Hearing on the Department of Health and Human Services' Fiscal Year 2018 Budget Request

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HEARING

BEFORE THE

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES

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Hearing on the Department of Health and Human Services' Fiscal Year 2018 Budget Request

U.S. House of Representatives,
Committee on Ways and Means,
Washington, D.C.

WITNESSES

Honorable Thomas E. Price, M.D.
Secretary, U.S. Department of Health and Human Services
Witness Statement

WAYS AND MEANS
CHAIRMAN KEVIN BRADY

Chairman Brady Announces Hearing on the Department of Health and Human Services' Fiscal Year 2018 Budget Request

House Committee on Ways and Means Chairman Kevin Brady (R-TX) announced today that the Committee will hold a hearing on the Department of Health and Human Services' Fiscal Year 2018 Budget Request. **The hearing will take place on Thursday, June 8, 2017 in 1100 Longworth House Office Building, beginning at 1:00 PM.**

Oral testimony at this hearing will be from the invited witness only. The sole witness will be the Honorable Thomas E. Price, M.D., Secretary, U.S. Department of the Health and Human Services. However, any individual or organization may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit written comments for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, http://waysandmeans.house.gov, select "Hearings." Select the hearing for which you would like to make a submission, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Thursday, June 22, 2017**. For questions, or if you encounter technical problems, please call (202) 225-3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission not in compliance with these guidelines will not be

printed, but will be maintained in the Committee files for review and use by the Committee.

All submissions and supplementary materials must be submitted in a single document via email, provided in Word format and must not exceed a total of 10 pages. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. The name, company, address, telephone, and fax numbers of each witness must be included in the body of the email. Please exclude any personal identifiable information in the attached submission.

Failure to follow the formatting requirements may result in the exclusion of a submission. All submissions for the record are final.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available at http://www.waysandmeans.house.gov/

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES' FISCAL YEAR 2018 BUDGET REQUEST

Thursday, June 8, 2017

House of Representatives,

Committee on Ways and Means,

Washington, D.C.

The committee met, pursuant to notice, at 1:06 p.m. in Room 1100 Longworth House Office Building, Hon. Kevin Brady [Chairman of the Committee] presiding.

*Chairman Brady. The committee will come to order. Good afternoon and welcome to today's hearing. Today our committee is honored to welcome our good friend and former colleague, Dr. Tom Price, to testify on President Trump's fiscal year 2018 budget proposal for the Department of Health and Human Services.

Mr. Secretary, thank you for being here, and a warm welcome back. Thank you. We look forward to your testimony. As a former member of this Committee for over six years, you have been closely involved with our efforts to improve the health care and welfare programs under our jurisdiction. Your work and leadership on this Committee helped set the stage for many of the crucial reforms we are pursuing today.

Already this year, we are moving forward with solutions to repeal Obamacare, which continues to hurt millions of Americans, and enact step-by-step reforms to return patient-centered health care to the American people. We are taking action on welfare reforms that will help more Americans move out of poverty and up the economic ladder. In building off the historic Medicare payment reforms enacted last Congress, we are working to improve choice, affordability, and quality in Medicare for current and future beneficiaries.

We are pleased to see many of these priorities reflected in President Trump's fiscal year 2018 budget proposals for the Department of Health and Human Services.

For example, the President's budget makes important strides to reduce inefficient and wasteful spending, reflects our efforts to repeal and replace Obamacare. It removes burdensome regulations harming the doctor-patient relationship. And the budget expects all those who can work to work, which is the surest way to economic independence, while prioritizing federal resources to provide real help to those most in need.

Although more must be done to preserve and strengthen Medicare for the long term, the President's budget reflects a meaningful step toward improving America's health care system. Today we are eager to explore ways we can work with President Trump and with Secretary Price to advance solutions that will improve the lives of all Americans.

When it comes to health care we know that true patient-centered reform is urgently needed. Obamacare is imploding as we speak. Premiums and out-of-pocket costs are skyrocketing. Choices are disappearing rapidly. And with the House passage of the American Health Care Act, we have taken a critical first step in our multi-phase effort to repeal and replace Obamacare.

But we all know there is more work to be done. To carefully uproot the law and restore patient-centered care, it will take sustained, coordinated effort from Congress, the White House, and the HHS.

I want to make this key point: in the immediate term, action must be taken to stabilize the individual insurance market and protect Americans from the consequences of Obamacare's collapse. We must work together to provide the certainty and appropriate resources to protect low-income Americans who have been forced to rely on Obamacare's deteriorating exchanges. Obamacare forced millions of Americans into a poorly-designed, government-run marketplace, and now plans are disappearing in Texas and throughout the country, leaving many low-income families with few, if any, places to turn for coverage.

Obamacare's design flaws were not the fault of the American people. People now trapped in Obamacare did what the government mandated them to do. They complied with the law. They should not be left out to dry.

And I think a particularly timely point today, as the Senate considers the AHCA, we must work together to deliver an expedited solution to help stabilize the insurance market and help lower premiums for Americans trapped in Obamacare today. We should act within our constitutional authority now to temporarily and legally fund cost-sharing reduction payments as we move away

from Obamacare and toward a patient-centered system that truly works for the American people.

Insurers have made clear the lack of certainty is causing 2018 proposed premiums to rise significantly. And when these payments are funded by Congress, families trapped in Obamacare should expect these proposed premiums to be reduced significantly.

When it comes to our Nation's welfare system, it is clear that our anti-poverty programs aren't delivering positive results for the American people. We have not seen major progress in moving families forward, despite spending hundreds of billions of dollars every year. We can and must do better, and it all starts with a simple and powerful principle: the best anti-poverty program is a job.

We have to emphasize work in exchange for welfare benefits. We must focus on positive outcomes. And we have to ensure that taxpayer funds are directed to evidence-based programs that truly deliver results for Americans in need. The current challenges we face in health care and welfare cannot be solved with the top-down Washington-knows-best approach. That model has failed the American people time and time again over the past eight years.

It is time to go a new direction, one where workers, families, job creators, and states are in the driver's seat. And, more important, it is time to get our economy moving again.

Mr. Secretary, we are committed to working with you, with President Trump, and with the Trump Administration to accomplish these crucial goals. And with today's conversation, we can continue moving forward together on solutions to improve the lives of all Americans.

*Chairman Brady. Again, Mr. Secretary, we are grateful for your time. We look forward to your testimony.

I will now yield to the distinguished ranking member, Mr. Neal, for the purposes of an opening statement.

*Mr. Neal. Thank you, Mr. Chairman.

Mr. Secretary, I am delighted you are here. This is a homecoming for you, and we are happy to have you with us this afternoon.

I understand how valuable the Secretary's time is, Mr. Chairman, so I hope that you are going to give members the latitude to talk about pertinent matters because of the fact that our questioning will be diminished to three minutes per question. So I understand that -- the Secretary's time, but I hope that that will allow our members on this side who would like to probe some of the positions that the Administration has offered sufficient opportunity to get that accomplished.

I want the American people to understand this afternoon the impact of the HHS budget before us today. It cuts so many programs on which middle-class families rely that I could go on well over a lot of time if I described all of them. It goes against every promise that President Trump made during the campaign, and would cut programs that help middle-class families, both young and old, across the United States.

For example, cuts to Medicaid would put at great health risk children, long-term care for seniors, and individuals who rely on mental health and opiate addiction programs. Medicaid is now the largest source of funding in the United States for substance abuse treatment, and I am sure everyone in this room knows somebody who is facing an addiction crisis.

The New York Times recently reported that, based on preliminary data they compiled, the drug overdose deaths in the United States will likely exceed 59,000 that occurred in 2016, the largest annual jump in our Nation's history. It is estimated that 19 percent -- that number will rise by since 2015, and likely to get even worse this year and next.

In addition to hard-working families, the cuts would harm hospitals, because they would take on significant uncompensated care, but with lower reimbursement rates. This is a recipe for health and economic disaster, not just for Medicaid, but for all Americans. Not only would patients receive lower-quality care, but cuts would create a devastating economic ripple affecting communities, and likely lead to significant job losses. We are all reminded today that, for most communities across the country, including mine, that our hospitals are now the largest employers.

The reality is that Medicaid is now a middle-class benefit. As more Americans celebrate living longer, new challenges have appeared: dementia and the general need for long-term care. We need to ensure that these programs are secure in the future to keep up with the strides that we are making to extend life expectancy.

Thanks to Medicaid, in Massachusetts, almost 100 percent of the children and 97 percent of adults have health insurance. It is clearly popular amongst the citizenry of the state. I remind my colleagues on the other side that Americans may not remember who brought them higher quality, lower-cost health care, but they certainly will remember who took it away.

Proposals to convert Medicaid to a block grant or per capita cap would shift costs to the states. I come from local government. You know exactly where those funds would end up: to balance the budget of something that is not even remotely related to health care.

Proposed Medicare cuts are staggering: $33.5 billion at a time when millions of Baby Boomers are beginning to rely on this critical program. We have a bipartisan responsibility to govern on behalf of the middle class and grow our economy, especially to avoid any self-inflicted damages. America's seniors earned their Medicare benefits, and I hope the Secretary will commit to working with Congress to make sure that Medicare and all of our obligations are paid on time and in full.

Mr. Secretary, because you are a trustee of both Medicare and Social Security, I know you want to make sure, in this budget, that we would not cut Social Security by the proposed $64 billion that has been offered over 10 years. And what is worse, these cuts are targeted toward people with severe disabilities. Medicare, Medicaid, and Social Security are now all linked. Because of these programs, your parents aren't living in your attic.

Other critical programs in our jurisdiction that face cuts include the Social Services Block Grant, and temporary assistance for needy families. The programs provide services that directly benefit vulnerable children, seniors, and disabled Americans.

Let me conclude by addressing a recent decision by health insurance companies to leave the market. As HHS Secretary, the health care world looks to you for leadership. And to date, the new Administration has not provided that unwavering leadership for the health care system that we have witnessed, in terms of the destabilized health insurance market.

I am referring to cost-sharing reduction subsidies. The President has toyed with whether he intends to keep them or not, and you and I both know that one reason for the premium increases and market instability recently reported in the press is because of that very issue. Table 25-1 of the analytical perspectives

has a clear line indicating that the budget assumes payments will go forward under current law.

Why the President continues to offer confusion is unclear. We will surely disagree. In spite of your budget, there is room for us to come to conclusions that will be supportive of the American people. For leadership purposes, I urge you and the President to make a decision, one way or the other, and then stick to it. The confusion in the marketplace is not helpful.

This budget would force middle-class Americans to pay more for less health care, strip down critical addiction rehabilitation services, create further chaos in health insurance markets, and devastate programs for families that need them in an effort to make their ends meet.

And with that I yield back my time.

*Chairman Brady. Thank you, Mr. Neal.

Today's sole witness is Dr. Tom Price, Secretary of the U.S. Department of Health and Human Services Committee (sic). As you know, we received your written statement, it will be made part of the formal hearing record. And we have reserved five minutes to deliver your oral remarks.

Secretary Price, welcome again. You may begin when you are ready.

STATEMENT OF THE HON. THOMAS E. PRICE, M.D., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (WASHINGTON, D.C.)

*Mr. Price. Thank you so much, Mr. Chairman, Ranking Member Neal, and members of the committee. I want to thank you for inviting me here today to discuss the President's budget for the Department of Health and Human Services for fiscal year 2018. It really is an honor to be back in the committee.

Whenever a budget is released in this town, the most common question is asked: how much? How much money does the budget spend on this program, or how much does it reduce from another program?

And, as a former Member of Congress, I understand the importance of this question. But too often it is treated as the only question worth asking about a budget, as if how much money a program spends is more important than -- or somehow more indicative of -- whether the program actually works.

President Trump's budget request (sic) does not confuse government spending with government success. The President understands that setting a budget is about more than establishing top-line spending levels. Done properly, the budget process is an exercise in reforming our federal programs to make sure that they do their job and use tax dollars wisely.

The problem with many of our federal programs is not that they are too expensive, or that they are too underfunded. The problem is that many of them simply don't work. Fixing a broken government program requires redesigning its structure and refocusing taxpayer resources to better serve those most in need. And that is exactly what President Trump's budget will do at HHS.

Consider Medicaid, the primary source of medical coverage for millions of low-income American families and seniors facing health challenges. If the amount of government spending were truly a measure of success, Medicaid would be hailed as one of the most successful programs in the history of the country.

Twenty years ago, annual spending on Medicaid was less than $200 billion. Within the next decade, it is estimated that it will top $1 trillion a year. Despite these significant investments, one-third of physicians who ought to be seeing Medicaid patients are not. And some research shows that enrolling in Medicaid doesn't necessarily improve health outcomes for the newly-eligible Medicaid population.

This suggests that we need structural reforms that empower states to serve their unique Medicaid populations in ways that are both compassionate and sustainable. Under current federal law, rules prevent states from focusing on their most vulnerable communities, and from testing new ideas to improve health outcomes and access to care. This budget changes that.

Now, HHS's mission of protecting the health of the American people involves far more than overseeing the Nation's health care and insurance systems. Health and Human Services is the world's leader in helping the health care sector prepare for cyber threats and responding to and protecting against public health emergencies. Recently I witnessed this important work firsthand while visiting with Ebola survivors in Liberia, and representing the United States at the G20 health ministerial meeting in Berlin, and the World Health Assembly in Geneva.

To support HHS's unique federal role in public health emergency preparedness and response, the President's budget provides $4.3 billion for disaster services

coordination and response planning, bio-defense and emerging infectious disease research, and development and stockpiling the critical medical countermeasures.

In addition, today America faces a new set of public health crises that we have been far less successful in resolving. Those are severe mental illness, opioid crisis, and childhood obesity. And, as Secretary, I am committing to leading HHS to address each of these three challenges. And the President's budget calls for investments and policy reforms that will enable us to do just that.

The budget calls for investments in high-priority mental health initiatives for psychiatric care, suicide, and homelessness prevention, and children's mental health, focusing especially on those suffering from serious mental illness. In 2015, over 52,000 Americans died of overdose. This budget calls for $800 million -- $811 million to support the Department's 5-part strategy to address this epidemic.

To invest in the health of the next generation and help the nearly 20 percent of school-aged children who are obese, we want to help them lead healthy and happy lives. The President's budget establishes a new $500 million American health block grant.

Additionally, the President's budget prioritizes women's health programs by investing in research to improve health outcomes for women, and increasing funding for the maternal and child health block grant and Healthy Start. Across HHS, funding is maintained for many vital program services for women, including community health centers and domestic violence programs and women's cancer screenings, and support mother and infant programs in the Office of Women's Health.

This budget demands tough choices, yes. And in this challenging physical environment there are no easy answers. With this budget, the new Administration charts a path toward a sustainable fiscal future, and ensures the dedicated resources provided enhance and protect the health and well-being of the American people.

Mr. Chairman, I am honored to be with you today, and I look forward to your questions. And it really is a great privilege and honor to be back with the committee.

Statement by Dr. Thomas Price
Secretary U.S. Department of Health and Human Services
on
The President's Fiscal Year 2018 Budget
before
Committee on Ways and Means

U.S. House of Representatives
June 8, 2017

Introduction

Chairman Brady, Ranking Member Neal, and Members of the Committee: thank you for inviting me to discuss the President's Budget for the Department of Health and Human Services (HHS) in Fiscal Year (FY) 2018. It is an honor to be here.

Whenever a budget is released, the most common question asked in Washington is "*how much*?" How much money does the budget spend on this program, how much does it cut from that other program?

As a former legislator, I understand the importance of this question. But too often, it's treated as the *only* question worth asking about a budget—as if how much a program spends is more important than, or somehow indicative of, whether the program actually works.

Measuring Success, Not Spending

President Trump's Budget request does not confuse government spending with government success. The President understands that setting a Budget is about more than establishing topline spending levels. Done properly, the budgeting process is an exercise in reforming our federal programs to make sure they actually work—so they do their job and use tax dollars wisely.

The problem with many of our federal programs is not that they are too expensive or too underfunded. The real problem is that they do not work—they fail the very people they are meant to help. In Aid to Families with Dependent Children, we had a program that undermined self-sufficiency and work. Congress did well when it realized the devastating long-term harm this program had on children, in particular, and took action by creating the Temporary Assistance for Needy Families (TANF) —a program that promoted the empowerment of parents through work. By helping more Americans climb out of poverty, TANF caseloads have declined by 75 percent through FY 2016. Under the TANF program, the employment of single mothers increased by 12 percent from 1996 through 2000, and even after the 2008 recession, employment for this demographic is still higher than before welfare reform. In the wake of the recession, the emphasis on work in TANF has increased the job entry rate, retention rate, and earnings gain rate for program participants.

Our Budget reduces TANF spending in part because we understand that the amount spent in the program has not been the key to its success. Our goal is to continue and even expand on the progress made since enactment of Welfare Reform. Toward that end, we would welcome an opportunity to work with Congress to further strengthen TANF so that States, Territories, and Tribes can can empower more low-income families to achieve financial independence .

Fixing a broken government program requires a commitment to reform—redesigning its basic structure and refocusing taxpayer resources on innovative means to serve the people that the program is supposed to serve. And sometimes it requires recognition that the program is unnecessary because the need no longer exists or there are other programs that can better meet the needs of the people that the program was originally designed to serve. That's exactly what President Trump's Budget will do, at HHS and across the Federal Government.

Consider Medicaid, a critical safety net program that is the primary source of medical coverage for millions of low-income American families and seniors facing some of the most challenging health circumstances.

If how much money the government spends on a program were truly a measure of success, Medicaid would be hailed as one of the most successful in history. Twenty years ago, annual government spending on Medicaid was less than $200 billion; within the next decade, that figure is estimated to top $1 trillion.

Despite these significant investments, one-third of doctors in America do not accept new Medicaid patients. Some research has shown that enrolling in Medicaid does not necessarily lead to healthier outcomes for the newly eligible Medicaid population. The Oregon Health Insurance Study replicated a randomized clinical trial by enrolling some uninsured people in Medicaid through a lottery. Comparing this population to those who remained without coverage, the data showed an increase in emergency room use for primary care, the probability of a diagnosis of diabetes, and the use of diabetes medication, but no significant effects on measures of physical health such as blood pressure, cholesterol, or average glycated hemoglobin levels (a diagnostic criterion for diabetes). However, the same Oregon data showed a significant reduction in rates of depression among those enrolled in Medicaid.

This mixed impact of Medicaid coverage on health outcomes suggests we need structural reforms that equip States with the resources and flexibility they need to serve their unique Medicaid populations in a way that is as compassionate and as cost-effective as possible.

Saving and Strengthening Medicaid through State Innovation

That's exactly what the President proposes in his Budget. Under current law, outdated, one-size-fits-all Federal rules prevent States from prioritizing Federal resources to their most vulnerable populations. States are also limited in testing new ideas that will improve access to care and health outcomes. The President's Budget will unleash state-level policymakers to advance reforms that are tailor-made to meet the unique needs of their citizens.

Over the next decade, these reforms will save American taxpayers an estimated $610 billion. They will achieve these savings by harnessing the innovative capacity of America's governors and state legislators who, informed directly by the people and those providing the services, have a proven record of developing creative, effective ways to meet the healthcare needs of friends and neighbors in need, while empowering them to manage their own health.

Furthermore, the Budget includes provisions to extend funding for the Children's Health Insurance Program. The Budget proposes to rebalance the Federal-State partnership through a series of reforms, including ending the Obamacare requirement for States to move certain children from CHIP into

Medicaid and capping eligibility at 250 percent of the Federal Poverty Level to return the focus of CHIP to the most vulnerable and low-income children.

These reforms will go a long way toward improving access to healthcare in America. But there is more work to be done. That's why the President's Budget commits to working with Congress to transition from the failures of Obamacare to a patient-centered system that empowers individuals, families, and doctors to make healthcare decisions.

HHS Advances the Health Security of the American People with a Focus on Preparedness and Response for Medical and Public Health Emergencies

As everyone here knows, HHS's mission of protecting and promoting the health of the American people involves far more than overseeing the nation's healthcare and insurance systems.

For generations, HHS has been the world's leader in responding to and protecting against public health emergencies—from outbreaks of infectious disease to chemical, biological, radiological, and nuclear threats—and assisting the health care sector to be prepared for cyber threats. I recently had the privilege of seeing the importance of this work during an international trip to Africa and Europe.

Visiting with Ebola survivors in Liberia and representing the United States at the G20 Health Ministerial Meeting in Berlin and then the World Health Assembly in Geneva reinforced just how vital a role HHS plays in preparing for, and responding to, domestic and global public health emergencies. To support HHS' unique Federal role in public health emergency preparedness and response, the President's Budget provides $4.3 billion for disaster services coordination and response planning, biodefense and emerging infectious diseases research, and development and stockpiling of critical medical countermeasures. These investments help ensure that state and local governments have the support and resources they need to save lives, protect property, and restore essential services and infrastructure for affected communities.

Key Public Health Priorities: Serious Mental Illness, Substance Abuse, and Childhood Obesity

In addition, today America faces a new set of public health crises that—if we're honest with ourselves—we have been far less successful in resolving. Those crises are: (1) serious mental illness; (2) substance abuse, particularly the opioid abuse epidemic; and (3) childhood obesity.

As Secretary, I am committed to leading HHS to address each of these three challenges. The President's Budget calls for the investments and policy reforms that will enable us to do just that.

The Budget invests in high-priority mental health initiatives to deliver hope and healing to the 43.1 million adults with mental illness[i], including nearly 10 million Americans suffering from a serious mental illness[ii], as well as the 19.6 million adults with both mental and substance use disorders,[iii] the 3.0 million adolescents who have experienced a major depressive episode[iv], and 350,000 adolescents with both a major depressive episode and substance use disorders .[v] These initiatives will target resources for psychiatric care, suicide prevention, homelessness prevention, and children's mental health. For example, the Budget proposes $5 million in new funding authorized by the 21st Century Cures Act for Assertive Community Treatment for Individuals with Serious Mental Illness. The Budget also includes a demonstration within the Children's Mental Health Services program to test the applicability of new

research from the National Institute of Mental Health on preventing or delaying the first episode of psychosis.

According to the Centers for Disease Control and Prevention (CDC), during 2015 drug overdoses accounted for 52,404 U.S. deaths, including 33,091 (63.1 percent) that involved an opioid. To combat the opioid epidemic sweeping across our land, the Budget calls for $811 million—an increase of $50 million above the FY 2017 continuing resolution—in support for the five-part strategy that has guided our Department's efforts to fight this scourge:

- (1) Improving access to treatment, including Medication-Assisted Treatment, and recovery services;
- (2) Targeting availability and distribution of overdose-reversing drugs;
- (3) Strengthening our understanding of the epidemic through better public health data and reporting;
- (4) Providing support for cutting edge research on pain and addiction; and
- (5) Advancing better practices for pain management.

This funding increase will expand grants to Health Resources Services Administration (HRSA) Health Centers targeting substance abuse treatment services from $94 million to $144 million. Also within this total, the Budget continues to fully fund the $500 million for State Targeted Response to the Opioid Crisis Grants that were authorized in the 21st Century Cures Act, which expand access to treatment for opioid addiction. Using evidence-based interventions, these grants address the primary barriers preventing individuals from seeking and successfully completing treatment and achieving and sustaining recovery.

Finally, the President's Budget invests in the health of the next generation by supporting services that promote healthy eating and physical activity, especially among the nearly 20 percent of school-aged children in America who are obese. The Budget establishes the new $500 million *America's Health* Block Grant, which will provide flexibility for States and Tribes to implement specific interventions that address leading causes of death and disability facing their specific populations. This could include interventions to spur improvements in physical activity and the nutrition of children and adolescents, and to treat leading causes of death such as heart disease.

Other Budget Highlights

The President's Budget prioritizes women's health programs through investing in research to improve health outcomes, maintaining support for women's health services, empowering women and families, and emphasizing prevention. For instance, funding for the Maternal and Child Health Block Grant and Healthy Start is increased to improve the health of mothers, children, and adolescents, particularly those in low-income families. In addition, funding is maintained for a variety of vital programs serving women across HHS, including, community health centers, domestic violence programs, women's cancer screenings and support, mother and infant programs, and the Office on Women's Health.

Conclusion

Members of the Committee, thank you for the opportunity to testify today and for your continued support of the Department. It is an incredible privilege to serve the American people as the Secretary of Health and Human Services and support its mission to protect the health and well-being of all Americans.

[i] Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Pg. 27 Retrieved from http://www.samhsa.gov/data/

[ii] Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Pg 27 Retrieved from http://www.samhsa.gov/data/

[iii] Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Retrieved from http://www.samhsa.gov/data/

[iv] Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Pg 38 Retrieved from http://www.samhsa.gov/data/

[v] Center for Behavioral Health Statistics and Quality. (2016). *Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health* (HHS Publication No. SMA 16-4984, NSDUH Series H-51). Page 40 Retrieved from http://www.samhsa.gov/data/

*Chairman Brady. Well, thank you, Mr. Secretary, for your excellent testimony. We will now proceed with the question and answer session. I will begin.

So during your time on the committee, you were well aware of our ongoing investigation of the Obama Administration's illegal funding of the Affordable Care Act's cost-sharing reduction payments. Are you able to comment on the ongoing litigation between the House and the Administration regarding these unfunded payments?

*Mr. Price. Well, Mr. Chairman, as you and the members of the committee know, that once you assume this role, the court challenged from House v. Burwell to House v. Price. And so, as the defendant in this case, I am limited in what I can say.

What I can say, however, is that the budget reflects the CSR payments for the next two years.

*Chairman Brady. Right, thank you. That was, I think, the point here. I think the improper and illegal way in which the Obama Administration financed these payments fuels continued uncertainty for Americans across the country. And they are just asking: Will there be health plans left to buy? If so, can I even afford it?

Clearly, congressional Republicans are committed, as you are, to a smooth transition away from Obamacare's failures and toward patient-centered care. And that includes, as you point out, legally funding these payments for a short period of time, consistent with their scheduled repeal in the American Health Care Act.

This will increase market stability and provide relief for Americans who have seen their premiums double under Obamacare, and for too long have been whipsawed between the law's forced plan cancellations and its punitive individual mandate. The Senate is expected to take up the health care plan soon. That lowers premiums, cuts taxes, reduces deficits. This summer is a critical one for insurer participation.

So, from your view, can you tell us what other proposals are included in this budget to shore up the damage caused by Obamacare and help lower premiums this year and next for those who are trapped in the current law?

*Mr. Price. Well, thank you, Mr. Chairman. I think it is important to think about this in terms of principles. And if you think about accessibility to health care, there are 20 million Americans right now who don't have health coverage. About six million of those have said they accept the penalty. Another 14 million or so took a waiver. Those are folks for whom the health coverage that is available out there doesn't suit them.

So we believe, as I know you do, that it is important to provide the opportunity for individuals to get the kind of coverage that they want, not that the government forces them to buy. And so, whatever reform comes about needs to be able to accommodate that, and given an array of options and choices for individuals.

And in terms of affordability, –there are so many things that were put in place with the law that we believe have made it that much more difficult for individuals to be able to afford the available coverage. You have seen the prices skyrocket, the premiums have gone up over 100 percent, on average, over the last 4 years, across the country. Many states -- three states have had over triple the premiums.

And then the deductibles have increased to such a point where there are so many folks out there who have coverage, but they don't have care, because they can't afford the deductible. So again, we believe it is incredibly important to provide for folks to have the kind of coverage that they want. That they can afford, yes, but that also provides them the care.

And then, so many of the kinds of things that empower patients, whether it is through choices or whether it is the ability to select their physician and the like, making it so that patients and families and doctors are making these decisions, and not Washington, D.C. Those are the principles that we hope we can adhere to.

*Chairman Brady. Right. Thank you, Dr. Price. And just to conclude, so the President's budget does include legally funding these payments for a short period of time for the cost-sharing reduction, consistent with the scheduled repeal under the American Health Care Act.

*Mr. Price. It is reflected in the budget.

*Chairman Brady. Yes, sir. Thank you very much. I will now recognized the distinguished ranking member, Mr. Neal, for any questions he may have.

*Mr. Neal. Thank you, Mr. Chairman.

Mr. Secretary, as you know, opioid addiction is raging throughout many of our communities across the country. And my state of Massachusetts had one of the highest rates of drug overdose deaths in the country during 2015. As the epidemic continues to ravage communities across the Commonwealth, we are recognizing this as a national problem.

Medicaid remains the biggest payer for substance use disorder treatment. Fortunately, Massachusetts expanded Medicaid under the Affordable Care Act, so many people who are struggling with addiction have access to these services through the state's Medicaid program.

The President's budget in the House-passed health care bill slashed Medicaid funding by $1.4 trillion, and would undoubtedly lead to cuts in substance use disorder treatment and coverage for Americans struggling with substance use disorders, including opioid addiction.

The budget compounds the problem by also eliminating millions of dollars in social service block grant funding dedicated to substance abuse treatment. I would urge you to reconsider these cuts that will put the states in a terrible position by choosing between care for the elderly, working families, people with disabilities, and individuals with substance abuse disorders like opioid addiction. These are incredibly, incredibly important services for our constituents, and the cuts you propose would make the devastation of this epidemic far worse.

The second issue I would like to raise is the level of funding for marketplace research and enrollment in the President's budget. As you know, we have made historic progress in lowering the uninsured rate in recent years, with just nine percent of the American people uninsured in 2016. The ACA built upon the experience we have had in Massachusetts, passed with the help of Governor Romney, creating a marketplace to purchase private insurance and expand Medicaid coverage.

None of that came easy. Massachusetts worked tirelessly to enroll people in coverage, even working with our beloved sports teams to encourage people to sign up. Today, over 10 years since our reform passed, we have seen the fruits of the investment, with 97 percent of our non-elderly adults insured, and 99 percent of children covered.

The Department you now lead has worked with stakeholders from all levels of government in both parties to faithfully implement the law, and ensure that Americans know what coverage options are available to them. With each passing year, we have gotten smarter, more data-driven, and more effective. This all requires funding and partnership from the highest levels of government.

Fortunately -- unfortunately, the President's budget slashes funding for the federal marketplace, and targets outreach and enrollment. Specifically, under the fiscal year 2018 budget that you proposed to cut funding for federal marketplace by 35 percent from last year's level, including outreach and enrollment. I hope you will reconsider these proposals.

We have made much progress, thanks to the efforts of community groups and dedicated public servants across the country. Pulling funding from their efforts will now undoubtedly lead to significant increases in the uninsured rate, and many American families would go without coverage and the care they need to help make ends meet.

Lastly, Mr. Secretary, Treasury Secretary Mnuchin has warned us that if Congress does not raise the debt limit before the August recess, we run the risk of a first-ever default on the full faith and credit of the United States. For that reason, privately with me and publicly in front of the Congress he has suggested as much, and he has urged us to act quickly on a clean debt limit increase. If we fail to act, we will have a devastating effect on the economy at home and internationally, since credit markets around the world rely upon the confidence that the U.S. treasury bond is still the safest investment on earth.

As a Social Security and Medicare trustee, you must be especially aware that if we don't raise the debt limit, the Trump Administration would be the first in history to fail to pay the earned Medicare and Social Security benefits. Mr. Secretary, will you join Secretary Mnuchin in supporting a clean debt limit increase?

*Mr. Price. I support the Secretary's statement.

*Mr. Neal. Thank you, Mr. Chairman.

*Chairman Brady. Thank you, Mr. Neal. Members will be advised, due to scheduling constraints, questions will be limited to three minutes.

With that, I recognize Mr. Nunes.

*Mr. Nunes. Thank you, Mr. Chairman.

Welcome back, Mr. Secretary. It is great to see you.

*Mr. Price. Good to see you.

*Mr. Nunes. I briefly want to discuss the American Health Care Act that recently passed out of the House of Representatives and now sits awaiting action in the Senate. There has been a lot of discussion about insurance companies denying coverage, based on pre-existing conditions. Now, from my perspective, that is now allowed in the bill that passed the United States Congress. And I know my state of California would likely never allow for a waiver.

But can you quickly confirm that, even in a waiver state, insurance companies will not be allowed to deny coverage? And I will give you a chance to expand on that, if you would like, Mr. Secretary.

*Mr. Price. Absolutely. The need to make certain that individuals with pre-existing illnesses and injuries are able to gain coverage is an absolute priority for the President and for our Department. And I believe that the bill that passed the House accommodates for that, and makes certain that individuals with pre-existing conditions are able to get coverage.

*Mr. Nunes. So, just so we can be perfectly clear, there is nothing in the bill that awaits action in the Senate that would allow for or that would deny coverage for pre-existing conditions?

*Mr. Price. In fact, on the contrary, I think there is a section or a paragraph that stipulates specifically that coverage cannot be denied based upon a pre-existing condition.

*Mr. Nunes. Thank you very much, Mr. Secretary. I would like to turn my attention to the new health care bill, and I want to talk about the merits of the plan. I don't think many people have really talked about the merits of the plan, and that is that if you don't have health care from the government, or you don't have health care from your employer, you will be allowed a tax credit to purchase health care.

And some people -- and not only here in Washington, but others -- have stated that, well, even if you give people these credits to use to go out and buy health care coverage, I have heard things like, well, no one would go and buy

coverage. I have even heard people say, well, you know, how are people that don't speak English going to go and buy coverage? How are kids going to go buy coverage?

I tend to disagree that, just because someone doesn't have a college degree or may not speak English very well, may not be their first language, I tend to disagree that those people are too stupid to be able to use somewhere between $2,000 up to $14,000 for their family to go buy coverage.

And, Mr. Secretary, in just the closing seconds that I have, if you could comment on the Americans' ability to use those credits.

*Mr. Price. Well, we have great confidence that if we put in place a system that provides for and allows for coverage that the American people want, that they will be able to purchase that coverage.

*Mr. Nunes. Thank you, Mr. Secretary. Great to see you.

*Mr. Price. Thank you.

*Mr. Nunes. I yield back, Mr. Chairman.

*Chairman Brady. Thank you.

Mr. Levin, you are recognized.

*Mr. Levin. I wasn't going to talk about your statement about pre-existing conditions, but the impact of waivers would mean that people with pre-existing conditions, if waivers were granted, would not be able to afford care. I hope others will bring that up.

You said in your statement the following, "The real problem is that federal programs do not work. They fail the very people they are meant to help." In the budget there is a proposal to reduce funding for NIH. I want to enter into the record a chart that shows how the budget, in real dollar terms, has dropped from 40 billion in 2003 to 34 billion this year. And now there is another proposed $6 billion cut.

Mr. Secretary, I checked recently and I want to refer to four break-throughs in recent times because of NIH funding: hepatitis C, there is now 100 percent treatment; cystic fibrosis, they have found a gene through NIH research, and they are on a path to have it become a chronic disease; AIDS funding has

dramatically changed that disease; and then cancer, there is remarkable break-throughs in immunology. I hope you will take another look at this dramatic, drastic proposal to cut NIH funding another $6 billion. I won't ask you now, I am afraid you might defend the budget cut. I hope, in good conscience with your experience, you will work to make sure it never happens. Those break-throughs show programs are helping human beings and saving lives.

Let me just ask you on cost sharing. Are you willing now to commit that the Administration will provide the monies that are now provided for cost sharing in future years?

*Mr. Price. As I mentioned before, Congressman, as a defendant in the suit, I am not able to say, for legal reasons, anything more than the budget accommodates and reflects the CSR payments --

*Mr. Levin. Okay, the budget cuts, but forget the legal case. Are you willing to say -- I know it is in the budget -- that the monies will be provided for cost sharing? Yes or no.

*Mr. Price. Sir, the monies are provided through Congress. No monies can be expended from the public treasury, except through a provision from Congress. So you all provide the monies.

*Mr. Levin. The monies now aren't being provided that way, sir.

*Chairman Brady. All time has expired.

Mr. Tiberi, you are recognized.

*Mr. Tiberi. Thank you, Mr. Chairman.

Thank you, Doc, for being here. We miss you.

*Mr. Price. Good to see you.

*Mr. Tiberi. So, this morning we held in this room a Joint Economic Committee hearing on the opioid crisis in America. And my state of Ohio has been particularly hit hard by this devastation that has spread across families, communities of all types.

Our Ohio attorney general, Mike DeWine, testified that last year or 2015 there were 4,169 Ohioans who died of accidental overdose, and that was a 36 percent increase from the year before.

So I know you and the President believe this is a priority, this is not just the Federal Government's responsibility, as Attorney General DeWine said. This is a multi-pronged approach, with local communities having to take the lead. But I know this is important to you, and important to the President. Can you talk about your priorities on this issue?

*Mr. Price. Well, thanks, Mr. Tiberi. This is an absolute priority of the President, and it is an absolute priority of mine, as Secretary in the Department. The numbers are just staggering, as you well know, and Ohio's challenge is America's challenge: 52,000 overdose deaths in 2015, 33,000 of those from opioids. And the numbers are only going up in 2016 and this year, as well.

We have put forward at the Department a five-point strategy to make certain that we have the highest level of recovery and treatment opportunities for folks, to make certain that we have got overdose-reversing drugs available as broadly as possible all across this Nation.

I visited southwest Ohio in a community there that is doing incredible work to stem that tide.

We need better data, public health surveillance. We need better data to figure out now just what is happening, why it is happening. Why are we seeing this remarkable increase, incredible increase of the scourge of opioid addiction?

And we also ought to be able to marry the data from the criminal justice system, where the drugs are, so that we are able to respond to the medical challenges that we will have.

Further, we need to make certain, as Mr. Levin said, that we are doing the kind of research, especially in this area. There are exciting new advances that are possible. The possibility through NIH working currently on a vaccine for addiction. Imagine that kind of incredible opportunity for folks that are imprisoned by this addiction.

And then, finally, fifth, the whole issue of pain management. How do we handle pain treatment in this Nation? And I would suggest to you that some

federal policies have, in fact, provided incentives to have us move in the wrong direction to provide more availability of opioids than fewer.

And so, it is an absolute priority. I am proud of the President's leadership on this, and I look forward to turning that curve in the right direction, which is downward.

*Mr. Tiberi. Thanks for your leadership. I yield back, Mr. Chairman.

*Mr. Price. Thank you.

*Chairman Brady. Thank you. Mr. Lewis, you are recognized.

*Mr. Lewis. Thank you, Mr. Secretary --

*Chairman Brady. Can you grab that microphone?

*Mr. Lewis. Thank you, Mr. Secretary, for being here. Mr. Secretary, during my years in Congress, I learned that supporters of a budget are often inclined to refer to it as a blueprint, a plan, a road map. Maybe even a path to prosperity or to the Promised Land. I have always referred to the budget as a moral document, a statement of values. It is clearly, as we can see, clear as daylight, whether the needs of the people are taken seriously by the elected representatives. I still believe that to be true today.

However, in this day and age, I believe the budget has the new meaning. For women and men in this country who go to work every single day, who live paycheck to paycheck, for their families who have placed their trust in this Administration, this budget is evidence. In a democracy, evidence is required to prove intent. You see cold, hard facts cannot be explained away.

Mr. Secretary, like you I also served on the Budget Committee, and I know how to read a budget. I know this proposal is not the result of thoughtlessness or ignorance. The White House budget makes the question or intent crystal clear. You cannot sweep these deep cuts and -- under a rug or hide it in a dark corner.

Over the last seven years, there have been meaningful promises made to the American people. In the last election, Republicans vowed to harm -- not to harm Medicaid, Medicare, or Social Security. Let me say it again. You pledged not to harm Medicaid, Medicare, or Social Security. This budget is Exhibit A, ensuring that the promise has already been broken.

Mr. Chairman, Americans are busy just trying to make ends meet. Most will not have time to watch this hearing, read it. This budget is wrong. How could they vote for one thing and get another?

On that day, members of this Committee will look back at this moment and point to the evidence, the crime this budget is a set of fingerprints. The fingerprints of this Administration is on this budget. It is mean-spirited. It is not good for America. We can do much better.

*Chairman Brady. Thank you. Time has expired.

Mr. Roskam, you are recognized.

*Mr. Roskam. Thank you, Mr. Chairman. Secretary Price, let's talk about the good things that are going on.

Now, I will say for the record that you used to sit right here. And, by definition, everybody that sits to your right, further down, is happy for you, but they are really happy that you left, because they can all move up. Myself and everybody this way, we are sincerely happy for you. So congratulations on this new assignment.

*Mr. Price. Thank you.

*Mr. Roskam. Now, Mr. Secretary, I know you have been active around the world of late. I know you have been traveling, I know you have been in West Africa. Can you give us a sense of what is going on, in terms of global health and the leadership role of the United States, in particular?

*Mr. Price. Well, thank you, Mr. Roskam. This is really an exciting story to tell, because the United States has provided world leadership in the area of global health security.

Through the WHO and other organizations, what we have done is rallied together tens of nations around the world to recognize that, in order to provide health security for not just the United States but the world, that it requires nations working together and making certain that there is a minimum level of ability to provide surveillance, to provide detection of infectious disease and potential pandemics, and then to provide treatment, and especially treatment on site in country.

I had the opportunity, as I mentioned, to visit Liberia a couple weeks ago. And I will tell you, the exciting and inspiring people that I met, the Americans who work for CDC, who work for the Department of Health and Human Services through CDC or through HRSA or through NIH, and are out there on the front lines, and those are the individuals that opened their arms to the folks who were suffering during the Ebola crisis. And the Liberian people and the Liberian Government and the individuals that I met there were so incredibly appreciative of what you all did in providing the resources so that we can lead in the world of global health security.

