) the congressional intelligence committees; and

(2) the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Homeland Security of the House of Representatives.

SEC. 715. REPORT ON COUNTER-MESSAGING ACTIVITIES.

(a) REPORT.—Not later than 60 days after the date of the enactment of this Act, the Under Secretary of Homeland Security for Intelligence and Analysis, consistent with the protection of sources and methods, shall submit to the appropriate congressional committees a report on the counter-messaging activities of the Department of Homeland Security with respect to the Islamic State and other extremist groups.

(b) ELEMENTS.—The report under subsection (a) shall include the following:

(1) A description of whether, and to what extent, the Secretary of Homeland Security, in conducting counter-messaging activities with respect to the Islamic State and other extremist groups, consults or coordinates with the Secretary of State, regarding the counter-messaging activities undertaken by the Department of State with respect to the Islamic State and other extremist groups, including counter-messaging activities conducted by the Global Engagement Center of the Department of State.

(2) Any criteria employed by the Secretary of Homeland Security for selecting, developing, promulgating, or changing the counter-messaging approach of the Department of Homeland Security, including any counter-messaging narratives, with respect to the Islamic State and other extremist groups.

(c) **APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.**—In this section, the term “appropriate congressional committees” means—

(1) the congressional intelligence committees; and

(2) the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Homeland Security of the House of Representatives.

SEC. 716. REPORT ON REPRISALS AGAINST CONTRACTORS OF THE INTELLIGENCE COMMUNITY.

(a) **REPORT.**—Not later than 180 days after the date of the enactment of this Act, the Inspector General of the Intelligence Community, consistent with the protection of sources and methods, shall submit to the congressional intelligence committees a report on reprisals made against covered contractor employees.

(b) **ELEMENTS.**—The report under subsection (a) shall include the following:

(1) Identification of the number of known or claimed reprisals made against covered contractor employees during the 3-year period preceding the date of the report and any evaluation of such reprisals.

(2) An evaluation of the usefulness of establishing a prohibition on reprisals against covered contractor employees as a means of encouraging such contractors to make protected disclosures.

(3) A description of any challenges associated with establishing such a prohibition, including with respect to the nature of the relationship between the Federal Government, the contractor, and the covered contractor employee.

(4) A description of any approaches taken by the Federal Government to account for reprisals against non-intelligence community contractors who make protected disclosures, including pursuant to section 2409 of title 10, United States Code, and sections 4705 and 4712 of title 41, United States Code.

(5) Any recommendations the Inspector General determines appropriate.

(c) **DEFINITIONS.**—In this section:

(1) **COVERED CONTRACTOR EMPLOYEE.**—The term “covered contractor employee” means an employee of a contractor of an element of the intelligence community.

(2) **REPRISAL.**—The term “reprisal” means the discharge or other adverse personnel action made against a covered contractor employee for making a disclosure of information that would be a disclosure protected by law if the contractor were an employee of the Federal Government.

The **SPEAKER** pro tempore. Pursuant to the rule, the gentleman from California (Mr. NUNES) and the gentleman from California (Mr. SCHIFF) each will control 20 minutes.

The Chair recognizes the gentleman from California (Mr. NUNES).

GENERAL LEAVE

Mr. NUNES. Mr. Speaker, I ask unanimous consent that all Members have 5 legislative days to revise and extend their remarks and to include extraneous material on H.R. 6393.

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

There was no objection.

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

Passing an annual intelligence authorization bill is the most important tool Congress has to conduct effective oversight of the activities of the United States Government. Today, Ranking Member SCHIFF and I are bringing a fiscal year 2017 intelligence authorization bill to the floor for the second time this year. When enacted, it will mark the seventh consecutive Intelligence Authorization Act.

In May, H.R. 5077 passed the House with a strong bipartisan vote. I am pleased to say that this bill, H.R. 6393, is likewise a bipartisan product that reflects the contributions of all of the committee’s members.

The bill contains provisions from H.R. 5077 that won wide bipartisan support in May and, after extensive negotiations with the Senate, incorporates numerous provisions from S. 3017, which was reported by the Senate Select Committee on Intelligence in June.

Because most of the intelligence budget involves highly classified programs, the committee’s schedule of authorizations and the bulk of the committee’s direction is found in the classified annex to the bill. This classified annex has been available in HVC-304 for all Members to review since yesterday.

At the unclassified level, I can report that the total funding authorized by H.R. 6393 balances fiscal discipline and national security. This bill will keep the intelligence base funding at the same share of the Bipartisan Budget Act discretionary cap as in fiscal year 2016 and is consistent with the administration’s amended budget request for overseas contingency operations. Furthermore, the bill funds the Military Intelligence Program in line with the levels of the conference version of the National Defense Authorization Act for Fiscal Year 2017.

The agreed text preserves key committee, House, and Senate funding initiatives that are vital to national security. The bill funds high-priority initiatives not included in the President’s request and trims requested increases that lack clear justifications. It reflects careful judgments as to which programs represent the best value for intelligence dollars in a challenging budget environment.

The bill will ensure that the men and women of our intelligence community have the funding, authorities, and support they need to carry out their mission and to keep us safe.

Before closing, I want to take a moment to thank the men and women of this country who serve in our intelligence community and thank the families of those who have lost their lives while serving in silence. I am honored to have gotten to know so many dedicated intelligence personnel in the course of the committee’s oversight work.

I would also like to thank all of the committee’s members—majority and

minority—for their contributions to this bill. The many hearings, briefings, and oversight visits by our members carried out during the year provide the inputs for the authorization and direction in this annual bill and ensure the intelligence community remains accountable to the robust oversight of the people’s elected Representatives.

I would like to thank my staff, including our staff director—Damon Nelson—George Pappas, Derek Harvey, Geof Kahn, Shannon Stuart, Michael Ellis, Scott Glabe, Jack Langer, Nick Ciarlante, Marissa Skaggs, Bill Flanagan, Lisa Major, Chelsey Campbell, Doug Presley, Andrew House, Steve Keith, and Angel Smith. I would also like to thank our two fellows from Los Alamos National Laboratory—Scott Miller and Phil Tubesing. I would also like to thank the committee’s shared staff—Brandon Smith, Kristin Jepson, and Kimberlee Kerr.

In closing, I would like to thank Mr. SCHIFF, my ranking member, who has been just a pleasure to work with over the last couple of years. Without his work and his staff’s hard work, we would not be in a position today in which we could stand up here with a strong bipartisan product.

Mr. Speaker, I would like to outline the joint explanatory statement to accompany the Intelligence Authorization Act of Fiscal Year 2017: **JOINT EXPLANATORY STATEMENT TO ACCOMPANY THE INTELLIGENCE AUTHORIZATION ACT FOR FISCAL YEAR 2017**

This joint explanatory statement reflects negotiations between the House Permanent Select Committee on Intelligence and the Senate Select Committee on Intelligence (hereinafter, “the Agreement”). The joint explanatory statement shall have the same effect with respect to the implementation of this Act as if it were a joint explanatory statement of a conference committee.

The joint explanatory statement comprises three parts: an overview of the application of the annex to accompany this statement; unclassified congressional direction; and a section-by-section analysis of the legislative text.

PART I: APPLICATION OF THE CLASSIFIED ANNEX

The classified nature of U.S. intelligence activities prevents the congressional intelligence committees from publicly disclosing many details concerning the conclusions and recommendations of the Agreement. Therefore, a classified Schedule of Authorizations and a classified annex have been prepared to describe in detail the scope and intent of the congressional intelligence committees’ actions. The Agreement authorizes the Intelligence Community (IC) to obligate and expend funds not altered or modified by the classified Schedule of Authorizations as requested in the President’s budget, subject to modification under applicable reprogramming procedures.

The classified annex is the result of negotiations between the House Permanent Select Committee on Intelligence and the Senate Select Committee on Intelligence. It reconciles the differences between the committees’ respective versions of the bill for the National Intelligence Program (NIP) and the Homeland Security Intelligence Program (HSIP) for Fiscal Year 2017. The Agreement also makes recommendations for the Military Intelligence Program (MIP), and the Information Systems Security Program

(ISSP), consistent with the National Defense Authorization Act for Fiscal Year 2017, and provides certain direction for these two programs.

The Agreement supersedes the classified annexes to the reports accompanying H.R. 5077—passed by the House on May 24, 2016—and S. 3017—reported by the Senate Select Committee on Intelligence on June 15, 2016. All references to the House-passed and Senate-reported annexes are made solely to provide the heritage of, and context for, specific provisions.

The classified Schedule of Authorizations is incorporated into the bill pursuant to Section 102. It has the status of law. The classified annex supplements and adds detail to clarify the authorization levels found in the bill and the classified Schedule of Authorizations. The classified annex shall have the same legal force as the report to accompany the bill.

PART II: SELECT UNCLASSIFIED CONGRESSIONAL DIRECTION

The Agreement supersedes H. Rept. 114-573 accompanying H.R. 5077—passed by the House on May 24, 2016—and S. Rept. 114-277 accompanying S. 3017—reported by the Senate Select Committee on Intelligence on June 15, 2016. The phrase “consistent with” is used solely to provide the heritage of, and context for, specific provisions by denoting the report(s) from which the Agreement’s unclassified direction derives.

Commercial Geospatial Intelligence Strategy

Consistent with S. Rept. 114-277 accompanying S. 3017, the Agreement encourages the Department of Defense (DoD), in building future-year budgets, to ensure continued funding is provided for implementation, through at least Fiscal Year 2021, of the Commercial Geospatial Intelligence Strategy issued by the National Geospatial-Intelligence Agency (NGA) in October 2015.

Space Launch Facilities

Consistent with S. Rept. 114-277 accompanying S. 3017, the Agreement directs the IC, in partnership with the U.S. Air Force, to consider the role and contribution of spaceports or launch and range complexes to our national security space launch capacity, and directs the Office of the Director of National Intelligence (ODNI), in consultation with DoD and the U.S. Air Force, no later than 90 days after the enactment of this Act, to brief the congressional intelligence committees on their plans to utilize such facilities.

National Reconnaissance Office Workforce Optimization Strategy

Consistent with S. Rept. 114-277 accompanying S. 3017, the Agreement directs the National Reconnaissance Office (NRO), no later than 90 days after the enactment of this Act, to conduct a workforce review to optimize the mix between government civilians and contractors and submit to the congressional intelligence committees a report containing a workforce optimization strategy.

Review of the National Intelligence University

The National Intelligence University (NIU) has made significant progress in recent years in its transition from a defense intelligence college to a national intelligence university that provides advanced education in a classified format. Such advanced education is integral to making intelligence a profession with recognized standards for performance and ethics and fostering an integrated IC workforce. While progress has been significant since the Director of National Intelligence (DNI) and Secretary of Defense agreed to redesignate Defense Intelligence Agency’s (DIA) National Defense Intelligence College as NIU in 2011, the institu-

tion must continue to adapt to functioning as a university with a robust research agenda, and to serving the entire IC, not just elements of DoD.

Fiscal years 2017 and 2018 are of great significance for NIU, as it moves its principal facility to the IC Campus at Bethesda, completes activities associated with its 2018 decennial regional accreditation reaffirmation, and receives a new president. The congressional intelligence committees believe that these developments position NIU to make further progress in its vision to become the center of academic life for the IC.

To guide these next steps, the Agreement directs DIA, in coordination with ODNI and the Office of the Under Secretary of Defense for Intelligence, to, no later than 30 days after enactment of this Act, select a five-member, external, and independent panel to conduct a review of NIU. The panel shall submit a report detailing the results of such review to the congressional intelligence and defense committees within 180 days of enactment of this Act. The panel should be composed of recognized academics, personnel from other DoD joint professional military education institutions, national security experts, and at least one member of NIU’s Board of Visitors.

This review and the resulting report shall, among other things, assess:

(1) Methods for ensuring a student body that is more representative of all IC elements;

(2) Incentives for IC elements to send personnel to NIU to earn a degree or certificate, to include designating attendance at NIU as positions reimbursable by ODNI and requiring IC elements to employ the workforce concept of “float” for personnel enrolled in higher-education programs;

(3) How certificate programs align with NIU’s unique value as an institution of advanced intelligence education;

(4) Methods to enhance NIU’s research program, to include publication of a journal, hosting of conferences and other collaborative fora, and more formalized relationships with intelligence studies scholars;

(5) Whether and how educational components of other IC elements could provide educational offerings as part of the NIU curriculum;

(6) Potential advantages and risks associated with alternative governance models for NIU, to include moving it under the auspices of ODNI; and

(7) The feasibility and resource constraints of NIU tailoring degree offerings to meet the needs of IC personnel at different stages in their careers, similar to DoD’s joint professional military education model.

Privacy and Civil Liberties Oversight Board priorities

Consistent with H. Rept. 114-573 accompanying H.R. 5077 and S. Rept. 114-277 accompanying S. 3017, the Agreement strongly encourages the Privacy and Civil Liberties Oversight Board (PCLOB) to prioritize the privacy rights and civil liberties of U.S. persons in any findings, recommendations, or other reports stemming from its in-depth examinations of counterterrorism activities governed by Executive Order 12333. The Agreement further encourages PCLOB to refrain from publishing any such materials in unclassified form until PCLOB has completed a thorough fact-finding process, and the congressional intelligence committees expect the IC will provide timely cooperation with that process.

Cost of living consideration

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement recommends that DIA evaluate alternate mechanisms for staffing overseas Combatant

Command intelligence centers, particularly those that are not co-located with Combatant Command headquarters, and identify cost-savings opportunities by reducing the number of personnel receiving living quarters allowance payments and shifting personnel to lower cost locations, including in the continental United States.

Defense Intelligence Agency education opportunities

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs DIA, no later than 180 days after the enactment of this Act, to:

(1) Provide for and fund a program that allows for DIA employees to attend civilian graduate degree programs for up to two years each, based on the standard length of the relevant program, provided that:

(a) Where DIA deems appropriate, employees may pursue academic programs extending beyond two years. Consistent with current practices, the program should be made available to at least five employees each year, with each employee receiving a full-time salary while participating in the program; and

(b) Each DIA participant shall be subject to any program approvals, service obligations, repayment obligations, and other requirements pertaining to academic programs, as prescribed by applicable laws and policies.

(2) Brief the congressional intelligence committees on the status of the program’s implementation.

Mental health prevalence

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs the National Security Agency (NSA), NGA, the Central Intelligence Agency (CIA), and DIA, no later than 180 days after the enactment of this Act, to provide a joint briefing to the congressional intelligence committees on the mental health screenings and related services that these agencies offer employees, both before and after they deploy to combat zones. Such briefing shall include a description of:

(1) Existing services available;

(2) Agency resources for and analysis of these services, including the frequency of use by employees compared to the total number returning from deployment; and

(3) How agencies with deployed civilian employees are sharing best practices and leveraging services or resources outside their agencies.

Review of the Office of the Director of National Intelligence

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs the President to form an independent, external panel of at least five individuals with significant intelligence and national security expertise to review ODNI’s roles, missions and functions and make recommendations, as needed, regarding its authorities, organization and resources. The panel shall:

(1) Evaluate ODNI’s ability to fulfill the responsibilities assigned to it in law given its current scope and structure;

(2) Assess whether any roles and responsibilities currently assigned to the DNI could be more effectively or efficiently executed by other IC components or government agencies outside the IC;

(3) Analyze the personnel, funding, and authorities required for each component of ODNI to perform each of its assigned responsibilities;

(4) Evaluate the organizational structure of ODNI;

(5) Review the size, role, purpose and function of ODNI’s mission centers;

(6) Assess the value of the national intelligence manager construct;

(7) Review the size and mix of the ODNI workforce—to include the ratio between cadre and detailees, the balance between government and contractors, and grade structure—to perform its roles, missions and functions; and

(8) Make recommendations regarding the above.

The Agreement directs the President, no later than 30 days after the enactment of this Act, to select the individuals who will serve on the external panel and notify the congressional intelligence committees of such selection.

In addition, the Agreement directs the panel, no later than 180 days after the enactment of this Act, to provide a report on this review to the congressional intelligence committees. This report shall be unclassified, but may contain a classified annex. The Agreement further directs ODNI to reimburse the Executive Office of the President for any costs associated with the review.

Improving pre-publication review

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs that, no later than 180 days after the enactment of this Act, the DNI shall issue an IC-wide policy regarding pre-publication review. The DNI shall transmit this policy to the congressional intelligence committees concurrently with its issuance. The policy should require each IC agency to develop and maintain a pre-publication policy that contains, at a minimum, the following elements:

(1) Identification of the individuals subject to pre-publication review requirements (“covered individuals”);

(2) Guidance on the types of information that must be submitted for pre-publication review, including works (a) unrelated to an individual’s IC employment; or (b) published in cooperation with a third party, e.g.—

(a) Authored jointly by covered individuals and third parties;

(b) Authored by covered individuals but published under the name of a third party; or

(c) Authored by a third party but with substantial input from covered individuals.

(3) Guidance on a process by which covered individuals can participate in pre-publication reviews, and communicate openly and frequently with reviewers;

(4) Requirements for timely responses, as well as reasoned edits and decisions by reviewers;

(5) Requirements for a prompt and transparent appeal process;

(6) Guidelines for the assertion of inter-agency equities in pre-publication review;

(7) A summary of the lawful measures each agency may take to enforce its policy, to include civil and criminal referrals; and

(8) A description of procedures for post-publication review of documents that are alleged or determined to reveal classified information but were not submitted for pre-publication review.

Additionally, the Agreement directs ODNI, no later than 180 days after the enactment of this Act, to provide to the congressional intelligence committees a report on the adequacy of IC information technology efforts to improve and expedite pre-publication review processes, and the resources needed to ensure that IC elements can meet this direction.

The Agreement further directs the DNI, no later than 270 days after the enactment of this Act, to certify to the congressional intelligence committees that IC elements’ pre-publication review policies, non-disclosure agreements, and any other agreements imposing pre-publication review obligations reflect the policy described above.

Student loan debt report

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs

ODNI, no later than 180 days after the enactment of this Act, to provide a report to the congressional intelligence committees on programs that seek to help IC personnel manage student loan debt. The report shall include details about each IC element’s program, including loan forgiveness, loan repayment, and financial counseling programs; efforts to inform prospective and current employees about such programs; and the number of employees who use such programs. The report shall also include an analysis of the benefits and drawbacks of creating new programs and expanding existing programs, and shall identify any barriers to the establishment of IC-wide programs.

Workforce development partnership

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs the DNI Chief Human Capital Officer, no later than 180 days after the enactment of this Act, to provide to the congressional intelligence committees an interagency briefing on new approaches, including outreach and advertising, the IC is considering or conducting to attract a diverse, robust information technology and Science, Technology, Engineering, and Math workforce to meet the increasing demands in the IC.

Distributed Common Ground/Surface System-Army

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement requests that the Army, no later than 90 days after the enactment of this Act, submit a plan to the congressional intelligence and defense committees on how the Army will fully incorporate Distributed Common Ground/Surface System-Army (DCGS-A) training into the readiness cycle for Army personnel. The plan should specifically address any lessons learned from the fielding of DCGS-A Increment 1 and any ongoing corrective actions to improve the roll-out of Increment 1, Release 2.

Common controller for unmanned aircraft systems

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement requests that the Army and the Marine Corps Intelligence Activity (MCIA), no later than 90 days after the enactment of this Act, jointly submit a report to the congressional intelligence and defense committees on the feasibility of developing a common controller for all Brigade and Below unmanned aircraft systems (UAS) airframes, as well as U.S. Marine Corps small unit UAS. The report should address the potential performance and operational benefits of a common controller, anticipated development costs, and anticipated life-cycle cost savings of a common controller.

Review of dual-hatting relationship

The congressional intelligence committees support further evaluation of the dual-hatting of a single individual as both Commander of U.S. Cyber Command (USCYBERCOM) and Director of the National Security Agency (DIRNSA).

Therefore, the Agreement directs the Secretary of Defense, no later than 180 days after the enactment of this Act, to provide to the congressional intelligence and defense committees a briefing that reviews and provides an assessment of the dual-hatting of DIRNSA and Commander, USCYBERCOM. This briefing should address:

(1) Roles and responsibilities, including intelligence authorities, of USCYBERCOM and NSA;

(2) Assessment of the current impact of the dual-hatting relationship, including advantages and disadvantages;

(3) Plans and recommendations on courses of action that would be necessary to end the

dual-hatting of DIRNSA and Commander, USCYBERCOM;

(4) Suggested timelines for carrying out such courses of action;

(5) Recommendations for any changes in law that would be required by the end of dual-hatting; and

(6) Any additional topics as identified by the intelligence and defense committees.

The congressional intelligence committees further believe that a larger organizational review of NSA should be conducted with respect to the eventual termination of the dual-hatting relationship. The congressional intelligence committees seek to promote the efficient and effective execution of NSA’s national intelligence mission. Specifically, the congressional intelligence committees believe that the organization of NSA should be examined to account for the evolution of its mission since its establishment, the current structure of the intelligence community, and the fact that the NSA is predominantly funded through the NIP.

Therefore, the Agreement further directs the DNI, no later than 180 days after the enactment of this Act, to conduct an assessment and provide a briefing to the congressional intelligence committees on options to better align the structure, budgetary procedures, and oversight of NSA with its national intelligence mission in the event of a termination of the dual-hatting relationship. This briefing should include:

(1) An assessment of the feasibility of transitioning NSA to civilian leadership appointed by the DNI in lieu of military leadership appointed by the Secretary of Defense;

(2) How NSA could be organizationally separated from DoD if USCYBERCOM were elevated to become a unified combatant command; and

(3) Any challenges, such as those requiring changes in law, associated with such a separation.

Acquisition security improvement

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs ODNI, no later than 180 days after the enactment of this Act, to review and consider amendments to Intelligence Community Directive (ICD) 801 to better reflect and anticipate supply chain and cybersecurity risks and threats, as well as to outline policies to mitigate both risks and threats. In particular, the review should examine whether to:

(1) Expand risk management criteria in the acquisition process to include cyber and supply chain threats;

(2) Require counterintelligence and security assessments as part of the acquisition and procurement process;

(3) Propose and adopt new education requirements for acquisition professionals on cyber and supply chain threats; and

(4) Factor in the cost of cyber and supply chain security.

The Agreement further directs ODNI, no later than 210 days after the enactment of this Act, to provide to the congressional intelligence committees a report describing the review, including ODNI’s process for considering amendments to ICD 801, and specifically addressing ODNI’s analysis and conclusions with respect to paragraphs (1) through (4) above.

Cyber information sharing and customer feedback

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs ODNI, no later than 120 days after the enactment of this Act, to brief the congressional intelligence committees on IC-wide efforts to share more information with the Department of Homeland Security (DHS) for further dissemination to the private sector.

This briefing shall specifically address types of information shared, metrics on output, tabulation of low output producing agencies, recommendations on how low output agencies can increase sharing, timeliness of information shared, and average total time it takes for information to transit the system.

The Agreement also directs ODNI, in coordination with the DHS Office of Intelligence and Analysis (I&A), to conduct a survey of government and private sector participants of the National Cybersecurity and Communications Integration Center (NCCIC). The survey shall be anonymous, provide an accurate assessment of the usefulness and timeliness of the data received, and determine if customers are satisfied with intelligence briefings on threat actors impacting their specific industry. The Agreement further directs ODNI, no later than one year after the enactment of this Act, to provide to the congressional intelligence and homeland security committees an unclassified report detailing the results of this survey.

Department of Homeland Security utilization of National Labs expertise

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs, no later than 180 days after the enactment of this Act, DHS I&A, in coordination with DOE Office of Intelligence and Counterintelligence (DOE-IN), to provide to the congressional intelligence committees a report on the current utilization of Department of Energy (DOE) National Labs expertise by DHS I&A. This report should address opportunities to increase DHS I&A's utilization of cybersecurity expertise of the National Labs as well as the budgetary implications of taking advantage of these potential opportunities.

Cybersecurity courses for Centers of Academic Excellence

Consistent with H. Rept. 114-573 accompanying H.R. 5077, the Agreement directs ODNI, no later than 180 days after the enactment of this Act, to submit to the congressional intelligence committees a report on improving cybersecurity training within NIP-funded undergraduate and graduate computer science programs. The report should specifically address:

- (1) The potential advantages and disadvantages of conditioning an institution's receipt of such funds on its computer science program's requiring cybersecurity as a precondition to graduation;
- (2) How Centers of Academic Excellence programs might bolster cybersecurity educational requirements; and
- (3) Recommendations to support the goal of ensuring that federally-funded computer science programs properly equip students to confront future cybersecurity challenges.

PART III: SECTION-BY-SECTION ANALYSIS AND EXPLANATION OF LEGISLATIVE TEXT

The following is a section-by-section analysis and explanation of the Intelligence Authorization Act for Fiscal Year 2017.

TITLE I—INTELLIGENCE ACTIVITIES

Section 101. Authorization of appropriations

Section 101 lists the United States Government departments, agencies, and other elements for which the Act authorizes appropriations for intelligence and intelligence-related activities for Fiscal Year 2017.

Section 102. Classified Schedule of Authorizations

Section 102 provides that the details of the amounts authorized to be appropriated for intelligence and intelligence-related activities and the applicable personnel levels by program for Fiscal Year 2017 are contained in the classified Schedule of Authorizations and that the classified Schedule of Authorizations shall be made available to the Commit-

tees on Appropriations of the Senate and House of Representatives and to the President.

Section 103. Personnel ceiling adjustments

Section 103 provides that the DNI may authorize employment of civilian personnel in Fiscal Year 2017 in excess of the number of authorized positions by an amount not exceeding three percent of the total limit applicable to each intelligence community (IC) element under Section 102, if necessary to the performance of important intelligence functions, and an amount not exceeding 10 percent of such limit, if necessary to convert the performance of any function of the element by contractors to performance by civilian personnel. The congressional intelligence committees intend that, for the purpose of Section 103, "contractor conversion" means that the number of contractor full-time equivalents shall decrease commensurate—on a one-for-one basis—with the number of contractors converted to government civilians.

Section 103 also requires that, not less than 30 days prior to authorizing a contractor conversion under this section, the DNI shall submit to the congressional intelligence committees a notification that includes a justification for making the conversion and a certification that such conversion is cost effective. The congressional intelligence committees intend that, in certifying that such conversion is cost effective, the DNI shall include a comparison of costs using a mature model that has been reviewed and accepted by the congressional intelligence committees.

Section 104. Intelligence Community Management Account

Section 104 authorizes appropriations for the Intelligence Community Management Account (ICMA) of the DNI and sets the authorized personnel levels for the elements within the ICMA for Fiscal Year 2017.

TITLE II—CENTRAL INTELLIGENCE AGENCY RETIREMENT AND DISABILITY SYSTEM

Section 201. Authorization of appropriations

Section 201 authorizes appropriations in the amount of \$514,000,000 for Fiscal Year 2017 for the Central Intelligence Agency Retirement and Disability Fund.

TITLE III—GENERAL INTELLIGENCE COMMUNITY MATTERS

Section 301. Restriction on conduct of intelligence activities

Section 301 provides that the authorization of appropriations by the Act shall not be deemed to constitute authority for the conduct of any intelligence activity that is not otherwise authorized by the Constitution or laws of the United States.

Section 302. Increase in employee compensation and benefits authorized by law

Section 302 provides that funds authorized to be appropriated by the Act for salary, pay, retirement, and other benefits for federal employees may be increased by such additional or supplemental amounts as may be necessary for increases in compensation or benefits authorized by law.

Section 303. Support to nonprofit organizations assisting intelligence community employees

Section 303 permits the DNI to engage in fundraising in an official capacity for the benefit of nonprofit organizations that provide support to surviving family members of a deceased employee of an element of the IC or otherwise provide support for the welfare, education, or recreation of IC employees, former employees, or their family members. Section 303 requires the DNI to issue regulations ensuring that the fundraising authority is exercised consistent with all relevant

ethical limitations and principles. Section 303 further requires that the DNI and the Director of the CIA notify the congressional intelligence committees within seven days after they engage in such fundraising.

Section 304. Promotion of science, technology, engineering, and math education in the intelligence community

Section 304 requires the DNI to submit a five-year investment strategy for outreach and recruiting efforts in the fields of science, technology, engineering, and mathematics (STEM), to include cybersecurity and computer literacy. Section 304 further requires elements of the IC to submit STEM investment plans supporting this strategy for each of the fiscal years 2018 through 2022, along with the materials justifying the budget request of each element for these STEM recruiting and outreach activities.

Section 305. Retention of employees of the intelligence community who have science, technology, engineering, or math expertise

Section 305 authorizes a new payscale to permit salary increases for employees in the IC with STEM backgrounds. Section 305 also requires notifications to individual employees if a position is removed from this new payscale. Section 305 further requires the head of each IC element to submit to the congressional intelligence committees a report on the new rates of pay and number of positions authorized under this payscale.

Section 306. Modifications to certain requirements for construction of facilities

Section 306 amends existing law regarding the requirements for inclusion in the Administration's annual budget request and clarifies that the requirement to notify the congressional intelligence committees of improvement projects with an estimated cost greater than \$1,000,000 for facilities used primarily by IC personnel includes repairs and modifications.

Section 307. Protections for independent inspectors general of certain elements of the intelligence community

Section 307 requires the ODNI to develop and implement a uniform policy for each identified Inspector General (IG) office in the IC to better ensure their independence. The provision specifies elements to be incorporated in such a policy including (a) guidance regarding conflicts of interest, (b) standards to ensure independence, and (c) a waiver provision. Section 307 further prohibits the DNI from requiring an employee of an OIG to rotate to a position in the element for which such office conducts oversight.

Section 308. Modification of certain whistleblowing procedures

Section 308 amends current law, including the Intelligence Community Whistleblower Protection Act (ICWPA), to provide for the direct transmission to Congress by IC inspectors general of whistleblower complaints containing classified information. Section 308 also makes clear that the provision does not prohibit IC inspectors general from notifying, or otherwise affect the authority of IC inspectors general to notify, heads of IC elements or the DNI, as the case may be, of a complaint or information.

Section 309. Congressional oversight of policy directives and guidance

Section 309 requires the DNI to submit to the congressional intelligence committees notifications of the issuance and a summary of the subject matter of any classified or unclassified Presidential Policy Directive, Presidential Policy Guidance, or other similar policy document issued by the President that assigns tasks, roles, or responsibilities to the IC, within the specified timeframes.

Section 309 further requires the DNI to notify the congressional intelligence committees when the DNI has issued guidance or direction to implement such policies, and to submit a copy of such guidance or direction to the committees.

Section 310. Notification of memoranda of understanding

Section 310 requires the head of each element of the IC to submit to the congressional intelligence committees copies of each memorandum of understanding or other agreement regarding significant operational activities or policy entered into between, or among, such element and any other entity or entities of the federal government within specified timeframes.

Section 310 does not require an IC element to submit to the congressional intelligence committees any memorandum or agreement that is solely administrative in nature, including a memorandum or agreement regarding joint duty or other routine personnel assignments. An IC element also may redact any personally identifiable information from a memorandum or agreement that must be submitted to the intelligence committees.

Section 311. Technical correction to Executive Schedule

Section 311 contains a technical correction regarding the annual rate of basic pay for the Director of the National Counter Proliferation Center.

Section 312. Maximum amount charged for declassification reviews

Section 312 prohibits the head of an element of the IC from charging reproduction fees for a mandatory declassification review in excess of reproduction fees that the head would charge for a request for information under the Freedom of Information Act (FOIA). It also permits agency heads to waive processing fees for declassification reviews in the same manner as for FOIA.

TITLE IV—MATTERS RELATING TO ELEMENTS OF THE INTELLIGENCE COMMUNITY

SUBTITLE A—OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

Section 401. Designation of the Director of the National Counterintelligence and Security Center

Section 401 renames the National Counterintelligence Executive as the “National Counterintelligence and Security Center,” with conforming amendments.

Section 402. Analyses and impact statements by Director of National Intelligence regarding proposed investment into the United States

Section 402 directs the DNI to submit to the congressional intelligence committees, after the completion of a review or an investigation of any proposed investment into the United States, any analytic materials prepared by the DNI. This requirement includes, but is not limited to, national security threat assessments provided to the Committee on Foreign Investment in the United States (CFIUS) in connection with national security reviews and investigations conducted by CFIUS pursuant to Section 721(b) of the Defense Production Act of 1950 (50 U.S.C. 4565). This section is not intended to limit the ability of the DNI to transmit supplementary materials to the congressional intelligence committees along with the threat assessments.

Section 402 also directs the DNI to provide the congressional intelligence committees with impact statements when the DNI determines a proposed investment into the United States will have an operational impact on the IC.

Section 403. Assistance for governmental entities and private entities in recognizing online violent extremist content

Section 403 requires the DNI to publish on a publicly available Internet website a list of all logos, symbols, insignia, and other markings commonly associated with, or adopted by, State Department-designated foreign terrorist organizations.

Subtitle B—Central Intelligence Agency

Section 411. Enhanced death benefits for personnel of the Central Intelligence Agency

Section 411 authorizes the Director of the CIA to pay death benefits substantially similar to those authorized for members of the Foreign Service, and requires the Director to submit implementing regulations to the congressional intelligence committees.

Section 412. Pay and retirement authorities of the Inspector General of the Central Intelligence Agency

Section 412 amends the Central Intelligence Agency Act of 1949 to authorize the IG of the CIA to consider certain positions as law enforcement officers for purposes of calculating retirement eligibility and entitlements under chapters 83 and 84 of title 5, United States Code, if such officer or employee is appointed to a position with responsibility for investigating suspected offenses against the criminal laws of the United States. Section 412 may not be construed to confer on the IG of the CIA, or any other officer or employee of the CIA, any police or law enforcement or internal security functions or authorities.

Subtitle C—Other Elements

Section 421. Clarification of authority, direction, and control over the Information Assurance Directorate of the National Security Agency

Section 421 restores authority, direction, and control over the Information Assurance Directorate of the NSA to the Under Secretary of Defense for Intelligence.

Section 422. Enhancing the technical workforce for the Federal Bureau of Investigation

Section 422 requires the Federal Bureau of Investigation (FBI) to produce a comprehensive strategic workforce report to demonstrate progress in expanding initiatives to effectively integrate information technology expertise in the investigative process. Section 422 further requires the report to include assessments of: (1) progress on training, recruitment, and retention of cyber-related personnel; (2) whether FBI officers with these skill sets are fully integrated in the FBI's workforce; (3) the FBI's collaboration with the private sector on cyber issues; and (4) the utility of reinstating and leveraging the FBI Director's Advisory Board.

Section 423. Plan on assumption of certain weather missions by the National Reconnaissance Office

Section 423 requires the Director of the NRO to develop a plan to carry out certain space-based environmental monitoring missions currently performed by the Air Force. It also authorizes certain pre-acquisition activities and directs that an independent cost estimate be submitted to the congressional intelligence and defense committees. The Director of NRO may waive the requirement of Section 423 if the Under Secretary of Defense for Acquisition, Technology, and Logistics, and the Chairman of the Joint Chiefs of Staff, jointly submit a certification to the congressional intelligence and defense committees.

TITLE V—MATTERS RELATING TO FOREIGN COUNTRIES

Section 501. Committee to counter active measures by the Russian Federation to exert covert influence over peoples and governments

Section 501 requires the President to establish an interagency committee to counter

active measures by the Russian Federation to exert covert influence over peoples and governments, and requires the Committee to report to appropriate committees of Congress annually on trends in active measures by the Russian Federation and on the Committee's key initiatives.

Section 502. Limitation on travel of accredited diplomats and consulars of the Russian Federation in the United States from their diplomatic post

Section 502 requires the Director of the FBI to certify that the FBI did not identify any violations by Russian diplomats and consulars of the applicable requirements to notify the United States Government in connection with the Russian diplomats' or consulars' travel, before the Secretary of State can permit Russian diplomats or consulars to travel in excess of 25 miles outside their diplomatic post. Section 502 also permits the Director to waive the aforementioned travel distance restrictions if the Director determines that such a waiver will further the law enforcement or national security interests of the United States.

Section 503. Study and report on enhanced intelligence and information sharing with Open Skies Treaty member states

Section 503 requires the DNI, with support of other federal agencies, to conduct a study to determine the feasibility of creating an intelligence sharing arrangement and database among parties to the Open Skies Treaty (OST) with higher frequency, quality, and efficiency than that currently provided by the parameters of the OST. Section 503 also requires the Director to issue a report that includes an intelligence assessment on Russian Federation warfighting doctrine, the extent to which Russian Federation flights under the Open Skies Treaty contribute to the warfighting doctrine, a counterintelligence analysis as to the Russian Federation's capabilities, and a list of the covered parties that have been updated with this information.

TITLE VI—PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD

Section 601. Information on activities of the Privacy and Civil Liberties Oversight Board

Section 601 requires the PCLOB to keep Congress and relevant IC elements fully and currently informed of its oversight activities.

Section 602. Authorization of appropriations for Privacy and Civil Liberties Oversight Board

Section 602 requires funds available to the PCLOB to be obligated or expended during a fiscal year only if such funds were specifically authorized by Congress for that fiscal year, and authorizes the full amount of the Administration's budget request for PCLOB for Fiscal Year 2017.

TITLE VII—REPORTS AND OTHER MATTERS

Section 701. Declassification review with respect to detainees transferred from United States Naval Station, Guantanamo Bay, Cuba.

Section 701 requires the DNI to complete a declassification review of intelligence reports prepared by the National Counterterrorism Center (NCTC) on past terrorist activities of each Guantanamo detainee held at Guantanamo after September 11, 2001, for the detainee's Periodic Review Board (PRB) sessions, transfer, or release from Guantanamo. The requirement applies both to detainees who have been transferred or released previously and to detainees transferred or released in the future. The provision also accounts for detainees whose transfer or release predated the establishment of the PRB or NCTC, or the latter's production of intelligence reports for PRB sessions, transfers, or releases.

Section 701 further requires the President to make any declassified intelligence reports

publicly available and, with respect to each detainee for whom intelligence reports are declassified, also make public unclassified summaries of measures being taken by receiving countries to monitor the detainee and prevent future terrorist activities. Section 701 requires the DNI to submit to the congressional intelligence committees a report setting forth the results of the declassification review, including a description of covered reports that were not declassified.