And you have seen the results of it, not just through the resolution of the Ebola crisis in Liberia, but through what Liberia itself was able to do recently when it had some meningococcal -- meningococcus outbreak. And what they were able to do is detect it, to isolate it, to then treat it, all in country, all by the themselves, along with the help of individuals from CDC. It is an incredibly inspiring story, and it is happening, yes, maybe below the surface, but it is to all of your good credit that we are able to do that, as a Nation. And the world understands the leadership that the United States provides.

*Chairman Brady. Thank you.

Mr. Doggett, you are recognized.

*Mr. Doggett. Thank you, Mr. Chairman, and thank you, Mr. Secretary, for being here.

As you know, on January the 11th, President Trump told us, "We have to do -- to create new bidding procedures for the drug industry, because they are getting away with murder. We are the largest buyer of drugs in the world, and yet we don't bid properly. We are going to start bidding. We are going to save billions of dollars."

Unfortunately, since then, we have had radio silence. In fact, we can't even get a tweet about the outrageous amount of price gouging that is occurring by pharmaceutical companies in this country.

The budget that you present today is deficient not only in the harm that it does, which is great, but in the omissions that it contains. And this is particularly true with reference to pharmaceutical prices. Unlike President Obama, who presented a budget that had a provision specifically addressing the high cost of drugs, and appeared to do the same thing that President Trump called for in January and last year by giving you, as Secretary, the authority to negotiate

drug prices for Medicare, said that it would save $140 billion by doing that, and included a provision increasing transparency of prescription drug pricing that would lead to another $21 billion in savings.

Your budget is silent on the issue of bidding or negotiating, or doing anything meaningful to stop prescription price gouging. And I would just ask you to provide an answer in writing, since my time is short, as to whether the Administration has rejected President Trump's bidding approach of January, as well as the approach that President Obama presented -- he likes to reject just about everything that has Obama associated with it -- or whether you have a plan to do something to implement what President Trump promised the American people last year he would do.

Second, we learned only this week about the outrageous overcharging of the government through the HHS office of inspector general on EpiPens, $1.27 billion. I would ask you to answer in writing regarding how much of that money the government is getting back in the alleged settlement that began last year that Mylan announced in November or December. And I will forward you documents on that.

And finally, 50 of us asked in April President Trump to use the existing authority he has right now so that taxpayers are able to access the drugs that they paid for, the research to get those drugs, in accordance with reasonable standards, asking the National Institutes of Health to be involved in that. We have received no answer to our inquiry to President Trump. And I will forward you a copy of that, and ask you to provide a written answer concerning what the Administration's position is. It seems to love to do executive orders, and could do one on this and help consumers across the country. Thank you.

*Mr. Price. Thank you.

*Chairman Brady. Thank you. His time is expired.

Mr. Smith, you are recognized.

*Mr. Smith of Nebraska. Thank you, Mr. Chairman. And certainly thank you, Mr. Secretary, for being here and sharing your expertise, in terms of serving our country as a former practicing physician. We are grateful for your service.

We know that the challenges are many, as I represent rural and remote areas of the country in Nebraska, critical-access hospitals are very important. I continue to work on the 96-hour rule, and trying to fix that. I think that stands in the

way of efficient care in many of these facilities. Also, the physician supervision issue remains to be a problem, and I hear a lot about this.

Certainly also, Nebraska hospitals, like their counterparts across the country in other states, continue to see reimbursements siphoned by the Bay State Boondoggle. I know that you were a cosponsor, when you were on this Committee, to get rid of that. And so I have reintroduced a bill in this Congress, and hoping that we can resolve that issue.

But let me focus a little bit on human services, and certainly well within your portfolio at HHS. The home visiting program, referred to as MIECHV, the Maternal Infant and Early Childhood Home Visiting Program, has been very successful. It has been very effective because it is evidence-based. And I am anxious to continue to work on this. We introduced a bill already. As you know, it is a voluntary home visiting program that increases economic self-sufficiency and reduces abuse and neglect in at-risk families. And so, the program, because it is evidence-based, I think has been successful.

Are there other programs in the federal human services area right now which require taxpayer dollars be spent on an evidence-based basis? And would you be supportive of finding ways to make more of our federal poverty programs evidence-based?

I think you have touched a little bit on this in your opening testimony. But are there some quick things that you could point to that we can work on?

*Mr. Price. Yes, this is incredibly important, because, as I mentioned, we so often measure success of a program by how much money goes into it in this town, as opposed to whether or not it is actually accomplishing its goal.

And so, one of the things that we are trying to do at the Department is -- there is so much intellectual knowledge and institutional knowledge within the Department -- but to charge folks to say, okay, if we were really measuring whether or not this program worked, what would we be measuring? Because it certainly wouldn't be how much money we put into it, it would be measuring whether or not people are aided, whether or not those moms are assisted in that early childhood care, and the like.

And so, if we focus on those things that actually have metrics that determine whether or not the program is working, then we can figure out where we ought to be potentially putting more resources. But unless you focus on the

outcomes, on the actual product that comes from the programs, you will never get that, because then you are only left with how much money goes in.

So, the maternal and infant and early childhood home visiting programs are so incredibly important, and I am really pleased to announce that in the budget we have increased the monies in that program because it is evidence-based.

*Mr. Smith of Nebraska. Thank you.

Thank you, Mr. Chairman.

*Chairman Brady. Thank you.

Mr. Thompson, you are recognized.

*Mr. Thompson. Mr. Secretary, thank you very much for being here. You know, Dr. Price, I am a bit mystified by the rhetoric on the so-called failures of the ACA. The Republicans and Administration officials have characterized individual insurance markets as being in a death spiral, and that the law is imploding, or collapsing. And these comments are at odds with the analysis from CBO, Joint Tax, Standard and Poors, and other experts, who have assessed this program.

And projections from experts come in spite of a string of Republican efforts to undermine the law, since its inception. The ACA was challenged in court the day it was signed into law. The court findings allowed states to reject Medicaid expansion and deny care to some of their residents. In 2013 Republicans snatched $3.5 billion from the co-op program.

In 2014 Republicans gutted the risk corridor program -- and this is the bipartisan stabilization tool that we use to stabilize Medicare Part D. Again, in 2014 the House Republicans filed suit, challenging the Administration's authority to distribute cost-sharing reductions.

And I would like to ask unanimous consent -- I have a list of other sabotage efforts that were put together by our Senate colleagues. And I want to note that the President has carried on this legacy of sabotage, and makes sport out of undermining the critical programs and deflecting blame for the consequences.

First, as you know, he issued the anti-ACA executive order. Then he cut outreach in the final week of the opening -- of the open enrollment. The IRS abandoned measures to tighten reporting for the individual mandate. There

have been repeated threats to withhold CSR payments. And, most important, the Administration has supported repeal legislation that would turn the individual market on its head, not to mention to eliminate pre-existing condition protections, levy an age tax, and impede some veterans' access to health care.

Taken all together, these actions created a great uncertainty in the marketplace. And this is what has driven up premiums for our middle-class Americans. This Administration will be wholly responsible for premium hikes we see coming this summer.

And, Mr. Chairman, again, I would like to ask unanimous consent to read into the record this list, titled "Sabotage and Uncertainty Jeopardizing the ACA Markets," and this is comments from insurers and regulators that confirm that this has been a coordinated effort to sabotage.

*Chairman Brady. Without objection.

Thompson SFR

FACT SHEET: Republican Efforts to Sabotage the Affordable Care Act

The Affordable Care Act (ACA) is providing middle-class families with stability and security. Instead of refighting old political battles over health care, Republicans should work with us to improve the law and help more people take advantage of its consumer protections and benefits, and strengthen the economy. Instead, Republicans want to go back to the days when insurance companies were in charge and could deny coverage to children with pre-existing conditions, charge women more than men, and run up premiums without any accountability. They are even working to sabotage the ACA by interfering with implementation and attempting to deny funding to set up the law for millions of Americans. That's not how our government should work.

Republicans Are Trying to Stop the Law from Working

Republicans are harassing groups who are trying to help Americans get health coverage. House Republicans on the Energy and Commerce Committee recently requested extensive disclosures from navigators that have received federal grants to assist individuals and businesses find health coverage under the ACA. These excessive requests for information, made at the peak of enrollment preparation activities, have been recognized by independent experts as being designed to stop or sabotage ACA implementation. States with the highest numbers of uninsured individuals, and smallest amount of resources, will be the most affected by the extra burden on navigators. Rep. Renee Ellmers (R-NC) said she would be pleased if her Committee's inquiry stymies nonprofit planning navigator work: "If this ended up resulting in a delay, I wouldn't be unhappy about it." [New Republic, 9/3/13; Salon, 9/4/13; Charlotte News-Observer, 9/7/13]

Republican Congressional offices are refusing to help their constituents enroll in health insurance plans offered on the new ACA marketplaces. Rep. Tim Huelskamp (R-KS) said he would direct constituents to call their former governor, HHS Secretary Kathleen Sebelius, with any questions about getting coverage under the law. Similarly, Rep. Jason Chaffetz (R-UT), said he will pass constituents on to the Administration: "We know how to forward a phone call." [The Hill, 6/15/13]

Georgia Insurance Commissioner: Office is "Doing everything in our power to be an obstructionist." During a speech to a county Republican dinner, Georgia Insurance Commissioner Ralph Hudgens vowed that he was doing "everything in our power to be an obstructionist" to implementation of the law. [Remarks of Commissioner Hudgens, 8/17/13]

Seven Republican-led states are working to undermine popular consumer protections. Texas, Florida, Alabama, Wyoming, Arizona, Oklahoma and Missouri have left at least part of the job of enforcing these consumer protections to federal authorities. A Kaiser Family Foundation poll in March showed that two-thirds of Americans had a favorable view of the ban on preexisting conditions (including 56% of Republicans) and 65% supported the medical loss ratio rule (including 62% of Republicans). [Washington Post, 8/28/13; KFF, 3/13]

Republicans Have Tried to Stop the ACA at the State Level

Laws in more than a dozen states led by Republicans are designed to interfere with outreach to consumers. Republican-led states have passed legislation that imposes licensing exams, fines that can run as high as $1,000 and onerous training requirements that almost double the hours required by the federal government. In Ohio, navigators won't be allowed to compare and contrast plans for customers looking to get health insurance, and in Missouri navigators are required to immediately cut off contact with any customers who at some point have talked to a professional broker or agent. The intent of these efforts is clearly to stop implementation and hurt the millions of Americans without health insurance. [Bloomberg, 8/23/13; The Washington Post, 8/28/13]

Florida passed a law repealing the ability of the state's insurance regulator to review unreasonable insurance rate proposals. The measure (SB 1842), eliminates the insurance commissioner's ability to approve, modify or reject rate increases for non-grandfathered plans filed in 2014 and 2015. This Florida law takes away a key ACA consumer protection that allows states to ensure their consumers are getting the best value for their insurance coverage. States with similar rate review authority have been able to "extract significant reductions" in rates filed by insurers. [PolitiFact.com, 8/1/13; Kaiser Family Foundation, 12/1/10]

In Missouri, a Republican-led ballot initiative resulted in forbidding state and local government officials from doing anything to help put the ACA in place for state residents. More than 850,000 Missourians are uninsured and many could qualify for subsidies to purchase health insurance through the new health insurance marketplaces, but because of the law passed in Missouri, finding the new health insurance marketplace is "like searching for a unicorn." [Washington Post, 8/29/13; New York Times, 8/2/13].

Sabotage and Uncertainty Jeopardizing ACA Marketplaces, Insurers and Regulators Confirm

Center on Budget and Policy Priorities

At the start of this year, the Affordable Care Act (ACA) marketplaces were poised for greater stability and success going forward. Unfortunately, initial 2018 individual market rate filings — along with statements from insurers and state regulators — show that sabotage by the Administration, and uncertainty created by both the Administration and Congress, is taking a toll.

Below is a collection of insurer and state regulator comments from across the country highlighting how Trump Administration sabotage and the threat of ACA repeal are increasing premiums and jeopardizing insurer participation for 2018. We'll update this page as additional insurers and state regulators comment.

California

Paul Markovich, President and CEO of Blue Shield of California (*Los Angeles Times*, May 18, 2017)

"'All this uncertainty is not helpful,' warned Blue Shield of California Chief Executive Paul Markovich, who said health plans were being forced to make plans to raise premiums to account for the turmoil, jeopardizing Americans' coverage."

Markovich (Vox, May 8, 2017)

"It's pretty clear we need more certainty to be able to file the rates assuming we get those federal payments. Short of that, we'd have to assume they're not being paid."

Dave Jones, California's State Insurance Commissioner (Memo to California insurers, April 24, 2017)

"In light of all the actions taken by the Trump Administration and House Leadership to undermine the ACA, I expect that health insurers will consider filing significant rate increases for 2018. Further, I am concerned that this needless uncertainty may, in some cases, cause insurers to leave markets entirely."

Colorado

Marguerite Salazar, Colorado's State Insurance Commissioner (*Los Angeles Times* , May 18, 2017)

"In Colorado, where most consumers continue to have multiple insurance choices, commissioner Marguerite Salazar said the Trump administration threatens the whole market. 'My fear is it may collapse,' she said."

Connecticut

ConnectiCare spokesperson (Modern HealthCare, May 10, 2017)

"ConnectiCare, one of two insurers selling individual plans in Connecticut, requested to increase rates by 15.2% on average. A spokeswoman for the company, which is a subsidiary of New York insurer EmblemHealth, said the proposed rates reflect legislative and regulatory uncertainties surrounding the 'weakening of the individual mandate' and the funding for cost sharing reduction subsidies, as well as higher medical and pharmacy costs and increased utilization."

Katherine Wade, Connecticut's State Insurance Commissioner (CBS News, May 9, 2017)

"The uncertainty that is driving the rates this year is how strictly the Internal Revenue Service is enforcing the individual mandate."

Iowa

John Naylor, CEO of Medica (*Washington Post*, May 12, 2017)

- *"'It is challenging to stay focused on our mission to provide access to high-quality affordable health care when there's noise around the system and a lack of clarity of rules,' said John Naylor, chief executive of Medica, who called the amount of uncertainty being thrown at insurers at the moment unprecedented."*
- *"We have to build brand recognition and we have to get in and serve the members, but first and foremost we need a set of rules to be able to design products and price products, so that we can properly quantify the risks. So, as we went into these markets, there were pretty clear rules in a given year: Here's how the market works. And then, all of a sudden, the rules changed."*
- *"Our goal is to be in these communities, and the interesting thing of being a nimble, regional health plan is we're kind of agile and nimble in terms of going with the punches. Who would have thought a month ago, we'd be sitting here?"*

Geoff Bartsh, Vice President of Medica (*Des Moines Register*, May 3, 2017)

"Bartsh said Congress isn't helping the situation by continuously arguing over how to change rules in midstream while insurers are trying to figure out their rates for 2018. When asked what advice he would have for current Medica customers in Iowa, Bartsh replied, 'call your elected officials.'"

John Forsyth, Chairman and CEO of Wellmark (Statement, April 3, 2017)

"While there are many potential solutions, the timing and relative impact of those solutions is currently unclear. This makes it difficult to establish plans for 2018."

Maryland

Chet Burrell, CEO of CareFirst (Bloomberg, May 9, 2017)

"'Failure to enforce the individual mandate makes it far likelier that healthier, younger individuals will drop coverage and drive up the cost for everyone,' Chet Burrell, chief executive officer of CareFirst, said in a statement. The insurer is asking for an at least 50 percent increase in premiums in Maryland. Burrell said uncertainty over the mandate played a 'significant role' in the insurer's rate requests."

Evergreen Health Inc. (Preliminary Rate Justification for 2018 Individual Commercial Products, May 2017)

"The primary drivers of the components of the proposed rate increases are uncertainty in 2018 market morbidity as a result of potential regulatory changes such as repeal of CSR subsidies and individual mandate."

New Hampshire

Roger Sevigny, Commissioner of New Hampshire's Department of Insurance (*Concord Monitor*, May 16, 2017)

"There is significant uncertainty now about what the market environment is going to be in 2018 and beyond, including whether cost-sharing reductions will be fully funded by the federal government."

New Mexico

Martin Hickey, CEO of New Mexico Health Connections (Vox, May 8, 2017)

"Uncertainty breeds higher costs. We have to plan for the worst case scenario until it finally gets decided. We have a lot of things to focus on, we're grinding out hours over rates, and it doesn't help that people are running around with zombie bills."

North Carolina

Brad Wilson, CEO, Blue Cross Blue Shield of North Carolina (*Washington Post*, May 26, 2017)

- *"The failure of the administration and the House to bring certainty and clarity by funding CSRs has caused our company to file a 22.9 percent premium increase, rather than one that is materially lower. That will impact hundreds of thousands of North Carolinians."*
- *"We filed a 22.9 rate increase for 2018 based on the assumption that the CSRs will not be in place. The rate increase would be 8.8 percent if the CSRs were guaranteed for 2018. Because they are not, the rate is 22.9 percent."*

Brian Tajlili, Director of Actuarial and Pricing Services, Blue Cross Blue Shield of North Carolina (Blue Cross Blue Shield of North Carolina Blog May 25, 2017))

"[C]ost-sharing reductions have a big impact on North Carolinians. That became clear to our actuaries as we looked at proposed rates for 2018. If the federal funding continued, we would have filed an average increase of just 8.8 percent for 2018. That's a difference of almost 14 percentage points – similar to what's happening across the nation. A recent analysis by the Kaiser Family Foundation said that the average Silver plan premium would be 19 percent higher without cost-sharing reduction payments to insurers. If you look past the questions about cost-sharing reductions, you can see that the ACA market in North Carolina has become more stable. Blue Cross NC has a better handle on expected medical costs among ACA participants in our state, which include our company's 502,000 customers for 2017. An increase of 8.8 percent for next year would have been our lowest proposed rate increase since beginning ACA coverage in 2014."

Blue Cross Blue Shield of North Carolina (Actuarial Memorandum, 2018 Individual ACA Single Risk Pool Rate Filing, May 2017)

"We believe the Individual ACA market will contract in 2017 and 2018, and that this will have a deteriorating effect on the overall market risk. We believe this is the result of:

- *The elimination of Federal funding of CSR payments, which will significantly increase rates for many members that do not receive APTC premium subsidies. This will drive many healthier individuals to exit the market.*
- *Consistent messaging from Federal policymakers stating their intent to abolish the ACA coverage mandates. We believe this will embolden many healthier individuals to drop coverage, no longer fearing enforcement of the mandate penalty."*

Oregon

Pat Allen, Director of Oregon's Department of Consumer and Business Services (The Bulletin, May 16, 2017)

"There is not a continued worsening of the cost of the market. So there are a lot of factors that will argue for fairly stable rates."

Laura Cali Robison, Oregon Insurance Commissioner (The Bulletin, May 16, 2017)

"We know there are still many unknowns facing insurers and consumers as we look ahead to 2018. Now that the filings are in, we will begin our vigorous review to ensure the proposed rate changes, including the potential impact of various sources of uncertainty, are actuarially sound and justified."

Pennsylvania

Teresa Miller, Pennsylvania's State Insurance Commissioner, and the CEOs of Highmark, Geisinger, UPMC Health Plan, Independence Blue Cross, and Capital Blue Cross (Joint letter to Health and Human Services Secretary Tom Price, April 26, 2017)

- *"Despite these challenges [in prior years], working together over the past year, we have put our market on a path toward stability."*
- *"Specifically, the most immediate drivers of instability are the weakening of the individual mandate, the uncertain status of funding for the cost sharing reductions and the absence of funding for overall market stabilization measures."*
- *"The absence of certainty regarding market parameters, and in particular those with direct financial consequence, magnify the risks of market participation in a way that issuers and regulators cannot ignore."*

Tennessee

Julie Mix McPeak, Tennessee State Insurance Commissioner (*The Tennessean*, May 12, 2017)

- *"We're interacting with Congress. We're interacting with the Trump administration and you're hearing: 'It's HHS. It's (Office of Management and Budget). It's the Department of Justice. It's the president himself.' We don't know how to get our information, and at least the urgency of those funding mechanisms, to the right person that's making the decision. It's been hard for us."*
- *"I asked my colleagues at a meeting of insurance commissioners nationwide, and no one feels optimistic about the market if CSRs are not funded. We would prefer for funding of those cost-sharing reductions through '19. Again figuring out who gets to make that decision has been tough for us as regulators."*
- *"It's that instability, that uncertainty, the insurers hate the most. They are going to price for that."*

Blue Cross Blue Shield of Tennessee (Letter to State Insurance Commissioner, May 9, 2017):

- *"I'm pleased to report that, though still very early, our 2017 performance has improved due to a combination of better claims experience and a more sustainable rate structure based on the medical needs of the members we're serving."*
- *"Given the potential negative effects of federal legislative and/or regulatory changes, we believe it will be necessary to price-in those downside risks, even at the prospect of a higher-than-average margin for the short term, or until stability can be achieved. These risks include but are not limited to the elimination of Cost Sharing Reduction subsidies (CSRs), the removal of the individual mandate and the collection of the health insurer tax."*
- *"And, while we hope this is unnecessary, we reserve the right not to sign our QHP agreement in September in the event of any post-bid changes that destabilize the market and affect our risk exposure."*

Washington

Peter Adler, President of Molina Healthcare in Washington (*Los Angeles Times*, May 18, 2017)

"If the federal government's full CSR funding commitments are in jeopardy, we believe that the viability of the exchange market is in immediate jeopardy of failing."

Mike Kreidler, Washington State Insurance Commissioner (Statement, April 25, 2017)

"An analysis by my office projects that failure to approve the [cost sharing reduction] payments could cause individual health insurance rates to increase by 6 percent to 20 percent next year in Washington state. And the threat to withhold the payments adds to health insurers' concerns about the viability of the individual market and their future participation in it."

Association of Washington Health Plans and Mike Kreidler, Washington State Insurance Commissioner (Letter to Secretary Price, April 8, 2017)

- *"It is critical to maintain enforcement of the personal responsibility requirement in order to avoid premium increases and to ensure access to care for all residents. In Washington state, my office performed economic modeling based on actual purchasing data from 2016. This modeling predicts that weakening enforcement of the individual mandate will result in people abandoning coverage, especially younger, healthier individuals."*
- *Failure to secure ongoing funding of CSRs (rather than as an annual discretionary funding matter) results in uncertainty year after year regarding funding, compounded by the timing of appropriations decisions made long after issuers are required to file their rates for the upcoming year. Fully funding CSRs will continue to ensure affordable health coverage options for lower income enrollees and a stable marketplace for issuers."*

Comments from Major National Insurers

Carl McDonald, Senior Vice President at HCSC, Marketplace Insurer in Illinois, Montana, New Mexico, Oklahoma, and Texas (Axios, May 23, 2017)

"'We still would've been profitable [without one-time cost reductions for 2017],' said Carl McDonald, HCSC's divisional senior vice president of treasury and business development. 'It's really been the individual [market] business that's driven the turnaround this year.' ... McDonald would not say what the company was doing for 2018, as rate filing deadlines approach and uncertainty lingers around the ACA's cost-sharing subsidies for low-income people. 'At this point, it's hard to say,' he said."

Cathryn Donaldson, Spokesperson for America's Health Insurance Plans (*New York Times*, May 22, 2017)

"We need swift action and long-term certainty on this critical program [CSRs]. It is the single most destabilizing factor in the individual market, and millions of Americans could soon feel the impact of fewer choices, higher costs and reduced access to care."

National Association of Insurance Commissioners (Letter to Mick Mulvaney, May 17, 2017)

"On behalf of the nation's state insurance commissioners, the primary regulators of U.S. insurance markets, we write today to urge the Administration to continue full funding for the cost-sharing reduction payments for 2017 and make a commitment that such payments will continue, unless the law is changed. Your action is critical to the viability and stability of the individual health insurance markets in a significant number of states across the country."

Joseph Swedish, Chairman and CEO of Anthem BlueCross BlueShield (CNBC, April 26, 2017)

"We are notifying our states that if we do not have certainty that CSRs [cost-sharing reduction payments] will be funded for 2018 by early June, we will need to evaluate appropriate adjustments to our filing," Swedish said. Those adjustments could include resubmitting higher rates increases, "or exiting certain individual ACA-compliant markets altogether."

J. Mario Molina, then-CEO of Molina (Letter to congressional leadership, April 27, 2017)

"If the CSR [cost sharing reduction payments] is not funded, we will have no choice but to send a notice of default informing the government that we are dropping our contracts for their failure to pay premiums and seek to withdraw from the Marketplace immediately. That would result in about 650,000 to 700,000 people losing insurance coverage in 2017, and we would not participate in Marketplace in 2018 resulting in over 1 million Americans losing health insurance coverage."

*Mr. Thompson. I yield back the balance of my time.

*Chairman Brady. Thank you.

Ms. Jenkins, you are recognized.

*Ms. Jenkins. Thank you, Mr. Chairman.

And thank you, Secretary Price. We are so thrilled to see you back with us today.

In the fiscal year 2018 budget, it states that a goal of the Department will be to reduce burdensome regulations. And I want to thank you for stating that explicitly, because there are two burdensome and unnecessary regulations that folks in Kansas need help with as soon as possible. I know you are familiar with them from your time on our committee.

The first priority is to address a 2010 regulation issued by CMS, in compliance with the Affordable Care Act, that required outpatient therapeutic services to be directly supervised by physicians. While that may not sound so burdensome for many urban hospitals, the rule applied only to critical access hospitals, which serve rural communities. And these hospitals can't afford to keep a doctor on staff at all times. And many can't afford to have a doctor on staff more than a couple of days a week.

Kansas, as you know, has the most critical access hospitals of any state, and so suffers from the threat of this rule every year. In my district alone, there are 26 critical access hospitals struggling with this very regulation.

Since 2014 I have introduced a temporary bill every year, worked with members of both parties to gain enough support to place them on the suspension calendar, worked with Senators of both parties to get support for annual legislative fixes introduced there, as well. And every year a temporary fix is passed into law. But then the process starts all over again, come the next January.

Can you pledge to work with me to permanently fix this problem?

*Mr. Price. Well, thank you, Ms. Jenkins. And you and I have spoken about this before. I know the challenge that exists in rural America, especially in critical access hospitals. And our goal is to make certain that the patients are

able to receive the kind of care that they need in those hospitals in a timely fashion, with appropriate personnel.

And your issue is very, very pertinent, and we are in the process of looking at it, as we speak.

*Ms. Jenkins. Thank you. We will look forward to working with you on that.

The second issue relates to the many hospital-based nursing programs that provide accredited training for nurses. Several years ago, and without warning, CMS changed the standards for those programs to receive funding on a pass-through basis. And the new standard presents a Catch-22 that does not allow them to remain accredited if they want to receive the funding from CMS.

In my congressional district alone, this leaves Stormont Vail Hospital and Baker School of Nursing in a difficult position. Again, will you just work with us to address that issue, as well?

*Mr. Price. Absolutely.

*Ms. Jenkins. Thank you, Mr. Secretary. I really appreciate your understanding of these priorities in the limited time given to discuss them with you today. I really looking forward to working with you on these and other issues.

And, Mr. Chairman, with that I would yield back.

*Chairman Brady. Thank you.

Mr. Larson, you are recognized.

*Mr. Larson. Thank you, Mr. Chairman. Mr. Chairman, I want to associate myself with the remarks of Mr. Thompson. And in -- specifically, the information that he submitted for the record. I think it is long overdue that the committee focus on what is imperiling Americans, as we speak.

The CBO report confirms that 23 million -- 23 million of your fellow Americans -- families, children -- they are going to be without insurance And the bill that passed the House was ram-rodded through, now appears that it was over in the Senate, and they put together a committee of 13, I guess, and Patty Murray and Bill Cassidy have a bill of their own that they are working on, and 23 million Americans are going to be without any coverage. And there is

nobody that seems to pretty much care about them, because it is too important to make political points at a time when they go to sleep every night wondering whether or not they are going to have care that they need.

People with pre-existing conditions, you talk about death spirals, it is our fellow citizens that look to their government to make a decision and to help them through this process.

It is agonizing to sit in a committee, to know where you have very little input, and to see a bill travel over to the House that, again, for political theater, is going to go through a great kabuki dance, and ultimately end up maybe -- maybe not, though Mitch McConnell has said today that they are going to use some kind of marshal law, whatever change in the rules they need in the Senate to bring to the Senate -- again, without hearing -- a bill that they will pass or not pass. Twenty-three million Americans will continue to suffer while Congress fiddles and diddles.

It is long overdue that we sat down and worked together. Yes, I think this side has admitted several times there were many flaws within the Affordable Care Act, but nothing that couldn't be fixed or repaired, along the lines of what the state of Massachusetts had where they put together a health care program by a Republican governor named Romney, and were able to work out the details of a philosophical plan instituted by the Heritage Foundation. It is long overdue that we work together on behalf of the 23 million Americans who will lose their insurance.

*Chairman Brady. Thank you.

Mr. Paulsen, you are recognized.

*Mr. Paulsen. Thank you, Mr. Chairman and Dr. Price. I want to welcome you back to the committee today.

Dr. Price, as you know, my home state of Minnesota has a long history of being on the cutting edge of a lot of medical innovation. That is certainly true today. During the last year I have had the opportunity to visit with several companies in Minnesota who are at the forefront of integrating technological advancements into health care delivery.

One of those companies is Zipnosis, that uses software as a service. They have become a disruptor in the telemedicine space by creating an online adaptive interview platform that improves patient outcomes and then drives down costs.

Another company I went to, NOVO Health, is using data-driven health incentives to help keep patients engaged in living a healthy lifestyle that reduces a -- long-term health complications.

And I also visited with another new start-up called Gravie, Incorporated, which is building tailored benefits packages that employers and employees actually want to use.

So these are three different companies doing very different things in the health care space. But what they have in common are two things: first, they are all harnessing that power of technology and innovation to build a better health care delivery model that has the potential to provide better outcomes for patients, and at the same time drive down costs. And then, secondly, during my visits with each of them, they all highlighted current regulatory barriers that have stood in the way of their progress.

So, Dr. Price, you know, what are some of the things that you think HHS will now be working on specifically in the innovation space to create that regulatory environment that protects patients and taxpayer resources, but also allows innovative companies like Zipnosis and NOVO Health and Gravie to thrive?

*Mr. Price. This is an incredibly important issue, because when I have talked to my former medical colleagues about the cutting-edge kinds of things that are out there, many of them will actually say that they no longer look to the United States companies to see what is actually pushing the envelope. They are looking to companies overseas because of the kind of regulatory barriers that are in place, or have been put in place, most often by the Federal Government.

So I am so thrilled that Scott Gottlieb has been confirmed at the FDA, because you know FDA is the entity that looks at so many of these devices and innovations and provides for a streamlined fashion for them to come to market. The President has charged him with -- absolutely committed to having an accelerated pace to get safe devices, safe innovations to market, so that patients are able to benefit.

But there are regulatory hurdles, there are hurdles in terms of reporting requirements, there are hurdles in terms of just the timeline that it takes to be able to put in place, say, a proposal and gain the feedback that is necessary from the Federal Government. We are going to do all that we can to make certain that the United States once again becomes the leader in the world when it comes to medical innovation.

*Mr. Paulsen. Thank you, Dr. Price.

*Chairman Brady. Thank you.

Mr. Blumenauer, you are recognized.

*Mr. Blumenauer. Thank you, Mr. Chairman.

Welcome back, Tom.

*Mr. Price. Thank you.

*Mr. Blumenauer. After having shared the dais with you for these many years, I look forward to a more robust give-and-take. I am sorry there was only time in your schedule to allow three minutes per member.

So I will just say something, because I am hopeful that there is an opportunity for some introspection because of your different role today. You are an appointee of a president who has vowed to destroy the ACA, and who has espoused a world health care view diametrically opposed to the independent experts, and indeed, most of the people in the health care community who appear before this Committee.

From the beginning of this Administration, the effort has been to increase the instability and make the ACA fail. Of course, since the Republicans controlled this Committee, there was never an effort to refine or fix relatively minor items that would have made its operation smoother. You could have given certainty to insurers, expanding the reinsurance program, not removing it. You could have expanded the cost-sharing subsidies or tax credits to help low-income individuals who were too poor to get the subsidy. Or you could have tackled the issue of high-cost prescription drugs, where the President has opened the window, that would continue to drive up health care costs.

All of these things could have been bipartisan measures that we could have talked about today.

When the President assumed office, his first action was to accelerate the uncertainty facing the health care industry with an executive order directing federal agencies to undermine the regulations. Indeed, the mandate -- which, as we all know, was a Republican idea that was incorporated into the ACA. You directed the Internal Revenue Service to stop enforcing the requirement to have

insurance. They could have stopped sending refunds to taxpayers if they failed to provide proof of insurance. You signaled no.

The Department cut advertising by 75 percent for television, canceled all digital advertising for ACA enrollment, leading, in some estimates, to a half-million fewer Americans getting coverage, which added to the instability.

There are further uncertainties about whether the President and your Department are going to continue to make key payments that are necessary to make sure the law functions as planned, providing subsidies on which millions of Americans depend. And this fuels uncertainty with insurance companies. And you can read their quotations in the papers this week.

I would hope that your new rule, with a responsibility for the overwhelming majority of people who want the system to continue and want it improved, that you could reflect on the possibility that you could actually enforce the law. You could promote it. You could work to not to actively undermine it.

I would hope that the Administration wouldn't be gleeful, but be sobered by millions of Americans who benefitted and relied on this program. I would hope that you would listen to the independent voices the doctors, the nurses, the hospitals, the insurance industry who rely on the Affordable Care Act and try and make it work.

You, after all, as a physician -- and you paraphrased the Hippocratic Oath when you -- repeatedly, when you were a member of this Committee, "First, do no harm." And you are in a position to not do further harm, as we work together, until and unless we get the Nirvana that the President has talked about, better health insurance, lower cost, and more people covered. There is nothing in the horizon that is going to do that. And unless and until we get it, we would hope that you would work with us to make the ACA work.

Thank you for your courtesy.

*Mr. Price. Thank you.

*Chairman Brady. Thank you.

Mr. Marchant, you are recognized.

*Mr. Marchant. Thank you, Mr. Chairman.

Good to see you, Mr. Secretary.

*Mr. Price. Good to see you, sir.

*Mr. Marchant. In September in Texas we had -- September the 1st, 2016, the CMS issued a notice to our Health and Human Services Commission that they were disallowing $26.8 million of federal payments under the 11-15 Medicaid waiver uncompensated pool payments.

This affects two main hospitals that I represent in Tarrant and Dallas County. Now there is some belief that this was an indirect punishment for Texas not expanding its Medicaid base under Obamacare. Can you tell me what the status of those reimbursements are? Can you tell me what the policy is going to be, going forward? And is there any hope that Texas will be able to change that interpretation?

*Mr. Price. Yes, Mr. Marchant. I think you know that there are ongoing discussions and conversations between the State of Texas and CMS about that waiver. And I had a conversation with the CMS administrator as recently as yesterday about this. So I am hopeful that we will be able to reach a conclusion.

*Mr. Marchant. Okay. Thank you very much.

Another thing is that Mr. Blumenauer and I are working together on some legislation that pertains to the home health documentation program, improvement -- it is called the Home Health Documentation Program Improvement Act, and it basically allows for the doctor's records to go with the patient when the evaluation is done to consider whether home health is appropriate or not.

I would like to get your comments on that particular approach to home health services.

*Mr. Price. Well, I think in this area and in all areas the more opportunity that we provide for patients to have access and control of their records, so that there is a seamless transition from caregiver to caregiver, and it is the patient that is selecting that caregiver, then the more efficient it is for the patient. We would decrease redundancies, duplications, tests, studies, costs in the system.

And so there is a lot of merit, we believe to having the patient have control of those records.

*Mr. Marchant. Thank you, Mr. Secretary.

I yield back.

*Chairman Brady. Thank you.

Mr. Kind, you are recognized.

*Mr. Kind. Thank you, Mr. Chairman.

Mr. Secretary, it is great to have you back to the committee.

*Mr. Price. Thank you, sir.

*Mr. Kind. The HHS budget calls for eliminating almost all of Wisconsin's federal rural health funding, including nearly a 50 percent funding cut to the rural health program, zeroing out funding for the Medicare rural hospital flexibility program, the Flex Program, small rural hospital improvement grant program, the SHIP program, the State Office of Rural Health Grants.

Together, these programs bring over a million-and-a-half into Wisconsin every year for rural health care activities and support. The SHIP program alone sends over half-a-million every year to rural hospitals throughout the state for quality improvement projects.

The Flex Program provides funding for quality improvement projects done in collaboration with Wisconsin Hospital Association, the Rural Wisconsin Health Cooperative, the American Heart Association, and many others. It also provides funding for in-depth financial analysis for rural hospitals, creating revenue, cycle recommendations, and follow-up support.

Finally, the State Office program creates the Wisconsin Office of Rural Health, allowing for the hosting and implementation of these grant programs, as well as provide physician recruiting, rural health newsfeed, a host of data, maps, other resources for rural health care and communities. And, according to a recent study done by the National Rural Health Association, nearly one in three rural hospitals are at risk of closure, due to proposed Medicare cuts and over $800 billion reduction in funding to Medicaid, our BadgerCare program.

I can certainly see Mick Mulvaney's fingerprints at OMB all over this. I have a hard time believing that your agency at HHS would embrace this declaration of war against a rural district such as mine and throughout our country. I look

forward to working with you at HHS to make sure that rural health has a place at the table.

I think there is great bipartisan support, making sure that we have got a voice, we have got a seat, and that these issues are concerned (sic). Because you know -- and given the district you formerly represented -- unless you have a strong, stable rural health care provider, it is impossible to retain and recruit the businesses and the good-paying jobs in those communities. These are often the anchors of community support, and the vibrancy of any rural community.

And so, rural health needs to be, I think, addressed in a specific way, given the unique and specific challenges that are placed in that area. I am especially troubled with what is moving through this Congress right now under the guise of health care reform: a $900 billion tax cut for the most wealthy, and to insurance companies, and to drug companies under the disguise of health care reform, cutting drastically Medicaid funding, increasing price discrimination against older Americans in rural areas such as mine, potentially allowing insurance companies to once again discriminate against individuals with pre-existing conditions.

There are opportunities for us to work together to improve what isn't working in the health care system. I would hope that we have an opportunity to retrench and take another run at the health care system. We can do so in a more collaborative and bipartisan basis than what has been worked on over the last few months.

Thanks for coming.

*Mr. Price. Thank you.

*Mr. Kind. Mr. Chairman, I yield back.

*Chairman Brady. Thank you.

Mr. Kelly, you are recognized.

*Mr. Kelly. Thank you, Chairman.

Dr. Price, always good to see you.

*Mr. Price. Great to see you, too.

*Mr. Kelly. If you could, I -- and I don't want to get too deep into this, but just to clarify things, could you address this fact, or this idea that somehow 23 million people are going to lose their insurance? The big factor there is people are going to be able to choose, not that they are going to lose, but they are going to be able to choose, right?

So these numbers that we keep throwing out there, kind of very scary to hear that, to think that somebody would be so cruel as to keep 24 million people from getting insurance, or 23 million -- the number just seems to go up and down, depending on who you are talking to, and what time of the day it is. Isn't the reality of it they are going to make a choice, and they may choose, because they don't have the individual mandate, just not to do it?

*Mr. Price. Yes, a couple points, and I appreciate the opportunity.

It is first important to understand and appreciate that there are 20 million Americans right now who don't have health coverage, 20 million Americans right now don't have health coverage under the plan that was supposed to make certain that everybody had health coverage. Now, they don't have health coverage because either they said, "No thanks, and we so disagree with what we are supposed to buy or mandated by the government to buy that we are willing to pay a penalty, pay a fine for that," or they have gotten a waiver.

But that ought to tell us is that we are not selling what they want to buy. And so, the individuals that the CBO cites are individuals that may not be covered under the current rubric, under the current plan, but that doesn't mean that they won't be covered, because our goal is to make certain that every single American has health coverage. But it is health coverage that they want to purchase for themselves and for their family, not that the government forces them to buy.

So the CBO, they have got a tough job, because what they are looking at is something in isolation. They are not looking at the entire plan and proposal that has been put forward. If you look at the entire plan, then again, our goal is to make certain that every single American -- we want to gain 100 percent coverage for individuals. But the only way that you do that is you make it so that individuals are able to select the coverage that they want.

*Mr. Kelly. Yes, and I can appreciate -- you know, you and I have talked many years about this. And because of where you are from, and what you do, and what your life was all about -- not only you, but also your wife.

You know, one of the other things, just wanted to talk real briefly, because we do have legislation would address this -- it is the benchcap -- or the benchmark cap in Medicare Advantage that is part of the Obamacare program, and it has caused a lot of seniors in my district and districts all over the country -- this problem goes -- it goes against the widely-shared goal of paying for quality.

Now, Mr. Kind and I have some legislation that addresses that. But I remember you and I would talk about these things and it got to the point -- it was how much will it take to fix this problem. And it always comes down to just a little more money. Not a little more money well spent, but just a little more money. And I think that, from time to time, we think that throwing dollars at a problem is the answer. But there are ways of addressing these inequities.

You have always had such a positive approach to it. So I am looking forward to actually working with somebody who understands that these are business models at the end of the day that have to be sustainable, not aspirational. That people can believe that they -- when they have health care coverage, they are going to have health care coverage.

I just think we have done a disservice to the citizens of the United States, making them think that somehow they are losing something because of hard-hearted or evil-minded people that are trying to do something that is truly sustainable, and not a promise we can't keep.

*Chairman Brady. Thank you.

*Mr. Kelly. Thank you, Doctor.

*Chairman Brady. All time has expired.

*Mr. Kelly. I am looking forward to working with you.

*Chairman Brady. Mr. Pascrell, you are recognized.

*Mr. Pascrell. This is a terrible business model. I will take your turn.

Dr. Price, welcome.

*Mr. Price. Thank you, sir.

*Mr. Pascrell. Many Americans would agree that this Administration has a lot of explaining to do when it comes to this budget.

As the co-chair and the co-founder of the Congressional Brain Injury Task Force -- and I take this issue because it is not billions of dollars we are talking about here, but it really reflects the nonsense throughout this budget.

For the past 17 years, the federal traumatic brain injury state grant program supported state efforts to address the needs of persons with brain injury. It has helped expand and improve services to under-served and served populations, including young people, veterans, and returning troops, and individuals with co-occurring conditions.

It was a $9 million program, a drop in the bucket, we would all agree. With 9 million this program was able to support only 18 of the States of the Union, meaning that with that level of funding we weren't coming close to reaching everyone in need. The Trump budget cut this program by two-thirds. If that isn't malfeasance in office, I don't know what is. We are only sticking with small stuff, though. I will get to the big stuff, if I have time.

Beyond problems associated combining three very different programs into one, this is their solution to the program. The last speaker talked about there is other ways, you just don't throw money at the -- we all know that, we are not stupid, we are not infantiles. We know you don't just throw money at the problem to solve it. But this was a tried and accomplished program that worked. It worked with our troops. How do you think states can meet the needs of everyone in the programs that have been cut? Let the states handle it? Where are they going to get the money? We will use our initiative.

Well, on page seven of the CBO report, it says this -- we are talking about waivers you talked about before -- one-sixth of the population live in states that will seek waivers from both a community rating and essential health benefits protections of the ACA. In these states, "less healthy individuals would face extremely high premiums." Too bad. And, over time, "would be unable to purchase comprehensive coverage with premiums close to those under current law, and might not be able to purchase coverage at all."

So, let's look to maternity. I mean you can't believe this. Everything is wonderful, everything is coming up roses. "Insurance would expect" -- oh, this is right from the CBO.

*Chairman Brady. All time being expired.

*Mr. Pascrell. Yes, you better believe the time is expired.

*Chairman Brady. We will go to two-to-one questioning. Mr. Renacci, you are recognized.

*Mr. Renacci. Thank you, Mr. Chairman, and thank you, Dr. Price. I remember calling you friend on the phone before I was elected, and then colleague, and then chairman, and now Secretary. So I applaud you being here.

*Mr. Price. Thank you.

*Mr. Renacci. And I appreciate your perspective when it comes to the budget. You were the budget chairman, as well. You know, with the greatest threat to our country is our national debt, you knew that when you were on the budget committee, so I applaud the budget that you have tried to put out there. It is not perfect, but it is a good starting point.

But we talk about the greatest threat -- and I have heard this from my colleagues -- the greatest threat to our country is our national debt. Today, justfacts.com reports that our national debt today is $61,000 per every citizen in the United States, 157,000 per every family. That is the threat that we have to worry about.

And we also had the Controller General come before the Budget Committee and say that our spending is unsustainable, and Medicaid expansion is part of that, is unsustainable. So I applaud what we are trying to do.

Also, I heard one of my colleagues talk about pre-existing conditions, and I want to just throw this out. There was a fact check, Washington Post. Four pinocchios that says pre-existing conditions could deny people coverage under the GOP health care. So that comment came out. I just want to respond to that.

I want to flip back, though, to the opioid crisis, which I do think is a serious issue. You know, Cleveland Clinic CEO Toby Cosgrove put the crisis in perspective when he said to me, "During the Vietnam War, 53,000 people died. And just last year 53,000 people died from the opioid overdoses -- essentially, the same amount of losses we had in Vietnam. The only difference is that we don't see the body bags coming home." So it is an issue, and it is a problem.

Back home in Ohio -- and Ohio, of course, is the number-one state in the country for opioid overdose and abuse, which I am not proud of, and it is one of

the things we have to change in Ohio. It is not about attorneys, it is not about policies, it is not about lawsuits. It is about people.

So I have met with countless constituents in the state of Ohio, and I have met with addicts to find out what their concerns are, why this is happening. And they tell me, look, there is a feeling of hopelessness, a feeling of not being able to, you know, feel like they are worth anything. And we got to look to that. It is not a lawsuit, it is about them.

And I want to get back to your testimony. You state that the current law prevents states from prioritizing federal resources to the most vulnerable populations, and that states are also limited in testing new ideas that will improve access to care and health outcomes. Knowing that tackling this crisis is a priority to you and President Trump, can you discuss maybe some of the current federal regulations that may hinder the states' ability to address the current opioid epidemic?

*Mr. Price. Yes, we have traveled around the country, as well, and to the state of Ohio also in this, to try to address this crisis. And one of the first impressions that I have gotten from visiting with addicts, with former addicts, with law enforcement, with local officials, with moms and dads and family members who have had folks who have died from overdoses is that feeling of hopelessness, yes, but also that the solutions are local solutions, that when communities come together and are able to rally around and lift folks up and help individuals regain that hopefulness, that that is one of the keys. And that is what we are trying to do, is to identify those evidence-based areas that are actually solving this problem, so that we can turn the corner.

*Mr. Renacci. Thank you.

*Chairman Brady. Thank you.

Mrs. Noem, you are recognized.

*Mrs. Noem. Thank you, Mr. Chairman. And thank you, Mr. Secretary, for being with us today.

*Mr. Price. Thank you.

*Mrs. Noem. You know, I appreciate your willingness to take on a leadership role in a Department that is impacting every single American's lives today, and we really need your help.

I want to ask you specifically for help with Indian Health Services, because they are failing our Native American Tribes. And in South Dakota we have third-world-country delivery of health care. And even though we have a new Administration, we haven't seen changes out of that department. And we need to fix it, and it starts with leadership within the agency. And I would love to have a longer conversation with you about that.

In fact, I am going to submit some questions for the record, if you would. And if you would answer those for me, that would be great, because I wanted to talk to you about health care today in a broader perspective. And because I want to associate myself with the comments of Representative Jenkins and Representative Smith on the struggle that we have in rural America and delivering health care, and making sure that services are there.

And we have heard the other side of the aisle talk today about the fact that Republicans are to blame for increased health care costs this summer, that Republicans are to blame for individuals who are not covered under health care. And we know, when you talk about coverage, that doesn't necessarily mean access. I talk to South Dakotans every single day that, under Obamacare, maybe have a policy, but they can't use it because their deductibles are so high they have no access to those health care opportunities in front of them.

So, I would like you to discuss, first of all -- and clarify the record of what we have heard here today. We are operating under current law and the challenges that we faced delivering health care to individuals out there and who are struggling. And if the legislation that we pass through this Committee was put into place, and we repealed the mandates, repealed the taxes, gave some new opportunities for the marketplace, how that would change our perspective and our opportunities in the future, I would just love to hear you -- because you have the experience, now you are in a different role today, you are sitting in a different chair -- tell me about the changes that we could see if we did health care reform and signed it into law.

*Mr. Price. Well, I think it is important -- and thank you for that, because I think it is important to think about what the mission is, what are the goals. And the goals are, again, to make certain that every single American has access to the kind of coverage that they want for themselves and for their families.

So, through the series of subsidies, tax credits, whatever you want to call them, we want to make certain that each American has the financial feasibility to be able to, one, purchase that coverage. Two, to be able to purchase coverage that they want, not that the government forces them to buy, so that what the Federal

Government says is right for one person may not be right for another person. And it is so important, because health care is absolutely unique to each and every individual.

So the kind of concerns that individuals have and the fear that they have about getting sick and not being able to afford coverage, we need to take that away. The opportunity that we have to provide that kind of reassurance to the American people through a system that allows for that coverage is so incredibly important, and that is our goal.

*Mrs. Noem. One of the Democrat members of the Committee stated here today that the high cost increases that we are going to see this summer are to blame because of Republicans. Would you blame that on Republicans or current law?

*Mr. Price. Well, the current law, as we demonstrated through the Department, has shown doubling of premiums and significant increases in the deductibles, which make it -- as you have said, many people have coverage but no care.

*Chairman Brady. The time is expired.

Mr. Crowley, you are recognized.

*Mr. Crowley. Thank you, Mr. Chairman.

We have very little limited time, Mr. Secretary, thank you for being here.

*Mr. Price. Thank you, Joe.

*Mr. Crowley. Welcome back to the Committee. Mr. Secretary, did you stand by the President's budget that he submitted to Congress for 2018?

*Mr. Price. The portion that I have available to me to have input into is the HHS budget, and I stand by that budget.

*Mr. Crowley. I suppose that is a form of honest loyalty. I appreciate your response.

But, Mr. Secretary, as you have heard so far, there is a lot of elements in the HHS budget that are very concerning to us and to our constituents, such as the deep cuts in Medicaid and Social Security and some of the other programs. These cuts reflect a troubling lack of concern for the real and

significant difference that these federal programs make in the lives of working Americans.

For example, when the budget proposed cutting heating assistance, the Administration said it was to "reduce the size and scope of the Federal Government." Well, I am sure that explanation will be comforting to the families in my district who struggle with high heating bills and very cold winters.

A budget is a statement of priorities. The priorities in this budget are simply wrong. Cuts for the sake of cuts are wrong.

And one area in particular that highlights this is the social services block grants. That is the programs that service vulnerable populations like frail seniors, at-risk youth, and working families. It funds Meals on Wheels programs. In some cases, it is the sole support for those programs. It funds adult protective services, so that seniors can continue to live in their homes, free from the fear of abuse, neglect, and exploitation, and not have to move into a nursing home and burden their working children. It funds child abuse interventions, keeping children safe.

That is the program you are eliminating, and the -- part of the budget that you support. I suspect that your former constituents back in Georgia six would be very disappointed and understanding that that portion, which comes under HHS, the portion that you are supporting of the budget the President has proposed, that is in this budget.

What really gets me is that this program for years has had bipartisan support. It was applauded as a model of "flexibility for states." Even former Ways and Means Chairman Dave Camp was one of the champions of SSBG, saying that, "SSBG has been a key source of flexible funding for critical social services." And now it is being eliminated because it is somehow too flexible?

That is particularly concerning when you are also talking about block-granting programs like Medicaid, because it is not just SSBG. We have a chart, and I would like to put it up on the screen.

[Chart]

*Mr. Crowley. Let's make reference to it. Heating assistance that helps over six million families a year eliminated. The community development block grant, helped at least 12 million people a year, has been eliminated under the

budget that you support. SSBG, funding -- funded services to 30 million people, including about 2 million seniors, is eliminated. The community service block grant served 15.6 million individuals, 37 percent of whom were in children and 21 percent seniors. They are eliminated under the portion of the budget that you support.

I dare say that if that budget were put before the Congress tomorrow, more than half of your colleagues on the other side of the aisle would vote against it.

I yield back the balance of my time.

*Chairman Brady. Thank you.

Mr. Holding, you are recognized.

*Mr. Holding. Thank you, Mr. Chairman.

Secretary Price, what a privilege to have you back here.

*Mr. Price. An honor.

*Mr. Holding. Albeit on the other side of the table there. I want to personally thank you for your response to my letter that I received recently with respect to FDA's deeming regulation, I am looking forward to continuing to work with you and your very able staff on that issue.

Shifting gears, I see in your Department's report on the individual market premium changes that in North Carolina the average annual premium cost increased from $2,800 in 2013 to almost 8,000 in 2017. So, obviously, in just four years, premiums in my state have almost tripled. And currently, 95 of North Carolina's 100 counties have only a single insurer in the ACA marketplace.

So my question to you, Secretary Price, is what actions in your Department were you taking to provide certainty to North Carolinians and insurers that North Carolina will have a viable insurance marketplace in the future?

*Mr. Price. Well, thank you, Mr. Holding. The truth of the matter is that there needs to be a change in the law. The current law is what has resulted in what we see right now, with doubling of the premiums, with individuals having deductibles that are unaffordable. You have three states where the premiums have tripled. You have got insurers vacating the market, almost by the

day. And the challenges that most of them note have occurred from 2013 to 2017.

So, what we are trying to do is to make certain that the opportunities that individuals have out there are ones that will allow them to get the kind of coverage that they want.

Earlier this spring, we put forward a market stabilization rule to try to make certain that insurers and states had greater opportunity to keep insurers in the market through the special enrollment periods and the grace periods for the purchase of coverage, to allow the states to be the ones that are defining what a qualified health plan is.

We sent letters to every single governor of the state about 1332 waivers to make certain that they knew they had other options in the area of the individual and small-group market, and 1115 waivers that let them know that they have more opportunities in the area of Medicaid coverage.

So what we are trying to do is to work under the current construct. But the fact of the matter is that the current construct is broken, and it needs to be fixed. And the only way to fix that robustly is through a change in the legislation.

*Mr. Holding. Thank you, Mr. Secretary.

Mr. Chairman, I yield back.

*Chairman Brady. Thank you.

Mr. Crowley?

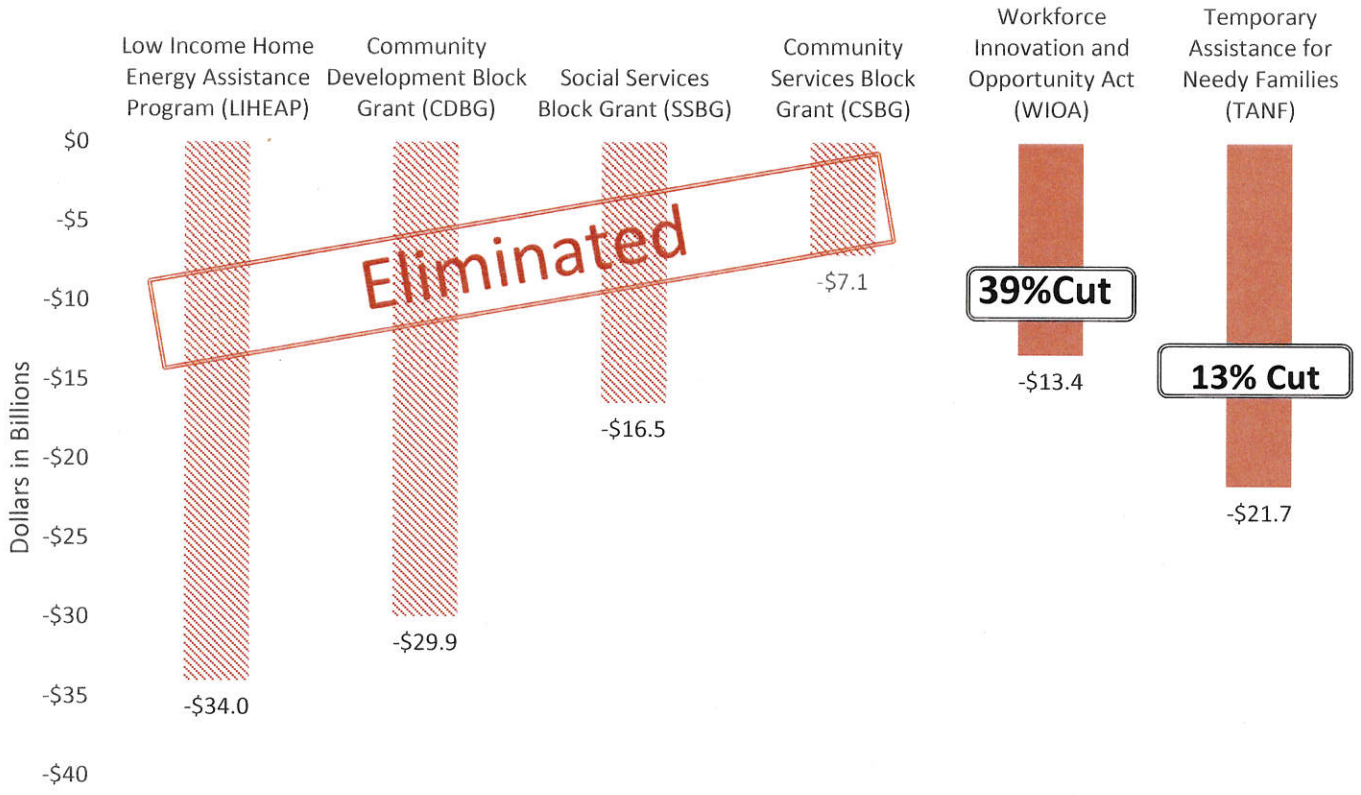
*Mr. Crowley. Mr. Chairman, I would ask unanimous consent to include in the record the chart that was previously displayed during my series of questioning of the Secretary.

*Chairman Brady. Yes, without objection.

Crowley SFR

Treatment of Major Block Grants in Trump Budget

Proposed Budget Cuts Over 10 years



Note: As compared to continued funding at FY2017 levels.

Prepared by the Democratic Staff of the Committee on Ways and Means 5/23/17

*Mr. Crowley. Thank you.

*Chairman Brady. Dr. Davis, you are recognized.

*Mr. Davis. Thank you, Mr. Chairman.

Thank you, Mr. Secretary. Welcome back. As you know, 184 Members of Congress from both sides of the aisle sent you a letter last week. I signed the letters, as did nine of my colleagues here on the Ways and Means Committee. The letter expresses concern over a 2014 rule issued by the Centers for Medicare and Medicaid Services on the topic of charitable premium assistance for plans in the Affordable Medical Care Act.

The interim guidance is highly ambiguous and unclear, and some insurers have interpreted it as being a license to refuse all charitable premium payments for all insurance products, including MediGap, for certain high-cost patients, such as people with end-stage renal disease.

In the letter we urge you to issue a new rule that adds the following to the existing list of entities from which premium and cost-sharing assistance is required to be accepted: bona fide non-profit charitable organizations; places of worship; local civic organizations, who are equally important, of course. Those charitable premium assistance programs must ensure that patients are empowered to select the plan that works best for their needs, based on the patient's own health and financial considerations.

Could you answer that in writing for us?

*Mr. Price. Yes, sir.

*Mr. Davis. And then, Mr. Chairman, I have been glad to see President Trump's -- acknowledge what a challenge child care is for working parents. But I see that your budget cuts support for child care by over $400 million a year. When you take into account all the different cuts to programs states use to support child care, even without those cuts you are projecting, that was in five years the number of children served will reach a record low.

We can do better for working parents and for children, and I hope that President Trump will stand behind what he said about child care, including reconsidering those cuts.

*Chairman Brady. Thank you.

Mrs. Black, you are recognized.

*Mrs. Black. Thank you, Mr. Chairman.

And again, welcome, Mr Secretary. It is so good to have you back here with us. I want to talk about the IPAB, the Independent Payment Advisory Board. It is projected to kick in as soon as this year, and I know that members of the Committee and also the American public are really deeply concerned about the idea of a board of bureaucrats who will have that sole purpose to cut the payments to health care providers for our senior citizens.

So, to be clear, their job is cutting seniors' access to health care, if it were to go into effect. In the absence of there being someone appointed to this IPAB at this particular point in time by either President Obama or President Trump, who would make those decisions in the IPAB without those bureaucrats already being assigned?

*Mr. Price. Under the current law, that responsibility falls to the Secretary.

*Mrs. Black. So that would be you --

*Mr. Price. That would be me.

*Mrs. Black. -- obviously, to make those decisions. Are there some thoughts about what you would have us do? Would you like us to get to work to repeal this, or -- what is your opinion on that?

*Mr. Price. The budget reflects an ending of the IPAB program.

*Mrs. Black. So that would be a good thing for our seniors, and I hope they are listening to know that we are well aware that this will hurt our seniors if it does go into effect.

The second thing that I would like to ask you really quickly is the area wage index that we have talked about before. But I want to especially talk about those rural hospitals in Tennessee and all throughout the United States, really, that are unfairly being reimbursed at lower rates with a flawed formula.

And when the formula was originally put into place, it reflected that an average rate of one would be what would be given, but there is not a single hospital in the states of Tennessee, Alabama, Georgia, Ohio, Texas, South Carolina, Louisiana, Kentucky, Arkansas, Iowa, Kansas, Missouri, or Utah that are either

at or above that "average level," which is very concerning, and really hurting us, especially in those rural hospitals.

So, I am looking forward to working with you and others in your staff to try to find a way to make this more equitable, so that those hospitals that are in -- doing a good job, and they are really trying to keep the cost down, and, in actuality, they are being punished because they are doing such a good job.

And so, rural hospitals, as you well know, are just so important in our districts. In my district I have a lot of them. And the thought that they are going to be closing down and leave people in those areas without any care is very concerning. So I hope that we can address this as soon as possible.

*Mr. Price. I look forward to that.

*Mrs. Black. Thank you.

*Mr. Price. Thank you.

*Mrs. Black. I yield back.

*Chairman Brady. Thank you.

Mr. Higgins, you are recognized.

*Mr. Higgins. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. I just want to talk about the Medicare Advantage program. Seventeen million, or a third of the Medicare population, is enrolled in Medicare Advantage programs. United Healthcare is a major player in this market, with 20 percent of the Medicare Advantage population, or over 3.5 million people. Are you familiar with the American Health Care Act, page 67, where private insurance companies can claim executive compensation as a business deduction from their federal taxes?

*Mr. Price. Not specifically, no.

*Mr. Higgins. Well, it is there. The Chief Executive Officer of United Healthcare was compensated $66 million in 2014. This provision of the bill that passed this Committee and the House will give United Healthcare executives a $15.5 million tax cut.

Are you familiar with the fact that three weeks ago the United States Department of Justice joined a lawsuit against United Healthcare for defrauding the Medicare Advantage program out of billions of dollars each year over the past seven years?

*Mr. Price. What I can say is that we have increased the amount of resources available for program integrity to try to keep those kinds of things from happening, if, in fact, that did occur.

*Mr. Higgins. Mr. Secretary, this is serious allegations of fraud out of a program that is administered out of your Department.

*Mr. Price. That is precisely why we have increased resources, so that program integrity can increase.

*Mr. Higgins. Well, what happened -- well, does this concern you, that we are providing, within the context of health care reform, a massive tax cut for a company that is under investigation for defrauding the American taxpayers out of, potentially, hundreds of millions of dollars, and, likely, billions of dollars each year?

*Mr. Price. As I said, the Department is absolutely committed to program integrity, and we have provided increasing resources, because it is one of the areas, actually, that allows for a significant return on that investment, if you will.

*Mr. Higgins. Well, claiming back my time, don't you think that, while this investigation is being carried out by the United States Department of Justice, that provision of the health care bill should be excluded, and this bill, the overall bill, should be voted on again, giving Members who have a sense of decency and fairness to vote on a bill that excludes a provision to give a massive tax cut to a company that is alleged to have defrauded the American people and the Medicare Advantage program out of hundreds of millions of dollars a year?

*Mr. Price. I will leave to the House the opportunity to take care of the legislation that they deal with.

*Chairman Brady. The time has expired. Thank you.

Mr. Rice, you are recognized.

*Mr. Rice. Thank you, Mr. Chairman, and thank you, Secretary Price, for appearing in front of us. I applaud your intelligence and your dedication to the people of the United States. I know you have been to my district and you have seen the medical care providers and you have seen the people, and you recognize the needs in our district -- in my district.

In South Carolina, where I am from, Georgia, where you are from, really not that dissimilar. I have a lot of rural communities, rural hospitals, and, you know, we will never get the cost of health insurance in line if we can't rein in the cost of health care. And one of the ways to do that is through telemedicine.

You know, these rural areas are connected to more sophisticated medical providers through telemedicine. And, in fact, in 2016 the South Carolina Telehealth Alliance conducted 135,000 patient interactions across almost 300 sites across the state. The Alliance uses telehealth in emergency rooms, patients' homes, clinicians' offices, correctional facilities, nursing homes, and schools to treat everything from a sore throat to a stroke.

In 2010, nearly 40 percent of stroke victims in my district had to be transferred to Charleston for treatment. Through the use of telestroke services, that percentage has dropped to 15.

So what I want to know is where are you on telemedicine, and what can we do to partner with the Administration to make sure that this procedure is used responsibly to both provide better care at a better cost?

*Mr. Price. Yes, this gets to the dynamism of health care, and the kinds of things that can occur to help patients in so many, many ways, especially in rural areas. So many questions about rural health care. Making certain that we have the highest quality care in rural areas of our country is an absolute priority. And telemedicine is one of the keys to that.

We have seen over the past decade or so an explosion in the ability of technology to be able to literally transport the problem -- not the patient, but the problem -- to a setting where there are experts that can be able to assist those individuals on the ground in the smaller communities. So it is an absolute priority.

Government is usually relatively poor at changing as rapidly as technology or the innovation that is out there. And one of the priorities that we have is to make it so that the health care system can be as dynamic as the innovation that is being created.

*Mr. Rice. Thank you, Mr. Secretary. I yield back my time.

*Chairman Brady. Thank you.

Ms. Sewell, you are recognized.

*Ms. Sewell. Thank you, Mr. Chairman.

And welcome back, Secretary Price. Thank you for coming today to provide our committee with insight about this Administration's budget priorities. The American people deserve clarity. Because the President told us he would not cut Medicare, Medicaid, or Social Security, we need only look at his tweets when he was candidate, when he was a candidate.

On May 17, 2015, candidate Donald Trump tweeted, "I was the first and only potential GOP candidate to state that there would be no cuts -- I repeat, no cuts -- to Social Security, Medicare, and Medicaid. Huckabee copied me."

On July 11, 2015, candidate Donald Trump said, "The Republicans who want to cut Social Security and Medicare are wrong. A robust economy will make America great again."

On October 30, 2015 he tweeted, "I am going to save Medicare and Medicaid. Carson wants to abolish it. And failing candidate Governor John Kasich doesn't have a clue. Weak."

So, Mr. Secretary, despite these promises, the Trump budget slashes Medicaid benefits by up to $64 billion over 10 years. Medicaid is cut by $1.4 trillion. And by extending sequester, the Trump budget includes a $33.5 billion Medicaid/Medicare (sic) cut.

So, Dr. Price, if Congress implements the recommendations of the budget, the fiscal year 2018 budget, I am assuming that President Trump would sign that bill. So that -- so, in effect, the President is breaking a very important promise.

The people that I represent back home in Alabama are looking for the truth. And it breaks my heart to know that millions of Medicare and Medicaid recipients across this country have put their trust in a man that would break their promises (sic).

Mr. Secretary, this is really about real health for real people. What is most offensive is that the Trump budget uses the cuts to funds -- the use of cuts to

these funds to actually provide a tax cut for the wealthiest Americans. Both in rhetoric and in our policies, we have been demonizing the programs that most people rely on. I think it is very clear, and my hope is that this Administration will not pass a budget that cuts Medicare, Medicaid, and Social Security.

I want to associate my comments with Mrs. Black, because she and I both are working on rural health and health care, and we want to make sure that the wage index is fair, across the board. So I want to work with you and her on that issue.

But make no mistake about it: I think the American people are watching. And we have to keep our promises. We shouldn't be cutting Social Security, Medicare, and Medicaid. And I can tell you that my constituents will indeed be watching.

Thank you, sir.

*Chairman Brady. Thank you.

Mrs. Walorski, you are recognized.

*Mrs. Walorski. Thank you, Mr. Chairman.

Mr. Secretary, thanks so much for being here. I had sent you a letter on this, I just wanted to mention it briefly today. But I just wanted to thank you for your incredible leadership, as you were talking about being in Africa, your global leadership, your concern about global health.

I just wanted to bounce a question off you and share with you my concern with the guidance the WHO secretariat developed and rushed through last year. It calls for significant new restrictions, and even prohibitions on the promotion and marketing of milk products for children up to the age of three. They provided no scientific evidence, they conducted no analysis of its potential impact. But now the WHO is incorrectly presenting their guidance as a new international standard, and it is pressuring governments to implement it.

I am concerned about the impact the WHO's guidance could have on children throughout the globe. I am concerned for no go reason bureaucrats at the WHO are leaving parents and caregivers without a critical tool that aids in a child's growth and development, and preventing doctors from sharing information on the full range of options available for a child's healthy development.

I sent you a letter with 15 of my colleagues, kind of addressing this, knowing that you are taking a lead in global health. I just wanted to get your thoughts on this. Did this issue come up a few weeks ago when you were at the World Health Assembly? And then -- and what can we do, as Congress, to maybe be helpful in your efforts on making sure that this does not become a precedent, and that maybe other agencies could use our help, as well? Just your thoughts on it.

*Mr. Price. Yes. No, I appreciate the question, the inquiry. And specifically to answer your question, no, I didn't have any conversations about this at the World Health Assembly.

But what we did do is begin the relationship development with other nations around the world that are leaders in the area of health care and global health security. And so I look forward to gaining this information, getting up to speed on it, and taking this information to other nations who are leaders in the World Health Organization so that we can respond to you appropriately.

*Mrs. Walorski. I appreciate it. I yield back. Thanks, Mr. Chairman.

*Chairman Brady. Well, thank you.

Ms. DelBene, you are recognized.

*Ms. DelBene. Thank you, Mr. Chair.

Thank you, Mr. Secretary, for being here with us today.

*Mr. Price. Thank you.

*Ms. DelBene. Mr. Secretary, in less than six months this Administration has already been devastating for Americans' health. This Administration has created chaos, confusion, instability in the market, and that has dramatically increased health insurance costs and leaves the middle-class families to foot the bill.

This Administration has taken steps to allow states to kick new mothers off of Medicaid if they can't find work within 60 days of giving birth. This Administration is rolling back protections for women by allowing employers to deny a woman access to birth control. This Administration is pushing a dangerous health care bill that allows insurance companies to again discriminate against people with pre-existing conditions.

And now, your Department has released the worst budget for women's health in a generation. Not only does it advance dangerous policies to impose a pregnancy tax and gut health coverage for maternity care and breast cancer screenings, not only does it decimate the Medicaid program, which provides health coverage to one in six women, but for the first time in history it also takes the extreme step of defunding Planned Parenthood, a trusted medical provider for 2.5 million Americans that performed more than 600,000 breast and cervical cancer screenings just last year.

The Congressional Budget Office -- I hope you are aware the Congressional Budget Office has estimated that nearly 400,000 patients served by Planned Parenthood would not find alternative care through community health centers and other providers.

And I hope you are also aware, Mr. Secretary, that the CBO also estimates that defunding Planned Parenthood actually increases the Nation's deficit by $130 million over the next decade. That means costing taxpayers more money and denying women health care. And it is something that my colleagues have brought up, in terms of making sure that, you know, we look at the numbers. This -- that decision would increase the deficit.

The CBO's rationale is that Planned Parenthood helps women plan their families. And by not -- denying them access, there will be thousands more unintended pregnancies in the Medicaid program. People across the country oppose this. They oppose this kind of attack because they know politicians have no right to interfere in a woman's personal medical decisions. And that includes decisions about where and when to get health care.

So I would strongly encourage you and President Trump to reconsider this reckless and misguided effort. Family planning should not be a partisan issue. Democratic women, Republican women, independent women all rely on contraception and family planning to decide the course of their lives and choose when or if to have a child. It is time for this Administration to stop the relentless tax on women and families. We deserve better.

And I yield back.

*Chairman Brady. Mr. Meehan, you are recognized.

*Mr. Meehan. Thank you, Mr. Chairman.

And thank you, Secretary, for being here today. We are very grateful to see your presence on what is most possibly the second most watched hearing today in Washington, D.C.

But in any event, I want to start by thanking you for the work you are doing on opioids. Second, thank you for the work that you are doing on increasing the cyber security associated with the medical records. And we are going to need that kind of leadership on a very, very vital issue.

There are two other sort of issues. One that I believe you have always been a proponent of, looking for ways that we can continue to improve the quality, while looking for ways to control costs. And one of those has been movement away from the fee-for-service model, and looking at experimental plans in which we can reward those who deal with payments that work on prevention.

Once we get into models like that, there are laws that have an impact, that may not make as much sense. And I speak specifically to the Stark Law, and the law that deals with anti-kickback. They had a very valid purpose at one point in time, but may not have the same applicability if we are dealing in the context of collaborations on preventative care. You, as a physician, know sometimes it makes sense for a doctor, who is not going to be rewarded for the number of times they use it, to have access to testing.

So if we can find ways to look at these kinds of experimental programs, will you commit the willingness of the agency to consider whether we should be looking at things like Stark and anti-kickback as whether there is space in there for some changes?

And then I would like, if you could, also, continue to pay attention to an unresolved issue about clinical laboratory payment reform. It is a small issue, but important because -- you may recollect there was a requirement for data regarding the definition of applicable laboratories, and also issues regarding data reporting and collection that have had difficulty in being computed because the actual response mechanisms weren't in place. And this deadline of March has passed, and these clinical laboratories are still in a situation in which they don't have the appropriate guidance. Anything you could do to continue to look at that issue I would be grateful for.

*Mr. Price. Yes, thank you very much.

*Chairman Brady. Thank you.

Ms. Chu, you are recognized.

*Ms. Chu. Secretary Price, as a doctor you swore to first do no harm. Yet you are here to defend this budget, which will do untold harm. This is a budget that embodies cruelty. It takes an axe to programs that assist our most vulnerable families, like Meals on Wheels, just to give $1 trillion of tax breaks to the wealthiest few.

There are many who lose out on this budget, but I want to take a moment to talk about what this budget will do to people living in my district, and to women, in particular.

I note that this morning you actually said to the Senate Finance Committee that the President's budget would provide for an increase of Medicaid. It is an unbelievable statement. The truth is, along with Trumpcare, your budget cut cuts Medicaid by $1.4 trillion.

You will force states like California to choose between long-term care for seniors and providing health care for children. And in my district, 20 percent, or nearly 150,000 people, will suddenly be at risk of losing health care services. And that is on top of all the ways this budget goes above and beyond to harm women.

Medicaid accounts for 75 percent of all publicly-funded family planning services, but you cut Medicaid by over $1 trillion. In California, half of low-income women of reproductive age are covered by Medicaid expansion, but you completely gut that through the Republican budget and Trumpcare. Without the opportunities to make their own health care choices, women around the country face a return to the last century, where reproductive choice was reserved for the select wealthy few.

Moreover, Medicaid funds almost half of all births in the United States. So not only are you cutting the program that helps American women choose when to have children, you are making it more difficult to access maternity care when their children are born. And, in fact, Trumpcare further harms pregnant women. The independent CBO specifically calls out maternity care, and says that insurers will no longer cover maternity care in states that get rid of essential health benefits.

And the options for women in this budget only get worse from there. This budget completely zeroes out the teen pregnancy prevention program, which is incomprehensible to me. Because of programs like this, teen pregnancy has

decreased by 55 percent in the last 20 years. In fact, without publicly-funded family planning programs, the teen pregnancy rate would be 73 percent higher than it is now.

And just last week we saw, through a leak, that this Administration seeks a final rule to make it easier for an employer to deny their employees access to birth control. Incredulously, this regulation suggested that women whose medical choices were vetoed by their bosses could seek family planning services from Medicaid. But remember, your budget cuts Medicaid by 1.4 trillion.

This budget has little for those who are not already rich. This is not first do no harm, but rather, first harm those in need.

*Chairman Brady. Thank you, Ms. Chu.

Mr. Curbelo, you are recognized.

*Mr. Curbelo. Thank you, Mr. Chairman.

Welcome, Secretary Price. It is good to have you back here in the Ways and Means Committee room. As you know, I represent South Florida, specifically the Florida Keys, which is one of the most beautiful parts of the world. But it is a county where residents who don't have employer-based health insurance or government-sponsored health insurance have one single insurance provider. That means no choices for the people of the Florida Keys.

Like so many Americans, they have become accustomed to higher premiums, fewer choices, and lower quality. So I certainly support the idea that we need a better health care system for our country. However, while Congress considers what that new system will be, I do think we need to protect the most vulnerable. And I am glad that this Administration has committed to funding the cost-sharing reductions that are dedicated to supporting Americans who would have a lot of trouble accessing the health care system but for them.

And I would like to encourage all of my colleagues here in the Congress to follow that lead and to support, during this transition period, funding this important program.

Also, Mr. Secretary, I wanted to bring up the National Institutes for Health. As you know, South Florida was hit hard last year by the Zika crisis. Obviously, it was a public health threat. It was also an economic threat to our

community. Can you commit to supporting the NIH and all of their efforts and research in vaccine development to make sure that, if the threat of Zika returns, which -- we are nearing the season -- that our government is prepared to support communities like South Florida and others throughout the country that are exposed to this threat?

*Mr. Price. Yes, thank you. Because of the resources that Congress has provided, significant resources have gone in to the production of -- the discovery and production of a vaccine for Zika. We are in phase 2b trials, as you likely know, a very exciting time. And we are very hopeful that we will be able to bring that online rapidly.

*Mr. Curbelo. So you can commit that all of those programs, all of that work that is being done, is going to continue for the foreseeable future?

*Mr. Price. Absolutely. It is a priority of the Department, and of the NIH, and it is a priority of the Administration.

*Mr. Curbelo. Thank you very much, Mr. Secretary.

I yield back, Mr. Chairman.

*Chairman Brady. Thank you, Mr. Curbelo.

Without objection, I would like to enter into the record a report by the American Action Forum that shows that 5.3 million Americans will be eligible for help with their premiums under the Republican health care plan than are currently assisted or eligible under the Affordable Care Act.

*Chairman Brady. Mr. Secretary, I would like to thank you for appearing before us today. I know it has been a long day --

*Ms. Sanchez. Mr. Chairman?

*Chairman Brady. -- and I appreciate --

*Ms. Sanchez. Mr. Chairman? I have not had an opportunity to speak.

*Chairman Brady. Yes, Ms. Sanchez, you are recognized.

*Ms. Sanchez. Thank you, Mr. Chairman.

Mr. Secretary, thank you for taking the time to appear before the committee today.

*Mr. Price. It is good to be with you.

*Ms. Sanchez. Frankly, I am baffled by how Administration officials such as yourself can continue to publicly state that the Republican health care bill and Trump Administration budget does not cut Medicaid spending, and that people will absolutely not lose coverage.

These statements simply do not line up with the scientific calculations made by the Congressional Budget Office. In fact, the CBO found that 23 million people will lose coverage, including 14 million fewer Medicaid enrollees. These calculations also include a cut of $834 billion in federal outlays for Medicaid.

On top of all that, the fiscal year 2018 Health and Human Services budget put out by the Trump Administration slashes another $610 billion from Medicaid, for a whopping total of $1.4 trillion.

Despite these cuts, Administration officials and congressional Republicans continue to claim that the Medicaid population will be cared for in a better way under our program, and that Medicaid spending under the proposal and under the budget goes up every single year.

Interestingly, the poor and the disabled aren't the only Americans that the Trump Administration is leaving out in the cold. The AHCA hits seniors by cutting short the solvency of the Medicare Trust Fund. The Trump budget cuts

the Temporary Assistance for Needy Families program, which helps working families afford child care.

What kind of voodoo math are you using to justify your statements claiming to help Americans, when you are taking over $1 trillion out of the system to pay for tax cuts for the rich? How are we supposed to believe Administration officials about what impacts these proposals will have, when they themselves have abused their power to increase their personal wealth?

For all the cries about the CBO score, Trump officials sure know how to make accurate calculations when it affects their bank accounts.

The truth is the Trump Administration can't justify their numbers when it comes to protecting the American people's bank account. Instead, they resort to attacking career officials or undermining the very people they appointed to do the jobs they have asked them to do. I simply don't understand how you can continue to perpetuate these myths that people will not be harmed under the Republican health care bill.

But I do want to follow up on something that Mr. Curbelo said, that the Administration has agreed to fund CSRs. Can you please confirm that that is true, that you will pay insurers?

*Mr. Price. As I said, I am the defendant in the case, House v. Price. And so, what I am able to share with you is what is in the budget, and that is that the budget reflects that CSR payments will be made for the next two years.

*Ms. Sanchez. Thank you, and I yield back my time.

*Chairman Brady. Thank you.

Mr. Secretary, again, thank you for being here today. We look forward to working with you on a broad range of health care issues and reform issues. We can do much better than the health care that too many people in Obamacare are trapped in today.

As you know, as a former member of the committee, you know members have two weeks to submit written questions to be answered later in writing. Those questions and your answers will be made part of the formal hearing record.