Section 702. Cyber Center for Education and Innovation Home of the National Cryptologic Museum

Section 702 amends 10 U.S.C. §449 to enable the establishment of a Cyber Center for Education and Innovation Home of the National Cryptologic Museum (the "Center"). Section 702 also establishes in the Treasury a fund for the benefit and operation of the Center.

Section 703. Oversight of national security systems

Section 703 amends 44 U.S.C. §3557 to codify and strengthen existing roles and responsibilities with regard to the oversight of national security systems.

Section 704. Joint facilities certification

Section 704 requires that before an element of the IC purchases, leases, or constructs a new facility that is 20,000 square feet or larger, the head of that element must first certify that all prospective joint facilities have been considered and that it is unable to identify a joint facility that meets its operational requirements, and it must list the reasons for not participating in joint facilities in that instance.

Section 705. Leadership and management of space activities

Section 705 requires the DNI, in consultation with the Secretary of Defense and the Chairman of the Joint Chiefs of Staff, to issue an update to the strategy for a comprehensive review of the United States national security overhead satellite architecture required in the Intelligence Authorization Act for Fiscal Year 2016. Section 705 further requires the DNI, in consultation with the Secretary of Defense, to submit a plan to functionally integrate the IC's governance, operations, analysis, collection, policy, and acquisition activities related to space and counterspace under the oversight of a single official, to be appointed by the DNI, in consultation with the Secretary of Defense. Section 705 also requires the DNI to submit a workforce plan for space and counterspace operations, policy, and acquisition. Section 705 further requires the Director of the NRO and the Commander of U.S. Strategic Command to submit a concept of operations and requirements documents for the Joint Interagency Combined Space Operations Center.

Section 706. Advances in life sciences and biotechnology

Section 706 requires the DNI to brief the congressional intelligence committees and the congressional defense committees on a proposed plan and actions to monitor advances in life sciences and biotechnology to be carried out by the DNI. Section 706 further requires the DNI to submit a written report and provide a briefing to the congressional intelligence committees and the congressional defense committees on the role of the IC in the event of a biological attack, including a technical capabilities assessment to address potential unknown pathogens.

Section 707. Reports on declassification proposals

Section 707 requires the DNI to provide the congressional intelligence committees with a report and briefing on the IC's progress in producing four feasibility studies undertaken in the course of the IC's fundamental

classification guidance review, as required under Executive Order 13526. Section 707 further requires the Director to provide the congressional intelligence committees with a briefing, interim report, and final report on the final feasibility studies produced by elements of the IC and an implementation plan for each initiative.

Section 708. Improvement in government classification and declassification

Section 708 assesses government classification and declassification in the digital era by requiring the DNI to review the system by which the Government classifies and declassifies national security information to improve the protection of such information, enable information sharing with allies and partners, and support appropriate declassification. Section 708 requires the DNI to submit a report with its findings and recommendations to the congressional intelligence committees. Section 708 further requires the DNI to provide an annual written notification to the congressional intelligence committees on the creation, validation, or substantial modification (to include termination) of existing and proposed controlled access programs, and the compartments and subcompartments within each. This certification shall include the rationale for each controlled access program, compartment, or subcompartment and how each controlled access program is being protected.

Section 709. Report on implementation of research and development recommendations

Section 709 requires the DNI to conduct and provide to the congressional intelligence committees a current assessment of the IC's implementation of the recommendations issued in 2013 by the National Commission for the Review of the Research and Development (R&D) Programs of the IC.

Section 710. Report on Intelligence Community Research and Development Corps

Section 710 requires the DNI to develop and brief the congressional intelligence committees on a plan, with milestones and benchmarks, to implement a R&D Reserve Corps, as recommended in 2013 by the bipartisan National Commission for the Review of the R&D Programs of the IC, including any funding and potential changes to existing authorities that may be needed to allow for the Corps' implementation.

Section 711. Report on information relating to academic programs, scholarships, fellowships, and internships sponsored, administered, or used by the intelligence community

Section 711 requires the DNI to submit to congressional intelligence committees a report on information that the IC collects on certain academic programs, scholarships, and internships sponsored, administered, or used by the IC.

Section 712. Report on intelligence community employees detailed to National Security Council

Section 712 requires the DNI to submit to the congressional intelligence committees a report listing, by year, the number of employees of an element of the IC who have been detailed to the National Security Council during each of the previous ten years.

Section 713. Intelligence community reporting to Congress on foreign fighter flows

Section 713 directs DNI to submit to the congressional intelligence committees a report on foreign fighter flows to and from terrorist safe havens abroad.

Section 714. Report on cybersecurity threats to seaports of the United States and maritime shipping

Section 714 directs the Under Secretary of Homeland Security for Intelligence and

Analysis (I&A) to submit to the congressional intelligence committees a report on the cybersecurity threats to seaports of the United States and maritime shipping.

Section 715. Report on counter-messaging activities

Section 715 directs the Under Secretary of Homeland Security for I&A to submit to the congressional intelligence committees a report on the counter-messaging activities of DHS with respect to the Islamic State and other extremist groups.

Section 716. Report on reprisals against contractors of the intelligence community

Section 716 directs the IC IG to submit to the congressional intelligence committees a report on known or claimed reprisals made against employees of contractors of elements of the IC during the preceding three-year period. Section 716 further requires the report to include an evaluation of the usefulness of establishing a prohibition on reprisals as a means of encouraging IC contractors to make protected disclosures, and any recommendations the IC IG deems appropriate.

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

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

Today, we are voting on the fiscal year 2017 Intelligence Authorization Act, which is the fourth major piece of legislation I have had the privilege of working on with Chairman NUNES and the membership of our committee.

I want to just return the compliment from the chairman. It is a great pleasure to work with him. One of the things I love about our committee is it is truly a refuge from a lot of the partisanship of this institution. To be able to grapple with some of the enormous challenges facing the country and to do so in a nonpartisan way is, I think, a real honor and privilege for all of us on the committee, and I thank the chairman for his leadership in making it so. He continues to be just an invaluable partner on the committee. Each bill we work on together proves anew what can be done when people work together constructively and in a nonpartisan manner to solve real problems.

Mr. Speaker, in this iteration of the bill, which the House first passed in the spring by an overwhelming 371-35 votes, we also had the privilege of working closely with our colleagues in the Senate, particularly Chairman BURR and Vice Chairman FEINSTEIN. As always, they have proven to be invaluable partners. Although we still have one or two issues unresolved, 98 percent of this bill represents agreements forged by bipartisan and bicameral behind-the-scenes efforts over the past few months.

We should be very proud of this bill, and I believe it is an even better bill than the one we passed in the spring. It preserves—and, in some cases, furthers—all of the priorities of our Members, including the initiatives of our Democratic Members. In particular, I want to highlight some of their contributions:

The bill includes Representative HIMES' provision to improve the timeliness and fairness of prepublication review process throughout the IC.

It includes Representative SEWELL's language on investment in Centers of Academic Excellence programs, helping to guarantee that a diverse array of students can take part in IC internships. It also includes her requirement to collect data to evaluate the IC's federally funded academic programs.

The bill includes Representative CARSON's provision to assist public and private entities in their swiftly removing terrorist content online; his provision on the cooperation and deconfliction between the Departments of Homeland Security and State regarding countering violent extremism programs; and his requirement to have the committee receive information on the operational impacts of foreign investment in the United States.

Representative SPEIER's four provisions are included, which would standardize declassification photocopying fees across the IC to promote the increased availability of information and enhance transparency; her provision to expand access to graduate education programs at the Defense Intelligence Agency; her language on obtaining information on the mental health resilience programs that are available to IC civilians returning from tours in combat zones; and her provision to study reprisals taken against IC contractors who make disclosures that would be legally protected if made by IC employees.

The bill includes Representative QUIGLEY's language to continue support to security services in Ukraine.

It includes Representative SWALWELL's three provisions, including one to track foreign fighters, another to analyze the status of loan forgiveness and debt counseling programs within the IC, and a provision to better understand how the Departments of Homeland Security and Energy take advantage of the expertise resident at our national labs.

It includes Representative MURPHY's three provisions to provide a report detailing cybersecurity threats to—or vulnerabilities in—systems employed by seaports and transshipment hubs, including efforts to improve our preparedness and response to a cyber attack; it has language to improve intelligence reporting with respect to Iran's compliance with the Joint Comprehensive Plan of Action; and it requires a report on security threats emanating from maritime smuggling routes and ways to better cooperate with other nations to mitigate these threats.

Let me also say that Patrick will be dearly missed when he leaves our committee at the end of this session. He has been a tremendously valuable member of the committee.

The IAA also furthers important privacy and transparency goals, including by fully authorizing the Privacy and Civil Liberties Oversight Board. The bill does not contain any legislative restrictions on the scope of the PCLOB's authority to review the impact of IC programs on the privacy and civil lib-

erties of Americans and non-U.S. persons. Thanks to Senate provisions that we have incorporated, it also advances declassification efforts, potentially getting much more information to the public.

There are no GTMO transfer restrictions from the bill, and the legislative text adds important provisions that are aimed at countering Russia's destabilizing efforts, including those targeting elections.

The legislation accommodates and resolves the vast majority of the administration's objections, which were laid out earlier this year.

Critically, this IAA also continues to address the key strategic questions we must continue to ask now and in the next administration in Congress:

First, are we focusing too much on the threats of the day at the expense of the threats of tomorrow?

It is easy to get distracted by non-stop crises, and it is harder to remain focused on the long term, even when the future can be far more dangerous than the present.

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We have spent significant resources on counterterrorism priorities in the Middle East and South Asia. We have to continue to focus on CT and the threat posed by ISIS and its followers, but we must not disregard the growing threat posed by Russia, whose global efforts at disruption must be checked, particularly against our allies and our alliances.

We must not turn away from threats posed by China, whose Naval adventurism, infiltration of the supply chain, and efforts to get around the CFIUS process in the United States—and to undermine data security more generally—challenge our security and business interests abroad and threaten our Asian partners.

Second, are we sufficiently protecting what we currently have, whether in space, at sea, or in the cyber realm?

Third, are we leveraging commercial products and services while at the same time making investments in revolutionary technologies that do not yet have commercial application?

Fourth, are we recruiting, training, and developing the most effective and diverse workforce as well as leveraging foreign intelligence relationships and building foreign partner capacity?

The U.S. has unquestionably the most advanced, capable, and reliable intelligence community in the world. This bill supports that workforce by identifying ways to promote travel, support language training, and increase diversity. It does this, in part, by expanding internship opportunities in the IC to students from diverse regions and backgrounds and allocates resources to building the capacity of our foreign partners. These are values we expect and demand from those partners, and they are central tenets of who we are as a country.

There are many unknowns about the incoming administration, particularly how it will utilize and interact with the IC. It is now more important than ever that we give the IC the tools it needs to keep us safe and provide the necessary oversight required to ensure that they act in a manner consistent with our values and at all times. That is why I am pleased that this year's IAA provides such critical oversight of the IC, ensuring our Nation is secure, privacy and civil liberties are safeguarded, and transparency and accountability are paramount.

I am proud to support the Intelligence Authorization Act, and I urge my colleagues to do the same. I urge the Senate to pass this bill and send the fiscal year '17 IAA to the President's desk or to continue to work with us to resolve any last differences before the end of the Congress.

I reserve the balance of my time.

Mr. NUNES. Mr. Speaker, I yield 2 minutes to the gentleman from Utah (Mr. STEWART).

Mr. STEWART. Mr. Speaker, I thank Chairman NUNES for allowing me to speak in support of the Intelligence Authorization Act.

Mr. Speaker, sometimes it is easiest for us to forget that the primary responsibility of the Federal Government is to help to keep us safe. I felt the weight of that responsibility while I was serving as an Air Force pilot for 14 years, and now I am reminded almost every day of that same responsibility in my role on the House Permanent Select Committee on Intelligence.

The truth is that we live in a dangerous world. The news is filled daily with troubling reports of terrorist attacks and dangerous activities. All of us are aware that just this week a young man, almost certainly inspired by terrorist ideology, attacked students and faculty at The Ohio State University.

It doesn't stop with terrorism. We also face tremendous threats from China, Russia, North Korea, the Ya'alons in Iran, and the list goes on and on.

I am grateful for the brave men and women around the world serving our military and in our intelligence communities who operate critical national security programs which protect Americans and keep us safe. That is why we must pass the Intelligence Authorization Act. Not only does this bill continue to authorize critical national security programs at a time when we face the most significant threat level since 9/11, it also contains good government provisions that have gained bipartisan support.

This bill shines light on Guantanamo Bay detainees, requiring a review of their past terrorist activities. It strengthens congressional oversight of privacy and civil liberties, and it also updates intelligence community whistle-blowing procedures.

Importantly, this bill does not contain any provisions related to surveillance authorities.

Mr. Speaker, this bill is critical to providing the intelligence community with the tools and the authorizations they need to protect Americans and our national security. I urge my colleagues to vote “yes” on this important bill.

Mr. SCHIFF. Mr. Speaker, I yield 3 minutes to the gentleman from California (Mr. SWALWELL), a very valuable member of our committee.

Mr. SWALWELL of California. Mr. Speaker, I stand here today in support of this bipartisan IAA and the many provisions that it has that will continue to strengthen and empower our intelligence community and those who serve and toil away for our national security.

This bill also contains a few provisions I have personally championed during my time on the House Permanent Select Committee on Intelligence. First, it includes the provision I added requiring a report from the Office of the Director of National Intelligence on programs across the IC, the intelligence community, to help students manage student loan debt and the viability of an IC-wide program, knowing that this is critical for our recruitment and retention of quality intelligence community members.

Second, the bill includes a provision that was originally a bipartisan, stand-alone bill with Representative LOBIONDO of New Jersey to track foreign fighters as they attempt to move to and from terrorist safe havens abroad. This bill passed the House at the end of last year by a vote of 423-0.

Finally, it includes a requirement for a report on the current utilization of our national laboratories by the intelligence divisions within the Department of Homeland Security and the Department of Energy, as well as ways these divisions can expand utilization of lab expertise on cybersecurity. I am honored to represent two of these laboratories, Lawrence Livermore and Sandia, and I have seen firsthand how important their work is to our national security.

This bill is the result of both parties and both Chambers coming together to prioritize our intelligence community and national security needs.

I also just want to echo what I have heard from our chairman and ranking member, which is that there is really nothing more fulfilling, especially during such national discord, to come to work every day and work with the members on this committee. I think maybe the secret sauce here is that the chairman and the ranking member are both Oakland Raiders fans. I don't know if there are other reasons they work well together, but it really is fulfilling to see that when you go into our committee hearing, Republicans and Democrats put party aside and put national security first.

I also want to say that I am going to miss two members as they depart the committee. That is, Congressman PATRICK MURPHY of Florida. He and I sat

next to each other. Although he was in a 2-year-long Senate race, he showed up every day, worked hard, asked tough questions on behalf of his constituents and national security. I am also going to miss Congressman MIKE POMPEO of Kansas, and I congratulate him on being nominated as the next director of the Central Intelligence Agency. I find him to be a person of deep integrity and character. I enjoyed traveling with him to Iraq last Easter, and I look forward to serving with him in his new role.

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

Mr. SCHIFF. Mr. Speaker, let me just say on behalf of the chairman and myself, we were Raiders fans even when they were a losing team. This is not a newfound preoccupation with the team.

Mr. Speaker, I yield 3 minutes to the gentlewoman from Alabama (Ms. SEWELL), another fabulous member of our committee.

Ms. SEWELL of Alabama. Mr. Speaker, today I rise in support of this year's Intelligence Authorization Act. Our national security is truly a bipartisan issue, and this legislation is a reflection of both parties' shared commitment to the safety and security of all Americans.

This bill helps provide our intelligence community with the necessary resources and capabilities to defend our Nation against ongoing and emerging threats around the world.

As the ranking member on the DOD Intelligence and Overhead Architecture Subcommittee, I was pleased that the language and direction in this bill continues to advance our capabilities on the ground and in space and provides necessary oversight of many critical DOD, NRO, and NGA programs. Additionally, this legislation takes important steps toward enhancing thorough oversight of our surveillance capabilities while continuing to make calculated investments in critically important strategic efforts.

In the IAA, we also invested in our greatest national resource, our people. I want to thank the chairman and ranking member for accepting provisions that I drafted to promote diversity in the IC workforce. We are now able to provide a summer internship program to students from the existing Centers of Academic Excellence and Intelligence. We also now hold the IC more accountable for doing a better job of developing a matrix to assess minority fellowship and internship programs and how they actually achieve their desired results, which is to increase the number of minorities hired by the IC.

Recently, I had the privilege of hosting a diversity in Intel summit. This event served as a rare opportunity for minority groups interested in the IC to gain insightful and helpful advice from top national security officials. It was truly a great occasion and it further reaffirms our committee's shared

commitment to helping to ensure robust diversity throughout the entire IC.

I was also pleased to successfully include bipartisan language that promotes accountability and transparency in the IC federally funded academic programs by requiring agencies to report on their recruitment and retention efforts. Increasing diversity and accountability in the IC is an issue of good governance and makes all of us better because it encourages unique and creative ways of problem-solving, which is increasingly necessary as we develop and we face more complex intelligence challenges.

As a committee, I am extremely proud of the work we have done. We took great pains to cut unnecessary funding while prioritizing the need to improve upon processes and be more efficient in the IC generally. The reality is that we live in a world where potential threats to our Nation are constantly developing and changing. As our military missions and intelligence objectives continue to evolve, we need an IC that is both diverse, agile, and adequately funded.

I am proud to support this year's Intelligence Authorization Act. I want to, again, thank the chairman and ranking member for all of their hard work. I urge my colleagues to support this important legislation.

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

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

Earlier this afternoon, we debated H.R. 3929, honoring the heroes of the Office of Strategic Services, the forerunner to our modern-day intelligence and special operations communities.

We honor them today to express our deepest gratitude for the contributions they made during World War II and its aftermath and our appreciation for the example they set for the present intelligence community and special operations heroes. They were part of America's Greatest Generation, one we will continue to honor, remember, and emulate. They faced a complex and dangerous world. They met those grave challenges on the desolate fields of Europe, the torrid seas of the Pacific, and in the shadows. Espionage and intelligence were critical to winning the war and to preserving the peace.

As we look forward to the future and to the dangerous world we inhabit today, we would do well to keep the examples set by that Greatest Generation in our minds. As they did, we should lead by example as much as by strength.

Thankfully, our intelligence community is the most capable and committed in the world to our ideals and to the rule of law. Every day, they seek to ensure that we are given the information necessary to guard and defend ourselves, our allies, and our partners. We remain grateful always for their hard work and dedication.

Again, my thanks to Chairman NUNES, to the members of HPSCI, particularly those who are leaving the committee, to the Senate for a remarkable bipartisan and bicameral effort, and to our excellent committee staff.

I want to thank the many public servants who have led the IC with whom we have had the chance to work over the past several years. In particular, I want to extend my thanks to those retiring or leaving their roles at the IC at the end of this administration, including Director of National Intelligence James Clapper and his deputy, Stephanie O'Sullivan; CIA Director John Brennan and his deputy, David Cohen; Assistant Secretary of the Treasury for Intelligence and Analysis Leslie Ireland, who today is retiring after 31 years of Federal service; and Under Secretary of Defense for Intelligence, Marcel Lettre.

Thank you as well to the incredibly capable leaders of the other elements of the IC who may remain beyond January 20th. Of course, most importantly, thank you to all the men and women of the intelligence community who silently and courageously protect our country day and night through their crucial work. We appreciate everything they do, and they have our continued support.

I also want to thank not only the HPSCI members, but the entire staff, including Michael Bahar, Tim Bergreen, Carly Blake, Robert Minehart, Linda Cohen, Amanda Rogers Thorpe, Wells Bennett, Rheanne Wirkkala, Thomas Eager, Patrick Boland, Kristin Jepson, Brandon Smith, and Kimberlee Kerr for all their valuable service.

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

We have four retiring members from our committee this year: Representative MURPHY, who was already spoken about earlier, did a great job attending a lot of the committee hearings or almost all of the committee hearings. We also have Representative JEFF MILLER, who served on this committee for a very long time and who is chairman of the Veterans' Affairs Committee; he is retiring. Also, Representative LYNN WESTMORELAND did a great job chairing our National Security Agency and Cybersecurity Subcommittee. Dr. JOE HECK, who chaired the Department of Defense Intelligence and Overhead Architecture Subcommittee, he is here on the floor with us this evening.

Finally, it is possibly premature, but we may not be able to congratulate Representative POMPEO on the House floor. He will have to have Senate confirmation next year, so I imagine he will be with the committee for a few months. But if we don't get a chance to come down to the House floor before he is approved by the Senate, I want to congratulate Mr. POMPEO. We are quite excited to have somebody from our committee to be chosen in the next administration to run the CIA.

I would urge my colleagues to support this bipartisan, bicameral bill, H.R. 6393.

I yield back the balance of my time. The SPEAKER pro tempore. The question is on the motion offered by the gentleman from California (Mr. NUNES) that the House suspend the rules and pass the bill, H.R. 6393.

The question was taken. The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. NUNES. 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 question will be postponed.

□ 1815

REPORT ON RESOLUTION PROVIDING FOR CONSIDERATION OF CONFERENCE REPORT ON S. 2943, NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2017

Mr. BYRNE, from the Committee on Rules, submitted a privileged report (Rept. No. 114-844) on the resolution (H. Res. 937) providing for consideration of the conference report to accompany the bill (S. 2943) to authorize appropriations for fiscal year 2017 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes, which was referred to the House Calendar and ordered to be printed.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, and the order of the House of today, proceedings will resume on questions previously postponed.

Votes will be taken in the following order:

The question on the motion to concur in the Senate amendment to H.R. 34 with an amendment;

The motion to suspend the rules and pass H.R. 6393; and

The motion to suspend the rules and pass H.R. 6304, if ordered.

The first electronic vote will be conducted as a 15-minute vote. Remaining electronic votes will be conducted as 5-minute votes.

TSUNAMI WARNING, EDUCATION, AND RESEARCH ACT OF 2015

The SPEAKER pro tempore. The unfinished business is the question on agreeing to the motion to concur in the Senate amendment to the bill (H.R. 34) to authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and Atmospheric Ad-

ministration, and for other purposes, with an amendment offered by the gentleman from Michigan (Mr. UPTON), on which a recorded vote was ordered.

The Clerk read the title of the bill. The SPEAKER pro tempore. The question is on agreeing to the motion. The vote was taken by electronic device, and there were—ayes 392, noes 26, not voting 16, as follows:

[Roll No. 592]

AYES—392

Abraham	Davidson	Huffman
Adams	Davis (CA)	Huizenga (MI)
Aderholt	Davis, Danny	Hultgren
Aguilar	Davis, Rodney	Hunter
Allen	DeFazio	Hurd (TX)
Amodei	DeGette	Hurt (VA)
Ashford	Delaney	Israel
Barletta	DelBene	Issa
Barr	Denham	Jackson Lee
Barton	Dent	Jeffries
Bass	DeSantis	Jenkins (KS)
Beatty	DeSaulnier	Jenkins (WV)
Becerra	Deutch	Johnson (GA)
Benishek	Diaz-Balart	Johnson (OH)
Bera	Dingell	Johnson, E. B.
Beyer	Dold	Johnson, Sam
Bilirakis	Donovan	Joyce
Bishop (GA)	Doyle, Michael	Kaptur
Bishop (MI)	F.	Katko
Bishop (UT)	Duckworth	Keating
Black	Duffy	Kelly (IL)
Blackburn	Duncan (SC)	Kelly (MS)
Blum	Duncan (TN)	Kelly (PA)
Blumenauer	Edwards	Kennedy
Bonamici	Ellison	Kildee
Bost	Ellmers (NC)	Kilmer
Boustany	Emmer (MN)	Kind
Boyle, Brendan	Engel	King (IA)
F.	Eshoo	King (NY)
Brady (PA)	Esty	Kinzinger (IL)
Brady (TX)	Evans	Kline
Brat	Farr	Knight
Brooks (IN)	Fincher	Kuster
Brownley (CA)	Fleischmann	LaHood
Buchanan	Fleming	LaMalfa
Bucshon	Flores	Lamborn
Burgess	Fortenberry	Lance
Bustos	Foster	Langevin
Butterfield	Foxo	Larsen (WA)
Byrne	Frankel (FL)	Larson (CT)
Calvert	Franks (AZ)	Latta
Capps	Frelinghuysen	Lawrence
Capuano	Fudge	Levin
Cárdenas	Gallego	Lieu, Ted
Carson (IN)	Garamendi	Lipinski
Carter (GA)	Garrett	LoBiondo
Carter (TX)	Gibbs	Loebsock
Cartwright	Gibson	Longren
Castor (FL)	Goodlatte	Long
Castro (TX)	Gowdy	Loudermilk
Chabot	Graham	Love
Chaffetz	Granger	Lowenthal
Chu, Judy	Graves (GA)	Lowey
Ciçilline	Graves (LA)	Lucas
Clark (MA)	Graves (MO)	Luetkemeyer
Clarke (NY)	Grayson	Lujan Grisham
Clawson (FL)	Green, Al	(NM)
Clay	Green, Gene	Lujan, Ben Ray
Cleaver	Griffith	(NM)
Clyburn	Grothman	Lynch
Coffman	Guinta	MacArthur
Cohen	Guthrie	Maloney,
Cole	Gutiérrez	Carolyn
Collins (GA)	Hanabusa	Maloney, Sean
Collins (NY)	Hanna	Marchant
Comer	Hardy	Marino
Comstock	Harper	Matsui
Conaway	Harris	McCarthy
Connolly	Hartzler	McCaul
Conyers	Hastings	McClintock
Cook	Heck (NV)	McCollum
Cooper	Heck (WA)	McGovern
Costa	Hensarling	McHenry
Costello (PA)	Herrera Beutler	McKinley
Courtney	Hice, Jody B.	McMorris
Cramer	Higgins	Rodgers
Crawford	Hill	McNerney
Crenshaw	Himes	McSally
Crowley	Hinojosa	Meehan
Cuellar	Holding	Meeks
Culberson	Honda	Meng
Cummings	Hoyer	Messenger
Curbelo (FL)	Hudson	Mica

Miller (FL) Roe (TN) Swalwell (CA)
 Miller (MI) Rogers (AL) Takano
 Moolenaar Rogers (KY) Thompson (CA)
 Mooney (WV) Rohrabacher Thompson (MS)
 Moore Rokita Thompson (PA)
 Moulton Rooney (FL) Thornberry
 Mullin Ros-Lehtinen Tiberi
 Murphy (FL) Roskam Tipton
 Murphy (PA) Ross Titus
 Nadler Rothfus Tonko
 Napolitano Rouzer Torres
 Neal Roybal-Allard Trott
 Neugebauer Royce Tsongas
 Newhouse Ruiz Turner
 Noem Ruppertsberger Upton
 Nolan Rush Valadao
 Norcross Russell Van Hollen
 Nunes Ryan (OH) Vargas
 O'Rourke Salmon Veasey
 Olson Sánchez, Linda Vela
 Palazzo T. Velázquez
 Pallone Sanchez, Loretta Vislosky
 Palmer Sarbanes Wagner
 Pascrell Scalise Walberg
 Paulsen Schiff Walden
 Payne Schrader Walker
 Pearce Schweikert Walorski
 Pelosi Scott (VA) Walters, Mimi
 Perlmutter Scott, Austin Walz
 Perry Scott, David Wasserman
 Peters Sensenbrenner Schultz
 Peterson Serrano Sessions
 Pingree Sewell (AL) Sherman
 Pittenger Shimpkus Shuster
 Pitts Sherman Simpson
 Pocan Shimkus Sinema
 Poliquin Shuster Sires
 Polis Simpson Slaughter
 Pompeo Sinema Smith (MO)
 Posey Sires Smith (NE)
 Price (NC) Slaughter Smith (NJ)
 Price, Tom Smith (TX)
 Quigley Renacci Smith (WA)
 Reed Ribble Speier
 Reichert Rice (NY) Stefanik
 Renacci Rice (SC) Stewart
 Ribble Richmond Stivers
 Roby Roby Stutzman

NOES—26

Amash Fitzpatrick Massie
 Babin Gohmert McDermott
 Bridenstine Gosar Meadows
 Brooks (AL) Grijalva Mulvaney
 Buck Huelskamp Ratcliffe
 DeLauro Jordan Sanford
 DesJarlais Labrador Schakowsky
 Doggett Lee Weber (TX)
 Farenthold Lummis

NOT VOTING—16

Brown (FL) Jones Rigell
 Carney Kirkpatrick Westmoreland
 Forbes Lewis Williams
 Gabbard Nugent Wilson (FL)
 Hahn Poe (TX)
 Joly Rangel

□ 1838

Messrs. DIAZ-BALART, ELLISON, and Ms. LOVE changed their vote from “no” to “aye.”

So the motion to concur was agreed to.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

Stated for:

Ms. WILSON of Florida. Mr. Speaker, I was unavoidably detained. Had I been present, I would have voted “yea” on rollcall No. 592.

INTELLIGENCE AUTHORIZATION ACT FOR FISCAL YEAR 2017

The SPEAKER pro tempore (Mr. BYRNE). The unfinished business is the vote on the motion to suspend the rules and pass the bill (H.R. 6393) to au-

thorize appropriations for fiscal year 2017 for intelligence and intelligence-related activities of the United States Government, the Community Management Account, and the Central Intelligence Agency Retirement and Disability System, and for other purposes, on which the yeas and nays were ordered.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from California (Mr. NUNES) that the House suspend the rules and pass the bill.

This is a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 390, nays 30, not voting 14, as follows:

[Roll No. 593]

YEAS—390

Abraham Courtney Grothman
 Adams Cramer Guinta
 Aderholt Crawford Guthrie
 Aguilar Crenshaw Hanabusa
 Allen Crowley Hanna
 Amodei Cuellar Hardy
 Ashford Culberson Harper
 Babin Cummings Harris
 Barletta Curbelo (FL) Hartzler
 Barr Davidson Hastings
 Barton Davis (CA) Heck (NV)
 Beatty Davis, Danny Heck (WA)
 Becerra Davis, Rodney Hensarling
 Benishek DeFazio Herrera Beutler
 Bera DeGette Hice, Jody B.
 Beyer Delaney Hill
 Bilirakis DeLauro Himes
 Bishop (GA) Denham Hinojosa
 Bishop (MI) Dent Holding
 Bishop (UT) DeSantis Holding
 Black DeSaunier Hoyer
 Blackburn DesJarlais Hudson
 Blum Deutch Huelskamp
 Bonamici Diaz-Balart Huffman
 Bost Dingell Huizenga (MI)
 Boustany Doggett Hultgren
 Boyle, Brendan Dold Hunter
 F. Donovan Hurd (TX)
 Brady (PA) Doyle, Michael Hurt (VA)
 Brady (TX) F. Israel
 Brat Duckworth Issa
 Bridenstine Duffy Jackson Lee
 Brooks (AL) Duncan (SC) Jeffries
 Brooks (IN) Edwards Jenkins (KS)
 Brownley (CA) Ellmers (NC) Jenkins (WV)
 Buchanan Emmer (MN) Johnson (GA)
 Buck Engel Johnson (OH)
 Bucshon Eshoo Johnson, E. B.
 Burgess Esty Johnson, Sam
 Bustos Evans Jordan
 Butterfield Joyce Farenthold
 Byrne Farr Kaptur
 Calvert Fincher Katko
 Capps Fitzpatrick Keating
 Cárdenas Fleischmann Kelly (IL)
 Carson (IN) Fleming Kelly (MS)
 Carter (GA) Flores Kelly (PA)
 Carter (TX) Fortenberry Kennedy
 Cartwright Foster Kildee
 Castor (FL) Poxx Kilmer
 Castro (TX) Frankel (FL) Kind
 Chabot Franks (AZ) King (IA)
 Chaffetz Frelinghuysen King (NY)
 Cicilline Fudge Kinzinger (IL)
 Clark (MA) Gallego Kline
 Clawson (FL) Garamendi Knight
 Clay Garrett Kuster
 Cleaver Gibbs LaHood
 Clyburn Gibson LaMalfa
 Coffman Gohmert Lamborn
 Cohen Goodlatte Lance
 Cole Gosar Langevin
 Collins (GA) Gowdy Larsen (WA)
 Collins (NY) Graham Larson (CT)
 Comer Granger Latta
 Comstock Graves (GA) Lawrence
 Conaway Graves (LA) Levin
 Connolly Graves (MO) Lewis
 Cook Grayson Lipinski
 Cooper Green, Al LoBiondo
 Costa Green, Gene Loebsock
 Costello (PA) Griffith Long

Loudermilk Perry Sires
 Love Peters Slaughter
 Lowenthal Peterson Smith (MO)
 Lowey Pingree Smith (NE)
 Lucas Pittenger Smith (NJ)
 Luetkemeyer Pitts Smith (TX)
 Lujan Grisham Poliquin Smith (WA)
 (NM) Pompeo Speier
 Luján, Ben Ray Posey Stefanik
 (NM) Price (NC) Stewart
 Lynch Price, Tom Stivers
 MacArthur Quigley Stutzman
 Maloney, Sean Ratcliffe Swalwell (CA)
 Carolyn Reed Thompson (CA)
 Maloney, Sean Reichert Thompson (MS)
 Marchant Renacci Thompson (PA)
 Marin Ribble Thornberry
 Matsui Rice (NY) Tiberi
 McCarthy Rice (SC) Tipton
 McCaul Richmond Titus
 McClintock Roby Tonko
 McCollum Roe (TN) Torres
 McHenry Rogers (AL) Trott
 McKinley Rogers (KY) Tsongas
 McMorris Rohrabacher Turner
 Rodgers Rokita Upton
 McSally Rooney (FL) Valadao
 Meadows Ros-Lehtinen Van Hollen
 Meehan Roskam Meehan
 Meeks Ross Vargas
 Meng Rothfus Veasey
 Messer Rouzer Vela
 Mica Roybal-Allard Velázquez
 Miller (FL) Royce Vislosky
 Miller (MI) Ruiz Wagner
 Moolenaar Ruppertsberger Walberg
 Mooney (WV) Rush Walden
 Moore Russell Walker
 Moulton Ryan (OH) Walorski
 Mullin Salmon Walters, Mimi
 Murphy (FL) Sánchez, Linda Walz
 Murphy (PA) T. Wasserman
 Nadler Sanchez, Loretta Schultz
 Napolitano Sanford Waters, Maxine
 Neal Sarbanes Weber (TX)
 Neugebauer Scalise Webster (FL)
 Newhouse Schiff Wenstrup
 Noem Schrader Westerman
 Nolan Schweikert Wilson (FL)
 Norcross Scott (VA) Wilson (SC)
 Nunes Scott, Austin Wittman
 Olson Scott, David Womack
 Palazzo Sensenbrenner Woodall
 Pallone Serrano Yarmuth
 Palmer Hunter Yoder
 Pascrell Sewell (AL) Yoho
 Paulsen Sherman Young (AK)
 Payne Shimpkus Young (IA)
 Pearce Shuster Young (IN)
 Pelosi Simpson Zeldin
 Perlmutter Sinema Zinke

NAYS—30

Amash Gabbard McDermott
 Bass Grijalva McGovern
 Blumenauer Gutiérrez Mulvaney
 Capuano Honda O'Rourke
 Chu, Judy Labrador Pocan
 Clarke (NY) Lee Polis
 Conyers Lieu, Ted Schakowsky
 DelBene Lofgren Takano
 Duncan (TN) Lummis Watson Coleman
 Ellison Massie Welch

NOT VOTING—14

Brown (FL) Jones Rangel
 Carney Kirkpatrick Rigell
 Forbes McNeerney Westmoreland
 Hahn Nugent Williams
 Joly Poe (TX)

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). There are 2 minutes remaining.

□ 1847

Mr. ELLISON and Ms. CLARKE of New York changed their vote from “yea” to “nay.”

So (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

PERSONAL EXPLANATION

Mr. RIGELL. Mr. Speaker, personal circumstances kept me from voting on the following votes. Had I been present, I would have voted "yea" on rollcall No. 592—21st Century Cures. "Yea" on rollcall No. 593—Intel Reauthorization.

ANNOUNCEMENT BY COMMITTEE ON RULES REGARDING AMENDMENT PROCESS FOR H.R. 5143, TRANSPARENT INSURANCE STANDARDS ACT OF 2016

Mr. SESSIONS. Mr. Speaker, this morning, the Rules Committee issued an announcement outlining the amendment process for H.R. 5143, the Transparent Insurance Standards Act of 2016.

The amendment deadline is set for Monday, December 5, at 10 a.m. Amendments should be drafted to the text of the Rules Committee Print 114-68, which contains the text of the bill, as reported by the Committee on Financial Services, with a modification, and can be found on the Rules Committee Web site.

Feel free to contact me or the staff if you have any questions.

ADOLFO "HARPO" CELAYA POST OFFICE

The SPEAKER pro tempore. The unfinished business is the question on suspending the rules and passing the bill (H.R. 6304) to designate the facility of the United States Postal Service located at 501 North Main Street in Florence, Arizona, as the "Adolfo 'Harpo' Celaya Post Office".

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Arizona (Mr. GOSAR) that the House suspend the rules and pass the bill.

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

A motion to reconsider was laid on the table.

DIRECTING THE CLERK OF THE HOUSE OF REPRESENTATIVES TO MAKE A CORRECTION IN THE ENROLLMENT OF H.R. 34

Mr. LANCE. Mr. Speaker, I send to the desk a concurrent resolution and ask unanimous consent for its immediate consideration in the House.

The Clerk read the title of the concurrent resolution.

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

There was no objection.

The text of the concurrent resolution is as follows:

H. CON. RES. 174

Resolved by the House of Representatives (the Senate concurring), That in the enrollment of

the bill (H.R. 34) to authorize and strengthen the tsunami detection, forecast, warning, research, and mitigation program of the National Oceanic and Atmospheric Administration, and for other purposes, the Clerk of the House of Representatives shall make the following correction: Amend the long title so as to read: "An Act to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes."

The concurrent resolution was agreed to.

A motion to reconsider was laid on the table.