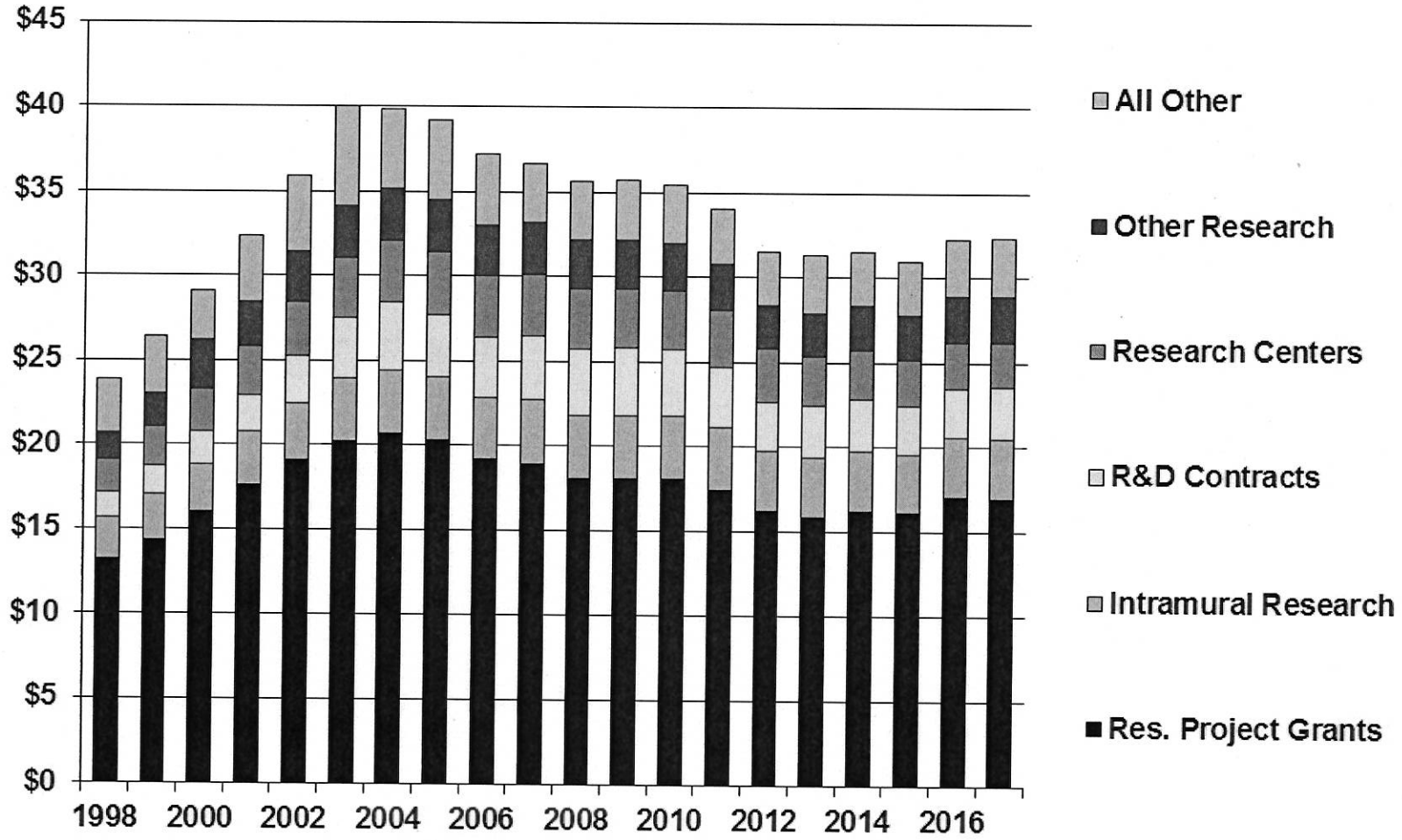
Again, thank you, Mr. Secretary. And with that, the committee stands adjourned. [Whereupon, at 3:06 p.m., the committee was adjourned.]

MEMBER QUESTIONS FOR THE RECORD

Levin SFR

NIH Budget by Funding Mechanism, 1998-2017

(budget authority in billions of constant FY 2016 dollars)



Source: AAAS Report: Research and Development series and agency budget documents. FY 2016 figures are latest estimates, FY 2017 is the President's request. © 2016 AAAS

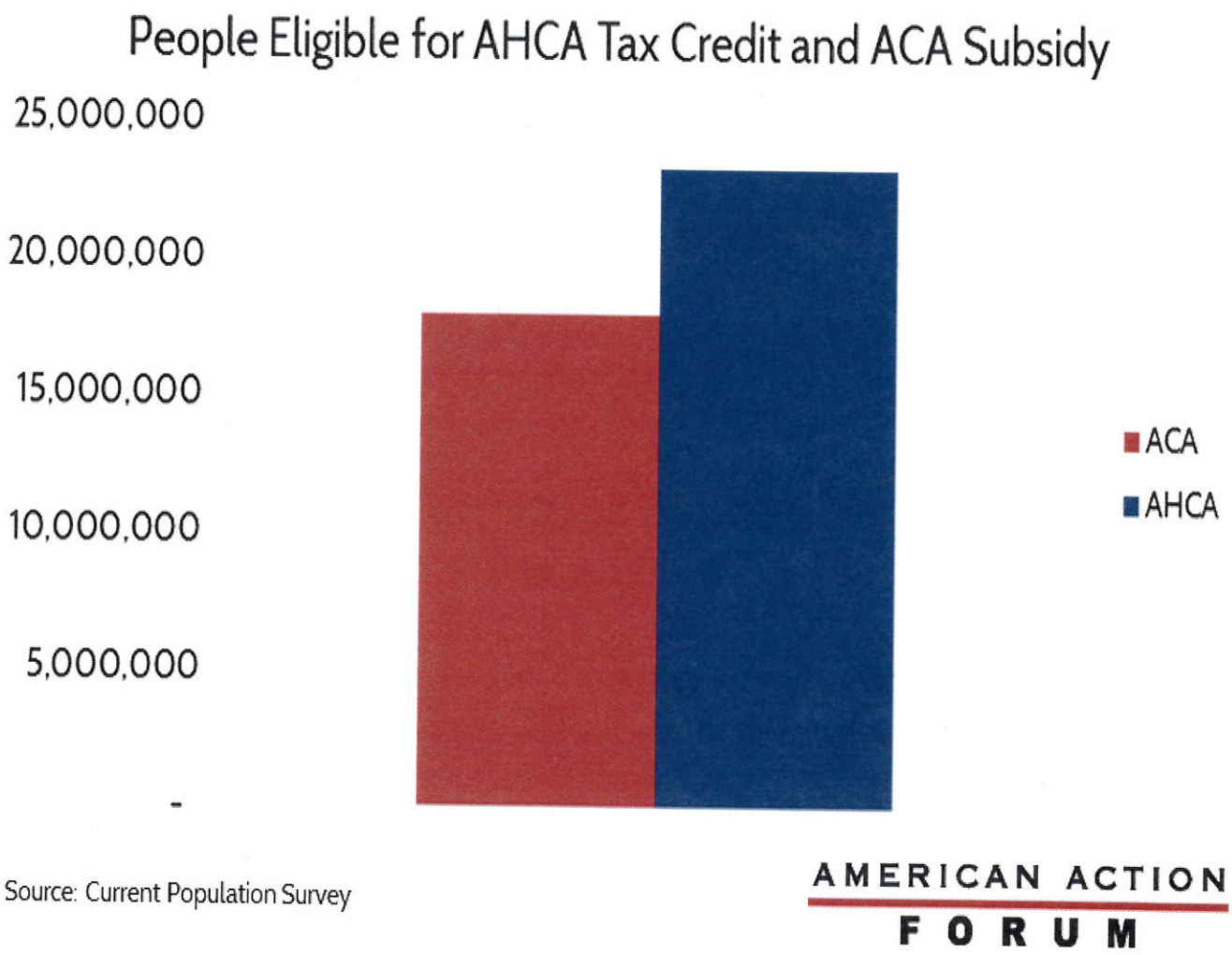
Brady SFR

Weekly Checkup

ACA and AHCA: Tax Credit Eligibility Differences

BRIANNA FERNANDEZ, JONATHAN KEISLING | JUNE 7, 2017

Among the current policies that the American Health Care Act (AHCA) would alter is the structure and eligibility of premium subsidies for the individual market. The AHCA replaces premium subsidies with an age-adjusted tax credit that is available to a wider range of incomes, including those who are currently in the so-called "coverage gap." However, the tax credit retains the same basic eligibility determinations that currently constrain the premium subsidy. Generally, consumers that have access to public health insurance or were offered insurance through their employer are ineligible, along with undocumented immigrants and incarcerated individuals.[1],[2] Using the 2016 March supplement of the Current Population Survey, it was found that roughly 23.3 million people would be eligible some sort of tax credit under the AHCA—roughly 5.3 million people more than are currently eligible for premium subsidies provided by the Affordable Care Act.[3]



[1] https://www.congress.gov/115/bills/hr1628/BILLS-115hr1628eh.pdf

[2] The Kaiser Family Foundation's estimates for illegal immigrants were used for this exercise and are available at: http://kff.org/health-reform/issue-brief/estimates-of-eligibility-for-aca-coverage-among-the-uninsured-in-2016/

[3] The March 2016 Current Population Survey (CPS) data and the 2016 ASEC March supplement were used in the calculation of each credit.

Representative Doggett (D-TX):

Question: *In a pre-inaugural press conference on January 11, and again in a speech in Louisville, KY on March 20, President Trump promoted "bidding" as a strategy for bringing down drug prices. He said that this was necessary because "the cost of medicine in this country is outrageous," and because the pharmaceutical industry is "getting away with murder."*

i. Has the Administration rejected President Trump's approach on drug pricing reform?
ii. Does it support bidding or price negotiation for Medicare?

Answer: High drug prices and costs are an issue of major concern for HHS and for the American people. This includes the millions of seniors who rely on Medicare for their drug coverage, and the taxpayers who have to foot the bill for government spending on this program. As you know, the President has made prescription drug prices an absolute priority and has charged us with making recommendations to his office on reducing drug prices. My team has been meeting with stakeholder groups from across the healthcare spectrum over the past several months in order to understand where there are areas of consensus. It is important that we move forward quickly, but also carefully, so that our policies do not have unintended consequences. We need to balance the goal of ensuring affordability and access with the mandate to continue supporting development of lifesaving innovations.

iii. Does it support drug importation, which President Trump also previously endorsed?

Answer: I share the President's concerns about the cost of prescription drugs and the need to ensure that Americans have access to medical products. As Congress pursues various policy options to address drug pricing, issues related to product safety, effectiveness, and quality should be considered. Policies must ensure that individuals are not receiving drugs that are contaminated, counterfeit, or contain varying amounts of active ingredients.

Question: *On May 31, 2017, the HHS Office of the Inspector General (OIG) sent a letter to the Senate Committee on the Judiciary, which estimated how much money Mylan owed to the U.S. government as a result of the improper classification of the EpiPen under the Medicaid Drug Rebate Program. According to the OIG, from 2006 to 2016, Mylan failed to pay an estimated $1.27 billion in rebates. There have been previous reports that the Department of Justice (DOJ) negotiated a $465 million settlement with Mylan, recouping a little less than a third of the money owed to American taxpayers.*

i. Has this settlement been approved and if so, for what amount?
ii. What specific steps have been taken to prevent such pharmaceutical company misconduct in the future?
iii. What investigation has been conducted to determine whether there are other drugs which have been improperly classified?

Answer: There is no approved settlement with any potential party. As you know, we otherwise cannot comment on any pending matter that the government may have involving Mylan or EpiPen. All questions should be directed to the Department of Justice.

Manufacturers that do not comply with classification requirements are in clear violation of the law. Under the Medicaid Drug Rebate Program (MDRP) authorizing statute, it is the responsibility of the manufacturer to properly report the classification of its drugs and the required pricing data (AMP, best price, customary prompt pay discounts, and nominal prices), and to pay the proper rebate amounts. CMS has provided sub-regulatory guidance and, more recently, regulatory guidance on these issues.

Since 2010, the Center for Medicaid & CHIP Services (CMCS) has taken a number of steps to improve the operations of the MDRP. Additionally, in October 2016, CMS began development of a new MDRP system that will update its existing information systems and enhance the agency's capacity to oversee the more than 23,000 drug classifications and rebates. The new system is scheduled to be completed and operational in approximately 2 years.

Question: *On April 4, 2017, 51 Members of Congress asked President Trump to use his authority to set guidelines for the usage of march-in rights, in order to protect taxpayer investments and taxpayer access to medications developed with taxpayer funding. We have received no answer or confirmation of receipt, despite repeated questions. A copy of the letter is attached.*

i. Why has the Administration not used existing legal authority to protect taxpayers?
ii. What is the Administration's answer to our request?

Answer: Thank you for your letter concerning the development of guidelines on the use of the Bayh-Dole Act march-in authority. The Trump Administration shares your concern about the issue of drug pricing more broadly; the Department is actively exploring policy options at our disposal to ensure taxpayers have access to the medications they need.

HHS considers the application of the march-in statute on a case-by-case basis, and is prepared to use its authority if presented with a case where the statutory criteria are not met for the commercialization and use of an NIH-funded, patented invention and march-in could in fact alleviate the public health need.

As mentioned, HHS is looking at the issue of drug pricing more broadly and continues to engage in discussions with stakeholders – internally, externally, and across the government - on this topic. Again, thank you for your leadership and we welcome your and your colleagues' input on this issue moving forward.

Question: *There have been multiple reports that the Administration is preparing to issue an executive order that largely adopts recommendations of the Pharmaceutical Research and Manufacturers Association (PhRMA), and that this order is being developed with the active*

participation of Joe Grogan, director of health programs for the Office of Management and Budget, who was the head of federal affairs for Gilead Science for the past five years.

I. With President Trump purportedly committed to "drain the swamp," why has Joe Grogan not been recused from working on issues on which he actively lobbied over the past five years, as required by the January 28 executive order on lobbying?

Answer: As Secretary of HHS, I am not in a position to answer this question. I would refer you to the White House and the Office of Management and Budget.

ii. Will this executive order be accompanied by an independent analysis of how each of these changes will lower the costs of drugs to consumers and the U.S. government?

Answer: The White House would be better able to speak to executive orders that it plans to issue.

iii. How would scaling back the 340B drug program reduce the rising cost of pharmaceuticals for consumers and the US government?

The President's FY18 Budget provides $10 million for the 340B Drug Pricing Program, the same level as the FY 2017 Continuing Resolution. Additionally, the Budget proposes to update regulatory authority in the 340B Drug Pricing Program to increase transparency and improve program integrity.

iv. Why are there no reported reforms aimed at lowering brand-name drug prices, despite the fact that brand-name drugs account for 72 percent of drug spending and only 10 percent of dispensed prescriptions?

Answer: One of the best ways to address the cost of brand-name drugs is to foster generic and bio-similar competition. Over the last decade alone, competition from safe and effective generic drugs has saved the healthcare system about $1.67 trillion. HHS is continuing to look for ways to ensure the affordability of drugs, including brand-name drugs. One example is FDA's recent announcement of a Drug Competition Action Plan in an effort to broaden access to medicines and help consumers lower their healthcare costs. As part of this plan, FDA very recently published a list of off-patent, off-exclusivity branded drugs without approved generics, and also implemented, for the first time, a new policy to expedite the review of generic drug applications where competition is limited.

v. Other than PhRMA and PhRMA-funded groups, which specific consumer groups have been consulted in preparing this executive order, when, and how?
vi. Which specific individual from the Administration is best able to provide testimony as a witness in a committee hearing to describe the effect of each provision of the order on drug prices and the process through which the order was developed?
vii. Does the Administration have a proposed date of publication for this executive order?

Answer: The White House would be better able to speak to executive orders that it plans to issue.

Representative Blumenauer (D-OR):

As you noted in your testimony, in Oregon, expanded Medicaid coverage led to increased use of preventive services like mammograms, better detection of diabetes and depression, and better mental health outcomes for those with depression. Most importantly, and what you didn't note, is that authors of the Oregon Health Insurance Study found that insurance—which Medicaid is—provided Oregonians with many other important benefits such as improved peace of mind and important financial protection from catastrophic health costs. I am proud of the work we have done in Oregon, which has buy-in from the beneficiary and provider communities. Your budget not only assumes the $839 billion cut to Medicaid in the American Health Care Act, but dramatically enlarges it by an additional $610 billion.

***Question:** How will cutting Medicaid by $1.4 trillion over the next 10 years allow states such as Oregon to continue to pay and provide for quality care?*

Answer: The President's FY18 Budget does not incorporate specific legislation that is before Congress right now. Therefore, it is not accurate to apply the specific Medicaid savings the CBO has estimated for legislation before Congress to the President's Budget. The President's proposed savings of $610 billion over 10 years would put the program on a sustainable fiscal path by capping Medicaid funding beginning in FY 2020 through per capita caps, or block grants, at state option. By strengthening the Federal and state Medicaid partnership, we will empower states like Oregon to develop innovative solutions to challenges they face, rather than telling states how they should run their programs.

Every state has different demographic, budgetary, and policy concerns that shape their approach to Medicaid. That is one of the reasons I believe a one-size-fits-all approach is not workable for a country as diverse as the United States.

Representative Higgins (D-NY):

I have grave concerns about the large cuts to medical research funding proposed in President Trump's Fiscal Year 2018 budget. In addition to the overall 20% cut to the budget of the National Institutes of Health, the specific proposal to restrict necessary, previously agreed-upon funding of research grants for extramural research at participants in initiatives like the Cancer Center program and Clinical Translational Science Award programs would devastate groundbreaking research currently being done across the country. These funds ensure that entities like Roswell Park Cancer Institute and the University at Buffalo in my district can conduct vital research that lead to potential life-saving treatments and even cures to debilitating diseases like cancer, multiple sclerosis, and diabetes.

Robust extramural grants have been a cornerstone of the NIH's research activities throughout its history. Since President Richard Nixon signed the National Cancer Act into law in 1971, extramural grant at National Cancer Institute specifically have expressly focused on the goal of ensuring that as many Americans as possible have access to the most advanced and highest quality treatments.

***Question:** How can you continue to fully implement the goals of laws like the National Cancer Act, since the practical implication of this proposal would be to specifically undermine it?*

Answer: The FY 2018 Budget presents an opportunity for HHS and NIH to reexamine how to optimize Federal investments in a way that best serves the American people. The FY 2018 Budget changes the reimbursement of indirect costs for NIH grants, which will be capped as a percentage of total research, in order to better target available funding toward high priority research. In addition, Federal research requirements for grantees will be streamlined to reduce grantee burden through targeted approaches as proposed by NIH. HHS is working with NIH to identify strategies to streamline processes and increase efficiencies, including reforming policies to release grantees from the costly and time-consuming indirect rate setting process and reporting requirements.

HHS will continue to invest resources in the highest priority research areas, including cancer. With regard to cancer research, specifically, the FY 2018 Budget aims to accelerate progress and research in cancer, including prevention and screening, from cutting edge basic science to wider uptake of standard of care.

Representative DelBene (D-WA):

Secretary Price, coverage and reimbursement policies in Medicare are limiting access to, and utilization of, telehealth and remote monitoring technologies. Under current law, coverage is restricted by the geographic locations where beneficiaries live and receive care, the type of technology used, and the services being furnished by their healthcare providers. Some of these restrictions have been waived in new payment models, but don't go far enough to provide the flexibility needed to maximize the medical benefits and cost-effectiveness offered by telehealth. As you know, bipartisan legislation has been introduced to expand telehealth services provided through these alternative payment models to test how telehealth can reduce costs and increase the quality of care for the treatment and management of certain chronic conditions. One of the core purposes of this bill is to collect data on expanded telehealth services to allow CMS, CBO and MedPAC to fully assess the cost-effectiveness of this model.

Question: *What do you think about this approach to modernizing the Medicare program and would you be willing to commit CMS/CMMI to undertaking a demonstration like this?*

Answer: The Administration is committed to ensuring that all Americans, especially those in rural areas, have access to the highest quality of care, and telehealth is one of the keys to that. Telehealth is an exciting innovation that will allow for individuals to access resources that are otherwise not available. We've seen an explosion in the ability of technology to allow a patient to receive care from a provider in another location while the patient remains in his or her home community. One of our priorities is to make the healthcare system as dynamic as the innovation that is being created to serve it.

Through its annual Medicare Physician Fee Schedule rulemaking, CMS has a process for adding services to the list of Medicare telehealth services for which payment can be made. This process provides the public with an ongoing opportunity to submit requests for adding services to the Medicare telehealth list. CMS carefully consider all requests to determine if additional services should be added to the telehealth list.

While Medicare statute only allows Medicare payment for telehealth services if beneficiaries are furnished the services while present in certain healthcare settings that are located in certain geographic areas, the CMMI statute permits waiving certain telehealth requirements for purposes of conducting payment and service delivery models. Some waivers related to telehealth have been made based on the needs of a particular initiative. For example, waivers of certain geographic limitations have been made with respect to otherwise covered telehealth services as necessary solely for purposes of testing the CMMI's Next Generation Accountable Care Organization Model. We anticipate learning from the evaluations of the CMMI models and other CMS initiatives, and we will continue to seek opportunities to test additional Medicare payment models, including those incorporating telehealth. CMMI is always seeking ideas to help shape the design of future payment and service delivery models. I appreciate your suggestions and look forward to working with you on this issue.

Representative Black (R-TN):

Complex Rehab wheelchairs and related accessories are used by a small population of people with high levels of disabilities such as ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury, and traumatic brain injury. As a result, Congress exempted CRT from the competitive bidding program in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

Unfortunately, in December of 2014 CMS posted sub-regulatory guidance that stated in 2016 it would use Medicare competitive bidding pricing information obtained from bids for Standard wheelchair accessories to reduce payment amounts for Complex Rehab wheelchair accessories (such as seat/back cushions, tilt/recline systems, and specialty controls). This went against the intent of MIPPA so Congress intervened in December of 2015 (via S. 2425) and again in the December of 2016 (via 21st Century Cures Act and H.R. 34) to delay payment reductions. These cuts are scheduled to take effect July 1, 2017.

***Question:** The need to resolve this matter has received strong bipartisan support in both the Senate and House along with the patient and clinician community. Given the history of Congressional support for preventing these cuts, is there a plan to ensure these cuts will not occur on July 1 so that beneficiaries with significant disabilities will be able to continue having access to the specialized equipment they need?*

Answer: CMS is committed to providing beneficiaries with access to the services and medical devices they need. On June 23, 2017, CMS issued a new policy on how adjustments to the fee schedule based on information from competitive bidding programs apply to wheelchair accessories and back and seat cushions used with group 3 complex rehabilitative power wheelchairs. As a result, effective July 1, 2017, payment for these items will continue to be based on the standard unadjusted fee schedule amounts, which will help to protect access to complex rehabilitative power wheelchair accessories on which people with significant disabilities depend.

Representative Johnson (R-TX):

Question: *Mr. Secretary, I'd like to know what role you believe physician-owned hospitals (POH) have in providing good, quality healthcare for patients and increasing affordability?*

Answer: The Affordable Care Act imposed additional restrictions on physician ownership and investment in Medicare-participating hospitals, banning new physician-owned hospitals (POHs) and limiting the expansion of existing POHs. We do, however, have the authority to grant exceptions to the expansion prohibition for certain applicable hospitals and high Medicaid facilities. In April 2017, as part of our Fiscal Year 2018 Medicare Hospital Inpatient Prospective Payment System and Long Term Acute Care Hospital Prospective Payment System Proposed Rule[1], we included a Request for Information regarding physician-owned hospitals. We are seeking public comments on the appropriate role of physician-owned hospitals in the delivery system and on how the current scope of and restrictions on physician-owned hospitals affects healthcare delivery, particularly regarding Medicare beneficiaries.

Question: *What would you say has been the impact of the Obamacare ban on the development of new POHs as well as the effective ban on the expansion of POHs on the healthcare sector, including its impact on patients and payers?*

Answer: CMS relies heavily on stakeholder feedback to make sure our actions promote access to care while reducing the burden on healthcare providers. That's why, in April 2017, as part of our Fiscal Year 2018 Medicare Hospital Inpatient Prospective Payment System and Long Term Acute Care Hospital Prospective Payment System Proposed Rule[2], we included a Request for Information regarding physician-owned hospitals. We are seeking public comments on the appropriate role of physician-owned hospitals in the delivery system and on how the current scope of and restrictions on physician-owned hospitals affects healthcare delivery, particularly regarding Medicare beneficiaries.

[1]Proposed Rule; RFI on page 20002 https://www.gpo.gov/fdsys/pkg/FR-2017-04-28/pdf/2017-07800.pdf
[2] Proposed Rule; RFI on page 20002 https://www.gpo.gov/fdsys/pkg/FR-2017-04-28/pdf/2017-07800.pdf

Representative Kelly (R-PA):

Complex Rehab wheelchairs and accessories are used by a small population of people with high levels of disabilities such as ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, and traumatic brain injury. For this reason, Congress exempted Complex Rehab Technology from the competitive bidding program established in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

Unfortunately, in 2014 CMS stated its intent to apply Medicare competitive bidding program pricing to Complex Rehab wheelchair accessories effective January 1, 2016. Congress has delayed these reductions twice; however, the cuts are scheduled to take effect July 1, 2017.

***Question:** Mr. Secretary, I am concerned with CMS' interpretation of the competitive bidding program which may reduce access to CRT accessories for people with disabilities. Do you plan to take action before July 1, 2017 to stop these cuts?*

Thank you for your attention and consideration of this important matter.

Answer: On June 23, 2017, CMS issued a new policy on how adjustments to the fee schedule based on information from competitive bidding programs apply to wheelchair accessories and back and seat cushions used with group 3 complex rehabilitative power wheelchairs. As a result, effective July 1, 2017, payment for these items will continue to be based on the standard unadjusted fee schedule amounts, which will help to protect access to complex rehabilitative power wheelchair accessories on which people with significant disabilities depend.

Representative Meehan (R-PA):

Question: *We need to address the long-term solvency of the Medicare program. I am working to draft legislation to modernize the Stark Law and Anti-Kickback Statute in order to support a transition from Medicare fee-for-service to value-based health care payment models. Pursuant to the President's "Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal," I look forward to working with you to make changes in regulations related to enforcement for technical violations of the Stark Law and Anti-Kickback Statute for any organization participating in an alternative payment model substantially similar to those currently or previously operated by CMS. Will you commit to supporting the move from Medicare fee-for-service payments toward value-based care models?*

Answer: Value-based programs reward healthcare providers with incentive payments for the quality of care they give to people with Medicare. These programs are part of CMS's larger quality strategy to reform how healthcare is delivered and paid for.

Enforcement responsibilities for the Stark Law and the Anti-Kickback Statute are shared by three government agencies: CMS, the Department of Justice, and the Department of Health & Human Services Office of Inspector General. Among other provisions, the Stark Law is a strict liability statute that prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies. The Anti-Kickback Statute prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of Federal healthcare program business; both civil and criminal penalties can be imposed for violations. HHS has published a number of regulations interpreting the Stark Law and the Anti-Kickback statute and promulgating Stark exceptions and Anti-Kickback Statute safe harbors. Like all finalized rules, these regulations were promulgated using the standard Administrative Procedure Act process, which includes a public comment period. However, we are always looking to improve our programs, and we are committed to – and welcome – feedback about how we can ensure strong program integrity, while encouraging innovative payment models and relieving burden on providers.

Question: *In light of the recent report issued by the Health Care Industry Cybersecurity Task Force, I was pleased to see that the Department of Health and Human Services (HHS) requested additional appropriations for cybersecurity efforts within the Office of the Secretary. Do you think it is feasible for HHS to coordinate with the private sector as well as federal and state officials to harmonize existing and future laws and regulations that affect health care industry cybersecurity? What is your response to the Task Force's recommendation that leadership for health care cybersecurity should be centralized? Could you describe the resources HHS has that are available to health care providers and stakeholders?*

Answer: HHS is currently reviewing the recommendations made by the Healthcare Industry Cybersecurity Task Force. Specifically, the Department is working to determine which (if any) of those recommendations can be implemented consistent with our current authorities,

resources, and policies. As part of this review, HHS will examine whether we can decrease regulatory burden on industry by increasing incentives for strong cybersecurity practices. HHS is also evaluating the feasibility of harmonizing the cybersecurity legal requirements under current authorities and the extent to which such harmonization may require legislative changes. In undertaking this evaluation, it is important for us to keep in mind that the healthcare industry is very diverse in size and technical capabilities, spanning from single doctor practices to multibillion dollar health insurance companies – and that the cybersecurity requirements imposed on such an industry have to be flexible and scalable.

HHS believes that it is reasonable and necessary for the Department to undertake this review process with our partners in Federal, State, and local agencies, as well as the private sector. Through coordination we can ensure that key cybersecurity policies, mandates, and guidelines are informed by the lessons learned – the "scalable best practices" noted in the Task Force report. This coordinated approach includes incident reporting and response activities and a federal-level cybersecurity framework, which promotes a shared cybersecurity language and accompanying standards, guidelines, and best practices, while recognizing the need for flexibility and scalability.

The FY 2018 President's Budget proposes an increase to enhance the Department's overall cybersecurity capacity. HHS is currently evaluating what additional flexibilities, if any, would be needed to ensure the Department's ability to retain necessary human capital skillsets so that the Department can adequately prepare for and respond to threats.

Question: *The Health Care Industry Cybersecurity Task Force report noted that the health care industry, like many industries, is experience challenges in recruiting and retaining qualified cybersecurity professionals. As IBM encourages a "new collar" jobs initiative for cybersecurity, what do you think is the appropriate role for the federal government in supporting health care cybersecurity workforce development and potentially developing standards for certifying advanced degree cybersecurity programs?*

Answer: We agree with the Task Force report that education and workforce development are critical to enhancing cybersecurity within the Healthcare and Public Health Sector. While workforce development is critical in every sector, the healthcare environment poses unique regulatory, clinical, and patient protection concerns that require specialized skills from information security professionals. As the Task Force notes, both public and private sectors have a role in defining the appropriate skill sets and certifications needed to provide adequate information security expertise within healthcare organizations. It follows, then, that the Federal Government would play a key role in supporting the creation of a cybersecurity workforce focused on the healthcare sector.

Question: *As you know, Medicare's enrollment rules are complex, and seniors do not receive notice from the Centers for Medicare and Medicaid Services (CMS) regarding their responsibility to enroll. This is why I introduced The Beneficiary Enrollment Notification and Eligibility Simplification Act, also known as the BENES Act. Because of these confusing rules, seniors may*

find themselves subject to a late enrollment penalty. The Part B late enrollment penalty permanently increases a beneficiary's premium by 10 percent for every 12 month period the beneficiary could have had Part B coverage, but did not. Others are paying for private coverage that is secondary coverage to Medicare. Without enrolling in Medicare, these seniors will find themselves responsible for significant out-of-pocket costs. One part of the solution is to require CMS, in cooperation with the Social Security Administration and the Internal Revenue Service, to issue notifications to individuals approaching eligibility about the enrollment rules and the coordination of Medicare coverage with other health insurance coverage. Do I have your commitment to work with Congress to ensure that the Medicare program, starting with the enrollment process, is structured in a manner that best serves its beneficiaries – current and future?

Answer: CMS works closely with the Social Security Administration to enroll eligible beneficiaries in the various components of Medicare. As part of this process, enrollees can chose which parts of Medicare they'd like to enroll in. Most people should enroll in Part A when they turn 65, even if they have health insurance from an employer because they paid Medicare taxes while they worked and therefore don't pay a monthly premium for Part A. Certain people may choose to delay Part B. In most cases, it depends on the type of health coverage they may have. As you note, if a beneficiary does not enroll on time, they may be subject to a late enrollment penalty of up to 10 percent for each full 12 month period they could have had Part B[4], but didn't sign up for it. They are responsible for paying this penalty for as long as they have Part B coverage. CMS notifies certain beneficiaries at the beginning of their initial enrollment period (IEP) about their automatic entitlement to hospital insurance (HI) and enrollment in supplementary medical insurance (SMI), if applicable based on where the beneficiary resides, in the IEP package. CMS mails the IEP package three months prior to the 25th month of disability benefit entitlement or three months prior to the month of age 65 attainment (i.e., the first month of the individual's IEP). The IEP package contains a Welcome to Medicare cover letter, the Welcome to Medicare booklet, the beneficiary's official Medicare card reflecting the HI and SMI entitlement dates, and a postage-paid envelope for the individual to use to send their SMI refusal to SSA.

The Administration is committed to making sure the Medicare enrollment process works for beneficiaries including how CMS informs people of their eligibility to enroll in Medicare and the consequences if they delay enrollment.

Question: *I appreciate the budget proposal's support for implementation of the market-based payment reform for clinical laboratory services. We have just passed the May 30, 2017, deadline for applicable labs to report payment rates and test volumes for their private payers. I continue to hear concerns from stakeholders regarding the definition of applicable laboratory and outstanding issues regarding data reporting and collection. Could you provide an update on the Agency's work to resolve these issues?*

[4] For more information see: https://www.medicare.gov/your-medicare-costs/part-b-costs/penalty/part-b-late-enrollment-penalty.html

Answer: CMS is committed to the successful implementation of the new private payer rate-based clinical laboratory fee schedule (CLFS) and looks forward to working with the laboratory industry to ensure accurate payment rates. As you noted, feedback from stakeholders indicated that many reporting entities would not be able to submit a complete set of applicable information to CMS by the March 31, 2017, deadline. In response, on March 30, 2017, CMS announced that it would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the CLFS and the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information. Since the enforcement discretion deadline of May 30 has now passed, CMS is currently performing a comprehensive analysis of the submitted CLFS data. We will continue to review the operations of the program and look forward to feedback on how to improve the program.

Question: *Civil Monetary Penalties (CMPs) are appropriate enforcement mechanisms that work to ensure patient safety and quality of care. However, I am hearing from providers in my District that enforcement action for long-term care facilities is not being conducted in a manner consistent with these goals. Data show great variation in CMS Regional Offices' issuance of CMPs. Since the third quarter of 2016, Regions 3 and 4 have levied significantly higher average per diem CMPs. What accounts for the variation of CMPs in different regions? What oversight does the CMS perform to prevent potentially excessive enforcement activities by Regional Offices? How does CMS ensure that the enforcement activities and CMPs do not jeopardize care in long-term care facilities?*

Answer: CMS's role is to ensure that the minimum quality standards for nursing home residents are met. This requires ensuring access to long-term care facilities that provide nursing home residents with safe and effective care. The goal of enforcement is to ensure swift and sustained compliance with the minimum health and safety standards. One of the enforcement mechanisms we are authorized to utilize is Civil Monetary Penalties (CMPs). CMPs can be established as per instance (one-time) or per diem. In general, the amount of the per diem CMPs is related to a number of factors including: the extent of non-compliance or harm to nursing home residents; the number of days of non-compliance; facility culpability; facility financial hardship; and others. We have found that variation in CMPs is largely attributable to the application of these factors in the context of the specific facts involved in any particular enforcement action.

CMS has been working towards cross-Regional consistency in CMP processes and policies. Since 2014, we have been conducting quarterly calls with all Regional Offices to discuss CMP policies and the outcomes for that Region. CMP data is routinely shared and discussed across Regions to ensure that others are aware of key markers related to enforcement.

Based on CMS' review to date, CMS has found that the variation in Region 3 and Region 4 seems to be based primarily on the extent to which noncompliance is found which started before the date of the survey (i.e., retroactive application of CMPs). When there is a per diem

CMP imposed and the concern started before the survey date, the fine accumulates until corrected.

CMS has discussed with Region 3 and Region 4 the extent to which there is regional variation.

To address this issue (retroactive application leading to high per diem CMPs), earlier this month CMS revised our policies and instruction in cases where noncompliance started before survey. In these cases, a per instance (one-time) CMP would generally be imposed except in cases of abuse and serious harm to residents. We also we recently released a policy for CMS Central Office review all CMP fines over $250,000. This ensures that there is consistent application of policies particularly for higher dollar value CMPs. (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-37.pdf)

We will continue to take a look at the CMP process and Regional practices. Our goals are to ensure that CMPs are applied in a consistent manner, that minimum quality standards are met for residents, and that we are continually evaluating the CMP process for effectiveness of leading to high quality care.

Question: *CMS policies should encourage self-reporting by long-term care facilities of deficiencies. Delays in surveys following self-reported deficiencies that are treated as violations of the Medicare and Medicaid conditions of participation put patient safety and care at risk.*

Additionally, when retroactive per diem CMPs are imposed, long-term care facilities are unfairly penalized as a result of these delays. What is the Agency's policy for long-term care facilities to self-reported deficiencies? Are self-reported deficiencies treated the same as those not reported by the facilities? If so, does that provide long-term care facilities with an incentive to self-report and proactively address issues?

Answer: Self-reported deficiencies are addressed in a number of different ways. CMS identifies and documents deficiency findings related to resident harm or nursing home noncompliance, whether the deficient practice was self-reported or identified on site. In certain cases, the statute and regulation allow for a 50 percent reduction of an imposed CMP when a facility self-reports its noncompliance. This reduction can occur if there is prompt correction, if the self-report is timely, and if the noncompliance did not result in serious harm or death of a resident.

Question: *The purpose of the survey process is to ensure that deficiencies are corrected to the benefit of the residents they care for, so how does CMS measure compliance if there are significant delays in responses to self-reported deficiencies?*

Answer: For any noncompliance that happened before the time of the onsite survey, CMS surveyors establish the extent of noncompliance, what the facility did to address it, when it started, and the extent to which the noncompliance still exists. Generally, a facility is held

harmless for the timing of the review of self-reported deficiencies if the facility swiftly addressed the concern and provides evidence that it was corrected prior to the start of the survey.

If there is an ongoing deficiency (for example, the facility self-reported, but did not take other action to correct or prevent future non-compliance), then delays in a response could mean that the facility did not fully self-correct until a survey team investigated. This can result in continued non-compliance over a longer period of time leaving residents at risk for harm, which could result in a per diem CMP.

Question: *How does CMS determine whether a per diem or a per incident CMP will be assessed? What guidance do Regional Offices use in determining whether and how to retroactively apply CMPs?*

Answer: CMS determines which type of CMP to impose based on the level and time of noncompliance identified, and whether or not the facility has taken action to correct its noncompliance. CMPs (Per Instance or Per Diem) are mostly imposed in situations where noncompliance has led to a resident(s) being harmed, or in immediate jeopardy of serious harm or injury. Examples include cases where residents sustain a fracture from a fall, develop pressure ulcers, or wander outside the facility unsupervised and into an unsafe environment. In general, per diem CMPs are imposed for noncompliance that is identified with no evidence of correction at the time of the survey. The objective of per diem CMPs is to incentivize the facility's return to compliance as quickly as possible. Per instance CMPs are generally imposed for isolated events of noncompliance, or when noncompliance occurred but evidence of the facility's correction exists. The objective of both types of CMPs is also to incentivize sustained compliance, thus preventing future harm to residents.

Question: *How does CMS ensure that Regional Office activities are in line with CMS policy and procedures?*

Answer: The Social Security Act (§§ 1819(h)(2)(B)(ii)(I) and 1919(h)(3)(C)(ii)(I)) authorizes the Secretary to impose a CMP for each day of noncompliance, and the Code of Federal Regulations (42 CFR §488.430(b)) states that CMS may impose a CMP for the number of days of past noncompliance since the last standard survey. That said, the guidance is intended to ensure that CMPs are imposed to incentivize swift and sustained compliance. CMS ensures that Regional Office activities are in line with CMS policy and procedures through several mechanisms described below:

1) CMP Analytic Tool – The CMP Analytic Tool contains guidance for Regional Offices on how to determine the type and amount of a CMP. This includes whether to impose a CMP for a date of noncompliance that occurred prior to the start date of the survey. The tool is structured to ensure that CMPs are imposed in a manner consistent with the objectives stated in the answer above. We have recently revised the CMP Analytic Tool described above.

2) Quarterly Calls - CMS has established quarterly calls between CMS Central Office and each Region. During these calls, we discuss enforcement policies and procedures and nursing homes designated as Special Focus Facilities due to poor quality. Semi-annually, we review Region specific-data compared to national enforcement data to discuss trends.

3) Monthly Calls - CMS Central Office hosts monthly calls with all Regional Offices to discuss survey and enforcement policies and procedures.

4) Enforcement Training - CMS developed a web-based enforcement training for Regional Office staff which reviews Federal enforcement policies and procedures on the major enforcement remedies.

5) Review of high dollar CMPs - Starting in July 2017, CMS Central Office began reviewing all CMPs over $250,000 with the CMS Regional Office for consistency with CMP policies and procedures.

As outlined in the efforts above, CMS is using a variety of approaches to ensure consistency with the policies and procedures.

CMS publicly released its guidance in the CMP analytic tool in December 2014 through a memorandum (S&C 15-16-NH). CMS monitors the imposition of CMPs, and all enforcement remedies, to ensure they are being implemented consistent with policy and their intent. This monitoring is conducted through analytic reports of utilization and regular discussions with CMS Regional Offices. If there are issues with how CMPs are imposed, CMS discusses the case and policies with its Regional Office and conducts additional training if necessary.

Finally, CMS analyzes other factors that may impact the amount of a CMP, such as the timing of a State's revisit survey to certify correction of deficient practices and achievement of compliance, and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which raised CMP amounts in 2016 and requires annual adjustments based on cost of living adjustments. CMS regularly reviews policies based on results and feedback from stakeholders and makes adjustments as necessary to make sure policies are consistent with the goals of achieving swift and sustained compliance, and reducing variation or large outliers throughout the country.

Question: *States have the option to use funds collected from CMPs on initiatives that support consumer involvement to ensure quality care in facilities and other facility improvement initiatives. Does CMS take steps to ensure a portion of monetary penalties remitted back to the states is invested in long-term care facility quality improvement? Do nursing long-term care facility providers have an opportunity to provide feedback to states or CMS on how funds are invested?*

Answer: CMS strongly supports States' reinvestment of CMP funds into projects that support the health and safety of long-term care residents. CMS has created a website[5] that describes the allowable uses of CMP funds, examples of successful projects, an annual report of the projects each State has funded, and a sample application that individuals interested in applying to use CMP funds may submit to a State. The site also includes a list of State contacts that individuals may contact with questions or to provide feedback.

[5] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment.html

Ranking Member Neal (D-MA):

State Data

Question: *Your budget documents show, and Director Mulvaney has stated, that an additional $610 billion is cut from Medicaid by "ratcheting down some of the growth rates" on the proposed per capita caps beyond the $834 billion cut included in the House American Health Care Act legislation, which you have also supported. Under these combined proposals, what would the growth rate be for federal Medicaid capped contributions in future years? Would you please share with us state-specific data about the combined level of federal spending reductions and the estimated increase in the number of Americans without insurance coverage?*

Answer: The President's FY18 Budget does not incorporate specific legislation that is before Congress right now. Therefore, it is not accurate to apply the specific Medicaid savings the CBO has estimated for legislation before Congress to the President's Budget. The Budget calls for refocusing Medicaid on the elderly, children, pregnant women, and individuals with disabilities. In fact, under the Budget, Medicaid spending will be higher over the next decade than the last decade by a significant margin.