END OF CUBA'S BRUTAL REGIME OF REPRESSION

(Mr. LAMALFA asked and was given permission to address the House for 1 minute.)

Mr. LAMALFA. Mr. Speaker, Fidel Castro led a brutal regime of oppression that imprisoned an island nation. While he and his family live like kings, the people of Cuba are repressed, starved, and forbidden any outside information.

According to credible sources and The Wall Street Journal, his regime may have killed up to 100,000 people. Thousands of political prisoners and human rights activists were brutally tortured and killed over the years.

Castro was eager to see the Soviet Union and the United States engage in a nuclear war, and even Soviet leader Nikita Khrushchev had to remind Castro that the point of putting the missiles in Cuba was to further Communist interests, not start Armageddon. "This is insane," Khrushchev said. "Fidel wants to drag us into the grave with him."

Under Castro, the Cuban Government refused to recognize the legitimacy of Cuban human rights organizations, alternative political parties, independent labor unions, or even a free press. He also denied international monitors, such as the International Committee of the Red Cross, to access the island to investigate human rights conditions.

With this vicious dictator finally dead, perhaps our close neighbor can finally be free. The people of Cuba can choose for themselves what they would like for their lives, rather than death squads and secret police imposing the will of a madman. I hope we can be supportive of a free Cuba and not further a bad regime.

PRESIDENT-ELECT TRUMP'S TREASURY NOMINATION

(Ms. KAPTUR asked and was given permission to address the House for 1 minute.)

Ms. KAPTUR. Mr. Speaker, I rise tonight in alarm over the stacking of Wall Street insiders in top positions for the incoming administration.

During his campaign, President-elect Donald Trump said the system is rigged. He said hedge fund managers are "getting away with murder" and that he would "tax Wall Street" and

called Washington, D.C., corrupt and promised to "drain the swamp." President-elect Trump even closed his campaign with a political ad bashing Goldman Sachs.

Yet now, according to media reports, he has chosen a second-generation Goldman Sachs partner, Steven Mnuchin, to serve as Treasury Secretary. He will take the post most responsible for watching and regulating the dangerous, high-risk, high-stakes gambling behavior of Wall Street, which he has himself engaged in for decades. He worked at Goldman Sachs for 17 years. His father worked there. His brother still works there, and he frequently returns for alumni and social gatherings. He was named the "Foreclosure King" after buying up the remains of IndyMac, a California-based mortgage lender, and evicted approximately 36,000 people who could not keep up their mortgage payments.

The last three administrations have had Goldman executives at the helm inside the White House and Treasury. While President-elect Trump promises to drain the swamp, he is not doing it. He is enlarging it.

GUARDING AGAINST FOREIGN INTERFERENCE IN FUTURE ELECTIONS

(Mr. CONNOLLY asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. CONNOLLY. Mr. Speaker, on October 7, 2016, the Department of Homeland Security and the Office of the Director of National Intelligence on Election Security released a joint statement saying: "The U.S. Intelligence Community is confident that the Russian Government directed the recent compromises of emails from U.S. persons and institutions, including from U.S. political organizations."

The U.S. Intelligence Community went on to explicitly state that "these thefts and disclosures are intended to interfere with the U.S. election process . . . only Russia's senior-most officials could have authorized these activities."

Despite this certification, the majority in this body has demonstrated zero interest in examining the unprecedented attack on one of our most cherished institutions, democratic free elections.

I am here today to plead with the majority to take an interest, not because I seek to undermine the results of the recent Presidential election. That is not my intention. Rather, it is my sincere hope that we understand the nature of the foreign interference and how to guard against it in all future elections.

PRECISION MEDICINE INITIATIVE

(Ms. JACKSON LEE asked and was given permission to address the House for 1 minute and to revise and extend her remarks.)

Ms. JACKSON LEE. Mr. Speaker, I rise in celebratory support of H.R. 34, the House amendment to the Senate amendment to the 21st Century Cures Act. As a breast cancer survivor, I am celebrating. As a Representative from the City of Houston, I am celebrating.

Because of the Texas Medical Center, this plan will provide an ambitious action that called for \$6.3 billion in mandatory funding to be delivered over the next 10 years to the National Institutes of Health. It also provides and estimated that every \$1 of NIH funding generates about \$2.21 in local economic growth and 402,000 jobs. But most of all, it will deal with the curing of diseases and developing research that will help save lives.

In furtherance of this initiative, this legislation before us allows for the creation of an innovation fund through the National Institutes of Health so that we can design the most innovative ways of curing disease, of helping children, of helping seniors, of helping people who are dealing with incurable disease.

The Cures Act is an act of the 21st century. It moves forward on the President's Precision Medicine Initiative.

I thank Mr. UPTON, Ms. DEGETTE, and all the Members. I serve as an original cosponsor. I am excited about the legislation, for it will save lives.

□ 1900

COMMEMORATING AND CELEBRATING THE LIFE OF MS. JACQUELINE ELLIS

The SPEAKER pro tempore (Mr. CARTER of Georgia). Under the Speaker's announced policy of January 6, 2015, the gentleman from Texas (Mr. AL GREEN) is recognized for 60 minutes as the designee of the minority leader.

Mr. AL GREEN of Texas. Mr. Speaker, I am honored to stand before the House tonight to commemorate and celebrate the life of my former Chief of Staff, Ms. Jacqueline Ellis.

Mr. Speaker, Ms. Ellis served well. In the sense of many, she was the 436th Member of Congress. She helped to educate not only new persons who were here in administrative capacities, but also Congresspersons. She helped us to understand what Congress was all about.

I am honored tonight to say some kind words about her and to acknowledge a colleague who is here and will be saying a word as well.

To my right is a photograph of my very dear friend and former coworker, Jacqueline Ellis. She was born in Mobile, Alabama. She was born at a time when persons of African ancestry could buy a hat, but they couldn't try it on; at a time when persons of African ancestry would have to step aside so that others could step forward; and at a time when persons of African ancestry were relegated to certain places in life, certain schools, and certain places of business. They had to go to the back

door for their food. They would drink from colored water fountains. She was born at a time when this country did not respect all of her rights.

Who could have known that when she was born in Mobile, Alabama, that she would make her way from Mobile to Capitol Hill?

There was no way to predict at the time of her birth that she would come to this Nation's Capitol and that she would serve three Members of Congress—one United States Senator and two U.S. Representatives: the Honorable Major Owens from New York's 11th Congressional District, the Honorable Senator Heflin. And, of course, she served in my office. No one could have known.

I think, quite frankly, that this speaks to the greatness of the country, that we have moved light years away from some of the circumstances that we had to endure earlier in the history of this country.

Notwithstanding all that has been done, there is still great work to be done. Tonight I want to say to you that this person born in Mobile during very difficult times has received an indication from the President of the United States of America that he was saddened to learn of her demise. I include in the RECORD a letter from the President.

THE WHITE HOUSE,
Washington, September 28, 2016.

Mr. CHRIS ELLIS,
Bowie, Maryland.

DEAR CHRIS: I was deeply saddened to learn of the loss of your sister, Jacqueline. My heartfelt condolences are with you as you reflect upon her life.

May cherished memories help temper your grief, and may you find comfort in the support of loved ones. Please know you will remain in my thoughts.

Sincerely,

BARACK OBAMA.

Mr. AL GREEN of Texas. She has also been honored by a good many of my colleagues here on the Hill, including the Honorable NANCY PELOSI, who sent a letter to my office and expressed verbally her condolences and her sympathies. She has also been honored by the Honorable STENY HOYER, by the Honorable JIM CLYBURN, and by the Honorable XAVIER BECERRA. She has been honored by Members of Congress in many capacities. We have a resolution that has been filed. This resolution is one that pays tribute to her. It has been signed on to by a good many Members of Congress as well.

So tonight I am pleased to say that Jacqueline Ellis, born in Mobile, Alabama, and matriculated her way to and through the Halls of Congress is now resting in peace.

She was a person that lived every day of her life in the sense that she was busy doing something for someone every day of her adult life. She worked up until the moment she was hospitalized. Literally, I was the last person to speak to her. She and I were going to an event, the ALC dinner, the Congressional Black Caucus dinner as it is

called, and she was there to pick me up and take me to the dinner. She called me and said to me: I will be waiting for you. I am downstairs.

I said that I will be down in about 10 minutes.

Within that period of time, she called me back and informed me that she needed to go to the hospital. I rushed down to her, and when I got there, the emergency assistance was already there. She called them prior to calling me apparently. I immediately assisted them, and we went to the hospital together. She stayed in the hospital for some days and made her transition.

The important point to make is that she was working. Her work was her life. She lived to perform her duties. She was on her job in the sense that she was assisting that evening, and she was there all day long. She was ill, but she would not stop working. There were times when we would ask that she take some time off, but she always wanted to come to work.

Her work was her inspiration in a sense. Her work was the thing that gave her a reason to continue to go on, and she never, ever complained. There is a song that speaks to the kind of person that she was because there are many of us right here in Congress who can relate to this. When you see the great eagle flying, you assume that it is the wings. But there is a song that addresses how it is that the eagle can soar to these high heights. That song says that it is not the wings, but rather it is the wind beneath the wings. She was the wind beneath the wings of a lot of people who were able to soar to high heights, a lot of people who did not understand all of what was before them when they accepted the responsibility to become a part of a congressional staff or a Member of Congress. She became the wind beneath their wings and helped to guide them through Congress.

I am pleased to tell you that we have had several celebrations of her life. We had one in this area immediately after her untimely demise—untimely to me because I had hoped that she would be with us a lot longer than she was. We also had a celebration of her life in her hometown of Mobile, Alabama, attended by a good many dignitaries and staffers from the Hill; a celebration of her life in Houston, Texas, similarly attended. She has been recognized and honored by people that she came in contact with.

She made a difference. I will relate one brief vignette before I ask my colleague to come to the podium. When I was looking for my first chief of staff—and she was my first and only chief of staff, I might add. When I was looking for my chief of staff, I was a neophyte in Congress, and I brought her on board. You are always unsure about a new hire, especially a person who is going to be key to the office, a person that everything sort of evolves around. So I was unsure as to whether or not I had made the right decision.

She and I were together, and I saw her pull over rather abruptly. She was driving. My recollection is that this happened more than once, but on this occasion, she was driving. When she pulled over, she ran over to a person, and I saw her hand the person something, and then she came back to the car. I immediately wanted to know who this was. Was it somebody that she knew? Because she did it so abruptly.

She said: No, I didn't know that person.

The person was not dressed in a suit and tie. The person did not have the appearance of what we would call status, although I think everybody has status. The person did not appear to be a captain of industry, if you will. She went over and she gave that person money. I found out later on that she would go to the credit union, and she would extract dollar bills—some stack; I don't know how many in the stack—and she would use that money to just give to people that she would encounter that she was of the opinion needed some help.

When she did it on that day, I knew that I had made the right decision because I then knew that I saw the sermon that many people preach. It is truly better to see a sermon than to say one, or to be one than to say one. I saw that day "love your neighbor as you love yourself." I saw on that occasion "help somebody."

I saw her live up to the true meaning of the spirit of the story of the Good Samaritan who saw the person in the streets of life and went over and took that person to the inn and said: Here is money. Use this to help this person. And if this is not enough, when I come back, I will give you more.

I saw the good neighbor in Jacqui Ellis. I knew then that I made a good hire because I had a person who would not only speak a sermon, but would be a sermon.

Mr. Speaker, I yield to the gentlewoman from Texas (Ms. JACKSON LEE), who is my colleague from Houston, Texas. The Honorable SHEILA JACKSON LEE hails from the 18th Congressional District. She serves on the Judiciary Committee, she serves on the Committee on Homeland Security, and she has served us in Congress for a good many years.

Ms. JACKSON LEE. Mr. Speaker, I thank my colleague, the Honorable AL GREEN of Texas.

Mr. Speaker, we are like family in this House, Republicans and Democrats, as we work together and work with our staff. I am very clear in the fact that Ms. Ellis was the only chief of staff that Congressman AL GREEN of Texas had, and that he made an A-plus choice, and she, likewise, in accepting his offer to be his chief of staff.

She was a 30-year veteran, and she brought to his office and brought to this House a sense of affection and love for the institution, for democracy, and for America. Not only did she have the privilege of working for Congressman

AL GREEN of Texas and he the privilege of having her as his chief of staff, she worked previously for Congressman Major Owens of New York, and the late former Alabama Senator Howard Heflin.

□ 1915

It means that she understood the institutions that helped to lay down the pillars of democracy.

She was a spiritual mother to the tens upon thousands of young people who came to this place with starry eyes to make a difference—spiritual mother, sister, mentor, and friend to many people, including elected and people of high ranking status.

She was a graduate of a historically Black college, and, as well, she had a background in government affairs.

But, more importantly, she had a big heart. And she was eager, as I am told by the staff, to be able to help all the new and young staff. They knew they could go to Jacqui Ellis.

She was a Christian woman as well, and she served on many important organizations. In particular, I worked for the Southern Christian Leadership Conference. She was a national board member, the organization founded by Dr. Martin Luther King, and Ralph David Abernathy, and where Andrew Young worked, and Josea Williams, and so many others. James Orange, and those of us young people who believed that we could overcome.

She was a recipient of the Ella Baker Award from the SCLC and Martin Luther King, III.

But where I got to see Jacqui really making it and doing it was in her leadership with C. Delores Tucker, and her work with the National Congress of Black Women. As a board member, I remember coming as a young Member of Congress, and we would go to that very famous breakfast, Congressman GREEN, the Sunday after the Congressional Black Caucus, and there was Jacqui. She was the orchestrator, the guider. She respected C. Delores Tucker. She honored the women who came. She was at their beck and call—we need this.

She was the person that the likes of Malcolm X's wife, Rosa Parks, and Coretta Scott King, because they used to come during their lifetime every year, and those of us who were young Members of Congress, she welcomed us with open arms and allowed us to sit in the royal place at the feet of these great women who she had come to know, and they had come to know and love her, as we held this wonderful program about the empowerment of women and, in particular, African American women.

She was, as well, the co-chair of the Bethune DuBois Institute, Inc. Leadership Forum and, as well, she has received awards from the Congressional Black Caucus.

So I close by simply saying, yes, she has a litany of accolades and honors. We wish that she could have lived on and on and on. Some say that the

young die young. We certainly believe that Jacqui Ellis, our friend, our lover of this institution, this great staff person, was taken way too young.

As I told my friend and colleague, earlier this year, I experienced an enormous tragedy in losing a dear staff person, who, though a short time, had become so much a part of our extended family. And so, Congressman GREEN, I know it hurts. It hurts many of her fellow staffers and friends. Certainly we know her family suffered great pain.

But I can say, as we salute great Americans, and each have done something in their way to move this country forward, I want to say that Jacqui Ellis lived in the greatest country in the world. It was already a great country. But she was so much a part of making this country a country that welcomed all of the young talent and those new faces that desired to be part of the greatness of this country. She did it with open arms and a big heart. We will miss her greatly, but she has left a legacy of service. As you have noted, she stopped along the highway of life and gave what she had to someone who looked like they needed it more.

So to Jacqui I say: farewell our dear friend, farewell, for you are certainly one who is a good and faithful servant. May you rest in peace.

Mr. AL GREEN of Texas. Mr. Speaker, I thank Ms. JACKSON LEE for her very, very kind words. She did know Jacqui well. She had a lot of respect for her. I appreciate her taking the time to come by this evening.

I want to also acknowledge that the Honorable EDDIE BERNICE JOHNSON was here but had to step away.

I want to also acknowledge that some 150 individuals have given us expressions concerning Jacqui, a number of organizations, at least 20, and we have 41 cosponsors of the resolution that I spoke of earlier, H. Res. 905, which expresses condolences to her family, and it commemorates her life.

Finally, we have elected officials, at least 64, including the President and former Secretary of State Hillary Clinton, who have expressed their sympathies and condolences. She was truly a person who touched a lot of people in a very positive way. I am honored to say that I was associated with her and that she truly made a difference in my life.

Mr. Speaker, as we travel the road of life, we meet many people. We remember some and a good many we do not. Jacqueline Ellis is someone that I will remember, and my belief is that a good many other persons who came into contact with her, whether it was for a very short period of time or for some duration, will remember her as well. These would include the members of the sorority that she was affiliated with, Delta Sigma Theta. She was very active in this sorority. She was loved, and is still loved, by the members of Delta Sigma Theta. They would come to the Hill on an annual basis and they

always took time to come by and visit her. She would always welcome them and provide services.

This is but one of the many organizations that will continue to honor her, I am sure. The others that will remember her that she came in contact with would be SCLC, as was mentioned by my colleague, the Southern Christian Leadership Conference. This was the organization that Dr. King led. This was the organization that fought for human rights, civil rights, and human dignity across the length and breadth of this country. She was part of that organization. In fact, she was on the board.

She and Martin King, not Martin King the father but Martin King, III, the son of Dr. King, were the very best of friends—the very best of friends. He has traveled great distances to pay tribute to her. He was there in Mobile, Alabama. He came here for the services that we had. And he always, when he was in Washington, DC, would take the time to come by our office to say hello to Jacqui.

People who met her along life's way would also include the Links. The Links was an organization that she was affiliated with and that she took great pride in assisting as they were having their various events. She was always helpful to other people to make sure that they were able to be successful in their endeavors. When you travel the road of life, the highway of life, you meet many people. You don't remember them all, but there are some who are special, and these are the persons who will stand out in your mind and will be remembered in the very years to come of your life.

So tonight, I am grateful that the leadership has allowed us this time to pay tribute to Jacqueline Ellis, who was born in Mobile, Alabama, on October 22, 1957, a very difficult time in the life of the country, and who made a transition on September 21 of 2016. She is gone, but she is not forgotten. She will be remembered. We are grateful that we have had an opportunity to commemorate her life and celebrate the wonderful person that she was.

GENERAL LEAVE

Mr. AL GREEN of Texas. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on the subject of my Special Order.

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

There was no objection.

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

Ms. EDDIE BERNICE JOHNSON of Texas. Mr. Speaker, today, I join my colleagues to recognize a true pillar in the congressional community, Ms. Jacqueline Ellis. Jacqui began working on Capitol Hill when it was not common for a woman, let alone a woman of color to work here, but she never let that stop her. Her path in life is admirable and truly shows her resilience and dedication to public service.

During her tenure, she changed the lives of countless men and women, particularly those of color that she came in contact with. It was not uncommon for her to give her all to anyone that came through her door without asking for recognition. She stayed humbled and committed to her purpose to fulfill her life's mission of service.

Her love and dedication to Delta Sigma Theta Sorority, Inc. was felt with all her sorors, especially those who work on Capitol Hill. She assisted with hosting Delta Days at the Nation's Capitol and ensured that all who attended felt welcomed and loved. She also was the matriarchic for Deltas on the Hill, which gave members of her sorority a space to laugh, love and support each other on Capitol Hill. To my colleagues who are members of Delta Sigma Theta Sorority, Inc., I mourn with you all today for the loss of your sister.

She was a true humanitarian and her presence is missed throughout the halls of the Capitol. My thoughts and prayers go out to her family, Congressman AL GREEN's staff, her sorors, and all those who she impacted in her lifetime.