Coverage Loss

Question: *Can you please provide for the Committee specific coverage tables showing the impact of the President Budget's proposals on Medicaid and CHIP in terms of individuals over the ten year window? I am asking for year by year coverage numbers, for Medicaid, and separately for CHIP, by category – 65 and older, blind and disabled, children, and adults.*

Answer: The Budget supports repealing and replacing Obamacare, including improving Medicaid's sustainability, refocusing Medicaid on the elderly, children, pregnant women, and individuals with disabilities, and providing States flexibility to innovate and design state-based solutions to provide better care to Medicaid beneficiaries. The Budget proposal offers support for additional Medicaid flexibilities that could be considered legislatively or administratively, including, for example, encouraging work and personal responsibility. The Budget does not, however, incorporate specific legislation before Congress right now, and as such, coverage tables are not available.

Health Security

Secretary Price, states need reliable, flexible federal Medicaid funding, especially after natural disasters like Hurricane Katrina, epidemics and public health emergencies like the Zika virus, opioid addiction or lead poisoning crisis in Flint, Michigan, and the cost of new treatments like the Hepatitis C drugs. Facing these cost increases, states knew that the federal government would pay its share to account for increased need. Under your proposal to cap federal Medicaid funding, states would have to pay for 100 percent of those additional Medicaid costs - forced to

cut other parts of their Medicaid program or simply being unable to address these crises or cover these new treatments.

Question: *Congress waited for 32 months after the lead poisoning was uncovered in Flint, Michigan - and 11 months after President Obama declared it a state of emergency - to send additional non-Medicaid aid to Flint. However, the flexibility in Medicaid ensured that the state could immediately cover eligible individuals in need. If Medicaid funding was capped, states would not have that ability. Yes or no, Mr. Secretary, should sick patients have to wait for Congress to free up new money if a state ran short under a block grant?*

Answer: See response below.

Question: *Florida and Texas are relying on Medicaid to help prevent the spread of the Zika virus and treat those affected. With broad Medicaid cuts, and capped funding, states might have to choose between preventing and treating those affected by an epidemic, or providing coverage for other vulnerable populations like seniors in nursing homes. If a state ran short of money under a block grant, which patients should a state turn away first? For example, should a state terminate coverage for a child with cancer, in order to pay for coverage for a child hospitalized with a mental illness?*

Answer: As you know Medicaid is the primary source of medical coverage for millions of low-income American families and seniors facing health challenges. However, its costs have been growing drastically without corresponding improvement in outcomes. The key problem isn't lack of funding; the key problem is lack of flexibility. The FY 2018 Budget puts Medicaid on a path to fiscal stability by restructuring Medicaid financing and providing states with long overdue flexibility.

Rigid and outdated Federal rules and requirements prevent states from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes.

We are committed to making sure that States have the flexibility to design their Medicaid programs to meet the needs of the most vulnerable in their state. By strengthening the federal and state Medicaid partnership, we will empower states to develop innovative solutions to challenges like Zika, rather than telling states how they should run their programs.

Question: *States faced $1.3 billion in higher Medicaid drug costs with the introduction of the then-new Hepatitis C drug Sovaldi in 2014. If a state's Medicaid block grant runs out of money, should a state not cover a new breakthrough treatment, or maybe only cover it for part of the year, turning away patients who get sick after a certain date?*

Answer: The FY 2018 Budget puts Medicaid on a path to fiscal stability by restructuring Medicaid financing and providing states with long overdue flexibility.

By strengthening the Federal and state Medicaid partnership, we will empower states to develop innovative solutions to challenges like high drug costs, rather than telling states how they should run their programs. Every state has different demographic, budgetary, and policy concerns that shape their approach to Medicaid. That is one of the reasons a one-size-fits-all approach is not workable for a country as diverse as the United States.

Opioids

The opioid epidemic is ravaging the country and new analysis from The New York Times indicates that 2016 could be the worst year ever for drug overdose deaths, exceeding 59,000.

There has also been incredible progress in treating opioid addiction and other substance use disorders, namely medication assisted treatment (MAT). In April, you posted a new HHS Strategy to Fight the Opioid Crisis and medication-assisted treatment was notably absent. In May, you remarked that medication-assisted treatment amounted to "substituting one opioid for another," directly contradicting guidance from HHS agencies. Since then, some 700 researchers and practitioners have called on you to set the record straight and I'd like to give you the opportunity to do that here today. Your prepared remarks today did in fact refer to medication-assisted treatment.

Question: *Can you clarify—is medication-assisted treatment part of the HHS strategy to combat the opioid epidemic? Do you believe the medication-assisted treatment amounts to "substituting one opioid for another" as you previously stated?*

Answer: HHS and the Trump Administration are committed to doing all that we can to end the scourge of opioids that is sweeping across this nation.

The Department and the Trump Administration are committed to bringing everything the Federal Government has to bear to address the health crisis opioids pose. At HHS, we have identified five specific strategies that we can bring to the fight: prevention, treatment, and recovery services; targeting availability and distribution of overdose-reversing drugs; strengthening timely public health data and reporting; supporting cutting-edge research; and advancing the practice of pain management.

One of the key pillars of our approach is improving access to treatment and recovery services, including medication-assisted treatment (MAT) with naltrexone, buprenorphine, or methadone. Through the State Targeted Response to the Opioid Crisis grants authorized in the 21st Century Cures Act, HHS is expanding access to opioid addiction treatment through evidence-based interventions, including MAT. We are targeting the primary barriers to seeking and entering treatment, as well as long-term adherence to treatment, and sustained recovery. This funding is critical to reversing the opioid epidemic.

HHS Actions to Shore up the Marketplace

Question: *Has the Department worked with plans and state insurance commissioners to ensure marketplace plans are offered in all areas?*

Answer: The ever-narrowing set of choices Americans are facing means that there is a very real chance some counties will have no insurers selling ACA plans in 2018. This is a situation we have been monitoring extremely closely, and working every day with states to address.

The Administration recognizes that states are the primary regulators of health insurance, and it remains imperative for the Executive Branch to empower states with more flexibility and control. Among other regulatory actions and guidance documents, the Department also finalized a Market Stability Rule in April, which tightened special enrollment periods, made it more difficult for enrollees to skip premium payments, adjusted the open enrollment period to align with other healthcare markets, lifted one-size-fits-all requirements regarding network access, and widened the actuarial value bands within which insurers can offer plans to patients.

Question: *Has the Department developed and funded a targeted marketing plan for the Marketplace in 2018?*

Answer: Please refer to the following excerpt regarding Federal Exchanges, Consumer Information and Outreach from the Centers for Medicare & Medicaid Service FY 2018 Justification of Estimates, also available at https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2018-CJ-Final.pdf

> *Consumer Information and Outreach: $573.5 million of which $0 million is funded through discretionary appropriations. CMS ensures consumers are fully supported not only during open enrollment, but throughout the plan year using mail, phone, and the website.*
>
> *The consumer call center is the primary means for consumers to ask questions, get help with online tools, complete an application, and get help with tax form questions, life changes and inconsistencies. The call center offers support in over 200 languages and is open 24 hours a day 7 days a week. A specialized center provides complex call resolutions and is staffed by experts in resolving multiple issues. Through the Government Printing Office (GPO), CMS prints and mails pertinent consumer notices including application status, data matching issues, and appeals.*
>
> *CMS conducts traditional media and direct mail as well as digital media public education and outreach campaigns leading up to and during the OEP to encourage participation in the FFE and FF-SHOP. CMS provides over 100 print and electronic educational publications in English and Spanish on a wide variety of topics including enrollment basics, financial assistance, individual responsibility payment, exemptions, and appeals. Many consumers have limited experience with health insurance, and this activity provides educational materials on understanding their benefits, how to use their coverage, and what costs they are responsible for. Year round on the ground community based support is available through Navigators that supply impartial information to*

consumers on enrolling, selecting a plan, and assisting with data inconsistency and tax issues.

Question: *Has the Administration taken action to ensure payments are targeted to plans with higher risk populations, for example by lowering the million dollar "attachment point" for the new risk adjustment model that begins in 2018?*

Answer: See response below.

Question: *Has the Administration worked to negotiate wider service areas for issuers that would expand market place choices in 2018?*

Answer: The Administration remains committed to providing needed flexibility to issuers to help attract healthy consumers to enroll in health insurance coverage, improve the risk pool and bring stability and certainty to the individual and small group markets, while increasing the options for patients and providers.

Further, the Administration recognizes that states are the primary regulators of health insurance, and we are committed to returning to states their traditional authority to regulate health plans. We seek to ensure that policies empower states to make decisions that work best for their markets, understanding that there are differences in markets from state to state. We will support state flexibility and control to create a free and open healthcare market in accordance with current statute.

Lastly, since January 20, 2017, HHS has issued several rules and guidance documents to improve the current healthcare market for consumers. Among some of the actions taken to date:

- February 15: Less than a month into the new Administration, HHS proposed a broad set of solutions to increase choices for patients and help stabilize insurance markets. Two measures would loosen restrictions on the type of plans that can be sold while others aim to discourage gaming the system and improve the health of the risk pool.
- February 17: HHS simplified the filing calendar for insurers and pushes back several deadlines, allowing insurers maximum time to offer the widest array of choices possible.
- February 23: HHS announced that people will continue to be allowed to keep their transitional plans plans if they like them, ensuring lower premiums and real choices for millions of Americans. (Since Obamacare went into effect, HHS permitted renewal of some individual and small-group plans that were out of compliance with certain ACA market reforms, but that policy was set to expire this year.)
- March 13: Secretary Price sent a letter to states encouraging them to apply for Innovation Waivers under section 1332 of Obamacare, which allows states to pursue innovative strategies to adapt many of the law's requirements to suit the state's specific needs.

- March 14: Secretary Price and CMS Administrator Verma sent a letter to America's governors laying out a policy vision for Medicaid innovation to give states flexibility to develop solutions that work for them.
- April 13: HHS finalized the market stabilization rule just two months after the proposal was released.
- May 11: HHS released a State Innovation Waiver Checklist to assist states applying for 1332 waivers.
- May 15: HHS announced it will propose a rule to provide small businesses with more healthcare choices by allowing eligible small employers to use the small-business healthcare tax credit offered under Obamacare in connection with purchasing SHOP coverage for their employees through the registered agent or broker of their choice. (Very few small businesses have bought insurance under the mechanism Obamacare created, the SHOP exchange.)
- May 17: HHS announced a plan to make it easier for Americans to sign up for insurance through private-sector web brokers instead of being redirected to purchase coverage through Healthcare.gov.
- June 8: HHS issued a Request for Information seeking input from the public about how to improve the regulation of the individual and small group insurance markets.

Cybersecurity

Question: *I'm concerned about the security of our health data. We've recently seen that even large corporations are not safe from hacking, data breaches and ransomware. HHS has a vital role to play in ensuring that providers share data across settings though the Office of the National Coordinator for Health IT (ONC) while also enforcing privacy standards under HIPAA through the Office for Civil Rights (OCR). Both of these agencies are subject to significant budget cuts in this year's President's budget—ONC by nearly 40%. And yet nobody thinks we are going to see fewer threats to health data security. I don't want our health system to suffer the same kind of attack that devastated Britain's National Health Service. How can you justify such substantial cuts to these functions when we face such serious threats? How are you going to ensure that HHS carries out its important statutory responsibilities in this space with fewer resources, both budgetary and in personnel? Can you please provide follow up to the Committee as to what functions a 40% cut in the ONC budget would eliminate or curtail?*

Answer: ONC has achieved great success in the electronic health record adoption rates among practitioners and clinics across the country. This success is reflected in the FY 2018 President's Budget; the President's Budget closes out ONC's adoption-related activities, to prioritize activities for standards and policy coordination and development. ONC will continue efforts related to achieving interoperability and reducing the burden to providers of health information technology. ONC integrates a clinical perspective in its work, and it strives to advance the availability, usability, and timeliness of clinical decision support and quality measurement; to identify and correct unsafe uses of health IT; and to engage consumers and healthcare providers in the policy development process. The funds proposed for privacy and security will

provide for the continued support for the position of Chief Privacy Officer and policy development and coordination of privacy and security in the context of broad health IT policy efforts.

The HHS Office for Civil Rights (OCR) will continue its work to robustly enforce the HIPAA Privacy, Security, and Breach Notification Rules and to issue guidance to improve understanding of those rules. Support for OCR's enforcement of HIPAA regulations comes from appropriated funds, as well as civil monetary penalties that OCR collects for violations of those rules and amounts paid to OCR in informal settlements of funds collected in HIPAA cases, consistent with section 13410 (c) (1) of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH).

LGBT Rights

Question: *Despite complete silence from President Trump and the White House, June is LGBT Pride month across the country. HHS made important progress in advancing LGBT rights in recent years. CMS finalized rules requiring federally funded providers to allow visitation by same sex partners and HHS codified collection of LGBT data across HHS surveys. The Trump Administration stands to reverse this important progress and threatens enforcement of civil rights law for LGBT Americans—part of an administration-wide effort to roll back civil rights enforcement that has been recently and widely reported in the press. Rather than working to improve data collection on LGBT Americans, your Department has moved to erase LGBT people from the Centers for Independent Living Annual Program Performance Report. The new head of HHS's Office for Civil Rights, Roger Severino, has a long record of opposing LGBT rights and the HHS budget proposes to cut OCR's funding—even as the office faces new challenges and increased threats to health data security. Can you commit today to ensuring that LGBT Americans and transgender Americans in particular, will not be denied due process under the civil rights laws that HHS enforces and that LGBT Americans will not be erased from HHS surveys? Will the Office for Civil Rights under Roger Severino ensure that LGBT Americans do not face discrimination in federally funded health care settings and that same sex couples can visit their loved ones when they are hospitalized and most in need?*

Answer: I believe that people from all walks of life should be treated fairly and with compassion – especially when it comes to their healthcare. That's how I operated as a physician taking care of patients for over 20 years and that's how I approach public service. Under my leadership at HHS, we will respect the inherent dignity of all persons, and will follow the law.

Meals on Wheels

Question: *Despite his repeated promises to protect them, older Americans took a lot of hits in President Trump's budget, with deep cuts to long-term care, cuts to Social Security disability benefits, cuts to Medicare health insurance counseling programs, and cuts to SSI disability benefits for elderly couples. I wanted to talk about the 2 million seniors who will lose services*

funded by the Social Services Block Grant, ranging from Meals on Wheels and other independent living supports to the Adult Protective Service. SSBG is the primary source of federal funding for state adult protective services, which investigate and address allegations of elder abuse. Zeroing out SSBG means more parents and grandparents will suffer physical maltreatment, neglect, and financial exploitation. When asked about these cuts, OMB Director Mulvaney suggested that Meals on Wheels "doesn't work," despite rigorous studies showing that home-delivered meals help seniors live independently and reduce the need for nursing home care. Is HHS's Administration on Aging unaware of the research? Has it been shared with Director Mulvaney?

Answer: The Administration believes that it is important to note that the Social Services Block Grant (SSBG) does not directly fund home delivered meals, although home delivered and congregate meals are an allowable use for SSBG funds. Home delivered meals for older Americans are financed through a combination of Federal, state, local and private funds. The vast majority of the Federal share comes through the Older Americans Act, administered through the Administration for Community Living at HHS. Funding for these important nutrition programs was maintained in the President's 2018 budget at the FY17 CR level.

Representative Noem (R-SD):

Secretary Price, as you know, the Great Plains Area of the Indian Health Service (IHS), of which my home state of South Dakota is a part, is experiencing a crisis that has resulted in poor care at best and patient deaths at worst.

Sadly, despite eight years of promises from the Obama Administration, the Great Plains was practically ignored during most of the last eight years until the most recent emergency erupted in late 2015.

As of the writing of this question, HHS has announced it is sending a team of senior staff to South Dakota to visit the Pine Ridge hospital, located on the Pine Ridge reservation, which is home to the Oglala Sioux Tribe. I am pleased at this development, and I thank you for your quick action after I raised this with you when you appeared before the Committee.

I have several additional questions related to your plans to improve state of IHS facilities in South Dakota, IHS processes and procedures, and most importantly, patient care:

***Question:** Do you have a strategy or plan to address the deficiencies in the Indian Health Service hospitals in South Dakota and across the Great Plains Area that have experienced accreditation issues – one that differs from the previous Administration's? If so, please describe it.*

Answer: The team of senior HHS staff that I sent to South Dakota, which included the Acting Surgeon General and the new Acting Director of the Indian Health Service, were charged with assessing in person the current status of affairs at Pine Ridge. The team found that progress has been made at the site in recent months; however there is still much work that needs to be done to bring the level of service at Pine Ridge up to standards. I have charged the Acting Director of IHS with the responsibility to address the issues that remain not only at Pine Ridge, but also in the other hospitals in the Great Plains Area that require attention. The team of senior HHS staff that visited South Dakota conducted a phone briefing with the South Dakota delegation staff on the trip. Moving forward, the agency will continue partnering closely with healthcare stakeholders in the Great Plains Area to pursue reforms that achieve sustainable improvements in quality and access to care and enhance accountability of IHS staff and providers.

***Question**: In the most recent omnibus legislation, Congress appropriated $29 million to the end of the fiscal year to address accreditation emergencies at IHS facilities. What do you intend to do with that money?*

Answer: The funding appropriated for accreditation emergencies is being used to address critical, quality healthcare services and needs related to meeting the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation. A portion of the funds were used for contracted emergency department services in three hospitals in the Great Plains Area, including Pine Ridge, Rosebud, and Omaha Winnebago. IHS Senior Leadership continues to evaluate and prioritize other funding needs—including, but not limited to, increased purchased and referred

care and collection shortfalls—based on the evolving situation in the Great Plains Area and ongoing implementation of the Quality Framework.

Question: *Do you have a plan to ensure IHS is appropriately capturing data on patient outcomes, staffing levels, and other critical data points necessary for Congress to conduct oversight of IHS' federally-operated facilities? If so, please describe it.*

Answer: IHS uses several measures to identify patient outcomes and staffing levels and provides the results to Congress in the annual budget submission. Items such as the Government Performance and Results Act (GPRA) provide information on key clinical outcomes and areas for improvement. IHS is able to extract Federal and tribal results from the clinical GPRA performance measures that are reported primarily from the outpatient setting. The measures are categorized thematically: diabetes (5 measures), dental (3 measures), immunizations (4 measures), prevention (16 measures consisting of cancer screenings, behavioral health and other measures). IHS has developed a Quality Framework to help ensure the delivery of reliable, high quality healthcare for the IHS Direct Service facilities. IHS planning documents related to staffing levels for new facilities are determined through the use of the Resource Requirements Methodology (RRM). Staffing levels for facilities (other than new facilities) are determined by local leadership based on community needs, the programs offered, and available funds for clinical staffing.

In 2016, IHS began tracking all federally funded vacancies, vacancy rates, and onboard staff on a nationwide basis and producing a quarterly vacancy report. The report identifies IHS direct service facilities with high healthcare provider vacancy rates to pinpoint critical staffing needs. Through the vacancy reports, IHS can refine recruitment and outreach efforts as well as recruitment and retention strategies. Unfunded staffing needs (positions) are not tracked using this process, but are part of the total picture of IHS staffing needs.

The Quality Framework Steering Committee has chartered three separate workgroups composed of members from all levels of IHS – service unit, area office and headquarters – to develop meaningful data sources and measure reporting for oversight and accountability of quality/safety-related domains. The Performance Accountability Dashboard Working Group is nearing completion of measure development and plans to begin measure testing in July 2017 for anticipated implementation of the dashboard by July 31, 2017. This dashboard will help IHS to monitor accountability of Service Units and Area Offices in meeting IHS policy, CMS certification requirements, and any other external accreditation standards, as well as active participation in quality improvement programs.

A standardized survey of patient experience has been developed by the Patient Experience Survey Working Group to collect locally, actionable quality improvement information from patients using tablet computer devices.[6] Administration of the survey via tablet devices will accelerate the collection and analysis of the data. The survey and method of administration

[6] OMB number 0917-0036; expiration date: 07/31/2018

was derived from a Federal-tribal collaboration between the working group and Southcentral Foundation in Anchorage, Alaska.

Question: *Many of private healthcare providers, especially community hospitals in South Dakota, have reported that IHS' poor performance has led to skyrocketing levels of uncompensated care. Not only does this endanger the financial health of these facilities, and therefore access to care for all people in the area, Native and non-Native, but also shifts the federal government's treaty and trust responsibilities to the private sector. How do you intend to rebuild the fractured relationships between IHS and private healthcare providers surrounding IHS facilities?*

Answer: We recognize the importance of establishing a senior IHS leadership team that has a comprehensive understanding and experience of the Indian Health Service, including the relationship that IHS facilities have with healthcare providers in their communities. Improvement in IHS's operations, including its relationships with stakeholders, is and continues to be a priority for the Department. In the specific situation of the Great Plains Area, IHS staff meets biannually with the South Dakota Hospital Association to address and resolve payment issues. The individual service unit staff at the local level also meets regularly with providers.

Question: *Can you commit that these facilities will be paid in a timely manner for services rendered?*

Answer: The IHS contracts with a Fiscal Intermediary to process medical and dental claims. The Contractor is Health Care Service Corporation, New Mexico Blue Cross and Blue Shield. The IHS contract requirement for timely claims processing is 97% of all clean claims will be paid within 30 days. For fiscal years 2014 to the present, the Contractor has exceeded this percentage requirement.

Question: *Do you have a plan to reform the Purchased/Referred Care (PRC) program's outdated and unfair financial distribution? If so, please describe it.*

Answer: The Director's Workgroup on Improving PRC is comprised of both Federal and tribal members from across the country. This workgroup is charged with discussing an array of PRC issues, including allocation methodology, to improve the program. The allocation methodology has been discussed a number of times with this Workgroup. Over 50 percent of the PRC Program's budget is operated by tribes. In 2015, the PRC Workgroup recommended to keep the formula unchanged and to review at the next meeting.

When the Director's Workgroup on Improving PRC meets this year, this will be one of the major topics for discussion. Changes to the PRC Distribution Formula would require additional tribal consultation.

Question: *Do you have a plan to reform the PRC program's outdated and convoluted referral system (the three-stage approval process)? If so, please describe it.*

Answer: The PRC authorization process adheres to 42 CFR 136 Subpart C. PRC regulations outline: 1) eligibility requirements for IHS beneficiaries to whom PRC services will be provided, 2) the requirement for residency within the PRC delivery area, 3) the establishment of medical priorities when funds are not sufficient to provide the volume of PRC services indicated as needed by the population residing in a PRC delivery area, and 4) notification requirements for authorization for PRC services. The IHS is the payer of last resort for beneficiaries eligible for PRC and requires PRC-eligible beneficiaries to apply for alternate resources (Medicare, Medicaid, or private insurance, etc.) if the beneficiary is eligible for them. At this time, the IHS does not have a plan to revise these regulations, but we are always happy to work with Congress and other stakeholders to consider mechanisms by which IHS could improve the provision of services in Indian Country, including the requirements for PRC referrals.

Representative Nunes (R-CA):

Question: *Ambulatory Surgery Centers (ASCs) have saved Medicare billions between 2007 and 2011 and play a critical role in delivering high-quality, cost-effective surgical and preventive care. Seeing as Medicare reimburses ASCs at 49% of the HOPD level for identical procedures, and the disparity is growing, do you plan to implement an inflationary update for ASCs?*

Answer: Currently, the ASC payment system is updated annually using the Consumer Price Index for All Urban Consumers as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. We are always interested in hearing feedback about how to improve our programs and pay appropriately for items and services furnished in different settings.

Question: *As you know, Congress exempted group 3complex rehabilitative power wheelchairs (CRT) and their accessories from the competitive bidding program under the Medicare Improvements for Patients and Providers Act. Congress has acted twice now to postpone competitive bidding pricing for critical Group 3 CRT wheelchair accessories. With these payment cuts quickly approaching on July 1, 2017, do you intend to use your authority to stop the application of competitive bidding pricing for standard wheelchairs on CRT wheelchair accessories?*

Answer: CMS is committed to providing beneficiaries with access to the services and medical devices they need. On June 23, 2017, CMS issued a new policy on how adjustments to the fee schedule based on information from competitive bidding programs apply to wheelchair accessories and back and seat cushions used with group 3 complex rehabilitative power wheelchairs[3]. As a result, effective July 1, 2017, payment for these items will continue to be based on the standard unadjusted fee schedule amounts, which will help to protect access to complex rehabilitative power wheelchair accessories on which people with significant disabilities depend.

[3] CMS FAQ, June 23, 2017 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/Downloads/2015-DMEPOS-FR-FAQs.pdf

Questions for the Record
Hearing on the Department of Health and Human Services'
FY 2018 Budget Request
June 8, 2017

Representative Tiberi (R-OH):

Question: *Secretary Price, I am sure you've seen the unfortunate news that Anthem, the only state insurer that provided plans in every single county in Ohio, is leaving the exchange and most of the individual market in 2018. Around 20 counties, one of which is in my district will have no ACA plan available in the marketplace. 1,700 residents of Muskingum County, Ohio, who are currently covered by Anthem, will not have the option of purchasing an exchange plan in 2018. I understand that you and your team have worked to stabilize the markets administratively. Could you elaborate on these efforts? Specifically, I want to know if you have given any thought to actions you can take to help plans re-enter Ohio— and similar states— especially when the American Health Care Act becomes law and a stable transition period away from the failures of Obamacare is in place.*

Answer: The Administration remains committed to providing needed flexibility to issuers to help attract healthy consumers to enroll in health insurance coverage, improve the risk pool and bring stability and certainty to the individual and small group markets, while increasing the options for patients and providers.

Further, the Administration recognizes that states are the primary regulators of health insurance, and we are committed to returning to states their traditional authority to regulate health plans. We seek to ensure that policies empower states to make decisions that work best for their markets, understanding that there are differences in markets from state to state. We will support state flexibility and control to create a free and open healthcare market.

Lastly, since January 20, 2017, HHS has issued several rules and guidance documents to improve the current healthcare market for consumers. Among some of the actions taken to date:

- February 15: Less than a month into the new Administration, HHS proposed a broad set of solutions to increase choices for patients and help stabilize insurance markets. Two measures proposed would loosen restrictions on the type of plans that can be sold while others aim to discourage gaming the system and improve the health of the risk pool.
- February 17: HHS simplified the filing calendar for insurers and pushes back several deadlines, allowing insurers maximum time to offer the widest array of choices possible.
- February 23: HHS announced that people will continue to be allowed to keep their transitional plans if they like them, ensuring lower premiums and real choices for millions of Americans. (Since Obamacare went into effect, HHS permitted renewal of some individual and small-group plans that were out of compliance with certain ACA market reforms, but that policy was set to expire this year.)

- March 13: Secretary Price sent a letter to states encouraging them to apply for Innovation Waivers under section 1332 of Obamacare, which allows states to pursue innovative strategies to adapt many of the law's requirements to suit the state's specific needs.
- March 14: Secretary Price and CMS Administrator Verma sent a letter to America's governors laying out a policy vision for Medicaid innovation to give states flexibility to develop solutions that work for them.
- April 13: HHS finalized the market stabilization rule just two months after the proposal was released.
- May 11: HHS released a State Innovation Waiver Checklist to assist states applying for 1332 waivers.
- May 15: HHS announced it will propose a rule to provide small businesses with more healthcare choices by allowing eligible small employers to purchase SHOP coverage for their employees through the registered agent or broker of their choice, rather than through healthcare.gov. (Very few small businesses have bought insurance under the mechanism Obamacare created, the SHOP exchange.)
- May 17: HHS announced a plan to make it easier for Americans to sign up for insurance through private-sector web brokers instead of being redirected to purchase coverage through Healthcare.gov.
- June 8: HHS issued a Request for Information seeking input from the public about how to improve the regulation of the individual and small group insurance markets.

Representative Johnson (R-TX):

Question: *Mr. Secretary, I'd like to know what role you believe physician-owned hospitals (POH) have in providing good, quality healthcare for patients and increasing affordability?*

Answer: The Affordable Care Act imposed additional restrictions on physician ownership and investment in Medicare-participating hospitals, banning new physician-owned hospitals (POHs) and limiting the expansion of existing POHs. We do, however, have the authority to grant exceptions to the expansion prohibition for certain applicable hospitals and high Medicaid facilities. In April 2017, as part of our Fiscal Year 2018 Medicare Hospital Inpatient Prospective Payment System and Long Term Acute Care Hospital Prospective Payment System Proposed Rule[1], we included a Request for Information regarding physician-owned hospitals. We are seeking public comments on the appropriate role of physician-owned hospitals in the delivery system and on how the current scope of and restrictions on physician-owned hospitals affects healthcare delivery, particularly regarding Medicare beneficiaries.

Question: *What would you say has been the impact of the Obamacare ban on the development of new POHs as well as the effective ban on the expansion of POHs on the healthcare sector, including its impact on patients and payers?*

Answer: CMS relies heavily on stakeholder feedback to make sure our actions promote access to care while reducing the burden on healthcare providers. That's why, in April 2017, as part of our Fiscal Year 2018 Medicare Hospital Inpatient Prospective Payment System and Long Term Acute Care Hospital Prospective Payment System Proposed Rule[2], we included a Request for Information regarding physician-owned hospitals. We are seeking public comments on the appropriate role of physician-owned hospitals in the delivery system and on how the current scope of and restrictions on physician-owned hospitals affects healthcare delivery, particularly regarding Medicare beneficiaries.

[1]Proposed Rule; RFI on page 20002 https://www.gpo.gov/fdsys/pkg/FR-2017-04-28/pdf/2017-07800.pdf
[2] Proposed Rule; RFI on page 20002 https://www.gpo.gov/fdsys/pkg/FR-2017-04-28/pdf/2017-07800.pdf

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[3] CMS FAQ, June 23, 2017 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/Downloads/2015-DMEPOS-FR-FAQs.pdf

Representative Kelly (R-PA):

Complex Rehab wheelchairs and accessories are used by a small population of people with high levels of disabilities such as ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, and traumatic brain injury. For this reason, Congress exempted Complex Rehab Technology from the competitive bidding program established in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

Unfortunately, in 2014 CMS stated its intent to apply Medicare competitive bidding program pricing to Complex Rehab wheelchair accessories effective January 1, 2016. Congress has delayed these reductions twice; however, the cuts are scheduled to take effect July 1, 2017.

***Question:** Mr. Secretary, I am concerned with CMS' interpretation of the competitive bidding program which may reduce access to CRT accessories for people with disabilities. Do you plan to take action before July 1, 2017 to stop these cuts?*

Thank you for your attention and consideration of this important matter.

Answer: On June 23, 2017, CMS issued a new policy on how adjustments to the fee schedule based on information from competitive bidding programs apply to wheelchair accessories and back and seat cushions used with group 3 complex rehabilitative power wheelchairs. As a result, effective July 1, 2017, payment for these items will continue to be based on the standard unadjusted fee schedule amounts, which will help to protect access to complex rehabilitative power wheelchair accessories on which people with significant disabilities depend.

Representative Meehan (R-PA):

Question: *We need to address the long-term solvency of the Medicare program. I am working to draft legislation to modernize the Stark Law and Anti-Kickback Statute in order to support a transition from Medicare fee-for-service to value-based health care payment models. Pursuant to the President's "Executive Order Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal," I look forward to working with you to make changes in regulations related to enforcement for technical violations of the Stark Law and Anti-Kickback Statute for any organization participating in an alternative payment model substantially similar to those currently or previously operated by CMS. Will you commit to supporting the move from Medicare fee-for-service payments toward value-based care models?*

Answer: Value-based programs reward healthcare providers with incentive payments for the quality of care they give to people with Medicare. These programs are part of CMS's larger quality strategy to reform how healthcare is delivered and paid for.

Enforcement responsibilities for the Stark Law and the Anti-Kickback Statute are shared by three government agencies: CMS, the Department of Justice, and the Department of Health & Human Services Office of Inspector General. Among other provisions, the Stark Law is a strict liability statute that prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies. The Anti-Kickback Statute prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of Federal healthcare program business; both civil and criminal penalties can be imposed for violations. HHS has published a number of regulations interpreting the Stark Law and the Anti-Kickback statute and promulgating Stark exceptions and Anti-Kickback Statute safe harbors. Like all finalized rules, these regulations were promulgated using the standard Administrative Procedure Act process, which includes a public comment period. However, we are always looking to improve our programs, and we are committed to – and welcome – feedback about how we can ensure strong program integrity, while encouraging innovative payment models and relieving burden on providers.

Question: *In light of the recent report issued by the Health Care Industry Cybersecurity Task Force, I was pleased to see that the Department of Health and Human Services (HHS) requested additional appropriations for cybersecurity efforts within the Office of the Secretary. Do you think it is feasible for HHS to coordinate with the private sector as well as federal and state officials to harmonize existing and future laws and regulations that affect health care industry cybersecurity? What is your response to the Task Force's recommendation that leadership for health care cybersecurity should be centralized? Could you describe the resources HHS has that are available to health care providers and stakeholders?*

Answer: HHS is currently reviewing the recommendations made by the Healthcare Industry Cybersecurity Task Force. Specifically, the Department is working to determine which (if any) of those recommendations can be implemented consistent with our current authorities,

resources, and policies. As part of this review, HHS will examine whether we can decrease regulatory burden on industry by increasing incentives for strong cybersecurity practices. HHS is also evaluating the feasibility of harmonizing the cybersecurity legal requirements under current authorities and the extent to which such harmonization may require legislative changes. In undertaking this evaluation, it is important for us to keep in mind that the healthcare industry is very diverse in size and technical capabilities, spanning from single doctor practices to multibillion dollar health insurance companies – and that the cybersecurity requirements imposed on such an industry have to be flexible and scalable.

HHS believes that it is reasonable and necessary for the Department to undertake this review process with our partners in Federal, State, and local agencies, as well as the private sector. Through coordination we can ensure that key cybersecurity policies, mandates, and guidelines are informed by the lessons learned – the "scalable best practices" noted in the Task Force report. This coordinated approach includes incident reporting and response activities and a federal-level cybersecurity framework, which promotes a shared cybersecurity language and accompanying standards, guidelines, and best practices, while recognizing the need for flexibility and scalability.

The FY 2018 President's Budget proposes an increase to enhance the Department's overall cybersecurity capacity. HHS is currently evaluating what additional flexibilities, if any, would be needed to ensure the Department's ability to retain necessary human capital skillsets so that the Department can adequately prepare for and respond to threats.

Question: *The Health Care Industry Cybersecurity Task Force report noted that the health care industry, like many industries, is experience challenges in recruiting and retaining qualified cybersecurity professionals. As IBM encourages a "new collar" jobs initiative for cybersecurity, what do you think is the appropriate role for the federal government in supporting health care cybersecurity workforce development and potentially developing standards for certifying advanced degree cybersecurity programs?*

Answer: We agree with the Task Force report that education and workforce development are critical to enhancing cybersecurity within the Healthcare and Public Health Sector. While workforce development is critical in every sector, the healthcare environment poses unique regulatory, clinical, and patient protection concerns that require specialized skills from information security professionals. As the Task Force notes, both public and private sectors have a role in defining the appropriate skill sets and certifications needed to provide adequate information security expertise within healthcare organizations. It follows, then, that the Federal Government would play a key role in supporting the creation of a cybersecurity workforce focused on the healthcare sector.

Question: *As you know, Medicare's enrollment rules are complex, and seniors do not receive notice from the Centers for Medicare and Medicaid Services (CMS) regarding their responsibility to enroll. This is why I introduced The Beneficiary Enrollment Notification and Eligibility Simplification Act, also known as the BENES Act. Because of these confusing rules, seniors may*

find themselves subject to a late enrollment penalty. The Part B late enrollment penalty permanently increases a beneficiary's premium by 10 percent for every 12 month period the beneficiary could have had Part B coverage, but did not. Others are paying for private coverage that is secondary coverage to Medicare. Without enrolling in Medicare, these seniors will find themselves responsible for significant out-of-pocket costs. One part of the solution is to require CMS, in cooperation with the Social Security Administration and the Internal Revenue Service, to issue notifications to individuals approaching eligibility about the enrollment rules and the coordination of Medicare coverage with other health insurance coverage. Do I have your commitment to work with Congress to ensure that the Medicare program, starting with the enrollment process, is structured in a manner that best serves its beneficiaries – current and future?

Answer: CMS works closely with the Social Security Administration to enroll eligible beneficiaries in the various components of Medicare. As part of this process, enrollees can chose which parts of Medicare they'd like to enroll in. Most people should enroll in Part A when they turn 65, even if they have health insurance from an employer because they paid Medicare taxes while they worked and therefore don't pay a monthly premium for Part A. Certain people may choose to delay Part B. In most cases, it depends on the type of health coverage they may have. As you note, if a beneficiary does not enroll on time, they may be subject to a late enrollment penalty of up to 10 percent for each full 12 month period they could have had Part B[4], but didn't sign up for it. They are responsible for paying this penalty for as long as they have Part B coverage. CMS notifies certain beneficiaries at the beginning of their initial enrollment period (IEP) about their automatic entitlement to hospital insurance (HI) and enrollment in supplementary medical insurance (SMI), if applicable based on where the beneficiary resides, in the IEP package. CMS mails the IEP package three months prior to the 25th month of disability benefit entitlement or three months prior to the month of age 65 attainment (i.e., the first month of the individual's IEP). The IEP package contains a Welcome to Medicare cover letter, the Welcome to Medicare booklet, the beneficiary's official Medicare card reflecting the HI and SMI entitlement dates, and a postage-paid envelope for the individual to use to send their SMI refusal to SSA.

The Administration is committed to making sure the Medicare enrollment process works for beneficiaries including how CMS informs people of their eligibility to enroll in Medicare and the consequences if they delay enrollment.

Question: *I appreciate the budget proposal's support for implementation of the market-based payment reform for clinical laboratory services. We have just passed the May 30, 2017, deadline for applicable labs to report payment rates and test volumes for their private payers. I continue to hear concerns from stakeholders regarding the definition of applicable laboratory and outstanding issues regarding data reporting and collection. Could you provide an update on the Agency's work to resolve these issues?*

[4] For more information see: https://www.medicare.gov/your-medicare-costs/part-b-costs/penalty/part-b-late-enrollment-penalty.html

Answer: CMS is committed to the successful implementation of the new private payer rate-based clinical laboratory fee schedule (CLFS) and looks forward to working with the laboratory industry to ensure accurate payment rates. As you noted, feedback from stakeholders indicated that many reporting entities would not be able to submit a complete set of applicable information to CMS by the March 31, 2017, deadline. In response, on March 30, 2017, CMS announced that it would exercise enforcement discretion until May 30, 2017, with respect to the data reporting period for reporting applicable information under the CLFS and the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information. Since the enforcement discretion deadline of May 30 has now passed, CMS is currently performing a comprehensive analysis of the submitted CLFS data. We will continue to review the operations of the program and look forward to feedback on how to improve the program.

Question: *Civil Monetary Penalties (CMPs) are appropriate enforcement mechanisms that work to ensure patient safety and quality of care. However, I am hearing from providers in my District that enforcement action for long-term care facilities is not being conducted in a manner consistent with these goals. Data show great variation in CMS Regional Offices' issuance of CMPs. Since the third quarter of 2016, Regions 3 and 4 have levied significantly higher average per diem CMPs. What accounts for the variation of CMPs in different regions? What oversight does the CMS perform to prevent potentially excessive enforcement activities by Regional Offices? How does CMS ensure that the enforcement activities and CMPs do not jeopardize care in long-term care facilities?*

Answer: CMS's role is to ensure that the minimum quality standards for nursing home residents are met. This requires ensuring access to long-term care facilities that provide nursing home residents with safe and effective care. The goal of enforcement is to ensure swift and sustained compliance with the minimum health and safety standards. One of the enforcement mechanisms we are authorized to utilize is Civil Monetary Penalties (CMPs). CMPs can be established as per instance (one-time) or per diem. In general, the amount of the per diem CMPs is related to a number of factors including: the extent of non-compliance or harm to nursing home residents; the number of days of non-compliance; facility culpability; facility financial hardship; and others. We have found that variation in CMPs is largely attributable to the application of these factors in the context of the specific facts involved in any particular enforcement action.

CMS has been working towards cross-Regional consistency in CMP processes and policies. Since 2014, we have been conducting quarterly calls with all Regional Offices to discuss CMP policies and the outcomes for that Region. CMP data is routinely shared and discussed across Regions to ensure that others are aware of key markers related to enforcement.

Based on CMS' review to date, CMS has found that the variation in Region 3 and Region 4 seems to be based primarily on the extent to which noncompliance is found which started before the date of the survey (i.e., retroactive application of CMPs). When there is a per diem

CMP imposed and the concern started before the survey date, the fine accumulates until corrected.

CMS has discussed with Region 3 and Region 4 the extent to which there is regional variation.

To address this issue (retroactive application leading to high per diem CMPs), earlier this month CMS revised our policies and instruction in cases where noncompliance started before survey. In these cases, a per instance (one-time) CMP would generally be imposed except in cases of abuse and serious harm to residents. We also we recently released a policy for CMS Central Office review all CMP fines over $250,000. This ensures that there is consistent application of policies particularly for higher dollar value CMPs. (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-37.pdf)

We will continue to take a look at the CMP process and Regional practices. Our goals are to ensure that CMPs are applied in a consistent manner, that minimum quality standards are met for residents, and that we are continually evaluating the CMP process for effectiveness of leading to high quality care.