Mrs. BEATTY. Mr. Speaker, I thank my good friend and Congressional Black Caucus colleague, Congressman AL GREEN of Texas, for leading tonight's Special Order Hour to honor and in memorial to beloved Congressional staffer, Jacqueline A. Ellis, known to most of us as Jacqui.

On September 21, 2016, the world lost Jacqueline Ellis, a beloved mentor, friend, colleague, and sister, and we, here in the halls of Congress, lost a legend.

Through her nearly 30 years of service in the people's House, Jacqui helped to expand diversity on the Hill and inspired countless young people to dedicate their lives to public service.

She served as a mentor for many young African-American staffers who came to Capitol Hill looking to make a difference in our nation.

When Jacqui became a House staffer in 1988, there were few people of color in the corridors of the Congress, but that did not dissuade Jacqui. Instead, it inspired her to assist and help numerous Black staffers thrive.

Upon her passing, hundreds of former and current Congressional staffers took to social media to share their stories and memories of Jacqui. Words like "good listener"—"wonderful woman"—"especially there to help young people"—and "enormously respected" were used.

As one of the first Black women to serve as a Chief of Staff on Capitol Hill, she was a trailblazer who opened the door so other that women of color could follow in her footsteps.

She founded the Organization of African-American Administrative Assistants for Chiefs of Staff in the House. And, she worked quietly behind the scenes to expand equality of opportunity and to strengthen our democracy.

Jacqui was also a proud member of Delta Sigma Theta Sorority, Inc., and one of my sorors. She was instrumental in planning and executing the annual "Delta Days" on the Hill.

She was also a proud member of The LINKS Incorporated and coordinated its Congressional Black Caucus Foundation Issues Forum.

Her charitable nature, her unbridled spirit, her selfless dedication to public service, and her strong faith will certainly be missed.

RECOGNIZING THE VIRGINIA DELEGATION

The SPEAKER pro tempore. Under the Speaker's announced policy of January 6, 2015, the gentleman from Virginia (Mr. GOODLATTE) is recognized for 60 minutes as the designee of the majority leader.

GENERAL LEAVE

Mr. GOODLATTE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on the subject of my Special Order.

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

There was no objection.

Mr. GOODLATTE. Mr. Speaker, today I and other Members of the House, most especially members of the Virginia delegation, but other House Members who served with three of our Virginia colleagues, are here to express our thanks and pay tribute to their service, to the people of Virginia, and the people of the United States of America. We are saddened to lose three members of our great Virginia delegation, but we have the utmost regard for all of them, and we wish them well in their future endeavors.

I am going to start by recognizing my dear friend and colleague on the House Judiciary Committee, Congressman RANDY FORBES. I remember when RANDY arrived here. I had known him many years before he was elected to the House. I was, frankly, thrilled when he decided to run for the House of Representatives and got elected. Of course, his first priority, representing the Fourth Congressional District, was to get on the House Armed Services Committee.

Once he secured that, he was looking for a second committee. I encouraged him to seek a position on the House Judiciary Committee and helped him in his effort to do that. He is a fine attorney and someone who was a great value to me and my predecessors who have had the honor of chairing the House Judiciary Committee.

Born and raised in Chesapeake, Virginia, RANDY FORBES has never forgotten who he is or where he came from. Growing up as the son of a World War II Normandy veteran, RANDY was raised on the values of duty, hard work, family, and faith. He carried those principles with him to Randolph-Macon College, where he graduated as valedictorian of his 1974 class, and throughout his years at the University of Virginia School of Law.

Since first elected to Congress in 2001, RANDY's highest priority has been to protect and defend our Nation, the fundamental freedoms it was founded upon, and the men and women who fight for those freedoms. As chairman of the House Armed Services Seapower and Projection Forces Subcommittee, RANDY is one of the Nation's forceful advocates for a strong national defense.

As a result of his dedicated efforts, Chairman FORBES is one of the few individuals to be honored with the highest civilian awards offered by both the United States Army and the United States Navy. He is also a senior member, as I mentioned, of the House Judiciary Committee where he serves as a member of the Subcommittee on Courts, Intellectual Property, and the Internet, as well as the Subcommittee on Crime, Terrorism, Homeland Security, and Investigations. And he is the founder and co-chairman of the Congressional Prayer Caucus and the Congressional China Caucus.

RANDY began his career in private law practice, ultimately becoming a partner in the largest law firm in southeastern Virginia. From 1989 to 2001, he served the Commonwealth of Virginia in the General Assembly.

He and his wife, Shirley, have four children and three grandchildren, which RANDY personally regards as his greatest achievement. And, no doubt, as a grandfather myself, I understand well that sentiment, and I wish him very well with his family and hope that he has much time to enjoy with them, but not too much time because he is too valuable to our country not to be afforded another opportunity to serve our country in some great capacity.

Congressman ROBERT HURT also served with distinction in the Virginia General Assembly, and then a little over 6 years ago came to visit me and my wife, Maryellen, in our home to talk about his possibility of seeking election to the Congress. We encouraged him to do just that, he did, and was successful.

ROBERT HURT is a member of the Financial Services Committee, which has jurisdiction over all aspects of the Nation's financial and housing sectors. Within the committee, he serves as the vice chairman of the Capital Markets and Government Sponsored Enterprises Subcommittee, and serves on the Housing and Insurance Subcommittee, as well as the Oversight and Investigations Subcommittee.

A native of Pittsylvania County, ROBERT began his time in public service in 2001, as a member of the Chatham Town Council. From 2002 to 2007, ROBERT served in the Virginia House of Delegates, representing parts of Pittsylvania County, Henry County, and the city of Martinsville.

□ 1930

Starting in 2008, ROBERT represented the 19th district in the Senate of Virginia for 2 years, which includes the city of Danville, Pittsylvania County, Franklin County, and part of Campbell County. He received his college education at Hampden-Sydney College in the district that he now represents in 1991. He obtained his law degree from the Mississippi College School of Law in 1995. From 1999 to 2010, ROBERT was engaged in a general law practice in the courthouse town of Chatham, where he lives with his wife, Kathy,

and their three sons—Charles, Clement, and John.

SCOTT RIGELL also was elected to Congress in the same year that Congressman HURT was, and we were delighted to have him come and join us as well, being another strong advocate for our Nation's defense. He serves on the House Committee on Appropriations. Since taking office in January 2011, Congressman RIGELL has made creating jobs, strengthening our military, controlling Federal spending, and changing Congress his most urgent priorities. In representing the Nation's largest military district, Congressman RIGELL is working to preserve our region's unique military assets and to support our men and women in uniform.

He was instrumental in the successful effort to keep all East Coast aircraft carriers based in Norfolk, and he introduced language that improved the maintenance of military housing, including in the fiscal year 2013 National Defense Authorization Act. With strong bipartisan support, the House and Senate passed Congressman RIGELL's Drywall Safety Act of 2012, which was signed into law by the President in early 2013. This legislation sets chemical standards for domestic and imported drywalls, establishes remediation guidelines for the disposal of all drywall, and expresses a sense of Congress that China must be held accountable for the damage this product has already caused in our community and across America.

Prior to his election to Congress, he was a successful entrepreneur, businessowner, and community leader—the founder of Freedom Automotive. Congressman RIGELL and his wife, Teri, previously owned automobile dealerships in Chesapeake, Hampton, Norfolk, and Virginia Beach. He served 6 years in the United States Marine Corps Reserve and rose to the rank of sergeant before receiving an honorable discharge. He earned his BBA from Mercer University and an MBA from Regent University.

He and his wife are the proud parents of four children and four grandchildren. They are competing well with the Forbes family in the grandchildren department, and I know they also will enjoy more time with those grandchildren; but I hope we see Congressman RIGELL serving his country in another capacity in the future as well.

At this time, I am delighted that we have Members whose districts adjoin Congressman RIGELL's, Congressman HURT's, and Congressman FORBES'. I know that Congressman ROB WITTMAN, who served on the Armed Services Committee with Congressman FORBES, has to be somewhere else; so I am going to turn to him first, and then I will turn to Congressman SCOTT. I am happy to yield to the gentleman.

Mr. WITTMAN. I thank the chairman.

Mr. Speaker, it truly is an honor and a privilege to reflect on the careers of

three dear friends as the gentleman spoke so eloquently about Congressman RANDY FORBES, Congressman SCOTT RIGELL, and Congressman ROBERT HURT. They have been true Virginia leaders. They are all statesmen in the truest sense of the word. They are all servant leaders in their putting others before themselves, and they have done that throughout their tremendous careers in public service.

RANDY FORBES is a dear friend. RANDY is one of those unique individuals who truly, truly puts others first in everything that he has done. I have known RANDY through the years, back to his days in the Virginia General Assembly, where he created great opportunities for folks, not only in the district that he represented, but he also made an impact on the State of Virginia. He was a very thoughtful and eloquent legislator. He understood what government's role was. He wanted to make sure that that was done properly. He also played a critical role in his party. The Grand Old Party was better off in Virginia because of RANDY FORBES' leadership. We were blessed to have him in that capacity there for a number of years. I have known RANDY as a dear friend but also, truly, as one of the most effective legislators whom we have seen up here on Capitol Hill.

His time, Mr. Chairman, on your Committee on the Judiciary is marked by many great accomplishments there as well as by some very sound and thoughtful judgments and, most importantly, by some very probing questions when it came time to interview panelists or witnesses who came before the Judiciary Committee.

He was extraordinarily adept at that as he was—and still is—on the House Armed Services Committee. It was tremendous to watch RANDY as he would pick apart an issue and get critical information from witnesses or panelists who came before our committee. Whether it was in a briefing or whether it was to really ascertain the facts of a situation, he was extraordinary in his opportunities there.

He really cares passionately about our Nation's military, about the men and women who serve and what we provide for them to serve. He has done a spectacular job in efforts to rebuild our Nation's Navy. In fact, this year, for the first time in 8 years, our Navy is actually back to growing again. We are building more ships than we are retiring, and that is due in no small part to RANDY FORBES' leadership and the things that he has done to make sure that things like our new carrier program with the *Ford*-class carriers and with our new *Ohio*-class replacement submarines, termed the *Columbia*-class, are on track, as well as the *Virginia*-class with our new destroyers. He has been extraordinary in making sure that he has been an advocate to ensure that our sailors have what they need as well as our marines have what they need, and he has done that every minute that he has served there on the Armed Services Committee.

I have learned a lot from RANDY. I have valued his counsel, but I have also watched his leadership as he has done things for our Nation that I think are extraordinarily important. I believe those accomplishments are things that will be valued and will have an effect on this Nation, not just in years to come but for decades to come. He has truly had that type of influence.

Mr. Chairman, I agree with you. I hope that Chairman RANDY FORBES of the Seapower and Projection Forces Subcommittee has an opportunity to continue to serve this Nation in another capacity in which he can use that expertise, that extraordinary history of leadership and legacy of leadership there on the House Armed Services Committee. I think our Nation will be better off for having RANDY there in a future capacity in leadership. I am hopeful that that will happen, and I truly value the things that he has done.

RANDY isn't somebody who just focuses on the Nation's military. He is also a fighter for our individual liberties and freedoms, specifically our religious liberties and freedoms. He has been the cofounder and co-chairman of the Congressional Prayer Caucus, where he has been a staunch advocate to make sure that we push back against those intrusions on our religious liberties and freedoms. He has done an extraordinary job there.

I value that relationship that I have with RANDY as a member of the Prayer Caucus and for the things that he has done. He has been unafraid to be out there in the forefront to make sure that he points out those efforts that are antifaith efforts and to make sure that he stands strong on the side of those folks who want to make sure that their religious beliefs are protected. He has done an extraordinary job there, not just here in Virginia, but also across the Nation. He has been seen as a true leader there. Again, it goes to the heart of that servant leader that RANDY truly is. We will miss him in those capacities. I know that he will continue to make sure that he is a beacon defending religious freedoms and liberties in whatever capacity he continues after his term here in Congress. We look forward to his efforts there also.

As well, the gentleman spoke of Congressman ROBERT HURT. ROBERT and I have a lot in common. ROBERT comes from the small town of Chatham in Pittsylvania County. He began there on the town council—the same place as I began in the little town of Montross. Both are very, very similar towns. ROBERT also has that heart of a servant leader by which he looked at where he could best serve his citizens there in the town of Chatham as well as going on to the general assembly there in Richmond, which is where he and I served in the house for a number of years. He went on to the State senate and then, later, here to the House of Representatives.

Mr. Chairman, just as you spoke of them, ROBERT and his wife, Kathy, graciously sat down with Kathryn and me to ask questions about what service would be like if he were to decide to run for the U.S. House of Representatives. Of course, we told him what the challenges were but also what he could accomplish in that role. I believe that he, again, put the Virginia way first in making sure that he was there to serve when he made that decision. It certainly was one that I know was a difficult one for him but was one that he came here with a lot of passion about as to what he could do to make a difference in the direction of this country, and ROBERT has continued that.

I have known ROBERT through the years. He has always been a man of deep personal conviction but also a man of deep passion. ROBERT is a lover of life, but he is also one who never backs away from an issue that he feels passionately about. As you know, I have watched ROBERT get up and give speeches. Boy, I will tell you, if it doesn't make the hair stand up on the back of your neck, nothing will. He is an effective standard-bearer for issues that are important to the Nation and to Virginia. He has been a real leader there on the Financial Services Committee, whereby he knows those issues backwards and forwards. Again, it is that background that he brings from his time in local and State government that, I think, makes him an extraordinarily effective legislator here.

We will certainly miss him, but I know that the next step in his career—with his wife, Kathy, and his three sons—will be one in which he will enjoy the time there in the small town of Chatham. I know he intends to go back and practice law there and get back to the important elements of what makes Chatham special and what makes Virginia special. We will miss him, but I know that he will be extraordinarily successful there.

I have known Representative SCOTT RIGELL for a number of years even prior to his coming to Congress. I will never forget the conversation that I had with him as he was—again, like ROBERT—thinking about running for Congress and how passionate he was about the direction this Nation was taking both in its deficit and its debt and as to what was happening to small businesses out there. As a small-business owner, he later went on to own some significant businesses there in the Tidewater area. He really saw what was unfolding in our Nation, and it caused him deep, deep concerns not only for himself and Teri, but also for his children and now for his grandchildren.

What a person of passion—and very eloquent. He was also a person who wanted to make sure that we reformed the way government conducted business. He and I had many, many deep conversations about what that would look like and how process is important and how doing the work of the Nation

was absolutely critical. Whether what we were doing was to help small businesses or what we were doing was to ensure that our Nation's military had what it needed or what we were doing was to address the Nation's finances, he was equally adept and well schooled in those subject areas. He was a quick study on issues but a thorough study. He was exhaustive in how he would look at information concerning legislation or what he could do on a particular issue, and I admired him for that because you knew, when SCOTT RIGELL came to the floor to vote, that he knew that bill and that issue backwards and forwards. In fact, many times, I would go to talk to him about a bill that was coming up, and I could guarantee that SCOTT knew it without limitations. He was very, very passionate about that.

That is the reason he came to Congress and what he came here to accomplish, and he did an extraordinary job in his years here. I deeply appreciate his service and the sacrifice that his family has put into this. As I know Teri will attest, there were long hours that were spent here. Teri came up here on the Hill many times and was by SCOTT's side; so, for the Rigell family, it really was a family affair in service. I know that he also has exciting things facing him in his next chapter of life and that his efforts will, indeed, continue to include public service; so we wish SCOTT and Teri and his entire family the best.

We all are changed for the better because of the service of these three Virginia gentlemen—three Virginia statesmen—and what they have done here to affect not only their communities, whether it is in Chesapeake or in Virginia Beach or in Chatham, Virginia, but what they all have done to affect our great Commonwealth of Virginia and the lasting mark that they have left here for our Nation. We are all indebted to their service, indebted to the legacies that they have left behind, and indebted in our making sure that we continue the legacies of passion for the issues that are important to our Nation, whether it is for our military, whether it is for our small businesses, whether it is for our Nation's financial predicament it finds itself in.

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All of them have brought lasting change to this body and will continue, I know, in further capacities in their life after. We thank them immensely. We are all better off for their service, and I know that we will continue to confer with them now as repositories of wisdom in the issues that we have to deal with going forward.

Mr. Speaker, I thank Chairman GOODLATTE, too, for taking the time tonight for all of us to be able to recognize their true servant leadership for the State of Virginia, their sacrifice, and truly the sacrifice of their families. As we all know, there is a sacrifice

of families, too, for Members that serve here in Congress.

Again, we wish SCOTT, RANDY, and ROBERT all the best. We wish them God's blessings in the years ahead. I know that they will continue to lead and to serve in different capacities, but in equally as effective capacities.

Mr. GOODLATTE. Mr. Speaker, I thank the gentleman for sharing his personal experiences, his friendships with these three outstanding Members of Congress.

I turn to the other neighboring Congressman, the Congressman from the Third Congressional District who has served with me for many years on the House Judiciary Committee until he went to become the ranking member on the House Education and the Workforce Committee and has served here as long as I have. He has much knowledge about that part of the world and about these three gentleman. I thank him for taking time this evening.

I yield to Congressman SCOTT.

Mr. SCOTT of Virginia. Mr. Speaker, I thank the gentleman from Virginia for yielding and for organizing tonight's Special Order.

Tonight, we honor three retiring members from the Virginia delegation to Congress: Congressmen RANDY FORBES, ROBERT HURT, and SCOTT RIGELL.

Despite our differences from time to time on national policy, the Virginia delegation has a long history of being able to constructively work together on issues of importance to the citizens of the Commonwealth of Virginia. Former-Senator John Warner, the longtime dean of our delegation, embodied this bipartisan work ethic, and we have already heard it referred to as the Virginia way of doing things.

During their service in Congress, RANDY, ROBERT, and SCOTT have each put their mark on this institution and on national policy.

ROBERT HURT has been a leader on the Financial Services Committee and focused on policies to expand economic opportunity in south side Virginia and communities around the Nation. A strong advocate for community banks and credit unions over his three terms in Congress, ROBERT has also worked to ensure that consumers are financially literate with the necessary information to make the best financial choices for their families. ROBERT has always fought for what he believed to be the best interest of his constituents, and so I wish him and his family well as he returns to his home in Chatham.

I have come to know SCOTT and RANDY very well as our congressional districts are adjacent to one another in the Hampton Roads area of Virginia. Along with our colleague, ROB WITTMAN, we have participated in countless joint appearances and events across Hampton Roads.

In both the private and public sector, SCOTT RIGELL has dedicated his life to serving the Hampton Roads community. In his three terms in Congress, he

has developed a well-deserved reputation as a pragmatic, bipartisan leader as he addresses the Nation's fiscal issues and reforming how Congress operates. We have been working together on many issues, but I especially appreciate his strong support and advocacy of the SAFE Justice Act, a comprehensive criminal justice reform bill that the gentleman from Wisconsin (Mr. SENSENBRENNER) and I introduced last year. I wish SCOTT, his wife Terry, and his children and grandchildren all the best as he transitions back to private life.

RANDY and I have become good friends during his time in Congress as we served together for many years on the House Judiciary Committee. Hampton Roads is the home to many military facilities, both private-sector defense contractors and military facilities, particularly those associated with the Navy. There is no Member of Congress who knows more about our Navy than RANDY FORBES. As chairman of the Seapower and Projection Forces Subcommittee of the Armed Services Committee, he has been an important voice on defense and shipbuilding policy. Hampton Roads has been fortunate to have RANDY fighting for our region's military and shipbuilding interests over the last 50 years. I will also miss working with him on modeling and simulation. He was the founder of the Modeling and Simulation Caucus. He promoted the modeling and simulation technology as a way to increase efficiency and to save the taxpayers money.

I wouldn't count RANDY out just yet. I know he will find ways to continue to serve our men and women in uniform in the months and years ahead, and so I wish him, his wife Shirley, and children and grandchildren well as they start the next chapter of their lives.

Mr. Speaker, I, again, want to thank the gentleman from Virginia (Mr. GOODLATTE) for organizing tonight's Special Order. The departure of Congressmen ROBERT HURT, SCOTT RIGELL, and RANDY FORBES is a loss for the House of Representatives and the Commonwealth of Virginia. Each of these men deserve our sincere gratitude for their service to our Nation and the civility that they have exemplified during their service.

Mr. GOODLATTE. Mr. Speaker, I thank the gentleman for his kind remarks about all three of these fine Representatives.

I yield to the gentlewoman from Indiana (Mrs. WALORSKI), who knows them as well.

Mrs. WALORSKI. Mr. Speaker, I rise today as we honor the exemplary service of three departing Members of this distinguished body. Congressmen RANDY FORBES, ROBERT HURT, and SCOTT RIGELL have served their districts and our Nation with honor and distinction, and they will be sorely missed.

I must take a moment and talk about the privilege I have had of serving

alongside my friend, RANDY FORBES, on the Armed Services Committee and on the Seapower and Projection Forces Subcommittee he chairs.

Over the past few years, as the Obama administration has sought to shrink the size of our Armed Forces and reduce the number of ships in our Navy, it has been RANDY that has led with a strong, passionate advocacy for our servicemembers and a strong, informed defender of our Navy.

Article I of the Constitution states that Congress shall have the power to provide and maintain a Navy. No one has fulfilled that task more honorably or diligently than Congressman RANDY FORBES.

RANDY, your experience and your insights will be missed in Congress and on the Armed Services Committee, but I look forward to see where your commitment to service leads you. Until then, my friend, I wish you fair winds and following seas.

Mr. GOODLATTE. Mr. Speaker, I yield to the gentleman from Iowa (Mr. KING), another valued member of the House Judiciary Committee who has served literally alongside Congressman FORBES.

I think you have sat next to him, if not close to each other, for many years on the committee.

Mr. KING of Iowa. Mr. Speaker, I am very pleased to have the privilege to have been yielded to from Chairman GOODLATTE of Virginia, who I know laments the departure of three very esteemed members of the Virginia delegation and people I have had a privilege to serve with. I certainly tip my hat to, bow to, and salute all three of them: Congressmen RANDY FORBES, SCOTT RIGELL, and ROBERT HURT.

I came here this evening to focus a majority of my remarks on that of Representative RANDY FORBES because, as Chairman GOODLATTE said, I have had the privilege to sit next to RANDY FORBES on the Judiciary Committee—and our memories are never always exactly right—but it could be for the full 14 years that I have been here. We have been either next to each other or within one seat of each other all that period of time.

I have long viewed RANDY FORBES as my wingman on the House Judiciary Committee. He is the anchor. He is a man who we know is a man of faith. He led the Prayer Caucus here for a good number of years. We know that he is a constitutionalist. He served on the Constitution and Civil Justice Subcommittee also with me for many, if not, all of those years. When a man puts that kind of commitment and effort into defending the Constitution and defending innocent unborn human life and defending the values and the anchors of our faith, of our families, of our Constitution and—by the way, on the Crime, Terrorism, Homeland Security, and Investigations Subcommittee—defending the rule of law and bringing about appropriate punishment for people who violate that law, that is the life of RANDY FORBES.

I may be wired a little tighter than RANDY. I would come and sit down on the Judiciary Committee, and I might be all wound up. RANDY was always the calming influence on me. I am sure Chairman GOODLATTE appreciates that; that RANDY would reach over and put his hand on my arm and he said: Now, Steve, here is where we are, here is where we are going.

There would also be times, though, he would turn his ear and he would listen to the arguments that I would make. We had hundreds and hundreds of conversations that helped shaped me as a Member of Congress, and they always were anchored in the right values. These are values you know come from a man who has demonstrated that here in the House of Representatives.

I thought, too, that RANDY was one of the best cross-examiners of a witness that I have seen in this United States Congress, and those among the best do serve on the Judiciary Committee. Those issues seem to come to us, and they refine your skill sets. RANDY would be sitting there. And as the line was coming down toward us on where we sat on seniority, I might want to talk about what is on my mind and chat with him a little bit on the other side.

I always knew that when RANDY had his pen up and he would have his research paper there and he would be taking notes in between that, what he was really doing, Mr. Speaker, was preparing himself to take—most of the times we only had 5 minutes—to take that witness down to the base facts that were necessary. RANDY did that as well as anybody that I have seen. It always was anchored in the rule of law, the Constitution, the faith, freedom, values and, of course, his strong support for the military and strengthening our military.

I wanted to put into the CONGRESSIONAL RECORD tonight, Mr. Speaker, something that impressed me about RANDY. It was after Hurricane Katrina hit New Orleans and RANDY FORBES went down in that area 6 months or a year afterwards. He came back with this data, which I wrote down and typed into my notes because it was something that just really gripped me.

The murder rate in New Orleans post-Katrina had risen to the point that it was 90 out of each 100,000 people who were victims of murder in New Orleans at that time. Only 1 out of 83.33 murders resulted in prison time, and only 1 in 10 murders resulted in an arrest. And of those total murders, only 1 in 8.33 resulted in convictions. So roughly 1 in 8 murders were solved. And that was a rate that is astonishingly high when you compare those numbers—90 of 100,000 murders, the violent death rate or the murder rate for New Orleans—where in the United States broadly it is around 6 per 100,000 as opposed to the 90 per hundred thousand. RANDY brought that kind of information back to me.

He was also a leader in the fight against gang violence and gang crime,

and he brought that case before the Judiciary Committee a number of times for us. Each time RANDY spoke, we did listen and it moved policy in the right directions.

One of the other things, Mr. Speaker, that I cherish is my perspective of this: Jo Ann Davis represented Virginia's First Congressional District at the time and passed away untimely in the year 2007. I went down to her funeral. I had, of course, served with Jo Ann and traveled overseas with her into the war zones. She was also on the Armed Services Committee.

RANDY FORBES gave the eulogy for former Congresswoman Jo Ann Davis. I remember sitting in that church in Virginia, and RANDY stepped up to speak about the life of Jo Ann Davis and, without notes, gave one of the most moving and deepest eulogies I have heard in my life. It would have been impossible for RANDY FORBES to give such a presentation had he not respected, revered, and loved Jo Ann Davis the way that he did and watched her moves. The things that she did in her life reflected upon him in a way that he could honor her life at a time like that that had to give comfort to the family and friends that were in that church that day.

I would express this about RANDY—and I hope he has a long time to serve America—but he has affected my life in a similar way. He has made me a better Congressman, and he has done so with dignity and with class.

The time that RANDY spent in public life, Mr. Speaker, from the time he was elected to the Virginia House of Delegates in 1990 until 1998, and then to the State Senate of Virginia in 1998 until 2001, when he came here midterm in June of 2001 and served in this Congress, and he will serve in this Congress until January 3 of 2017. That is going to add up to somewhere really close to 27 years—26½ years, at least—of service to the Commonwealth of Virginia and the United States of America.

His wife, Shirley, is a class act and anyone that knows her knows that. Their four children—Neil, Jamie, Jordan, and Justin—I hope they know tonight that they hit the jackpot when they were born into the family of RANDY and Shirley Forbes.

I hit the jackpot when I had the privilege to be seated next to RANDY FORBES, and I hope that I can do my best to carry on that kind of legacy that he is leaving with us. He has made us all better. The United States of America is better, the Commonwealth of Virginia is better, and I appreciate the service that Congressman RANDY FORBES has given to our country.

Mr. GOODLATTE. Mr. Speaker, I thank the gentleman from Iowa for that heartfelt appreciation of these three Members.

I yield to the gentleman from the great State of Maine (Mr. POLIQUIN). He represents my alma mater, Bates College. He is just about to start his sec-

ond term in Congress, but he makes friends fast. So I am delighted that he is here to say a few words about these three outstanding individuals as well.

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Mr. POLIQUIN. Mr. Speaker, I thank Chairman GOODLATTE for yielding. We are very proud in our Second District of Maine to house Bates College, which I understand is the chairman's alma mater.

I would like to speak a little bit today, Mr. Speaker, about these three gentlemen from Virginia, from a slightly different perspective, as a freshman Member of Congress and someone who has a business background but not a legislative background.

RANDY FORBES has been a tremendous help to my district by giving me counsel when it comes to Bath Iron Works and the tremendous shipbuilding skills that BIW has, making the best destroyers that keep our country safe and the best shipbuilders in the world. RANDY FORBES' guidance on the Committee on Armed Services to help secure additional funding for BIW is something that I will never forget and something that the 6,000 workers at Bath Iron Works in Bath, Maine, have a debt of gratitude to Mr. FORBES for his help in that regard.

SCOTT RIGELL, as a businessowner here in Virginia in the auto dealership area, has also been incredibly helpful to me in sitting on the Committee on Financial Services, Mr. Speaker, that deals with credit when it comes to the auto dealerships extending that credit to consumers, and SCOTT's guidance in that regard has been very, very helpful.

I do serve on the House Committee on Financial Services with Representative ROBERT HURT, who has become a very good friend and someone whom I have turned to on many occasions to make sure I understand what the legislative process is, Mr. Speaker.

As a business professional, I understand what needs to be done to move our country forward, move our economy forward, and to create more jobs in Maine and throughout the country; but the gears of how Congress works is something that has been new to me, and I want to thank ROBERT HURT very much for the patience he has extended to me to answer questions I have had. He is a very thoughtful man. He is someone who knows this process inside and out, and he has been very helpful to me, along with Mr. FORBES and Mr. RIGELL.

I thank Chairman GOODLATTE for giving me an opportunity to salute these tremendous gentlemen from the Commonwealth of Virginia, for extending their help to me as a freshman, to our State, and to our country. Congratulations to all these wonderful Congressmen.

Mr. GOODLATTE. I thank the gentleman for his kind words and for taking the time to share them with us this evening.

I yield now to the gentleman from the Ninth Congressional District of Virginia (Mr. GRIFFITH), my friend and neighboring Congressman. He served in the Virginia General Assembly with both RANDY FORBES and ROBERT HURT and was elected to Congress the same year that ROBERT HURT was. He knows all three of these individuals well, and I appreciate him taking the time this evening to participate as well.

Mr. GRIFFITH. Mr. Speaker, I thank Congressman GOODLATTE for yielding. It is my honor and privilege to be here to recognize these three Virginians who have served their Commonwealth so well.

SCOTT RIGELL and I were elected along with ROBERT HURT back in the same year, back in 2010. I got to know SCOTT when I got here. He is the one of the three who are retiring whom I did not know prior to coming to service in Congress. I learned that he was a hard worker, a dedicated public servant, someone who truly believed in trying to do everything the right way. Like myself every now and then, he was a little bit of a maverick and would cut his own way, but that is important in Congress, that we don't all walk in lockstep, that we work together but that we respect each other's opinions. SCOTT RIGELL is a gentleman who certainly does that, and as a Representative, he has done that very well.

I go next to RANDY. With the exception of, I think, probably Congressman SCOTT has known RANDY longer, having served a couple years in the State legislature before he came to Congress with RANDY, I think I have served longer with RANDY because I served with him first in the house of delegates, where he was a role model, one of the leaders on the floor in the Virginia House.

He then moved on to the Senate just before Republicans took control of the House for the first time in 120-some years. He was a feisty floor debater, one who was always prepared, and somebody that I looked up to and used as a role model in trying to figure out how I was going to behave on the floor and act as a gentleman and yet be determined and fierce in defending my positions. RANDY FORBES always did that in the Virginia House. He then went on to the Virginia Senate, where he, likewise, defended his positions and was known as a leader.

Then he came to Congress, where he kept saying to me: You would love it. There are so many policy issues that you would get into.

He enjoyed his time here very much, and not because he felt that it was just something that he enjoyed doing, but because he could take his talents and serve the people of the Commonwealth of Virginia with those talents and serve his Nation, the United States of America, with those talents as well.

I suspect that we will see RANDY doing other public service in the not-too-distant future, but I am so very glad that I had the opportunity tonight

to talk about his service to the Commonwealth of Virginia and to the United States.

Last but certainly not least, my friend ROBERT HURT. ROBERT came after me into the Virginia House of Delegates. He, too, made the error of moving over to the senate. I think Congressman SCOTT made that error, too. But ROBERT HURT and I got to be friends in the house of delegates. He was a newer member. He had to make some tough decisions early on. We didn't always agree, but I told him to stick to his viewpoint and that he would be fine.

He is just a fantastic individual, a good friend. I am sorry that he decided to retire. I welcome his successor, but I am sorry that he decided to retire because I really enjoyed bouncing ideas off of him and sitting in the back row and talking about everything from birds that we might have seen alive or dead somewhere along the highway or keeping notes on some of the flora and fauna of our part of Virginia. Our districts abutted. Where Congressman GOODLATTE and I share the Roanoke Valley, Congressman HURT and I shared Henry County and that area as well, and it was truly an honor to serve with him.

I didn't get to serve with any of the gentlemen on a committee. We have heard a lot of great testimony about what great committee members they were. I did not have that opportunity, but I did get to serve with them in the House for two of them and here on this floor for 6 years. It was an honor and a privilege to work with them and to learn from them and to watch as they behaved as gentlemen ought to do in a society and in a place where we may disagree, but we can be agreeable while we disagree on issues.

Mr. GOODLATTE. I thank the gentleman for his kind remarks as well. Does the gentleman have any further remarks? I want to thank all of the Members who took time this evening to honor these three colleagues. I know that there are many more who wish them well.

The RECORD is open, and I know some additional Members will put remarks into the RECORD, but I just want to close by saying that I was proud to serve with all three of them. They are strong advocates for their constituents. They have a strong love for their country, and they are fighters for limited government and individual responsibility and the free enterprise system. They believe very strongly in lower taxes and less government regulation.

They work hard for their families in passing legislation that strengthens American families and, most especially, they are all strong believers in a strong national defense and have worked hard for their Nation in this body. They deserve all of the accolades they have received this evening and many, many more. I wish them God-speed and great futures with their families and their future endeavors.

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

Mr. HULTGREN. Mr. Speaker, I rise today to recognize three friends and colleagues from Virginia who have served the House of Representatives and the American people faithfully and with whom I have enjoyed working during our time together in the House.

Congressmen SCOTT RIGELL, RANDY FORBES and ROBERT HURT will be greatly missed, and I personally will miss them as they leave office at the end of this 114th Congress.

I have valued SCOTT RIGELL's strong faith and commitment to regular Bible study ever since we entered Congress together in 2011.

He regularly seeks God's wisdom as he serves his constituents. I have appreciated the way in which he models his faith and convictions as a servant of the people.

RANDY FORBES has also demonstrated that true wisdom comes from the Source of all wisdom.

His founding of the Congressional Prayer Caucus as a body to encourage Members of Congress as they seek the Lord in all things has been meaningful to me personally and an inspiration to many of our like-minded colleagues.

ROBERT HURT and I have worked together on the Financial Services Committee, and I have appreciated his role defending our community banks as Vice-Chair of the Capital Markets Subcommittee.

I've had the great opportunity to work with him on the Investment Advisers Modernization Act and his contribution has made it easier for private equity to invest in our economy and grow jobs.

As they return to private life, each one of these men should be proud of the service they have rendered to their constituents and their country and the mark they have left on this institution and on those, like myself, who have had the privilege to serve alongside them.

SENATE BILLS REFERRED

Bills of the Senate of the following titles were taken from the Speaker's table and, under the rule, referred as follows:

S. 2944. An act to require adequate reporting on the Public Safety Officers' Benefits program, and for other purposes; to the Committee on the Judiciary.

S. 3438. An act to authorize the Secretary of Veterans Affairs to carry out a major medical facility project in Reno, Nevada; to the Committee on Veterans' Affairs.

ENROLLED BILL SIGNED

Karen L. Haas, Clerk of the House, reported and found truly enrolled a bill of the House of the following title, which was thereupon signed by the Speaker:

H.R. 4665. An act to require the Secretary of Commerce to conduct an assessment and analysis of the outdoor recreation economy of the United States, and for other purposes.

ADJOURNMENT

Mr. GOODLATTE. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 8 o'clock and 10 minutes

p.m.), under its previous order, the House adjourned until tomorrow, Thursday, December 1, 2016, at 10 a.m. for morning-hour debate.

EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XIV, executive communications were taken from the Speaker's table and referred as follows:

7660. A letter from the Chief Counsel, Federal Emergency Management Agency, Department of Homeland Security, transmitting the Department's final rule — Suspension of Community Eligibility, Ulster County, NY, et al. [Docket ID: FEMA-2016-0002; Internal Agency Docket No.: FEMA-8453] received November 21, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Financial Services.

7661. A letter from the Regulations Coordinator, Centers for Medicare and Medicaid Services, Department of Health and Human Services, transmitting the Department's Major final rule — Medicaid and Children's Health Insurance Programs: Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP [CMS-2334-F2] (RIN: 0938-AS27) received November 28, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7662. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Spodoptera frugiperda Multiple Nucleopolyhedrovirus strain 3AP2; Exemption from the Requirement of a Tolerance [EPA-HQ-OPP-2015-0488; FRL-9953-40] received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7663. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Greenhouse Gas Reporting Rule: Leak Detection Methodology Revisions and Confidentiality Determinations for Petroleum and Natural Gas Systems [EPA-HQ-OAR-2015-0764; FRL-9955-12-OAR] (RIN: 2060-AS73) received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7664. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's Major final rule — Formaldehyde Emission Standards for Composite Wood Products [EPA-HQ-OPP-2016-0461; FRL-9949-90] (RIN: 2070-AJ44) received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7665. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Findings of Failure to Attain the 1997 PM_{2.5} Standards; California; San Joaquin Valley [EPA-R09-OAR-2016-0494; FRL-9955-53-Region 9] received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7666. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Endothall; Pesticide Tolerances [EPA-HQ-OPP-2014-0613; FRL-9953-97] received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec.

251; (110 Stat. 868); to the Committee on Energy and Commerce.

7667. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Designation of Areas for Air Quality Planning Purposes; Ohio; Redesignation of the Ohio Portion of the Campbell-Clermont KY-OH Sulfur Dioxide Nonattainment Area [EPA-R05-OAR-2015-0599; FRL-9955-37-Region 5] received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7668. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Clarification of Requirements for Method 303 Certification Training [EPA-HQ-OAR-2014-0492; FRL-9955-50-OAR] (RIN: 2060-AR97) received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7669. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Air Plan Approval; FL Infrastructure Requirements for the 2010 1-hour NO₂ NAAQS [EPA-R04-OAR-2014-0507; FRL-9955-49-Region 4] received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7670. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Air Plan Approval/Disapproval; AL Infrastructure Requirements for the 2010 1-hour NO₂ NAAQS [EPA-R04-OAR-2014-0756; FRL-9955-29-Region 4] received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7671. A letter from the Director, Regulatory Management Division, Environmental Protection Agency, transmitting the Agency's final rule — Addition of Hexabromocyclododecane (HBCD) Category; Community Right-to-Know Toxic Chemical Release Reporting [EPA-HQ-TRI-2015-0607; FRL-9953-28] (RIN: 2025-AA42) received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7672. A letter from the Deputy Director, Regulations Policy and Management Staff, FDA, Department of Health and Human Services, transmitting the Department's final rule — Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets [Docket No.: FDA-2011-N-0697] (RIN: 0910-AG26) received November 23, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Energy and Commerce.