Question: *CMS policies should encourage self-reporting by long-term care facilities of deficiencies. Delays in surveys following self-reported deficiencies that are treated as violations of the Medicare and Medicaid conditions of participation put patient safety and care at risk.*

Additionally, when retroactive per diem CMPs are imposed, long-term care facilities are unfairly penalized as a result of these delays. What is the Agency's policy for long-term care facilities to self-reported deficiencies? Are self-reported deficiencies treated the same as those not reported by the facilities? If so, does that provide long-term care facilities with an incentive to self-report and proactively address issues?

Answer: Self-reported deficiencies are addressed in a number of different ways. CMS identifies and documents deficiency findings related to resident harm or nursing home noncompliance, whether the deficient practice was self-reported or identified on site. In certain cases, the statute and regulation allow for a 50 percent reduction of an imposed CMP when a facility self-reports its noncompliance. This reduction can occur if there is prompt correction, if the self-report is timely, and if the noncompliance did not result in serious harm or death of a resident.

Question: *The purpose of the survey process is to ensure that deficiencies are corrected to the benefit of the residents they care for, so how does CMS measure compliance if there are significant delays in responses to self-reported deficiencies?*

Answer: For any noncompliance that happened before the time of the onsite survey, CMS surveyors establish the extent of noncompliance, what the facility did to address it, when it started, and the extent to which the noncompliance still exists. Generally, a facility is held

harmless for the timing of the review of self-reported deficiencies if the facility swiftly addressed the concern and provides evidence that it was corrected prior to the start of the survey.

If there is an ongoing deficiency (for example, the facility self-reported, but did not take other action to correct or prevent future non-compliance), then delays in a response could mean that the facility did not fully self-correct until a survey team investigated. This can result in continued non-compliance over a longer period of time leaving residents at risk for harm, which could result in a per diem CMP.

Question: *How does CMS determine whether a per diem or a per incident CMP will be assessed? What guidance do Regional Offices use in determining whether and how to retroactively apply CMPs?*

Answer: CMS determines which type of CMP to impose based on the level and time of noncompliance identified, and whether or not the facility has taken action to correct its noncompliance. CMPs (Per Instance or Per Diem) are mostly imposed in situations where noncompliance has led to a resident(s) being harmed, or in immediate jeopardy of serious harm or injury. Examples include cases where residents sustain a fracture from a fall, develop pressure ulcers, or wander outside the facility unsupervised and into an unsafe environment. In general, per diem CMPs are imposed for noncompliance that is identified with no evidence of correction at the time of the survey. The objective of per diem CMPs is to incentivize the facility's return to compliance as quickly as possible. Per instance CMPs are generally imposed for isolated events of noncompliance, or when noncompliance occurred but evidence of the facility's correction exists. The objective of both types of CMPs is also to incentivize sustained compliance, thus preventing future harm to residents.

Question: *How does CMS ensure that Regional Office activities are in line with CMS policy and procedures?*

Answer: The Social Security Act (§§ 1819(h)(2)(B)(ii)(I) and 1919(h)(3)(C)(ii)(I)) authorizes the Secretary to impose a CMP for each day of noncompliance, and the Code of Federal Regulations (42 CFR §488.430(b)) states that CMS may impose a CMP for the number of days of past noncompliance since the last standard survey. That said, the guidance is intended to ensure that CMPs are imposed to incentivize swift and sustained compliance. CMS ensures that Regional Office activities are in line with CMS policy and procedures through several mechanisms described below:

1) CMP Analytic Tool – The CMP Analytic Tool contains guidance for Regional Offices on how to determine the type and amount of a CMP. This includes whether to impose a CMP for a date of noncompliance that occurred prior to the start date of the survey. The tool is structured to ensure that CMPs are imposed in a manner consistent with the objectives stated in the answer above. We have recently revised the CMP Analytic Tool described above.

2) Quarterly Calls - CMS has established quarterly calls between CMS Central Office and each Region. During these calls, we discuss enforcement policies and procedures and nursing homes designated as Special Focus Facilities due to poor quality. Semi-annually, we review Region specific-data compared to national enforcement data to discuss trends.

3) Monthly Calls - CMS Central Office hosts monthly calls with all Regional Offices to discuss survey and enforcement policies and procedures.

4) Enforcement Training - CMS developed a web-based enforcement training for Regional Office staff which reviews Federal enforcement policies and procedures on the major enforcement remedies.

5) Review of high dollar CMPs - Starting in July 2017, CMS Central Office began reviewing all CMPs over $250,000 with the CMS Regional Office for consistency with CMP policies and procedures.

As outlined in the efforts above, CMS is using a variety of approaches to ensure consistency with the policies and procedures.

CMS publicly released its guidance in the CMP analytic tool in December 2014 through a memorandum (S&C 15-16-NH). CMS monitors the imposition of CMPs, and all enforcement remedies, to ensure they are being implemented consistent with policy and their intent. This monitoring is conducted through analytic reports of utilization and regular discussions with CMS Regional Offices. If there are issues with how CMPs are imposed, CMS discusses the case and policies with its Regional Office and conducts additional training if necessary.

Finally, CMS analyzes other factors that may impact the amount of a CMP, such as the timing of a State's revisit survey to certify correction of deficient practices and achievement of compliance, and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which raised CMP amounts in 2016 and requires annual adjustments based on cost of living adjustments. CMS regularly reviews policies based on results and feedback from stakeholders and makes adjustments as necessary to make sure policies are consistent with the goals of achieving swift and sustained compliance, and reducing variation or large outliers throughout the country.

Question: *States have the option to use funds collected from CMPs on initiatives that support consumer involvement to ensure quality care in facilities and other facility improvement initiatives. Does CMS take steps to ensure a portion of monetary penalties remitted back to the states is invested in long-term care facility quality improvement? Do nursing long-term care facility providers have an opportunity to provide feedback to states or CMS on how funds are invested?*

Answer: CMS strongly supports States' reinvestment of CMP funds into projects that support the health and safety of long-term care residents. CMS has created a website[5] that describes the allowable uses of CMP funds, examples of successful projects, an annual report of the projects each State has funded, and a sample application that individuals interested in applying to use CMP funds may submit to a State. The site also includes a list of State contacts that individuals may contact with questions or to provide feedback.

[5] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment.html

Representative A. Smith (R-NE):

Question: *Section 1115A of the Social Security Act (SSA) provides broad authority to waive certain aspects of the title 18 of the SSA. Do you believe this authority allows CMS to waive section 3141 of the Patient Protection and Affordable Care Act. If so, do you plan to use this authority to do so? Please explain your reason in responding to both questions. As you may recall, prior to enactment of this change, Medicare used a state-by-state budget neutrality policy for the wage indexing. On April 28, 2017, I introduced H.R. 2224, Repeal of the Obamacare Bay State Boondoggle, which will address this issue by amending title XVIII of the Social Security Act to apply budget neutrality on a State-specific basis in the calculation of the Medicare hospital wage index floor for non-rural areas.*

Answer: Medicare law requires that payments to hospitals paid under the Inpatient Prospective Payment System (IPPS) be adjusted, in a budget neutral manner, to reflect area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Under this law, Medicare uses the wage index to adjust Medicare payments, consistent with the relative costs of labor among hospitals paid under the IPPS in different geographic areas. Section 4410 of the Balanced Budget Act of 1997 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the "rural floor." As you note, section 3141 of the Affordable Care Act requires that a national budget neutrality adjustment be applied in implementing the rural floor.

The Innovation Center was established by section 1115A of the Social Security Act (as added by section 3021 of the Affordable Care Act). Congress created the Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures …while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits. Under the authority of section 1115A(d)(1) of the Social Security Act, the Secretary may waive requirements under titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of testing such models. At this time, the Innovation Center has not found waiving Section 3141 necessary for testing any of the current models.

Representative Black (R-TN):

Complex Rehab wheelchairs and related accessories are used by a small population of people with high levels of disabilities such as ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury, and traumatic brain injury. As a result, Congress exempted CRT from the competitive bidding program in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008.

Unfortunately, in December of 2014 CMS posted sub-regulatory guidance that stated in 2016 it would use Medicare competitive bidding pricing information obtained from bids for Standard wheelchair accessories to reduce payment amounts for Complex Rehab wheelchair accessories (such as seat/back cushions, tilt/recline systems, and specialty controls). This went against the intent of MIPPA so Congress intervened in December of 2015 (via S. 2425) and again in the December of 2016 (via 21st Century Cures Act and H.R. 34) to delay payment reductions. These cuts are scheduled to take effect July 1, 2017.

***Question:** The need to resolve this matter has received strong bipartisan support in both the Senate and House along with the patient and clinician community. Given the history of Congressional support for preventing these cuts, is there a plan to ensure these cuts will not occur on July 1 so that beneficiaries with significant disabilities will be able to continue having access to the specialized equipment they need?*

Answer: CMS is committed to providing beneficiaries with access to the services and medical devices they need. On June 23, 2017, CMS issued a new policy on how adjustments to the fee schedule based on information from competitive bidding programs apply to wheelchair accessories and back and seat cushions used with group 3 complex rehabilitative power wheelchairs. As a result, effective July 1, 2017, payment for these items will continue to be based on the standard unadjusted fee schedule amounts, which will help to protect access to complex rehabilitative power wheelchair accessories on which people with significant disabilities depend.

Representative Noem (R-SD):

Secretary Price, as you know, the Great Plains Area of the Indian Health Service (IHS), of which my home state of South Dakota is a part, is experiencing a crisis that has resulted in poor care at best and patient deaths at worst.

Sadly, despite eight years of promises from the Obama Administration, the Great Plains was practically ignored during most of the last eight years until the most recent emergency erupted in late 2015.

As of the writing of this question, HHS has announced it is sending a team of senior staff to South Dakota to visit the Pine Ridge hospital, located on the Pine Ridge reservation, which is home to the Oglala Sioux Tribe. I am pleased at this development, and I thank you for your quick action after I raised this with you when you appeared before the Committee.

I have several additional questions related to your plans to improve state of IHS facilities in South Dakota, IHS processes and procedures, and most importantly, patient care:

***Question:** Do you have a strategy or plan to address the deficiencies in the Indian Health Service hospitals in South Dakota and across the Great Plains Area that have experienced accreditation issues – one that differs from the previous Administration's? If so, please describe it.*

Answer: The team of senior HHS staff that I sent to South Dakota, which included the Acting Surgeon General and the new Acting Director of the Indian Health Service, were charged with assessing in person the current status of affairs at Pine Ridge. The team found that progress has been made at the site in recent months; however there is still much work that needs to be done to bring the level of service at Pine Ridge up to standards. I have charged the Acting Director of IHS with the responsibility to address the issues that remain not only at Pine Ridge, but also in the other hospitals in the Great Plains Area that require attention. The team of senior HHS staff that visited South Dakota conducted a phone briefing with the South Dakota delegation staff on the trip. Moving forward, the agency will continue partnering closely with healthcare stakeholders in the Great Plains Area to pursue reforms that achieve sustainable improvements in quality and access to care and enhance accountability of IHS staff and providers.

***Question**: In the most recent omnibus legislation, Congress appropriated $29 million to the end of the fiscal year to address accreditation emergencies at IHS facilities. What do you intend to do with that money?*

Answer: The funding appropriated for accreditation emergencies is being used to address critical, quality healthcare services and needs related to meeting the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation. A portion of the funds were used for contracted emergency department services in three hospitals in the Great Plains Area, including Pine Ridge, Rosebud, and Omaha Winnebago. IHS Senior Leadership continues to evaluate and prioritize other funding needs—including, but not limited to, increased purchased and referred

care and collection shortfalls—based on the evolving situation in the Great Plains Area and ongoing implementation of the Quality Framework.

Question: *Do you have a plan to ensure IHS is appropriately capturing data on patient outcomes, staffing levels, and other critical data points necessary for Congress to conduct oversight of IHS' federally-operated facilities? If so, please describe it.*

Answer: IHS uses several measures to identify patient outcomes and staffing levels and provides the results to Congress in the annual budget submission. Items such as the Government Performance and Results Act (GPRA) provide information on key clinical outcomes and areas for improvement. IHS is able to extract Federal and tribal results from the clinical GPRA performance measures that are reported primarily from the outpatient setting. The measures are categorized thematically: diabetes (5 measures), dental (3 measures), immunizations (4 measures), prevention (16 measures consisting of cancer screenings, behavioral health and other measures). IHS has developed a Quality Framework to help ensure the delivery of reliable, high quality healthcare for the IHS Direct Service facilities. IHS planning documents related to staffing levels for new facilities are determined through the use of the Resource Requirements Methodology (RRM). Staffing levels for facilities (other than new facilities) are determined by local leadership based on community needs, the programs offered, and available funds for clinical staffing.

In 2016, IHS began tracking all federally funded vacancies, vacancy rates, and onboard staff on a nationwide basis and producing a quarterly vacancy report. The report identifies IHS direct service facilities with high healthcare provider vacancy rates to pinpoint critical staffing needs. Through the vacancy reports, IHS can refine recruitment and outreach efforts as well as recruitment and retention strategies. Unfunded staffing needs (positions) are not tracked using this process, but are part of the total picture of IHS staffing needs.

The Quality Framework Steering Committee has chartered three separate workgroups composed of members from all levels of IHS – service unit, area office and headquarters – to develop meaningful data sources and measure reporting for oversight and accountability of quality/safety-related domains. The Performance Accountability Dashboard Working Group is nearing completion of measure development and plans to begin measure testing in July 2017 for anticipated implementation of the dashboard by July 31, 2017. This dashboard will help IHS to monitor accountability of Service Units and Area Offices in meeting IHS policy, CMS certification requirements, and any other external accreditation standards, as well as active participation in quality improvement programs.

A standardized survey of patient experience has been developed by the Patient Experience Survey Working Group to collect locally, actionable quality improvement information from patients using tablet computer devices.[6] Administration of the survey via tablet devices will accelerate the collection and analysis of the data. The survey and method of administration

[6] OMB number 0917-0036; expiration date: 07/31/2018

was derived from a Federal-tribal collaboration between the working group and Southcentral Foundation in Anchorage, Alaska.

Question: *Many of private healthcare providers, especially community hospitals in South Dakota, have reported that IHS' poor performance has led to skyrocketing levels of uncompensated care. Not only does this endanger the financial health of these facilities, and therefore access to care for all people in the area, Native and non-Native, but also shifts the federal government's treaty and trust responsibilities to the private sector. How do you intend to rebuild the fractured relationships between IHS and private healthcare providers surrounding IHS facilities?*

Answer: We recognize the importance of establishing a senior IHS leadership team that has a comprehensive understanding and experience of the Indian Health Service, including the relationship that IHS facilities have with healthcare providers in their communities. Improvement in IHS's operations, including its relationships with stakeholders, is and continues to be a priority for the Department. In the specific situation of the Great Plains Area, IHS staff meets biannually with the South Dakota Hospital Association to address and resolve payment issues. The individual service unit staff at the local level also meets regularly with providers.

Question: *Can you commit that these facilities will be paid in a timely manner for services rendered?*

Answer: The IHS contracts with a Fiscal Intermediary to process medical and dental claims. The Contractor is Health Care Service Corporation, New Mexico Blue Cross and Blue Shield. The IHS contract requirement for timely claims processing is 97% of all clean claims will be paid within 30 days. For fiscal years 2014 to the present, the Contractor has exceeded this percentage requirement.

Question: *Do you have a plan to reform the Purchased/Referred Care (PRC) program's outdated and unfair financial distribution? If so, please describe it.*

Answer: The Director's Workgroup on Improving PRC is comprised of both Federal and tribal members from across the country. This workgroup is charged with discussing an array of PRC issues, including allocation methodology, to improve the program. The allocation methodology has been discussed a number of times with this Workgroup. Over 50 percent of the PRC Program's budget is operated by tribes. In 2015, the PRC Workgroup recommended to keep the formula unchanged and to review at the next meeting.

When the Director's Workgroup on Improving PRC meets this year, this will be one of the major topics for discussion. Changes to the PRC Distribution Formula would require additional tribal consultation.

Question: *Do you have a plan to reform the PRC program's outdated and convoluted referral system (the three-stage approval process)? If so, please describe it.*

Answer: The PRC authorization process adheres to 42 CFR 136 Subpart C. PRC regulations outline: 1) eligibility requirements for IHS beneficiaries to whom PRC services will be provided, 2) the requirement for residency within the PRC delivery area, 3) the establishment of medical priorities when funds are not sufficient to provide the volume of PRC services indicated as needed by the population residing in a PRC delivery area, and 4) notification requirements for authorization for PRC services. The IHS is the payer of last resort for beneficiaries eligible for PRC and requires PRC-eligible beneficiaries to apply for alternate resources (Medicare, Medicaid, or private insurance, etc.) if the beneficiary is eligible for them. At this time, the IHS does not have a plan to revise these regulations, but we are always happy to work with Congress and other stakeholders to consider mechanisms by which IHS could improve the provision of services in Indian Country, including the requirements for PRC referrals.

Ranking Member Neal (D-MA):

State Data

Question: *Your budget documents show, and Director Mulvaney has stated, that an additional $610 billion is cut from Medicaid by "ratcheting down some of the growth rates" on the proposed per capita caps beyond the $834 billion cut included in the House American Health Care Act legislation, which you have also supported. Under these combined proposals, what would the growth rate be for federal Medicaid capped contributions in future years? Would you please share with us state-specific data about the combined level of federal spending reductions and the estimated increase in the number of Americans without insurance coverage?*

Answer: The President's FY18 Budget does not incorporate specific legislation that is before Congress right now. Therefore, it is not accurate to apply the specific Medicaid savings the CBO has estimated for legislation before Congress to the President's Budget. The Budget calls for refocusing Medicaid on the elderly, children, pregnant women, and individuals with disabilities. In fact, under the Budget, Medicaid spending will be higher over the next decade than the last decade by a significant margin.

Coverage Loss

Question: *Can you please provide for the Committee specific coverage tables showing the impact of the President Budget's proposals on Medicaid and CHIP in terms of individuals over the ten year window? I am asking for year by year coverage numbers, for Medicaid, and separately for CHIP, by category – 65 and older, blind and disabled, children, and adults.*

Answer: The Budget supports repealing and replacing Obamacare, including improving Medicaid's sustainability, refocusing Medicaid on the elderly, children, pregnant women, and individuals with disabilities, and providing States flexibility to innovate and design state-based solutions to provide better care to Medicaid beneficiaries. The Budget proposal offers support for additional Medicaid flexibilities that could be considered legislatively or administratively, including, for example, encouraging work and personal responsibility. The Budget does not, however, incorporate specific legislation before Congress right now, and as such, coverage tables are not available.

Health Security

Secretary Price, states need reliable, flexible federal Medicaid funding, especially after natural disasters like Hurricane Katrina, epidemics and public health emergencies like the Zika virus, opioid addiction or lead poisoning crisis in Flint, Michigan, and the cost of new treatments like the Hepatitis C drugs. Facing these cost increases, states knew that the federal government would pay its share to account for increased need. Under your proposal to cap federal Medicaid funding, states would have to pay for 100 percent of those additional Medicaid costs - forced to

cut other parts of their Medicaid program or simply being unable to address these crises or cover these new treatments.

Question: *Congress waited for 32 months after the lead poisoning was uncovered in Flint, Michigan - and 11 months after President Obama declared it a state of emergency - to send additional non-Medicaid aid to Flint. However, the flexibility in Medicaid ensured that the state could immediately cover eligible individuals in need. If Medicaid funding was capped, states would not have that ability. Yes or no, Mr. Secretary, should sick patients have to wait for Congress to free up new money if a state ran short under a block grant?*

Answer: See response below.

Question: *Florida and Texas are relying on Medicaid to help prevent the spread of the Zika virus and treat those affected. With broad Medicaid cuts, and capped funding, states might have to choose between preventing and treating those affected by an epidemic, or providing coverage for other vulnerable populations like seniors in nursing homes. If a state ran short of money under a block grant, which patients should a state turn away first? For example, should a state terminate coverage for a child with cancer, in order to pay for coverage for a child hospitalized with a mental illness?*

Answer: As you know Medicaid is the primary source of medical coverage for millions of low-income American families and seniors facing health challenges. However, its costs have been growing drastically without corresponding improvement in outcomes. The key problem isn't lack of funding; the key problem is lack of flexibility. The FY 2018 Budget puts Medicaid on a path to fiscal stability by restructuring Medicaid financing and providing states with long overdue flexibility.

Rigid and outdated Federal rules and requirements prevent states from pioneering delivery system reforms and from prioritizing Federal resources to their most vulnerable populations, which hurts access and health outcomes.

We are committed to making sure that States have the flexibility to design their Medicaid programs to meet the needs of the most vulnerable in their state. By strengthening the federal and state Medicaid partnership, we will empower states to develop innovative solutions to challenges like Zika, rather than telling states how they should run their programs.

Question: *States faced $1.3 billion in higher Medicaid drug costs with the introduction of the then-new Hepatitis C drug Sovaldi in 2014. If a state's Medicaid block grant runs out of money, should a state not cover a new breakthrough treatment, or maybe only cover it for part of the year, turning away patients who get sick after a certain date?*

Answer: The FY 2018 Budget puts Medicaid on a path to fiscal stability by restructuring Medicaid financing and providing states with long overdue flexibility.

By strengthening the Federal and state Medicaid partnership, we will empower states to develop innovative solutions to challenges like high drug costs, rather than telling states how they should run their programs. Every state has different demographic, budgetary, and policy concerns that shape their approach to Medicaid. That is one of the reasons a one-size-fits-all approach is not workable for a country as diverse as the United States.

Opioids

The opioid epidemic is ravaging the country and new analysis from The New York Times indicates that 2016 could be the worst year ever for drug overdose deaths, exceeding 59,000.

There has also been incredible progress in treating opioid addiction and other substance use disorders, namely medication assisted treatment (MAT). In April, you posted a new HHS Strategy to Fight the Opioid Crisis and medication-assisted treatment was notably absent. In May, you remarked that medication-assisted treatment amounted to "substituting one opioid for another," directly contradicting guidance from HHS agencies. Since then, some 700 researchers and practitioners have called on you to set the record straight and I'd like to give you the opportunity to do that here today. Your prepared remarks today did in fact refer to medication-assisted treatment.

Question: *Can you clarify—is medication-assisted treatment part of the HHS strategy to combat the opioid epidemic? Do you believe the medication-assisted treatment amounts to "substituting one opioid for another" as you previously stated?*

Answer: HHS and the Trump Administration are committed to doing all that we can to end the scourge of opioids that is sweeping across this nation.

The Department and the Trump Administration are committed to bringing everything the Federal Government has to bear to address the health crisis opioids pose. At HHS, we have identified five specific strategies that we can bring to the fight: prevention, treatment, and recovery services; targeting availability and distribution of overdose-reversing drugs; strengthening timely public health data and reporting; supporting cutting-edge research; and advancing the practice of pain management.

One of the key pillars of our approach is improving access to treatment and recovery services, including medication-assisted treatment (MAT) with naltrexone, buprenorphine, or methadone. Through the State Targeted Response to the Opioid Crisis grants authorized in the 21st Century Cures Act, HHS is expanding access to opioid addiction treatment through evidence-based interventions, including MAT. We are targeting the primary barriers to seeking and entering treatment, as well as long-term adherence to treatment, and sustained recovery. This funding is critical to reversing the opioid epidemic.

HHS Actions to Shore up the Marketplace

Question: *Has the Department worked with plans and state insurance commissioners to ensure marketplace plans are offered in all areas?*

Answer: The ever-narrowing set of choices Americans are facing means that there is a very real chance some counties will have no insurers selling ACA plans in 2018. This is a situation we have been monitoring extremely closely, and working every day with states to address.

The Administration recognizes that states are the primary regulators of health insurance, and it remains imperative for the Executive Branch to empower states with more flexibility and control. Among other regulatory actions and guidance documents, the Department also finalized a Market Stability Rule in April, which tightened special enrollment periods, made it more difficult for enrollees to skip premium payments, adjusted the open enrollment period to align with other healthcare markets, lifted one-size-fits-all requirements regarding network access, and widened the actuarial value bands within which insurers can offer plans to patients.

Question: *Has the Department developed and funded a targeted marketing plan for the Marketplace in 2018?*

Answer: Please refer to the following excerpt regarding Federal Exchanges, Consumer Information and Outreach from the Centers for Medicare & Medicaid Service FY 2018 Justification of Estimates, also available at https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/Downloads/FY2018-CJ-Final.pdf

> *Consumer Information and Outreach: $573.5 million of which $0 million is funded through discretionary appropriations. CMS ensures consumers are fully supported not only during open enrollment, but throughout the plan year using mail, phone, and the website.*
>
> *The consumer call center is the primary means for consumers to ask questions, get help with online tools, complete an application, and get help with tax form questions, life changes and inconsistencies. The call center offers support in over 200 languages and is open 24 hours a day 7 days a week. A specialized center provides complex call resolutions and is staffed by experts in resolving multiple issues. Through the Government Printing Office (GPO), CMS prints and mails pertinent consumer notices including application status, data matching issues, and appeals.*
>
> *CMS conducts traditional media and direct mail as well as digital media public education and outreach campaigns leading up to and during the OEP to encourage participation in the FFE and FF-SHOP. CMS provides over 100 print and electronic educational publications in English and Spanish on a wide variety of topics including enrollment basics, financial assistance, individual responsibility payment, exemptions, and appeals. Many consumers have limited experience with health insurance, and this activity provides educational materials on understanding their benefits, how to use their coverage, and what costs they are responsible for. Year round on the ground community based support is available through Navigators that supply impartial information to*

consumers on enrolling, selecting a plan, and assisting with data inconsistency and tax issues.

Question: *Has the Administration taken action to ensure payments are targeted to plans with higher risk populations, for example by lowering the million dollar "attachment point" for the new risk adjustment model that begins in 2018?*

Answer: See response below.

Question: *Has the Administration worked to negotiate wider service areas for issuers that would expand market place choices in 2018?*

Answer: The Administration remains committed to providing needed flexibility to issuers to help attract healthy consumers to enroll in health insurance coverage, improve the risk pool and bring stability and certainty to the individual and small group markets, while increasing the options for patients and providers.

Further, the Administration recognizes that states are the primary regulators of health insurance, and we are committed to returning to states their traditional authority to regulate health plans. We seek to ensure that policies empower states to make decisions that work best for their markets, understanding that there are differences in markets from state to state. We will support state flexibility and control to create a free and open healthcare market in accordance with current statute.

Lastly, since January 20, 2017, HHS has issued several rules and guidance documents to improve the current healthcare market for consumers. Among some of the actions taken to date:

- February 15: Less than a month into the new Administration, HHS proposed a broad set of solutions to increase choices for patients and help stabilize insurance markets. Two measures would loosen restrictions on the type of plans that can be sold while others aim to discourage gaming the system and improve the health of the risk pool.
- February 17: HHS simplified the filing calendar for insurers and pushes back several deadlines, allowing insurers maximum time to offer the widest array of choices possible.
- February 23: HHS announced that people will continue to be allowed to keep their transitional plans plans if they like them, ensuring lower premiums and real choices for millions of Americans. (Since Obamacare went into effect, HHS permitted renewal of some individual and small-group plans that were out of compliance with certain ACA market reforms, but that policy was set to expire this year.)
- March 13: Secretary Price sent a letter to states encouraging them to apply for Innovation Waivers under section 1332 of Obamacare, which allows states to pursue innovative strategies to adapt many of the law's requirements to suit the state's specific needs.

- March 14: Secretary Price and CMS Administrator Verma sent a letter to America's governors laying out a policy vision for Medicaid innovation to give states flexibility to develop solutions that work for them.
- April 13: HHS finalized the market stabilization rule just two months after the proposal was released.
- May 11: HHS released a State Innovation Waiver Checklist to assist states applying for 1332 waivers.
- May 15: HHS announced it will propose a rule to provide small businesses with more healthcare choices by allowing eligible small employers to use the small-business healthcare tax credit offered under Obamacare in connection with purchasing SHOP coverage for their employees through the registered agent or broker of their choice. (Very few small businesses have bought insurance under the mechanism Obamacare created, the SHOP exchange.)
- May 17: HHS announced a plan to make it easier for Americans to sign up for insurance through private-sector web brokers instead of being redirected to purchase coverage through Healthcare.gov.
- June 8: HHS issued a Request for Information seeking input from the public about how to improve the regulation of the individual and small group insurance markets.

Cybersecurity

Question: *I'm concerned about the security of our health data. We've recently seen that even large corporations are not safe from hacking, data breaches and ransomware. HHS has a vital role to play in ensuring that providers share data across settings though the Office of the National Coordinator for Health IT (ONC) while also enforcing privacy standards under HIPAA through the Office for Civil Rights (OCR). Both of these agencies are subject to significant budget cuts in this year's President's budget—ONC by nearly 40%. And yet nobody thinks we are going to see fewer threats to health data security. I don't want our health system to suffer the same kind of attack that devastated Britain's National Health Service. How can you justify such substantial cuts to these functions when we face such serious threats? How are you going to ensure that HHS carries out its important statutory responsibilities in this space with fewer resources, both budgetary and in personnel? Can you please provide follow up to the Committee as to what functions a 40% cut in the ONC budget would eliminate or curtail?*

Answer: ONC has achieved great success in the electronic health record adoption rates among practitioners and clinics across the country. This success is reflected in the FY 2018 President's Budget; the President's Budget closes out ONC's adoption-related activities, to prioritize activities for standards and policy coordination and development. ONC will continue efforts related to achieving interoperability and reducing the burden to providers of health information technology. ONC integrates a clinical perspective in its work, and it strives to advance the availability, usability, and timeliness of clinical decision support and quality measurement; to identify and correct unsafe uses of health IT; and to engage consumers and healthcare providers in the policy development process. The funds proposed for privacy and security will

provide for the continued support for the position of Chief Privacy Officer and policy development and coordination of privacy and security in the context of broad health IT policy efforts.

The HHS Office for Civil Rights (OCR) will continue its work to robustly enforce the HIPAA Privacy, Security, and Breach Notification Rules and to issue guidance to improve understanding of those rules. Support for OCR's enforcement of HIPAA regulations comes from appropriated funds, as well as civil monetary penalties that OCR collects for violations of those rules and amounts paid to OCR in informal settlements of funds collected in HIPAA cases, consistent with section 13410 (c) (1) of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH).

LGBT Rights

Question: *Despite complete silence from President Trump and the White House, June is LGBT Pride month across the country. HHS made important progress in advancing LGBT rights in recent years. CMS finalized rules requiring federally funded providers to allow visitation by same sex partners and HHS codified collection of LGBT data across HHS surveys. The Trump Administration stands to reverse this important progress and threatens enforcement of civil rights law for LGBT Americans—part of an administration-wide effort to roll back civil rights enforcement that has been recently and widely reported in the press. Rather than working to improve data collection on LGBT Americans, your Department has moved to erase LGBT people from the Centers for Independent Living Annual Program Performance Report. The new head of HHS's Office for Civil Rights, Roger Severino, has a long record of opposing LGBT rights and the HHS budget proposes to cut OCR's funding—even as the office faces new challenges and increased threats to health data security. Can you commit today to ensuring that LGBT Americans and transgender Americans in particular, will not be denied due process under the civil rights laws that HHS enforces and that LGBT Americans will not be erased from HHS surveys? Will the Office for Civil Rights under Roger Severino ensure that LGBT Americans do not face discrimination in federally funded health care settings and that same sex couples can visit their loved ones when they are hospitalized and most in need?*

Answer: I believe that people from all walks of life should be treated fairly and with compassion – especially when it comes to their healthcare. That's how I operated as a physician taking care of patients for over 20 years and that's how I approach public service. Under my leadership at HHS, we will respect the inherent dignity of all persons, and will follow the law.

Meals on Wheels

Question: *Despite his repeated promises to protect them, older Americans took a lot of hits in President Trump's budget, with deep cuts to long-term care, cuts to Social Security disability benefits, cuts to Medicare health insurance counseling programs, and cuts to SSI disability benefits for elderly couples. I wanted to talk about the 2 million seniors who will lose services*

funded by the Social Services Block Grant, ranging from Meals on Wheels and other independent living supports to the Adult Protective Service. SSBG is the primary source of federal funding for state adult protective services, which investigate and address allegations of elder abuse. Zeroing out SSBG means more parents and grandparents will suffer physical maltreatment, neglect, and financial exploitation. When asked about these cuts, OMB Director Mulvaney suggested that Meals on Wheels "doesn't work," despite rigorous studies showing that home-delivered meals help seniors live independently and reduce the need for nursing home care. Is HHS's Administration on Aging unaware of the research? Has it been shared with Director Mulvaney?

Answer: The Administration believes that it is important to note that the Social Services Block Grant (SSBG) does not directly fund home delivered meals, although home delivered and congregate meals are an allowable use for SSBG funds. Home delivered meals for older Americans are financed through a combination of Federal, state, local and private funds. The vast majority of the Federal share comes through the Older Americans Act, administered through the Administration for Community Living at HHS. Funding for these important nutrition programs was maintained in the President's 2018 budget at the FY17 CR level.

Representative Doggett (D-TX):

Question: *In a pre-inaugural press conference on January 11, and again in a speech in Louisville, KY on March 20, President Trump promoted "bidding" as a strategy for bringing down drug prices. He said that this was necessary because "the cost of medicine in this country is outrageous," and because the pharmaceutical industry is "getting away with murder."*

i. Has the Administration rejected President Trump's approach on drug pricing reform?
ii. Does it support bidding or price negotiation for Medicare?

Answer: High drug prices and costs are an issue of major concern for HHS and for the American people. This includes the millions of seniors who rely on Medicare for their drug coverage, and the taxpayers who have to foot the bill for government spending on this program. As you know, the President has made prescription drug prices an absolute priority and has charged us with making recommendations to his office on reducing drug prices. My team has been meeting with stakeholder groups from across the healthcare spectrum over the past several months in order to understand where there are areas of consensus. It is important that we move forward quickly, but also carefully, so that our policies do not have unintended consequences. We need to balance the goal of ensuring affordability and access with the mandate to continue supporting development of lifesaving innovations.

iii. Does it support drug importation, which President Trump also previously endorsed?

Answer: I share the President's concerns about the cost of prescription drugs and the need to ensure that Americans have access to medical products. As Congress pursues various policy options to address drug pricing, issues related to product safety, effectiveness, and quality should be considered. Policies must ensure that individuals are not receiving drugs that are contaminated, counterfeit, or contain varying amounts of active ingredients.

Question: *On May 31, 2017, the HHS Office of the Inspector General (OIG) sent a letter to the Senate Committee on the Judiciary, which estimated how much money Mylan owed to the U.S. government as a result of the improper classification of the EpiPen under the Medicaid Drug Rebate Program. According to the OIG, from 2006 to 2016, Mylan failed to pay an estimated $1.27 billion in rebates. There have been previous reports that the Department of Justice (DOJ) negotiated a $465 million settlement with Mylan, recouping a little less than a third of the money owed to American taxpayers.*

i. Has this settlement been approved and if so, for what amount?
ii. What specific steps have been taken to prevent such pharmaceutical company misconduct in the future?
iii. What investigation has been conducted to determine whether there are other drugs which have been improperly classified?

Answer: There is no approved settlement with any potential party. As you know, we otherwise cannot comment on any pending matter that the government may have involving Mylan or EpiPen. All questions should be directed to the Department of Justice.

Manufacturers that do not comply with classification requirements are in clear violation of the law. Under the Medicaid Drug Rebate Program (MDRP) authorizing statute, it is the responsibility of the manufacturer to properly report the classification of its drugs and the required pricing data (AMP, best price, customary prompt pay discounts, and nominal prices), and to pay the proper rebate amounts. CMS has provided sub-regulatory guidance and, more recently, regulatory guidance on these issues.

Since 2010, the Center for Medicaid & CHIP Services (CMCS) has taken a number of steps to improve the operations of the MDRP. Additionally, in October 2016, CMS began development of a new MDRP system that will update its existing information systems and enhance the agency's capacity to oversee the more than 23,000 drug classifications and rebates. The new system is scheduled to be completed and operational in approximately 2 years.

Question: *On April 4, 2017, 51 Members of Congress asked President Trump to use his authority to set guidelines for the usage of march-in rights, in order to protect taxpayer investments and taxpayer access to medications developed with taxpayer funding. We have received no answer or confirmation of receipt, despite repeated questions. A copy of the letter is attached.*

i. Why has the Administration not used existing legal authority to protect taxpayers?
ii. What is the Administration's answer to our request?

Answer: Thank you for your letter concerning the development of guidelines on the use of the Bayh-Dole Act march-in authority. The Trump Administration shares your concern about the issue of drug pricing more broadly; the Department is actively exploring policy options at our disposal to ensure taxpayers have access to the medications they need.

HHS considers the application of the march-in statute on a case-by-case basis, and is prepared to use its authority if presented with a case where the statutory criteria are not met for the commercialization and use of an NIH-funded, patented invention and march-in could in fact alleviate the public health need.

As mentioned, HHS is looking at the issue of drug pricing more broadly and continues to engage in discussions with stakeholders – internally, externally, and across the government - on this topic. Again, thank you for your leadership and we welcome your and your colleagues' input on this issue moving forward.

Question: *There have been multiple reports that the Administration is preparing to issue an executive order that largely adopts recommendations of the Pharmaceutical Research and Manufacturers Association (PhRMA), and that this order is being developed with the active*

participation of Joe Grogan, director of health programs for the Office of Management and Budget, who was the head of federal affairs for Gilead Science for the past five years.

I. With President Trump purportedly committed to "drain the swamp," why has Joe Grogan not been recused from working on issues on which he actively lobbied over the past five years, as required by the January 28 executive order on lobbying?

Answer: As Secretary of HHS, I am not in a position to answer this question. I would refer you to the White House and the Office of Management and Budget.

ii. Will this executive order be accompanied by an independent analysis of how each of these changes will lower the costs of drugs to consumers and the U.S. government?

Answer: The White House would be better able to speak to executive orders that it plans to issue.

iii. How would scaling back the 340B drug program reduce the rising cost of pharmaceuticals for consumers and the US government?

The President's FY18 Budget provides $10 million for the 340B Drug Pricing Program, the same level as the FY 2017 Continuing Resolution. Additionally, the Budget proposes to update regulatory authority in the 340B Drug Pricing Program to increase transparency and improve program integrity.

iv. Why are there no reported reforms aimed at lowering brand-name drug prices, despite the fact that brand-name drugs account for 72 percent of drug spending and only 10 percent of dispensed prescriptions?

Answer: One of the best ways to address the cost of brand-name drugs is to foster generic and bio-similar competition. Over the last decade alone, competition from safe and effective generic drugs has saved the healthcare system about $1.67 trillion. HHS is continuing to look for ways to ensure the affordability of drugs, including brand-name drugs. One example is FDA's recent announcement of a Drug Competition Action Plan in an effort to broaden access to medicines and help consumers lower their healthcare costs. As part of this plan, FDA very recently published a list of off-patent, off-exclusivity branded drugs without approved generics, and also implemented, for the first time, a new policy to expedite the review of generic drug applications where competition is limited.

v. Other than PhRMA and PhRMA-funded groups, which specific consumer groups have been consulted in preparing this executive order, when, and how?
vi. Which specific individual from the Administration is best able to provide testimony as a witness in a committee hearing to describe the effect of each provision of the order on drug prices and the process through which the order was developed?
vii. Does the Administration have a proposed date of publication for this executive order?

Answer: The White House would be better able to speak to executive orders that it plans to issue.

Representative Blumenauer (D-OR):

As you noted in your testimony, in Oregon, expanded Medicaid coverage led to increased use of preventive services like mammograms, better detection of diabetes and depression, and better mental health outcomes for those with depression. Most importantly, and what you didn't note, is that authors of the Oregon Health Insurance Study found that insurance—which Medicaid is—provided Oregonians with many other important benefits such as improved peace of mind and important financial protection from catastrophic health costs. I am proud of the work we have done in Oregon, which has buy-in from the beneficiary and provider communities. Your budget not only assumes the $839 billion cut to Medicaid in the American Health Care Act, but dramatically enlarges it by an additional $610 billion.

***Question:** How will cutting Medicaid by $1.4 trillion over the next 10 years allow states such as Oregon to continue to pay and provide for quality care?*

Answer: The President's FY18 Budget does not incorporate specific legislation that is before Congress right now. Therefore, it is not accurate to apply the specific Medicaid savings the CBO has estimated for legislation before Congress to the President's Budget. The President's proposed savings of $610 billion over 10 years would put the program on a sustainable fiscal path by capping Medicaid funding beginning in FY 2020 through per capita caps, or block grants, at state option. By strengthening the Federal and state Medicaid partnership, we will empower states like Oregon to develop innovative solutions to challenges they face, rather than telling states how they should run their programs.

Every state has different demographic, budgetary, and policy concerns that shape their approach to Medicaid. That is one of the reasons I believe a one-size-fits-all approach is not workable for a country as diverse as the United States.

Representative Higgins (D-NY):

I have grave concerns about the large cuts to medical research funding proposed in President Trump's Fiscal Year 2018 budget. In addition to the overall 20% cut to the budget of the National Institutes of Health, the specific proposal to restrict necessary, previously agreed-upon funding of research grants for extramural research at participants in initiatives like the Cancer Center program and Clinical Translational Science Award programs would devastate groundbreaking research currently being done across the country. These funds ensure that entities like Roswell Park Cancer Institute and the University at Buffalo in my district can conduct vital research that lead to potential life-saving treatments and even cures to debilitating diseases like cancer, multiple sclerosis, and diabetes.

Robust extramural grants have been a cornerstone of the NIH's research activities throughout its history. Since President Richard Nixon signed the National Cancer Act into law in 1971, extramural grant at National Cancer Institute specifically have expressly focused on the goal of ensuring that as many Americans as possible have access to the most advanced and highest quality treatments.

***Question:** How can you continue to fully implement the goals of laws like the National Cancer Act, since the practical implication of this proposal would be to specifically undermine it?*

Answer: The FY 2018 Budget presents an opportunity for HHS and NIH to reexamine how to optimize Federal investments in a way that best serves the American people. The FY 2018 Budget changes the reimbursement of indirect costs for NIH grants, which will be capped as a percentage of total research, in order to better target available funding toward high priority research. In addition, Federal research requirements for grantees will be streamlined to reduce grantee burden through targeted approaches as proposed by NIH. HHS is working with NIH to identify strategies to streamline processes and increase efficiencies, including reforming policies to release grantees from the costly and time-consuming indirect rate setting process and reporting requirements.

HHS will continue to invest resources in the highest priority research areas, including cancer. With regard to cancer research, specifically, the FY 2018 Budget aims to accelerate progress and research in cancer, including prevention and screening, from cutting edge basic science to wider uptake of standard of care.

Representative DelBene (D-WA):

Secretary Price, coverage and reimbursement policies in Medicare are limiting access to, and utilization of, telehealth and remote monitoring technologies. Under current law, coverage is restricted by the geographic locations where beneficiaries live and receive care, the type of technology used, and the services being furnished by their healthcare providers. Some of these restrictions have been waived in new payment models, but don't go far enough to provide the flexibility needed to maximize the medical benefits and cost-effectiveness offered by telehealth. As you know, bipartisan legislation has been introduced to expand telehealth services provided through these alternative payment models to test how telehealth can reduce costs and increase the quality of care for the treatment and management of certain chronic conditions. One of the core purposes of this bill is to collect data on expanded telehealth services to allow CMS, CBO and MedPAC to fully assess the cost-effectiveness of this model.

Question: *What do you think about this approach to modernizing the Medicare program and would you be willing to commit CMS/CMMI to undertaking a demonstration like this?*

Answer: The Administration is committed to ensuring that all Americans, especially those in rural areas, have access to the highest quality of care, and telehealth is one of the keys to that. Telehealth is an exciting innovation that will allow for individuals to access resources that are otherwise not available. We've seen an explosion in the ability of technology to allow a patient to receive care from a provider in another location while the patient remains in his or her home community. One of our priorities is to make the healthcare system as dynamic as the innovation that is being created to serve it.

Through its annual Medicare Physician Fee Schedule rulemaking, CMS has a process for adding services to the list of Medicare telehealth services for which payment can be made. This process provides the public with an ongoing opportunity to submit requests for adding services to the Medicare telehealth list. CMS carefully consider all requests to determine if additional services should be added to the telehealth list.

While Medicare statute only allows Medicare payment for telehealth services if beneficiaries are furnished the services while present in certain healthcare settings that are located in certain geographic areas, the CMMI statute permits waiving certain telehealth requirements for purposes of conducting payment and service delivery models. Some waivers related to telehealth have been made based on the needs of a particular initiative. For example, waivers of certain geographic limitations have been made with respect to otherwise covered telehealth services as necessary solely for purposes of testing the CMMI's Next Generation Accountable Care Organization Model. We anticipate learning from the evaluations of the CMMI models and other CMS initiatives, and we will continue to seek opportunities to test additional Medicare payment models, including those incorporating telehealth. CMMI is always seeking ideas to help shape the design of future payment and service delivery models. I appreciate your suggestions and look forward to working with you on this issue.

Representative A. Smith (R-NE):

Question: *Section 1115A of the Social Security Act (SSA) provides broad authority to waive certain aspects of the title 18 of the SSA. Do you believe this authority allows CMS to waive section 3141 of the Patient Protection and Affordable Care Act. If so, do you plan to use this authority to do so? Please explain your reason in responding to both questions. As you may recall, prior to enactment of this change, Medicare used a state-by-state budget neutrality policy for the wage indexing. On April 28, 2017, I introduced H.R. 2224, Repeal of the Obamacare Bay State Boondoggle, which will address this issue by amending title XVIII of the Social Security Act to apply budget neutrality on a State-specific basis in the calculation of the Medicare hospital wage index floor for non-rural areas.*

Answer: Medicare law requires that payments to hospitals paid under the Inpatient Prospective Payment System (IPPS) be adjusted, in a budget neutral manner, to reflect area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Under this law, Medicare uses the wage index to adjust Medicare payments, consistent with the relative costs of labor among hospitals paid under the IPPS in different geographic areas. Section 4410 of the Balanced Budget Act of 1997 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the "rural floor." As you note, section 3141 of the Affordable Care Act requires that a national budget neutrality adjustment be applied in implementing the rural floor.

The Innovation Center was established by section 1115A of the Social Security Act (as added by section 3021 of the Affordable Care Act). Congress created the Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures …while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits. Under the authority of section 1115A(d)(1) of the Social Security Act, the Secretary may waive requirements under titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of testing such models. At this time, the Innovation Center has not found waiving Section 3141 necessary for testing any of the current models.

Questions for the Record
Hearing on the Department of Health and Human Services'
FY 2018 Budget Request
June 8, 2017

Representative Tiberi (R-OH):

Question: *Secretary Price, I am sure you've seen the unfortunate news that Anthem, the only state insurer that provided plans in every single county in Ohio, is leaving the exchange and most of the individual market in 2018. Around 20 counties, one of which is in my district will have no ACA plan available in the marketplace. 1,700 residents of Muskingum County, Ohio, who are currently covered by Anthem, will not have the option of purchasing an exchange plan in 2018. I understand that you and your team have worked to stabilize the markets administratively. Could you elaborate on these efforts? Specifically, I want to know if you have given any thought to actions you can take to help plans re-enter Ohio— and similar states— especially when the American Health Care Act becomes law and a stable transition period away from the failures of Obamacare is in place.*

Answer: The Administration remains committed to providing needed flexibility to issuers to help attract healthy consumers to enroll in health insurance coverage, improve the risk pool and bring stability and certainty to the individual and small group markets, while increasing the options for patients and providers.

Further, the Administration recognizes that states are the primary regulators of health insurance, and we are committed to returning to states their traditional authority to regulate health plans. We seek to ensure that policies empower states to make decisions that work best for their markets, understanding that there are differences in markets from state to state. We will support state flexibility and control to create a free and open healthcare market.

Lastly, since January 20, 2017, HHS has issued several rules and guidance documents to improve the current healthcare market for consumers. Among some of the actions taken to date:

- February 15: Less than a month into the new Administration, HHS proposed a broad set of solutions to increase choices for patients and help stabilize insurance markets. Two measures proposed would loosen restrictions on the type of plans that can be sold while others aim to discourage gaming the system and improve the health of the risk pool.
- February 17: HHS simplified the filing calendar for insurers and pushes back several deadlines, allowing insurers maximum time to offer the widest array of choices possible.
- February 23: HHS announced that people will continue to be allowed to keep their transitional plans if they like them, ensuring lower premiums and real choices for millions of Americans. (Since Obamacare went into effect, HHS permitted renewal of some individual and small-group plans that were out of compliance with certain ACA market reforms, but that policy was set to expire this year.)

- March 13: Secretary Price sent a letter to states encouraging them to apply for Innovation Waivers under section 1332 of Obamacare, which allows states to pursue innovative strategies to adapt many of the law's requirements to suit the state's specific needs.
- March 14: Secretary Price and CMS Administrator Verma sent a letter to America's governors laying out a policy vision for Medicaid innovation to give states flexibility to develop solutions that work for them.
- April 13: HHS finalized the market stabilization rule just two months after the proposal was released.
- May 11: HHS released a State Innovation Waiver Checklist to assist states applying for 1332 waivers.
- May 15: HHS announced it will propose a rule to provide small businesses with more healthcare choices by allowing eligible small employers to purchase SHOP coverage for their employees through the registered agent or broker of their choice, rather than through healthcare.gov. (Very few small businesses have bought insurance under the mechanism Obamacare created, the SHOP exchange.)
- May 17: HHS announced a plan to make it easier for Americans to sign up for insurance through private-sector web brokers instead of being redirected to purchase coverage through Healthcare.gov.
- June 8: HHS issued a Request for Information seeking input from the public about how to improve the regulation of the individual and small group insurance markets.

JOHN B. LARSON
FIRST DISTRICT, CONNECTICUT

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Congress of the United States
House of Representatives
Washington, DC 20515-0701

June 22, 2017

The Honorable Tom Price, MD
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Price:

Thank you for your testimony before the Ways & Means Committee on the President's FY2018 budget proposal for the Department of Health and Human Services. In order to complete the record for the hearing, please respond to the following questions regarding several important bipartisan bills addressing patient access issues with upcoming deadlines:

1) When you were a member of the House, you cosponsored legislation to protect access to complex rehab wheelchairs and related accessories for Medicare beneficiaries with high level needs due to ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury, and traumatic brain injury. Despite clear Congressional intent to exclude CRT wheelchair and accessories from the Competitive Bid Program, CMS decided to apply Competitive Bid Program pricing information to reduce the rates for critical CRT wheelchair accessories. Congress acted twice to delay this rule, one in 2015 and again in 2016. The most recent delay passed by Congress will expire at the end of June. Will HHS address this patient access issue immediately using its authority?

2) On May 26, 2017, a letter was sent to you to request that you use statutory authority to implement an appropriate inflationary update measure to ambulatory surgery centers. The current update factor threatens patient access to high quality, cost-effective surgical and preventative care by limiting access to ASCs. It was signed by 25 bipartisan members. As a member of the House, you previously supported this policy. Will HHS respond and outline HHS' plan to help patients who receive care at ASCs?

3) In 2015, the House and Senate passed into law the Steve Gleason Act of 2015 (P.L. 114-40) to improve Medicare regulations and protect patient access to medically necessary Speech Generating Devices (SGDs) for individuals with communication disabilities by removing SGDs from the "Capped Rental" category until October 1, 2018. The bill was a direct response to steps taken by the Centers for Medicare and Medicaid Services in April 2014, which categorized SGDs as "Capped Rental" under Medicare. This prohibited

payments for devices when patients entered a hospital, nursing facility, or hospice care jeopardizing the ability for patients to communicate with their doctors, loved ones, and caregivers. Will HHS work with CMS in order to make this exclusion from "Capped Rental" permanent before the October 2018 expiration?

Please send your response to the attention of Sylvia Lee on my staff at 1501 Longworth House Office Building, Washington, DC 20515. In addition to a hard copy, please submit an electronic copy of your response to Sylvia.lee@mail.house.gov.

Thank you again for your testimony and your attention to these questions.

Sincerely,

John B. Larson
Member of Congress
(CT01)

Congress of the United States
Washington, DC 20515

April 4, 2017

President Donald J. Trump
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Re: Use Existing Taxpayer Protection Rights Law to Lower Prescription Drug Prices Now

Dear President Trump,

We write regarding your oft-stated commitment to bring down pharmaceutical prices. You have said that the pharmaceutical industry is "getting away with murder" and called drug prices "astronomical." We urge you to use your existing statutory authority to respond to soaring drug costs harming so many American families.

Currently, the federal government grants companies (including foreign companies) monopoly pricing power to overcharge American taxpayers for life-saving medications developed through taxpayer-financed research. The government prevents competitors from entering the market, thus removing any market forces that might keep drugs affordable. Your Administration already has legal authority to prevent pricing excesses by promoting competition, while protecting taxpayer investments and addressing the failures of government-approved monopolies. This health and taxpayer protection issue is one that the prior Administration declined to address.

When taxpayer-funded federal research results in a new drug patent, the National Institutes of Health (NIH) is permitted to require the patent holder to license the federally-funded intellectual property to third parties, under certain circumstances. This power, granted in 1980 through the Bayh-Dole Act, authorizes federal agencies that fund private research to retain certain rights in patented inventions.

Under 35 U.S.C. §203(a)(2), when "action is necessary to alleviate health and safety needs which are not being reasonably satisfied" or, as noted in 35 U.S.C. §201(f), when the benefits of the patented product are not "available to the public on reasonable terms," the government can assert what are sometimes called "march-in rights," but would be better described as "taxpayer protection rights." By exercising these rights, the government can encourage competition and lower prices by allowing other manufacturers to produce and sell the taxpayer-funded drug. Unfortunately, NIH has never utilized this taxpayer protection law.

Drug manufacturers and patients need clarity. We urge you to direct NIH to issue public guidelines on the circumstances that will likely require it to invoke taxpayer protection rights. Reasonable and transparent guidelines would discourage drug price gouging and create a more competitive market for drugs developed using tax dollars. American taxpayers should be able to access publicly-funded medications on reasonable terms, instead of being burdened with unreasonable prices.

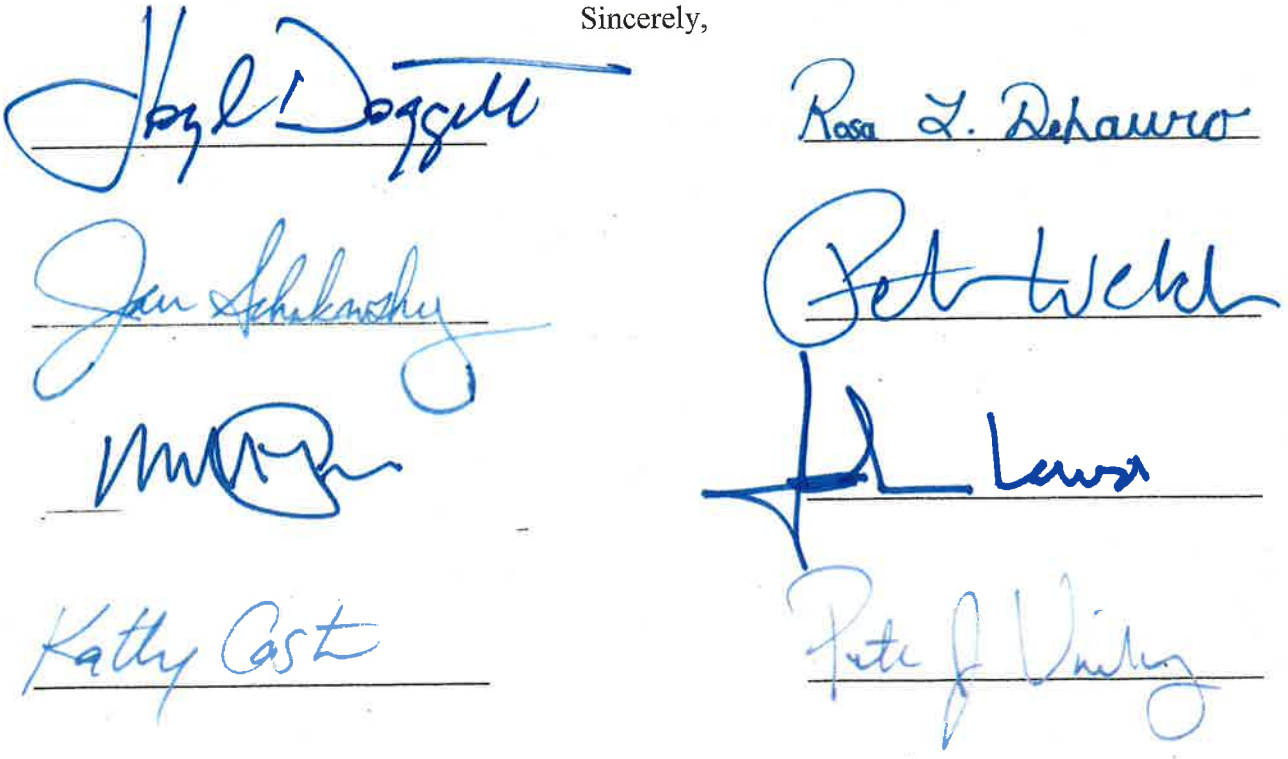
Last year, NIH also refused to hold a hearing on whether to exercise its statutory rights on Xtandi, a prostate cancer drug developed at the University of California, Los Angeles (UCLA) through taxpayer-supported research grants, but licensed to a Japanese company. As a result, Americans are still paying two to four times more than consumers in other high-income countries for a life-saving medication developed with our tax dollars—without even the benefit of a public hearing to determine why NIH refused to protect taxpayers.

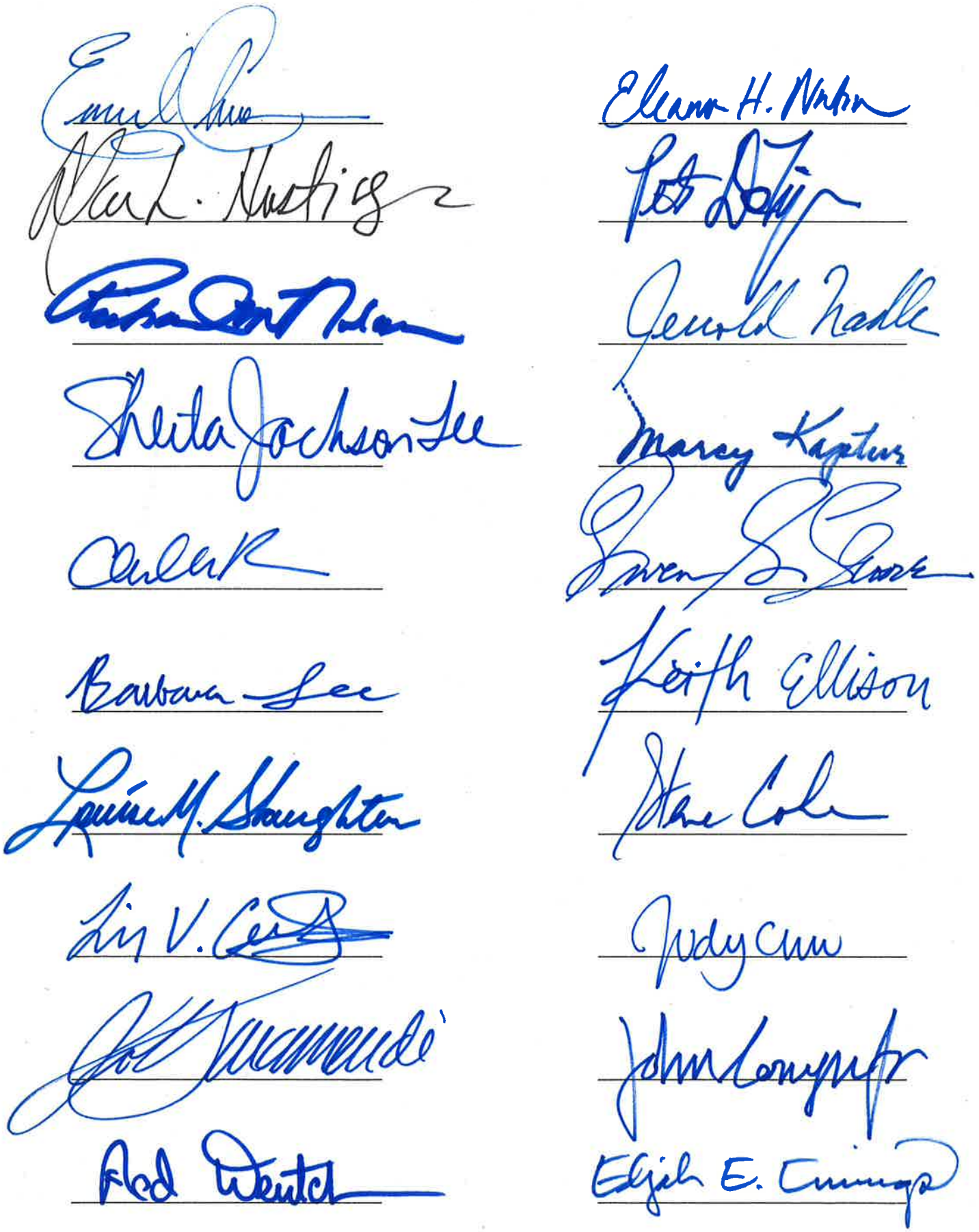
We are confident that reasonable guidance can be developed to address price gouging with transparency and fairness. We want pharmaceutical manufacturers to have the certainty of clear guidelines that indicate when taxpayer protection rights would apply, so that they can perform in a constructive way that avoids ever necessitating use of this extraordinary remedy. Since companies that do not engage in price gouging would not be affected, innovation and industry partnerships with public research institutions would not be threatened.

With adequate guidance, pharmaceutical companies should make better-informed pricing decisions that reflect the value of the taxpayer investment. High prescription drug prices are not limited to one treatment or one disease. Rising prices are reflected in ballooning Medicare and Medicaid drug budgets, and hit consumers through rising premiums, greater cost-sharing, and the higher prevalence of high-deductible plans. With drug prices continuing to soar and Americans continuing to struggle to access life-saving medications, your quick use of this taxpayer protection law will provide significant help to American families.

We look forward to your prompt response on this strategy to promote competition, target bad actors, and protect taxpayer investments.

Sincerely,





Carol Shea-Porter

Bernie Thompson

Karen Bass

Mark Takano

Brian Higgins

PUBLIC SUBMISSIONS FOR THE RECORD

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Ways and Means

On

Department of Health and
Human Services' Fiscal Year 2018 Budget Request

June 8, 2017
1:00 p.m.

1100 Longworth House Office Building

National Association of Chain Drug Stores (NACDS)
1776 Wilson Blvd, Suite 200
Arlington, VA 22209
703-549-3001
www.nacds.org

Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Brady, Ranking Member Neal, and the Members of the Committee on Ways and Means for the opportunity to submit a statement for the hearing on "Department of Health and Human Services' (HHS) Fiscal Year 2018 Budget Request."

NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to improve the quality and affordability of health care services. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 178,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 21 countries. Please visit nacds.org.

As the face of neighborhood health care, chain pharmacies and pharmacists work on a daily basis to provide the best possible care and the greatest value to their patients with respect to access to critical medications and pharmacy services. We help to assure that patients are able to access their medications and take them properly. NACDS believes retail pharmacists can play a vital role in improving and sustaining the Medicare and Medicaid programs by greatly improving beneficiary health while reducing program spending including better health through improved medication adherence, and through improving access for underserved beneficiaries with chronic conditions in the Medicare Part B Program. As this Committee examines the HHS budget request for 2018 we offer the following for its consideration.

Pharmacist Provider Status

As the U.S. healthcare system continues to evolve, a prevailing issue will be the adequacy of access to affordable, quality healthcare. The national physician shortage coupled with the evolution of health insurance coverage will have serious implications for the nation's healthcare system. Access, quality, cost, and efficiency in healthcare are all critical factors—especially to the medically underserved. The medically-underserved population includes seniors with cultural or linguistic access barriers, residents of public housing, persons with HIV/AIDS, as well as rural populations and many others. Many of these beneficiaries suffer from multiple chronic conditions. Significant consideration should be given to policies and initiatives that enhance healthcare capacity and strengthen community partnerships to offset provider shortages, particularly in communities with medically-underserved populations.

Pharmacists play an increasingly important role in the delivery of services, including key roles in new models of care beyond the traditional fee-for-service structure. In addition to medication adherence services such as medication therapy management (MTM), pharmacists are capable of providing many other cost-saving services, subject to state scope of practice laws. Examples include access to health tests, helping to manage chronic conditions such as diabetes and heart disease, and expanded immunization services. However, the lack of pharmacist recognition as a provider by third-party payors, including Medicare and Medicaid, limits the number and types of services pharmacists can provide, even though they are fully qualified to do so. Retail pharmacies are often the most readily accessible healthcare provider. Research shows that nearly all Americans (91 percent) live within five miles of a retail pharmacy. Such access is vital in reaching the medically underserved.

We urge you to increase access to much-needed services for underserved Medicare beneficiaries by supporting H.R. 592/S. 109, the *Pharmacy and Medically Underserved Areas Enhancement Act*, which will allow Medicare Part B to utilize pharmacists to their full capability by providing those underserved beneficiaries with services, subject to state scope of practice laws, not currently reaching them. This important legislation would lead not only to reduced overall healthcare costs, but also to increased access to healthcare services and improved healthcare quality, all of which are vital to ensuring a strong Medicare program.

Value of Medication Adherence and MTM

Medications are the primary intervention to treat chronic disease and are involved in 80% of all treatment regimens.[1] Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, have 50 different prescriptions filled per year, account for 76% of all hospital admissions, and are 100 times more likely to have a preventable hospitalization.[2] Yet medication management services are poorly integrated into existing healthcare systems. Poor medication adherence alone costs the nation approximately $290 billion annually—13% of total healthcare expenditures—and results in avoidable and costly health complications.[3] Thus, given the importance of medications in achieving patient care outcomes and lowering overall healthcare costs, it is critical that policies are implemented to encourage greater care integration across the healthcare continuum and promote financial accountability for safe and appropriate medication use.

[1] http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf
[2] Ibid.
[3] "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease;" New England Healthcare Institute, Cambridge, MA, 2009.

A growing body of evidence suggests that when physicians, nurses, pharmacists, and other healthcare professionals work collaboratively, better health outcomes are achieved. Pharmacies in particular provide access to highly-trained and highly-trusted health professionals. The unique reach and access points of pharmacy provide a means of continuous care and oversight between scheduled visits. Medication related services provided by community pharmacists improve patient care, enhance communication between providers and patients, improve collaboration among providers, optimize medication use for improved patient outcomes, contribute to medication error prevention, assist with hospital readmission cost avoidance goals, and enable patients to be more actively involved in medication self-management. Examples of the value of these services include:

- A 2013 CMS report found that Medicare Part D MTM programs consistently and substantially improved medication adherence for beneficiaries with chronic diseases. This included savings of nearly $400 to $525 in lower overall hospitalization costs.[4]

- A study of published research on medication adherence conducted by Avalere Health in 2013 concluded that the evidence largely shows that patients who are adherent to their medications have more favorable health outcomes such as reduced mortality and use fewer healthcare services, especially hospital readmissions and ER visits. Such outcomes lead to less expensive healthcare costs, relative to non-adherent patients.[5]

- How and where MTM services are provided also impact its effectiveness. A study published in the January 2012 edition of *Health Affairs* found that a pharmacy-based intervention program increased adherence for patients with diabetes and that the benefits were greater for those who received counseling in a retail, face-to-face setting as opposed to a phone call from a mail-order pharmacist. The interventions were cost-effective, with a return on investment of approximately $3 for every $1 spent. These findings highlight the central role that pharmacists can play in promoting the appropriate initiation of and adherence to therapy for chronic diseases.[6]

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[4] "Medication Therapy Management in Chronically Ill Populations: Final Report;" Centers for Medicare and Medicaid Services (CMS); August 2013 (http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf).
[5] "The Role of Medication Adherence in the U.S. Healthcare System;" Avalere Health; June 2013 (http://www.avalerehealth.net/research/docs/20130612_NACDS_Medication_Adherence.pdf).
[6] "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients;" *Health Affairs,* January 2012 (http://content.healthaffairs.org/content/31/1/120.full).

Despite the proven value of medication adherence and MTM, the Medicare Part D MTM Program historically has seen low enrollment and utilization rates. Over the years, CMS has made programmatic changes they believed would increase eligibility and enrollment. However, these changes have not led to increased MTM eligibility and utilization. In 2012, there were approximately 27.2 million people enrolled in either a MA-PD (9.9 million) or a PDP (17.3 million). Of the more than 27 million beneficiaries, only 3.1 million were enrolled in an MTM program (11.4%). These figures fall well short of the CMS estimate that approximately 25% of the beneficiaries would be eligible for MTM.

NACDS has long been supportive of exploring new and innovative approaches to improve the Part D MTM program. One of the approaches we believe can be successful is the Enhanced MTM Model pilot being conducted by the Center for Medicare and Medicaid Innovation. This pilot gives Part D plans the opportunity to utilize new and innovative approaches to MTM, such as more efficient outreach and targeting strategies and tailoring the level of services to the beneficiary's needs. NACDS believes the Enhanced MTM Pilot program presents an opportunity to create better alignment of program incentives and has the potential to lead to improved access to MTM services for beneficiaries and greater medication adherence.

To ensure the success of the Enhanced MTM model, NACDS believes retail pharmacists must be included in the Enhanced Model Pilot programs. As preparations are made for the second year of the pilot, ways to maximize utilization of retail community pharmacists and their unique ability to improve medication adherence should be considered.

Transparency in Use of Fees in the Part D Program

NACDS supports transparency between Medicare Part D plans and retail pharmacies in the use of direct and indirect remuneration (DIR) fees, post-adjudication fees, and quality and performance-based network fees by prescription drug plans in the Medicare program.

The Centers for Medicare and Medicaid Services (CMS) recently released a fact sheet on the use and impact of DIR fees by plan sponsors in the Medicare Part D program. The fact sheet reported that the use of DIR by Part D sponsors has been "growing significantly in recent years" and has led to an increase in beneficiary cost-sharing and an increase in subsidy payments made by Medicare.

The increasing use of fees in the Part D program is also a growing problem for retail pharmacies. Retail pharmacies have to conduct business in an environment where they are unsure if a reimbursement they received is the "final reimbursement" or if a fee will be applied at some future point. This may lead some pharmacies to question their ability to continue to participate in certain Part D networks, which ultimately endangers beneficiary access to prescription drugs.

The Social Security Act clearly gives CMS the authority to regulate the use of fees in the Medicare program. We believe that CMS should issue guidance clarifying the appropriate use, submission, and approximation of fees in the Medicare program, including in quality and performance-based payment structures. Such guidance should also clarify the components of DIR fees, such as direct product and service reimbursement, as well as quality and performance-based program reimbursement. DIR fees must be separately tracked and reported by plans to ensure their transparent use. In seeking guidance, NACDS is not asking CMS to regulate the types of fees plans can use, how or when plans can use fees, or the dollar amounts for such fees. Rather, we are seeking guidance that would require clarity and consistency in how fees are used and applied.

We urge Congress to advise CMS on the importance of issuing guidance to improve transparency between plans and pharmacies in prescription drug reimbursement structures. Specifically, we urge Congress to advise CMS on the importance of issuing guidance to improve consistency in disclosures to pharmacies on how fees are defined, how they will be calculated, the timing for fee collection, how fees will be reported to pharmacies at the claim level detail (thus allowing reconciliation of reimbursement), and the parameters for pharmacies to "earn" back the fee post reconciliation. Increased transparency in the Medicare program will benefit CMS, participating pharmacies, and beneficiaries alike.

Lowering Prescription Drug Costs

NACDS shares the goal of reducing the cost of prescription drugs and believes community pharmacies are ideally situated to help through services designed to improve medication adherence and the promotion of generic drugs as safe, cost-effective alternatives. Retail community pharmacies are the closest healthcare providers to patients with respect to prescription medications. A March 2017 survey of registered voters conducted by *Morning Consult* and commissioned by NACDS found that eight-in-ten respondents believe that pharmacists are credible sources of information about how to save money on prescription drugs—the highest rating of healthcare professionals tested. In addition to the ability of improved adherence and increased transparency (as detailed above) to impact drug costs, NACDS recommends other beneficial changes, such as:

- Generic Utilization: Pharmacies have long promoted generic drugs as safe, cost-effective alternatives. Increasing the use of generic drugs is one of the most effective ways to reduce prescription costs**.** For every one percent increase in generic utilization, the Medicaid program could save $558 million. For example, if all other states could match the generic utilization rate of Hawaii (82.7%), the Medicaid program could save $6.56 billion annually. Community pharmacies have a higher generic dispensing rate (71%) than any other practice setting.

- Risk Evaluation and Mitigation Strategy (REMS): The REMS program requires manufacturers to ensure the benefits of a drug or biological product outweigh its risks. However, some manufacturers unfortunately are using the REMS Elements to Assure Safe Use (ETASU) requirements to prevent competition for products. Specifically, certain companies are employing restricted distribution networks to deny manufacturers of generics and biosimilars access to product samples they need to compete. An analysis by Matrix Global Advisors found that utilizing these networks to prevent generic competition costs the health care system $5.4 billion annually, including $1.8 billion to the federal government. Also, it could result in approximately $140 million in lost savings for every $1 billion in biologics sales. NACDS supports closing loopholes to boost generic-medication access and lower costs.

- Biosimilars: NACDS supports policies that promote confidence in and encourage increased use of more cost-effective biosimilar medications. FDA should adopt naming policies for biosimilar drugs and biologics that are consistent with the naming conventions for brand and generic small molecule drugs, that is assigning the same individual nonproprietary name ("INN") to a biosimilar drug product that is assigned to the reference biologic drug counterpart. Special naming policies for biosimilar drugs (and other biological drugs) that deviate from the traditional naming scheme can undermine prescriber and patient confidence in biosimilar products, thereby discouraging their use and jeopardizing the savings that could otherwise be achieved through increased use of more cost-effective biosimilar products. Without robust generic competition, brand biological products could cost the United States healthcare system $120 billion by 2024, according to projections from Express Scripts. However, a 2014 report published by the Rand Corporation found that the use of biosimilars could provide a $44.2 billion reduction in direct spending on biologic medications over the next ten years.

Conclusion

NACDS thanks the Committee for your consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

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Testimony of the National Rural Health Association (NRHA)
Concerning HRSA's Programs Impacting Rural Health
Submitted for the Record to the Committee on Ways and Means – FY 2018

The National Rural Health Association (NRHA) is pleased to provide the Committee on Ways and Means with a statement for the record on Fiscal Year 2018 funding levels for programs with a significant impact on the health of rural Americans.

NRHA is a national nonprofit membership organization with a diverse collection of 21,000 individuals and organizations who share a common interest in rural health. The Association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research.

NRHA is advocating support for a group of rural health program that assist rural communities in maintaining and building a strong health care delivery system into the future. Most importantly, these programs help increase the capacity of the rural health care delivery system and true safety net providers. Rural Americans, on average, are poorer, sicker and older than their urban counterparts. Programs in the rural health safety net increase access to health care, help communities create new health programs for those in need and train the future health professionals that will care for the 62 million rural Americans. With modest investments, these programs evaluate, study and implement quality improvement programs and health information technology systems.

Funding for the rural health safety net is more important than ever as rural America is facing a hospital closure crisis. Seventy-nine rural hospitals have closed, 10,000 rural jobs lost and 1.2 million rural patients have lost access to their nearest hospital since 2010. Even more concerning is that 673 rural hospitals are at risk of closure, meaning sustained Medicare cuts threaten the financial viability of 1 in 3 rural hospitals. The loss of these hospitals would mean 11.7 million patients would lose access to care in their community. Continued cuts to rural providers have taken their toll, forcing far too many closures. Medical deserts are appearing across rural America, leaving many of our nation's most vulnerable populations without timely access to care.

Important rural health programs supported by NRHA are outlined below.

State Offices of Rural Health (SORH) provide state specific infrastructure for rural health policy. SORH is the counterpart to the federal rural health research and policy framework. SORH forms an essential link between small rural communities and the state and federal resources to develop long term solutions to rural health problems. These funds provide necessary capacity to states for the administration of critical rural health programs, assist in strengthening rural health care delivery systems, and maintaining rural health as a focal point within each state. SORH plays a key role in assisting rural health clinics, community health centers, and small, rural hospitals assess community health care needs. This program creates a state focus for rural health interests, brings technical assistance to rural areas, and helps frontier communities tap state and national resources available for health care and economic development. SORH forms an essential connection to other state agencies and local communities; allowing federal resources to best address the unique needs of rural communities. Request: $12.5 million.

Rural Health Research and Policy program forms the federal infrastructure for rural health policy and the Federal Office of Rural Health Policy (FORHP). FORHP administrates important rural health programs, coordinates activities related to rural health care, and analyzes the possible effects of

policy on the 60 million rural Americans and advises the Department of Health and Human Services (HHS) Secretary on access to care, the viability of rural hospitals, and the availability of physicians and other health professionals. These grants provide policy makers with policy-relevant research on problems facing rural communities in providing access to quality affordable care and to improving population health in rural America. By funding rural health research centers across the country, these grants produce a mix of health services research, epidemiology, public health, geography, medicine, and mental health. This program allows rural America to have a coordinated voice in HHS, in addition to providing expertise to agencies such as the Centers for Medicare and Medicaid Services. Request: $10.4 million.

The **National Health Service Corps (NHSC)** plays an important role in maintaining the health care safety net by placing primary health care providers in the most undeserved rural communities. NHSC is a network of 8,000 primary health care professionals, and 10,000 sites (September 2010). However, the demand for primary care providers far exceeds the supply, and the needs of rural communities continue to grow. Seventy-seven percent of the 2,050 rural counties in the United States are designated as primary care Health Professional Shortage Areas (HPSAs) and 60 percent of rural Americans live in a mental health professional shortage area. Rural areas have fewer than half as many primary care physicians per 100,000 people as urban areas. Rural communities must have the resources necessary to hire primary care, dental and behavioral health providers. Request: $337 million.

Rural Health Outreach and Network Grants provide capital investment for planning and launching innovative projects in rural communities that will become self-sufficient. These grants are unique federal grants in that they allow a great deal of flexibility for the community to build a program around their community's specific needs. Grant funds are awarded for communities to develop needed formal, integrated networks of providers that deliver primary and acute care services. The grants have led to successful projects including information technology networks, oral screenings, and preventative care. Due to the community nature of the grants and the focus on sustainability after the grant term has run out – 85 percent of the grantees continue to deliver services a full five years after federal funding ends. Request: $72.4 million.

Rural Hospital Flexibility Grants fund quality improvement and emergency medical service projects at Critical Access Hospitals (CAHs). These grants allow rural communities to improve access to care, develop increased efficiencies, and improved quality of care by leveraging the services of CAHs, Emergency Medical Services (EMS), clinics, and health practitioners. These grants serve an important function in increasing information technology activities in rural America. Also funded in this line is the Small Hospital Improvement Program (SHIP), which provides grants to more than 1,500 small rural hospitals (50 beds or less) across the country to improve business operations, focus on quality improvement, and ensure compliance with health information privacy regulations. Request: $50.4 million.

The Office for the Advancement of Telehealth (OAT) supports the provision of clinical services at a distance, reduces rural provider isolation, fosters integrated delivery systems through network development, and tests a broad range of telehealth applications. Long-term, telehealth promises to improve the health of millions of Americans, save money by reducing unnecessary office visits and hospital stays, and provide continuing education to isolated rural providers. OAT coordinates and promotes the use of telehealth technologies by fostering partnerships between federal and state agencies and private sector groups. Since telehealth is still an emerging field with new approaches and technologies; continued investment in the infrastructure and development is needed. Request: $21 million.

The Rural Opioid Overdose Reversal Grant helps reduce the occurrences of morbidity and mortality related to opioid overdoses in rural communities through the purchase and placement of emergency devices used to rapidly reverse the effects of opioid overdoses. The grant also helps train licensed health care professionals and emergency responders on the use of opioid reversals. Rural

communities are struggling with prescription opioids and heroin abuse. While opioid use generally is on the rise nationwide, the rate of overdose deaths in non-metro counties is 45% higher than in metro counties. Request: $11.1 million.

Title VII Health Professions Training Programs (with a significant rural focus):

• **Area Health Education and Centers (AHECs)** encourage and provide financial support to those training to become health care professionals in rural areas. Without this experience and support in medical school, far fewer professionals would be aware of the needs of rural communities and even fewer would make the commitment to practice in rural areas. AHECs support the recruitment and retention of physicians, students, faculty and other primary care providers in rural and medically underserved areas. It has been estimated that nearly half of AHECs would shut down without federal funding, placing future access to health care in rural communities at risk. Request: $33.5 million.

• **Rural Physician Pipeline Grants** help medical colleges develop rural specific curriculum and to recruit students from rural communities that are likely to return to their home regions to practice. This "grow-your-own" approach is one of the best and most cost-effective ways to ensure a robust rural workforce into the future. Request: $5.3 million.

• **Geriatric Programs** train health professionals in geriatrics, including funding for Geriatric Education Centers (GEC). There are currently 47 GECs nationwide that ensure access to appropriate and quality health care for seniors. Rural America has a disproportionate share of our nation's elderly and is more likely to have physician shortages than urban locations. Without this program, rural health care provider shortages would grow. Request: $42.8 million.

The National Rural Health Association appreciates the opportunity to provide our recommendations to the Committee. These programs are critical to the rural health delivery system and help maintain access to high quality care in rural communities. We greatly appreciate the support of the Committee and look forward to working with Members of the Committee to continue making these important investments in rural health.

National
Family Planning
& Reproductive Health Association

Testimony of Clare Coleman, President & CEO
National Family Planning & Reproductive Health Association

Submitted to the House Committee on Ways and Means

Statement for the Record Re: The President's Fiscal Year 2018 Budget
Held June 8, 2017

My name is Clare Coleman; I am the President & CEO of the National Family Planning & Reproductive Health Association (NFPRHA), a national membership association representing providers and administrators committed to helping people get the family planning education and care they need to make the best choices for themselves and their loved ones. Many of NFPRHA's members receive federal funding from Medicaid and through Title X of the federal Public Health Service Act, the only federally funded, dedicated family planning program for low-income and uninsured people. These cornerstones of the nation's public health safety net are essential resources for those providing access to high-quality services in communities across the country. As a result, NFPRHA respectfully disagrees with the administration's priorities laid out in its fiscal year (FY) 2018 budget.