7673. A letter from the Secretary, Department of the Treasury, transmitting a six-month periodic report on the national emergency with respect to the stabilization of Iraq that was declared in Executive Order 13303 of May 22, 2003, pursuant to 50 U.S.C. 1641(c); Public Law 94-412, Sec. 401(c); (90 Stat. 1257) and 50 U.S.C. 1703(c); Public Law 95-223, Sec. 204(c); (91 Stat. 1627); to the Committee on Foreign Affairs.

7674. A letter from the Secretary, Department of the Treasury, transmitting a final report on the national emergency with respect to Burma that was declared in Executive Order 13047 of May 20, 1997, pursuant to 50 U.S.C. 1641(c); Public Law 94-412, Sec. 401(c); (90 Stat. 1257) and 50 U.S.C. 1703(c); Public Law 95-223, Sec. 204(c); (91 Stat. 1627); to the Committee on Foreign Affairs.

7675. A letter from the Secretary, Department of the Treasury, transmitting a six-month periodic report on the national emergency with respect to Yemen that was declared in Executive Order 13611 of May 16, 2012, pursuant to 50 U.S.C. 1641(c); Public Law 94-412, Sec. 401(c); (90 Stat. 1257) and 50 U.S.C. 1703(c); Public Law 95-223, Sec. 204(c); (91 Stat. 1627); to the Committee on Foreign Affairs.

7676. A letter from the Assistant Legal Adviser, Office of Treaty Affairs, Department of State, transmitting a report concerning international agreements other than treaties entered into by the United States to be transmitted to the Congress within the sixty-day period specified in the Case-Zablocki Act, pursuant to 1 U.S.C. 112b(a); Public Law 92-403, Sec. 1(a) (as amended by Public Law 108-458, Sec. 7121(b)); (118 Stat. 3807); to the Committee on Foreign Affairs.

7677. A letter from the Assistant Secretary for Export Administration, Bureau of Industry and Security, Department of Commerce, transmitting the Department's final rule — Clarifications and Revisions to Military Aircraft, Gas Turbine Engines and Related Items License Requirements [Docket No.: 151030999-6552-02] (RIN: 0694-AG76) received November 28, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Foreign Affairs.

7678. A letter from the Assistant Secretary, Legislative Affairs, Department of State, transmitting the Department's final rule — Amendment to the International Traffic in Arms Regulations: Corrections and Clarifications [Public Notice: 9757] (RIN: 1400-AE05) received November 22, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Foreign Affairs.

7679. A letter from the Supervisory Management and Program Analyst, M/MPBP/POL, Office of Acquisition and Assistance, U.S. Agency for International Development, transmitting the Agency's final rule — Requirement for Nondiscrimination against End-Users of Supplies or Services ("Beneficiaries") under USAID-Funded Contracts (RIN: 0412-AA81) received November 28, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Foreign Affairs.

7680. A letter from the Senior Procurement Executive, Office of Acquisition Policy, General Services Administration, transmitting the Administration's summary presentation of final rules — Federal Acquisition Regulation; Federal Acquisition Circular 2005-92; Introduction [Docket No.: FAR 2016-0051, Sequence No.: 6] received November 21, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Oversight and Government Reform.

7681. A letter from the Senior Procurement Executive, Office of Acquisition Policy, General Services Administration, transmitting the Administration's final rule — Federal Acquisition Regulation: Removal of Regulations Relating to Telegraphic Communication [FAC 2005-92; FAR Case 2015-035; Item II; Docket No.: 2015-0035, Sequence No.: 1] (RIN: 9000-AN23) received November 21, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Oversight and Government Reform.

7682. A letter from the Senior Procurement Executive, Office of Acquisition Policy, General Services Administration, transmitting the Administration's final rule — Federal Acquisition Regulation; Federal Acquisition Circular 2005-92, Technical Amendments [FAC 2005-92; Item III; Docket No.: 2016-0052; Sequence No.: 5] received November 21, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law

104-121, Sec. 251; (110 Stat. 868); to the Committee on Oversight and Government Reform.

7683. A letter from the Senior Procurement Executive, Office of Acquisition Policy, General Services Administration, transmitting the Administration's final rule — Federal Acquisition Regulation; Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation [FAC 2005-92; FAR Case 2015-024; Item I; Docket No.: 2015-0024, Sequence No.: 1] (RIN: 9000-AM90) received November 21, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Oversight and Government Reform.

7684. A letter from the Administrator, U.S. Agency for International Development, transmitting the Agency's Semiannual Report of the Office of the Inspector General for the period ending September 30, 2016, pursuant to Sec. 5 of the Inspector General Act of 1978, as amended; to the Committee on Oversight and Government Reform.

7685. A letter from the Director, Office of Sustainable Fisheries, NMFS, National Oceanic and Atmospheric Administration, transmitting the Administration's temporary rule — Fisheries of the Northeastern United States; Atlantic Bluefish Fishery; Quota Transfer [Docket No.: 151130999-6225-01] (RIN: 0648-XE868) received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Natural Resources.

7686. A letter from the Acting Director, Office of Sustainable Fisheries, NMFS, National Oceanic and Atmospheric Administration, transmitting the Administration's temporary rule — Snapper-Grouper Fishery of the South Atlantic; 2016 Recreational Accountability Measure and Closure for the South Atlantic Other Jacks Complex [Docket No.: 120815345-3525-02] (RIN: 0648-XE774) received November 18, 2016, pursuant to 5 U.S.C. 801(a)(1)(A); Public Law 104-121, Sec. 251; (110 Stat. 868); to the Committee on Natural Resources.

7687. A letter from the Secretary, Department of Transportation, transmitting the Department's report titled "Transportation Infrastructure Finance and Innovation Act 2016 Report to Congress", pursuant to 23 U.S.C. 609(a); Public Law 105-178, Sec. 1503(a) (amended by Public Law 114-94, Sec. 2001(h)); (129 Stat. 1444); to the Committee on Transportation and Infrastructure.

7688. A letter from the Assistant Secretary for Legislation, Department of Health and Human Services, transmitting the Department's report entitled "Recovery Auditing in Medicare Fee-For-Service for Fiscal Year 2015", pursuant to 42 U.S.C. 1395ddd(h)(8); Aug. 14, 1935, ch. 531, title XVIII, Sec. 1893(h)(8) (as amended by Public Law 109-432, Sec. 302(a)); (120 Stat. 2992); ; jointly to the Committees on Energy and Commerce and Ways and Means.

REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. THORNBERRY: Committee on Conference. Conference report of S. 2943. An act to authorize appropriations for fiscal year 2017 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes (Rept. 114-840). Ordered to be printed.

Mr. CHAFFETZ: Committee on Oversight and Government Reform. H.R. 5384. A bill to amend title 44, United States Code, to restrict the distribution of free printed copies of the Federal Register to Members of Congress and other officers and employees of the United States, and for other purposes (Rept. 114-841, Pt. 1). Referred to the Committee of the Whole House on the state of the Union.

Mr. CHAFFETZ: Committee on Oversight and Government Reform. H.R. 6186. A bill to amend title 5, United States Code, to extend certain protections against prohibited personnel practices, and for other purposes (Rept. 114-842). Referred to the Committee of the Whole House on the State of the Union.

Mr. CHAFFETZ: Committee on Oversight and Government Reform. H.R. 6303. A bill to designate facilities of the United States Postal Service, to establish new ZIP Codes, and for other purposes (Rept. 114-843). Referred to the House Calendar.

Mr. BYRNE: Committee on Rules. House Resolution 937. Resolution providing for consideration of the conference report to accompany the bill (S. 2943) to authorize appropriations for fiscal year 2017 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes (Rept. 114-844). Referred to the House Calendar.

DISCHARGE OF COMMITTEE

Pursuant to clause 2 of rule XIII, the Committee on House Administration discharged from further consideration. H.R. 5384 referred to the Committee of the Whole House on the state of the Union, and ordered to be printed.

PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XII, public bills and resolutions of the following titles were introduced and severally referred, as follows:

By Mr. JENKINS of West Virginia:

H.R. 6403. A bill to amend the Internal Revenue Code of 1986 to provide additional new markets tax credits for distressed coal communities; to the Committee on Ways and Means.

By Mr. BOUSTANY (for himself and Mr. DOGGETT):

H.R. 6404. A bill to permit occupational therapists to conduct the initial assessment visit under a Medicare home health plan of care for certain rehabilitation cases; to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. GRAYSON:

H.R. 6405. A bill to amend the Internal Revenue Code of 1986 to extend for one year the exclusion from gross income of discharge of qualified principal residence indebtedness; to the Committee on Ways and Means.

By Mr. GRAYSON:

H.R. 6406. A bill to amend the Internal Revenue Code of 1986 to extend for two years the exclusion from gross income of discharge of qualified principal residence indebtedness; to the Committee on Ways and Means.

By Mr. KILMER (for himself and Mr. NEWHOUSE):

H.R. 6407. A bill to direct the Secretary of Veterans Affairs to submit to the Committees on Veterans' Affairs of the Senate and the House of Representatives a report regarding the organizational structure of the Department of Veterans Affairs, and for

other purposes; to the Committee on Veterans' Affairs.

By Mr. LANGEVIN:

H.R. 6408. A bill to amend the Internal Revenue Code of 1986 to expand the new energy efficient home credit, and for other purposes; to the Committee on Ways and Means.

By Mr. MEADOWS:

H.R. 6409. A bill to protect freedom of speech in America's electoral process and ensure transparency in campaign finance; to the Committee on House Administration.

By Mr. PALLONE:

H.R. 6410. A bill to prohibit the commercial harvesting of Atlantic striped bass in the coastal waters and the exclusive economic zone; to the Committee on Natural Resources.

By Mr. PALLONE:

H.R. 6411. A bill to amend the Federal Water Pollution Control Act to clarify that fill material cannot be comprised of waste; to the Committee on Transportation and Infrastructure.

By Mr. PALLONE:

H.R. 6412. A bill to amend the Oil Pollution Act of 1990 to require oil polluters to pay the full cost of oil spills, and for other purposes; to the Committee on Transportation and Infrastructure.

By Mr. PALLONE:

H.R. 6413. A bill to amend the Internal Revenue Code of 1986 to require oil polluters to pay the full cost of oil spills, and for other purposes; to the Committee on Transportation and Infrastructure, and in addition to the Committees on the Budget, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. TONKO (for himself, Mr. MCKINLEY, and Mr. KILMER):

H.R. 6414. A bill to encourage and increase the use of crowdsourcing and citizen science methods within the Federal Government to advance and accelerate scientific research, literacy, and diplomacy, and for other purposes; to the Committee on Oversight and Government Reform.

By Mr. LANCE:

H. Con. Res. 174. Concurrent resolution directing the Clerk of the House of Representatives to make a correction in the enrollment of H.R. 34; considered and agreed to. Considered and agreed to.

By Mr. LIPINSKI (for himself and Mr. BROOKS of Alabama):

H. Con. Res. 175. Concurrent resolution expressing the sense of Congress that Congress and the President should prioritize the reduction and elimination, over a reasonable period of time, of the overall trade deficit of the United States; to the Committee on Ways and Means.

By Mr. SALMON (for himself, Mr. HECK of Nevada, Ms. DUCKWORTH, Ms. JUDY CHU of California, Mr. ROHRBACHER, Mr. CLEAVER, Ms. GABBARD, Mr. CARTER of Georgia, Mr. BARTON, Mr. MARINO, Ms. BORDALLO, Mr. HONDA, Mr. BISHOP of Michigan, and Mr. PETERS):

H. Con. Res. 176. Concurrent resolution honoring in praise and remembrance the extraordinary life, steady leadership, and remarkable, 70-year reign of King Bhumibol Adulyadej of Thailand; to the Committee on Foreign Affairs.

By Mr. TONKO (for himself and Mr. MCKINLEY):

H. Res. 938. A resolution recognizing the Weatherization Assistance Program during its 40th anniversary year for its history of reducing the energy costs of families with low incomes, making low-income households healthier and safer, positively impacting the

environment, and supporting jobs and new technology; to the Committee on Energy and Commerce.

By Mr. WELCH:

H. Res. 939. A resolution expressing the sense of the House of Representatives that access to digital communications tools and connectivity is necessary to prepare youth in the United States to compete in the 21st century economy; to the Committee on Energy and Commerce.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 7 of rule XII of the Rules of the House of Representatives, the following statements are submitted regarding the specific powers granted to Congress in the Constitution to enact the accompanying bill or joint resolution.

By Mr. JENKINS of West Virginia:

H.R. 6403.

Congress has the power to enact this legislation pursuant to the following:

Article 1 Section 8 of the United States Constitution.

By Mr. BOUSTANY:

H.R. 6404.

Congress has the power to enact this legislation pursuant to the following:

Clause 1 of Section 8 of Article I of the United States Constitution.

By Mr. GRAYSON:

H.R. 6405.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, of the United States Constitution.

By Mr. GRAYSON:

H.R. 6406.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8, of the United States Constitution.

By Mr. KILMER:

H.R. 6407.

Congress has the power to enact this legislation pursuant to the following:

Article 1, Section 8 of the United States Constitution.

By Mr. LANGEVIN:

H.R. 6408.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 1

By Mr. MEADOWS:

H.R. 6409.

Congress has the power to enact this legislation pursuant to the following:

According to Article 1, Section 4, Clause I "The Times and Manner of holding Elections for Senators and Representatives, shall be prescribed in each State by the Legislature thereof; but the Congress may at any time by Law make or alter such Regulations, except as to the Places of chusing Senators."

By Mr. PALLONE:

H.R. 6410.

Congress has the power to enact this legislation pursuant to the following:

Clause 7 of Section 9 of Article I of the Constitution

By Mr. PALLONE:

H.R. 6411.

Congress has the power to enact this legislation pursuant to the following:

Clause 7 of Section 9 of Article I of the Constitution

By Mr. PALLONE:

H.R. 6412.

Congress has the power to enact this legislation pursuant to the following:

Clause 3 of Section 8 of Article I of the Constitution

By Mr. PALLONE:

H.R. 6413.

Congress has the power to enact this legislation pursuant to the following:

Clause 1 of Section 8 of Article I of the Constitution

By Mr. TONKO:

H.R. 6414.

Congress has the power to enact this legislation pursuant to the following:

Article I, Section 8, Clause 1

The Congress shall have Power to lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts, and Excises shall be uniform throughout the United States.

ADDITIONAL SPONSORS

Under clause 7 of rule XII, sponsors were added to public bills and resolutions, as follows:

H.R. 188: Ms. KELLY of Illinois, Mr. RANGEL, and Ms. LOFGREN.

H.R. 213: Mr. QUIGLEY, Mr. FOSTER, Mr. WELCH, and Mr. SESSIONS.

H.R. 2274: Mr. LOEBBACH.

H.R. 2573: Mr. LOBIONDO.

H.R. 2920: Mrs. DAVIS of California, Ms. LEE and Mr. GUTIÉRREZ.

H.R. 3119: Ms. NORTON, Ms. WILSON of Florida, Mr. QUIGLEY, Mr. SEAN PATRICK MALONEY of New York, Ms. LEE, Mr. MCDERMOTT, Mr. HIMES, Mr. SMITH of Washington, and Mr. HECK of Washington.

H.R. 3166: Mr. POLIS.

H.R. 3314: Mr. JORDAN.

H.R. 3535: Ms. ROS-LEHTINEN.

H.R. 3770: Ms. NORTON.

H.R. 3799: Mr. JENKINS of West Virginia.

H.R. 4298: Mr. ROGERS of Alabama, Ms. KUSTER, Ms. MOORE, Mr. PASCRELL, and Mr. BROOKS of Alabama.

H.R. 4380: Ms. LOFGREN.

H.R. 4621: Mr. COHEN.

H.R. 4818: Mr. MOONEY of West Virginia.

H.R. 4907: Ms. SCHAKOWSKY and Mr. GOHMERT.

H.R. 4919: Mrs. HARTZLER.

H.R. 4938: Ms. FUDGE and Ms. ADAMS.

H.R. 5167: Mr. MULLIN.

H.R. 5373: Ms. DELAURO.

H.R. 5488: Mr. QUIGLEY, Mr. LOWENTHAL, and Mr. GUTIÉRREZ.

H.R. 5500: Ms. DELBENE.

H.R. 5650: Mr. CUMMINGS.

H.R. 5899: Mr. DESAULNIER.

H.R. 5902: Mr. CICILLINE.

H.R. 5951: Mr. BYRNE.

H.R. 5965: Mr. GUTIÉRREZ.

H.R. 5980: Mr. QUIGLEY.

H.R. 5999: Mr. LOUDERMILK, Mr. BABIN, and Mr. WITTMAN.

H.R. 6037: Mr. WALZ, Mr. YOUNG of Alaska, Ms. MICHELLE LUJAN GRISHAM of New Mexico, Mrs. BEATTY, Mr. BLUMENAUER, and Mr. CICILLINE.

H.R. 6166: Mr. BUCSHON and Mr. CARSON of Indiana.

H.R. 6176: Mr. RATCLIFFE.

H.R. 6226: Mr. CONAWAY and Mr. KEATING.

H.R. 6234: Mr. THOMPSON of California.

H.R. 6287: Mr. BROOKS of Alabama.

H.R. 6292: Mr. SENSENBRENNER.

H.R. 6329: Mr. VARGAS, Mr. CONYERS, and Ms. LOFGREN.

H.R. 6339: Mr. STEWART.

H.R. 6340: Mr. ENGEL, Mr. KENNEDY, Ms. TSONGAS, Mr. RUIZ, Mr. POCAN, Ms. Hanabusa, Ms. ROYBAL-ALLARD, Mr. CARSON of Indiana, Ms. DELAURO, Mr. Ribble, and Ms. TITUS.

H.R. 6346: Ms. MENG.

H.R. 6382: Mr. SCHIFF, Mr. CAPUANO, Mr. MEEKS, Mr. RUIZ, Mr. POCAN, Mr. CONNOLLY, and Mr. MCDERMOTT.

H.J. Res. 9: Mr. ROGERS of Alabama.

H.J. Res. 103: Mr. COHEN.

H. Con. Res. 33: Mr. GOHMERT.

H. Con. Res. 159: Mr. TIPTON, Ms. JACKSON LEE, and Mr. COHEN.

H. Res. 540: Mr. HIGGINS, Mr. GARAMENDI, and Ms. PINGREE.

H. Res. 750: Mr. GENE GREEN of Texas.

H. Res. 861: Mr. QUIGLEY and Ms. KUSTER.

H. Res. 931: Ms. LEE.