Publicly funded family planning services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers, and other private nonprofit organizations. For decades, these diverse provider networks have helped ensure that millions of poor and low-income individuals as well as those who are underinsured or uninsured receive access to high-quality family planning and other preventive health services in all 50 states, the District of Columbia, and US territories.

Oppose Cuts to Medicaid
The president's proposal advances congressional proposals that, if enacted, would cut more than $627 billion from Medicaid, alter the structure and financing of the program, and dismantle the provider network, deepening a crisis in public health. NFPRHA opposes the end to or rollback of Medicaid expansion, either of which would reduce the number of people with access to Medicaid, thereby leading to fewer people getting health care, even-greater increases in rates of sexually transmitted diseases, and a reversal of the reduction in rates of unintended pregnancy.

Furthermore, these proposed changes to the structure and financing of Medicaid will compound the demands being place on the publicly funded family planning safety net. NFPRHA opposes both per capita caps and block grants. Both proposals would inevitably shift costs to states, forcing them to make choices about program eligibility, benefits, and provider payments in order to adapt to new funding constraints. Medicaid beneficiaries would also likely face new barriers to coverage, such as premiums and other cost-sharing requirements.

Increase Support for Title X
An analysis published in the *American Journal of Public Health* last year found that, in order for publicly funded providers to meet the needs of all low-income, uninsured women of reproductive age for family planning services, the Title X program would need to be supported with approximately $737 million annually. This estimate is based on the presumption that the Medicaid expansion resulting from the Affordable Care Act remains unchanged. The president's budget requests only level funding ($286.5 million), a fraction of what is needed to serve low-income, uninsured women across the country. It is also important to note that the Title X program also supports men, so the resource needs identified in the analysis are extremely conservative. Since FY 2010, Title X has dropped from $317.5 million annually to $286.5 million annually, leading to a loss of approximately 1.2 million patients from the network.

The ongoing threat of the Zika virus has only increased demand on Title X providers. The CDC-confirmed causal linkage between babies born with microcephaly and pregnant women infected with the Zika virus reinforced the simple concept that in a time of public health emergency, women will turn to Title X-funded providers for thorough counseling, risk assessment, and access to family planning services. As summer returns throughout the United States, public health experts expect the Zika virus to continue to spread domestically and demand for education and services to rise again.

Oppose Cuts to Other Safety Net Programs
NFPRHA is further troubled by proposals to eliminate several maternal-child health programs, the Social Services Block Grant, and the Teen Pregnancy Prevention Program. Each of these programs is a vital part of the federal government's role in fostering healthy women, children, and families. NFPRHA also opposes the harmful reductions to the National Center for HIV/AIDS, Viral Hepatitis, STIs, and TB Prevention; Temporary Assistance for Needy Families; Special Supplemental Nutrition Program for Women, Infants, and Children; Ryan White HIV/AIDS program; and rural health programs. Budgets for each of these programs are already stretched thin, and these further reductions will harm the patients our providers serve.

Oppose Harmful Budget Riders
NFPRHA is deeply concerned by the harms to the Title X network and other health care programs that would be caused by the budget rider that seeks to prohibit any funding in the Labor-HHS appropriations bill from going to essential community providers that provide abortions or contract with abortion providers and that received more than $23 million in Title X funding in FY 2016. The implicit intention of this proposed rider is to exclude Planned Parenthood affiliates, which are key networks within the publicly funded family planning safety net. A recent analysis by the Guttmacher Institute found that Planned Parenthood serves 32% of all safety-net contraceptive clients despite having just 6% of the nation's safety-net family planning providers. Our members, from federally qualified health centers to local public health departments to universities and school-based programs to private non-profits, rely on Planned Parenthood to offer patients high quality services and share the patient load in communities with high levels of need for publicly funded family planning.

Conclusion

Millions of low-income women and men depend on the safety-net programs for affordable access to the family planning and preventive health services that help them stay healthy. However, this budget would jeopardize the capacity of our nation's public health infrastructure to help these vulnerable individuals and families as well as the broader social services and health care safety net. **NFPRHA urges the Committee to reject the president's budget proposal.**

NACDD
National Association of Councils on Developmental Disabilities

Statement for the Record Submitted By:
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Dear Chairman Brady and Ranking Member Neal:

The National Association of Councils on Developmental Disabilities (NACDD) is pleased to submit this statement for the record to you and the Members of the Committee in advance of the hearing on the Department of Health and Human Services' Fiscal Year 2018 Budget Request scheduled for June 8, 2017. NACDD is the national membership organization for the Councils on Developmental Disabilities (DD Councils) appointed by Governors, and located in every state and territory. NACDD respectfully requests that Congress appropriate $76 million for the DD Councils in FY 2018 and makes no changes to the structure or funding level of the DD Councils as proposed in in the President's Fiscal Year 2018. The DD Councils are funded through the U.S. Dept. of Health and Human Services, Administration for Community Living: Administration on Intellectual and Developmental Disabilities.

NACDD's funding history includes:

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016/2017
NACDD's Request	$75,000,000	$75,000,000	$75,000,000	$75,000,000	$76,000,000
Actual Appropriations	$74,774,000	$70,661,000*	$70,876,000	$71,692,000	$73,000,000

*After sequestration

The DD Councils were first authorized in 1970. They are currently part of the Developmental Disabilities Assistance and Bill of Rights Act (DD Act). The DD Act has always been a bipartisan piece of legislation. The DD Councils are catalysts that create effective solutions and fulfill the mandate to improve service and systems with and for people with developmental disabilities (DD). The central purpose of the DD Act is to "is to assure that individuals with developmental disabilities and their families participate in the design of and have access to needed community services, individualized supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all

facets of community life, through culturally competent programs."[1] DD Councils consist of people with DD, their families, representatives of other programs funded under the DD Act, other stakeholders in the community, and representatives of state agencies. The President's FY 2018 budget proposal to restructure the DD Councils would remove the voices of persons with DD from the DD Act. Losing the direct input of persons with DD about how to create and improve services and systems to support them will dilute the entire essence of the DD Act. The DD Councils are charged with investing in dynamic and innovative programs that improve state services and systems with the limited funding they receive. By statute, the DD Councils are required to expend 70 percent of their funding on programs that serve people with DD in the community. The DD Councils, through their innovative programming and investments, ensure persons with DD can realize the same goals we all have, to receive a quality education, live in their communities, and be taxpayers.

For 47 years, the DD Councils, in partnership with the University Centers for Excellence in Developmental Disabilities (UCEDDs) and Protection and Advocacy program for Developmental Disabilities (P&As) have provided critical services and supports for those with DD and their families. The concept of the triumvirate in the DD Act was designed by and for individuals with DD and was masterful in its partnering together of three distinctly different programs that together work collaboratively to meet the overall intended purpose of the DD Act through their individual responsibilities. The DD Councils, P&As, and UCEDDs are linked in their responsibilities ensuring a well-trained cadre of experts providing services to individuals with DD and their families, protecting the rights of individuals with DD, and ensuring that people with DD are fully included in the work to improve services and systems to make them fully inclusive.

The DD Act requires DD Councils to assess and review federal and state programs for people with DD and develop a comprehensive five-year state plan to address the needs of persons with DD. The state plan is carried out by a series of identified goals, objectives and activities designed to address the identified needs. The DD Councils are unique in that people with DD, who are encountering barriers and challenges, are the majority of the people creating the state's plan for how it can address those barriers and challenges through investing in dynamic and innovative programs. The DD Councils just began their first year of a new five-year state plan that lays out the goals, objectives, and activities of the DD Council, and what each DD Council will accomplish in the next five years with its funding.

Employment is a key component of community living. Given the high unemployment, underemployment and low employment retention rates for persons with DD, the majority of DD Councils have prioritized efforts in their state plans to improve employment outcomes for persons with DD. More than half of the DD Councils have led in implementing an innovative program, *Project Search*, which immerses students in employment opportunities during their final years of special education. The projects teach independence and work skills that meet the needs of both the individuals and the employers. About 80 percent of graduates of *Project Search* go on to hold regular, paid, integrated employment with employers. For example, five years ago, the Kansas Developmental Disabilities Council implemented *Project Search* and the management and support of the program was transferred to a Managed Care Company. As of 2017, the *Project Search* program has expanded three times without any financial support from the DD Council.

[1] 42 U.S.C. 15001(b).

The Mississippi Developmental Disabilities Council graduated its first Project Search class in May of 2016. In addition, the Council funded the Farm Entrepreneurship and Independence Initiative at $70,000. This initiative uses an employment model of youth inclusiveness in the Delta, which pairs youth with and without disabilities to train and employ young farmers. Students are grouped in threes (one with a disability and two without disabilities), who are then familiarized with farming. Students have the opportunity to learn new skills associated with processing, sorting, packaging, quality control, food safety transportation and record keeping. Students in the program also gain the skills and knowledge to help farmers meet the Good Agricultural Practice (GAP) food safety standards.

DD Councils also fund programs that support quality education for people with DD. Education is critical to securing competitive community-based employment, launching and advancing one's career, being independent and economically self-sufficient, and achieving personal goals. The Massachusetts Developmental Disabilities Council undertook a pilot initiative to provide a unique educational opportunity to teach teenagers and young adults with intellectual and other developmental disabilities skills that will assist them in gaining independence as adults. The program includes a core curriculum and elective options, and a practicum that must be completed in order to graduate. Thirty-one students successfully graduated from Independence College in 2016, and over 50 students have applied for enrollment in 2017.

The Maryland Developmental Disabilities Council funded the development of an online training for childcare providers about serving children with disabilities that offers Continuing Education Units. It is the second most requested training on a national website for providers. Available nation-wide, over 500 people have enrolled in the program. The Council also has produced two videos for $5000 about the inclusion of children with disabilities, which they use to train over 14,000 childcare providers.

Many DD Councils work to ensure that people with DD are able to safely and fully access all aspects of life in the community. For example, the Florida Developmental Disabilities Council (FDDC) in partnership with the Florida Department of Transportation (FDOT) implemented two transportation voucher pilot programs in 2016. FDDC and FDOT funded $75,000 to each project for a total of $150,000 per site: one urban and one rural. The voucher pilot enabled HARTPlus to contract with Yellow Cab of Tampa. Prior to the voucher pilot, HARTPlus required a three-day notice to provide rides to its 3,000 clients, only serving individuals within ¾ mile of the standard bus schedule and each trip cost HARTPlus $36. The voucher pilot allowed HARTPlus to secure trips for $16 per person for up to a 7.6-mile ride. As a result, HARTPlus was able to offer 27,813 trips at a cost of $445,008, rather than the typical cost of $1,001,268, saving $556,260. Riders now receive 24-hour service and are able to book trips for a multitude of purposes. This availability to efficient transportation positively affected safety and satisfaction while opening the door to a wider variety of community access, including employment and recreational events.

HARTPlus credits the voucher pilot with its 8% growth, improved on-time performance and its ability to exceed expectations in accessibility to wheelchair users. The urban model is self-supporting after one year of funding, and the rural model is working towards independent sustainability with a second year of funding. Preliminary reports from the rural model include an individual who transitioned from working at McDonald's earning $8.05 per hour to welding,

now earning $16.00 per hour and another individual who initially had to turn down a job offer was able to become an employee at Walmart.

The Missouri Developmental Disabilities Council has led a Victimization Task Force that includes several state agencies, DD service providers, the UCEDD, the P&A, various victim services stakeholders, (FBI Victim's Unit, rape crisis centers, abuse hotlines, forensic interviewers, law enforcement, the Attorney General's Office), persons with disabilities who had been victimized, parents of children with DD, MO Ombudsman and other stakeholders. The task force identified gaps and barriers in the various systems and as a result, developed approximately 40 recommendations for the state to work to implement to improve safety and ensure victims are protected from abuse. To educate people about the issue, the DD Council provided a $200,000 grant to the Arc in MO to implement an awareness campaign with the tag line, "It's Happening." A website (www.andwecanstopit.org) was established that provides information, and resources for community members to recognize when someone is being victimized, and how it can be reported.

Unfortunately, the timely need for the establishment of the Victimization Task Force and implementation of the recommendations was seen in April 2017. A man with intellectual and developmental disabilities was reported missing when a new service provider took over management of the group home where he was living. The police discovered the man's body in a storage container that was filled with concrete. The discovery of the man's body indicated that he had likely died several months before he was reported as missing by the provider. To address this serious failure of the system, once the outcome of the investigation is known, the Council plans to re-convene the Victimization Task Force and work with stakeholders to identify and recommend additional changes to policies that must be made to keep people with DD safe.

As you can see in the examples above, the funding provided to the DD Councils ensures that people with DD have the opportunity to achieve what we all want, to receive a quality education, live in and fully access all parts of the community, and be taxpayers. The President's budget proposal to combine the DD Councils with two other entities that represent different parts of the disability community, are not national in scope, have different authorizing statutes and mandates, will result in a significant loss of the voices of and focus on those living with DD. Under this proposed structure and funding reduction, the DD Councils will not be able to meet the stated goals of the DD Act that has led to significant improvements in the lives of persons with DD in the last 47 years.

In summary, the DD Councils are highly accountable for their outcomes and bring the voice of individuals with DD to the forefront in making decisions of how to improve services and systems. NACDD requests that the DD Councils be provided their requested funding for Fiscal Year 2018 and are not restructured into a brand new program called *Partnerships for Innovation, Inclusion, and Independence*, just as they begin their important work in their new five-year state plan.

Majority to benefit from repeal of ACA

The repeal of Obamacare is a blessing to 94 percent of Americans who were or would be paying more for less coverage to provide insurance to 6 percent of Americans who allegedly would gain insurance coverage. More than 310 million Americans would be forced to pay higher premiums and accept larger deductibles and copays to provide coverage to these ³uninsured people.² The Senators and Congressmen demanding that the government be more generous with *your* tax dollars will not pay *one dime* extra out of their own pockets to provide this largess.

Their phony generosity and fake compassion is nauseating

Liberals in congress should dry their tears give up their pensions and Cadillac health care plans and give *their* money to the poor. They feign concern for constituents, while indemnifying themselves with generous health care benefits and pensions plans designed to indemnify themselves into perpetuity. Using taxpayers¹ money to protect themselves from the chaos they have created in our economy.

The repeal of the Affordable Care Act was inevitable. It was a bad idea poorly drafted and never really implemented. Some argued that the Republicans should have just stood by and let it implode. But that was never really an option. The majority of voters realized the ACA raised premiums, deductibles and copays to the point that most people in the middle class were essentially self-insured. They were purchasing catastrophic insurance at inflated prices, while increasing the cost of health care for everyone.

From the time the ACA (Obamacare) was passed, it never met any of its ³goals² it was too expensive and unattractive to younger patients who were better off going without coverage. As with all insurance, a very small group of patients benefit at the expense of the majority of premium payers.

Additionally, Obamacare sought to provide insurance coverage for routine care. That is not insurance, but simply a subsidy. This subsidy, like most of the features in the ACA, drove up prices. The Affordable Care Act was not affordable and did not provide care for the vast majority of Americans.

From its inception, the goal of the ACA was to make liberals look and feel like they were being generous with other peoples money. Government run programs are notoriously inefficient. By design they are structured to add administrative costs that eventually smother the real reason for the program. The term ³cost overrun² was invented to describe

government programs. It encouraged the development of tax exempt, non-profit organizations that use their status to mask exorbitantly expensive charges.

This new legislation could provide Americans with the last clear chance to cut health care spending in half. While the rest of the world spends less than 8 percent of its GDP for health care, America is spending double that amount. This effectively increases the cost of all goods sold by American manufacturers, making it a long-term recipe for disaster.

Restructuring health care delivery is essential to reducing costs.

Medical oligopolies have no incentives to save money. They will actively seek to destroy innovation and technologies that could lower the total cost of health care. We can no longer tolerate their ³benevolent² bullying. The problem in America is too much government involvement in business and health care. The solutions will come from the private sector and not the government.

These oligopolies were created by the *Stark Laws* that prohibited doctors from owning their own hospitals and then referring patients to these facilities for care. Hospital administrators, who are not providers, quickly stepped in and agreed to make these doctors employees of the facilities and encouraged them to refer patients to their employer¹s facilities. This actually compounded the problem and made it worse. The facilities executives are rarely providers and have no contact with the patient. Their only concern is the bottom line and maximizing billing. They seek to appear charitable, while raking in excessive payments to fund overpriced executives who add nothing to health care delivery. Their business model requires patients to over-utilize health care services and goods.

New legislation will provide perhaps the last opportunity to improve care and reduce costs. Eliminating the Stark provisions and divesting the oligopolies of the tax-exempt status is essential. Allowing physicians to own their own facilities and compete directly will reduce costs. The oligopolies never produced any economies of scale. In fact, it has produced just the opposite, because they focused on maximizing their payments from the government to increase their revenue and swallow their competition.

Although promoted by the FTC for ³managed competition,² they were in fact structured to obfuscate the truth and maximize their profit. If you have ever tried to read your hospital bill, you know that clarity and economy were not the goals.

Conservatives need to do a better job explaining that lowering corporate tax rates and health care costs will create more jobs. Private sector corporations employ many

Americans and their stocks fund employee pension plans, all of which is tied to the success of these private corporations.

Liberals want you to believe patients will die because of the repeal of Obamacare. That is not true. But unless we get government spending under control, we will kill off private sector jobs and destroy what¹s left of manufacturing in America. Socialism has never worked and is unsustainable. We need to wake up and shrink our government.

Repealing the ACA is the essential first step.

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IDSA
Infectious Diseases Society of America

June 8, 2017

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
United States House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
United States House of Representatives
1139E Longworth Office Building
Washington, DC 20515

Dear Chairman Brady and Ranking Member Neal:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for scheduling the hearing with Health and Human Services Secretary Tom Price to discuss the administration's FY2018 budget proposal, including the Centers for Medicare and Medicaid Services (CMS). As an update on the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) and the Merit-Based Incentive Payment System (MIPS) was provided in the budget proposal, we wanted to focus several key concerns our members have raised regarding payment reform. Specifically, we wished to highlight the determination of evaluation and management codes, and MACRA implementation. We urge you to raise these issues with Secretary Price during and after the hearing.

The Value of Infectious Diseases Physicians

Infectious Diseases (ID) physicians make significant contributions to patient care, biomedical research, and public health. Their leadership and services save lives, prevent costly and debilitating diseases, and drive biomedical innovation. ID physician involvement in patient care is associated with significantly lower rates of mortality and 30-day readmission rates in hospitalized patients, shorter lengths of hospital stay, fewer intensive care unit (ICU) days, and lower Medicare charges and payments.

ID physicians provide life-saving care to patients with serious infections such as HIV and hepatitis C infections related to the opioid epidemic. ID doctors lead public health, public safety, and national biosecurity activities to prevent, control, and respond to outbreaks in healthcare settings and the community. They respond to emerging infections such as Ebola and Zika virus infections, and also to re-emerging infections such as the recent measles outbreak in Minnesota. ID physicians also lead antibiotic stewardship programs to optimally use antibiotics for the best clinical outcomes while limiting drivers of further antibiotic resistance. Routinely, ID clinicians care for highly complex patients with serious infections requiring refined management or they thoughtfully assist in preventing infection in at risk patients. ID physicians conduct research leading to breakthroughs in the understanding of emerging and re-emerging diseases leading to efforts at control and treatment. Finally, ID physicians help lead the way in the development of urgently needed new antimicrobial drugs, diagnostics, and vaccines.

The Practice of Infectious Diseases is Currently Under-valued and Jeopardizes the Next Generation of Infectious Disease Physicians

Despite the importance of ID physicians' work, the care they provide is undervalued by the current payment system. If not addressed, this fundamentally threatens the

future ID workforce and consequently their patients and the nation's health. When questioned about career choices, a 2014 IDSA survey of 600 Internal Medicine residents (in-training) found high interest in ID but decisions to ultimately chose another field instead. Low salary was the most often cited reason for not choosing ID as the average starting ID salary is less than positions taken that do not require additional training such as hospital medicine. Average salaries for ID physicians are significantly lower than those for most other specialties and only slightly higher than the average salary of general Internal Medicine physicians, even though ID training and certification requires an additional two to three years of training.

With this shift over recent years, the number of residents applying for ID fellowship declined steadily from 2013 to 2016, and the number of open training positions increased during the same period. While the number of residents applying for ID fellowships rose slightly in 2017, and open positions declined, these changes are attributable to administrative changes in the "match" program. Regardless, the data indicate a problem in the workforce pipeline.

Regarding compensation, over 90% of provided ID physician care is accounted by evaluation and management (E/M) services. These cognitive encounters are undervalued by the current payment systems compared to procedural practices (e.g., surgery, cardiology, and gastroenterology). This accounts for the significant compensation disparity between ID physicians and specialists who provide more procedure-based care, as well as physicians who provide similar E/M services but who have received payment increases because their specialty enrollment designation is as "primary care physicians." Based on CMS data, cognitive E/M services comprise a higher percentage of services provided by ID physicians than those provided by primary care physicians such as Internal Medicine, Family Medicine or Pediatrics.

The Need to Revalue Evaluation and Management Services

Current E/M codes fail to reflect the increasing patient complexity in both inpatient and outpatient E/M work that covers the vast majority of ID care. Without revising codes or other approaches, the payment system will not address this fundamental problem of wherein fair value is far from the work rendered in time-consuming complex care that cannot be hurried. This is driving fewer young physicians to enter the specialty of ID. ID physicians often care for more chronic illnesses, including HIV, hepatitis C, and recurrent or difficult infections. Such care involves preventing complications and avoiding the use of complicated and unnecessary diagnostic and therapeutic pathways. ID physicians also conduct post-visit work, such as care coordination including laboratory review, patient counseling, and other necessary follow up.

IDSA urges the Subcommittee to direct CMS to undertake the research needed to better identify and quantify inputs that accurately capture the elements of complex medical decision-making. We were pleased that report language in this regard was included in the FY2017 House and Senate Labor, Health, and Human Services Appropriations bills and affirmed in the FY2017 Consolidated Appropriations Act. We would appreciate the Committee's efforts to ask CMS to conduct these studies. Such studies should take into account the evolving health care delivery models that place growing reliance on team-based care. It should also consider patient case-mix or risk-adjustment as a component to determining complexity. Research activities should include the direct involvement of physicians who mostly provide only cognitive care. Specifically, this research should:

1. Describe in detail the full range of intensity for E/M services, placing a premium on the assessment of data and medical decision making;
2. Define discrete levels of service intensity based on observational and electronically stored data combined with expert opinion;
3. Develop documentation expectations for each service level;
4. Provide efficient and meaningful guidance for documentation and auditing; and
5. Ensure accurate relative valuation as part of the Physician Fee Schedule.

MACRA Implementation Challenges
When MACRA was enacted, IDSA and our members were hopeful that it would provide an opportunity to realign physician payment to truly incentivize high quality care while addressing the disparity in the compensation of ID physicians. We were hopeful that the Quality Payment Program (QPP) that incorporates both the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) options would offer significant improvements over the then existing quality programs. However, as implementation moves forward, we are concerned that the APM option, offering significant incentives, will not be accessible to physicians in small or mid-sized practices; and that the MIPS program, as currently structured, misses many opportunities to provide quality-based incentives.

The implementation of the new QPP will have a profound impact on ID physicians. CMS estimates that approximately 5,544 ID physicians will be participating in the MIPS program. Approximately 43% (2,300) of those physicians will experience a negative payment adjustment, equaling a $12 million loss in Medicare allowed charges across the specialty. Given this projection, IDSA has offered CMS a series of recommendations to strengthen the MIPS program geared toward providing the highest quality ID physician services, which we outline for the Committee.

Additional ID Quality Measures
First, while we are pleased that MACRA provides CMS with additional funding for measure development, current Physician Quality Reporting System (PQRS) measures are not well-aligned with infectious disease practices. We urge the Committee to encourage CMS to use part of this funding towards the development of ID quality measures.

We believe the lack of relevant ID quality measures within the MIPS is partly due to the time and the cost of measure development. The additional funding from the MACRA offers an invaluable opportunity for CMS to assist in the development of measures where gaps exist.

This is mostly due to the overwhelming proportion of ID clinical services delivered in the inpatient setting while most of the PQRS measures previously developed apply to face-to-face encounters in the outpatient setting. Aside from measures related to HIV, HCV, pneumonia vaccination and influenza immunization, there are no truly ID-specific measures on which ID specialists can report.

IDSA continues to propose relevant and meaningful ID measures for CMS to consider within the QPP. Last year, we submitted two additional measure concepts (Appropriate Use of anti-MRSA Antibiotics and 72-hour Review of Antibiotic Therapy for Sepsis) into the CMS Measures Under Consideration (MUC) process. Both related advancing quality measurement of antimicrobial stewardship at the physician-level. We hope the Committee will encourage CMS to advance these for inclusion on the list of applicable measures under the quality component of MIPS. Antibiotic stewardship is critical to prevent the misuse of antibiotics that drive the development of antibiotic resistance—a serious and growing public health crisis that claims at least 23,000 lives in the US a year according to the Centers for Disease Control and Prevention (CDC). Lack of good antibiotic prescribing also complicates a host of other medical services including the care of preterm infants, immunocompromised patients, solid organ and bone marrow transplants, cancer chemotherapy and many surgical procedures.

Improvement Activities (IAs) under MIPS
IDSA believes ID physicians will have the most impact in MIPS through IAs in the QPP. We encourage CMS ensure that a robust array of appropriate ID activities be available in list of clinical practice improvement activities.

IDSA is pleased that CMS is proposing the implementation of an antibiotic stewardship program (ASP) as an IA. We recommend CMS strengthen this approach by establishing ID physician leadership of an ASP as a high weight IA while maintaining participation in an ASP as a medium

weight IA. The CDC has recommended that all ASPs have a single leader who will be responsible for the program outcomes, noting that physicians—particularly those with formal training in infectious diseases—have been highly effective in this role. Further, the Joint Commission's Prepublication Standards for Antimicrobial Stewardship specifically cites the involvement of an infectious diseases physician in ASPs.

CMS has issued a proposed rule to require ASPs in acute care hospitals, and a final rule also requiring ASPs in long term care facilities, aligned with the goals and objectives of the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB). The growing need for stewardship activities and expert leaders to ensure their success underscores the importance of making ID physician leadership of ASP leadership a high weight IA.

IDSA is also pleased that CMS has included emergency preparedness and response activities in the IA list. However, we strongly believe preparedness should go beyond volunteering for emergency response, disaster assistance, domestic and international humanitarian work. It is critical that our hospitals and health systems build the capacity to respond to public health emergencies, as recent examples include outbreaks of Ebola virus, Zika virus, MERS-CoV, pandemic influenza and other viral diseases. ID physicians are heavily involved in these intensive efforts that often involve coordination of care across multiple departments in a hospital or a health system coordinating with public health entities regarding needs assessments, protocol development, communications plans and other activities. IDSA recommends that CMS add additional IAs to encompass leadership and participation in a wide array of health care facility preparedness and response activities.

Conclusion

Once again, we thank the Committee for its attention to CMS and physician payment. We look forward to continuing work with you in order to meet the evolving needs of our patients.

Sincerely,

William G. Powderly, MD, FIDSA
President, IDSA

Comments for the Record
U.S. House of Representatives
Committee on Ways and Means
The Department of Health and Human Services'
Fiscal Year 2018 Budget Request
Thursday, June 8, 2017, 1:00 PM
1100 Longworth House Office Building

By Michael G. Bindner
Center for Fiscal Equity

Chairman Brady and Ranking Member Neal, thank you for the opportunity to submit these comments for the record to the House Ways and Means Committee. As always, our proposals are in the context of our basic proposals for tax and budget reform, which are as follows:

- A Value Added Tax (VAT) to fund domestic military spending and domestic discretionary spending with a rate between 10% and 13%, which makes sure very American pays something.
- Personal income surtaxes on joint and widowed filers with net annual incomes of $100,000 and single filers earning $50,000 per year.
- Employee contributions to Old Age and Survivors Insurance (OASI) with a lower income cap, which allows for lower payment levels to wealthier retirees without making bend points more progressive.
- A VAT-like Net Business Receipts Tax (NBRT), which is essentially a subtraction VAT with additional tax expenditures for family support, health care and the private delivery of governmental services, to fund entitlement spending and replace income tax filing for most people (including people who file without paying), the corporate income tax, business tax filing through individual income taxes and the employer contribution to OASI, all payroll taxes for hospital insurance, disability insurance, unemployment insurance and survivors under age 60.

Discretionary activities of the Department of Health and Human Services would be funded by the VAT. While some of our VAT proposals call for regional breakdowns of taxing and spending, they do not for this department. While some activities, such as the Centers for Disease Control, exist outside the Washington, DC metro area, even these are site specific rather than spread out on a nation-wide basis to serve the public at large. While some government activities benefit from national and regional distribution, health research will not.

The one reform that might eventually be considered in this area is to more explicitly link government funded research with ownership of the results, so that the Department might fund some of their operations with license agreements for some of the resulting research, enabling an expanded research agenda without demanding a higher budget allocation.

Of course, regionalization is possible if the Uniformed Public Health Service is put into the role of seeing more patients, particularly elderly patients and lower income patients who are less than well served by cost containment strategies limiting doctor fees. Medicaid is notoriously bad because so few doctors accept these patients due to the lower compensation levels, although we are encouraged the health care reform is attempting to reduce that trend. Medicare will head down that road shortly if something is not done about the Doc Fix. It may become inevitable that we expand the UPHS in order to treat patients who may no longer be able to find any other medical care. If that were to happen, such care could be organized regionally and funded with regionally based taxes, such as a VAT.

The other possible area of cost savings has to do with care, now provided for free, on the NIH campus. While patients without insurance should be able to continue to receive free care, patients with insurance likely could be required to make some type of payment for care and hospitalization, thus allowing an expansion of care, greater assistance to patients who still face financial hardship in association with their illnesses and a restoration of some care that has been discontinued due to budget cuts to NIH. This budget contains even more cuts. These should not be allowed. Rather, previous cuts must be restored.

The bulk of our comments have to do with health and retirement security.

One of the most oft-cited reforms for dealing with the long-term deficit in Social Security is increasing the income cap to cover more income while increasing bend points in the calculation of benefits, the taxability of Social Security benefits or even means testing all benefits, in order to actually increase revenue rather than simply making the program more generous to higher income earners. Lowering the income cap on employee contributions, while eliminating it from employer contributions and crediting the employer contribution equally removes the need for any kind of bend points at all, while the increased floor for filing the income surtax effectively removes this income from taxation. Means testing all payments is not advisable given the movement of retirement income to defined contribution programs, which may collapse with the stock market – making some basic benefit essential to everyone.

Moving the majority of Old Age and Survivors Tax collection to a consumption tax, such as the NBRT, effectively expands the tax base to collect both wage and non-wage income while removing the cap from that income. This allows for a lower tax rate than would otherwise be possible while also increasing the basic benefit so that Medicare Part B and Part D premiums may also be increased without decreasing the income to beneficiaries**.** Increasing these premiums essentially solves their long term financial problems while allowing repeal of the Doc Fix.

If personal accounts are added to the system, a higher rate could be collected, however recent economic history shows that such investments are better made in insured employer voting stock rather than in unaccountable index funds, which give the Wall Street Quants too much power over the economy while further insulating ownership from management. Too much separation gives CEOs a free hand to divert income from shareholders to their own compensation through cronyism in compensation committees, as well as giving them an incentive to cut labor costs more than the economy can sustain for consumption in order to realize even greater bonuses.

Employee-ownership ends the incentive to enact job-killing tax cuts on dividends and capital gains, which leads to an unsustainable demand for credit and money supply growth and eventually to economic collapse similar to the one most recently experienced.

Note that this budget reintroduces the Obama proposal for a chained CPI, which echoed both the Rivlin-Domenici and the Simpson Bowles Commissions. No additional fund has been proposed for poor seniors or the disabled, which means there will be suffering. This should not be allowed without some readjustment of base benefit levels, possibly by increasing the employer contribution and grandfathering in all retirees. This is easily done using our proposed NBRT, which replaces the Employer Contribution to OASI and all of DI and should be credited equally to all workers rather than being a function of income.

The NBRT base is similar to a Value Added Tax (VAT), but not identical. Unlike a VAT, an NBRT would not be visible on receipts and should not be zero rated at the border – nor should it be applied to imports. While both collect from consumers, the unit of analysis for the NBRT should be the business rather than the transaction. As such, its application should be universal – covering both public companies who currently file business income taxes and private companies who currently file their business expenses on individual returns.

A key provision of our proposal is consolidation of existing child and household benefits, including the Mortgage Interest and Property Tax Deductions, into a single

refundable Child Tax Credit of at least $500 per month, per child, payable with wages and credited against the NBRT rather than individual taxes. **Ending benefits for families through the welfare system could easily boost the credit to $1000 per month for every family, although the difference would also be made up by lowering gross and net incomes in transition, even for the childless.**

Assistance at this level, especially if matched by state governments may very well trigger another baby boom, especially since adding children will add the additional income now added by buying a bigger house. Such a baby boom is the only real long-term solution to the demographic problems facing Social Security, Medicare and Medicaid, which are more demographic than fiscal. Fixing that problem in the right way adds value to tax reform. **Adopting this should be scored as a pro-life vote, voting no should be a down check to any pro-life voting record.**

The NBRT should fund services to families, including education at all levels, mental health care, disability benefits, Temporary Aid to Needy Families, Supplemental Nutrition Assistance, Medicare and Medicaid. Such a shift would radically reduce the budget needs of HHS, while improving services to vulnerable populations, although some of these benefits could be transferred to the Child Tax Credit.

The NBRT could also be used to shift governmental spending from public agencies to private providers without any involvement by the government – especially if the several states adopted an identical tax structure. Either employers as donors or workers as recipients could designate that revenues that would otherwise be collected for public schools would instead fund the public or private school of their choice. Private mental health providers could be preferred on the same basis over public mental health institutions. This is a feature that is impossible with the FairTax or a VAT alone.

To extract cost savings under the NBRT, allow companies to offer services privately to both employees and retirees in exchange for a substantial tax benefit, provided that services are at least as generous as the current programs. Employers who fund catastrophic care would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates, but not so much that the free market is destroyed. Increasing Part B and Part D premiums also makes it more likely that an employer-based system will be supported by retirees.

Enacting the NBRT is probably the most promising way to decrease health care costs from their current upward spiral – as employers who would be financially responsible

for this care through taxes would have a real incentive to limit spending in a way that individual taxpayers simply do not have the means or incentive to exercise. While not all employers would participate, those who do would dramatically alter the market. In addition, a kind of beneficiary exchange could be established so that participating employers might trade credits for the funding of former employees who retired elsewhere, so that no one must pay unduly for the medical costs of workers who spent the majority of their careers in the service of other employers.

Conceivably, NBRT offsets could exceed revenue. In this case, employers would receive a VAT credit.

The Administration believes that the Affordable Care Act is failing. This is most likely not true, but it one day will be if funding is removed and coverage is gutted for the most vulnerable. The key question is whether the incentives for the uninsured are not adequate in the light of pre-existing condition reform to make them less risk averse than investors in the private insurance market, the whole house of cards may collapse – leading to either single payer or the enactment of a subsidized public option (which, given the nature of capitalism, will evolve into single payer). While no one knows how the uninsured will react over time, the investment markets will likely go south at the first sign of trouble.

We suggest to the Secretary that he have an option ready when this occurs. Enactment of a tax like the NBRT will likely be necessary in the unlikely event the ACA collapses. It could also be used to offset non-wage income tax cuts proposed by the House, rather than cutting coverage for older, poorer and sicker Americans. Single-payer is inevitable unless the President is simply blowing smoke about the ACA failing.

As to the Medicaid decision, if enough states refuse the additional funding for Medicaid to cover the uninsured, the likely consequence should be total federal funding (which would also please adherents to the Hyde Amendment).

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

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Committee on Ways and Means
The Department of Health and Human Services'
Fiscal Year 2018 Budget Request
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All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears:

This testimony is not submitted on behalf of any client, person or organization other than the Center itself, which is so far unfunded by any donations.

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Discretionary activities of the Department of Health and Human Services would be funded by the VAT. While some of our VAT proposals call for regional breakdowns of taxing and spending, they do not for this department. While some activities, such as the Centers for Disease Control, exist outside the Washington, DC metro area, even these are site specific rather than spread out on a nation-wide basis to serve the public at large. While some government activities benefit from national and regional distribution, health research will not.

The one reform that might eventually be considered in this area is to more explicitly link government funded research with ownership of the results, so that the Department might fund some of their operations with license agreements for some of the resulting research, enabling an expanded research agenda without demanding a higher budget allocation.

Of course, regionalization is possible if the Uniformed Public Health Service is put into the role of seeing more patients, particularly elderly patients and lower income patients who are less than well served by cost containment strategies limiting doctor fees. Medicaid is notoriously bad because so few doctors accept these patients due to the lower compensation levels, although we are encouraged the health care reform is attempting to reduce that trend. Medicare will head down that road shortly if something is not done about the Doc Fix. It may become inevitable that we expand the UPHS in order to treat patients who may no longer be able to find any other medical care. If that were to happen, such care could be organized regionally and funded with regionally based taxes, such as a VAT.

The other possible area of cost savings has to do with care, now provided for free, on the NIH campus. While patients without insurance should be able to continue to receive free care, patients with insurance likely could be required to make some type of payment for care and hospitalization, thus allowing an expansion of care, greater assistance to patients who still face financial hardship in association with their illnesses and a restoration of some care that has been discontinued due to budget cuts to NIH. This budget contains even more cuts. These should not be allowed. Rather, previous cuts must be restored.

The bulk of our comments have to do with health and retirement security.

One of the most oft-cited reforms for dealing with the long-term deficit in Social Security is increasing the income cap to cover more income while increasing bend points in the calculation of benefits, the taxability of Social Security benefits or even means testing all benefits, in order to actually increase revenue rather than simply making the program more generous to higher income earners. Lowering the income cap on employee contributions, while eliminating it from employer contributions and crediting the employer contribution equally removes the need for any kind of bend points at all, while the increased floor for filing the income surtax effectively removes this income from taxation. Means testing all payments is not advisable given the movement of retirement income to defined contribution programs, which may collapse with the stock market – making some basic benefit essential to everyone.

Moving the majority of Old Age and Survivors Tax collection to a consumption tax, such as the NBRT, effectively expands the tax base to collect both wage and non-wage income while removing the cap from that income. This allows for a lower tax rate than would otherwise be possible while also increasing the basic benefit so that Medicare Part B and Part D premiums may also be increased without decreasing the income to beneficiaries**.** Increasing these premiums essentially solves their long term financial problems while allowing repeal of the Doc Fix.

If personal accounts are added to the system, a higher rate could be collected, however recent economic history shows that such investments are better made in insured employer voting stock rather than in unaccountable index funds, which give the Wall Street Quants too much power over the economy while further insulating ownership from management. Too much separation gives CEOs a free hand to divert income from shareholders to their own compensation through cronyism in compensation committees, as well as giving them an incentive to cut labor costs more than the economy can sustain for consumption in order to realize even greater bonuses.

Employee-ownership ends the incentive to enact job-killing tax cuts on dividends and capital gains, which leads to an unsustainable demand for credit and money supply growth and eventually to economic collapse similar to the one most recently experienced.

Note that this budget reintroduces the Obama proposal for a chained CPI, which echoed both the Rivlin-Domenici and the Simpson Bowles Commissions. No additional fund has been proposed for poor seniors or the disabled, which means there will be suffering. This should not be allowed without some readjustment of base benefit levels, possibly by increasing the employer contribution and grandfathering in all retirees. This is easily done using our proposed NBRT, which replaces the Employer Contribution to OASI and all of DI and should be credited equally to all workers rather than being a function of income.

The NBRT base is similar to a Value Added Tax (VAT), but not identical. Unlike a VAT, an NBRT would not be visible on receipts and should not be zero rated at the border – nor should it be applied to imports. While both collect from consumers, the unit of analysis for the NBRT should be the business rather than the transaction. As such, its application should be universal – covering both public companies who currently file business income taxes and private companies who currently file their business expenses on individual returns.

A key provision of our proposal is consolidation of existing child and household benefits, including the Mortgage Interest and Property Tax Deductions, into a single

refundable Child Tax Credit of at least $500 per month, per child, payable with wages and credited against the NBRT rather than individual taxes. **Ending benefits for families through the welfare system could easily boost the credit to $1000 per month for every family, although the difference would also be made up by lowering gross and net incomes in transition, even for the childless.**

Assistance at this level, especially if matched by state governments may very well trigger another baby boom, especially since adding children will add the additional income now added by buying a bigger house. Such a baby boom is the only real long-term solution to the demographic problems facing Social Security, Medicare and Medicaid, which are more demographic than fiscal. Fixing that problem in the right way adds value to tax reform. **Adopting this should be scored as a pro-life vote, voting no should be a down check to any pro-life voting record.**

The NBRT should fund services to families, including education at all levels, mental health care, disability benefits, Temporary Aid to Needy Families, Supplemental Nutrition Assistance, Medicare and Medicaid. Such a shift would radically reduce the budget needs of HHS, while improving services to vulnerable populations, although some of these benefits could be transferred to the Child Tax Credit.

The NBRT could also be used to shift governmental spending from public agencies to private providers without any involvement by the government – especially if the several states adopted an identical tax structure. Either employers as donors or workers as recipients could designate that revenues that would otherwise be collected for public schools would instead fund the public or private school of their choice. Private mental health providers could be preferred on the same basis over public mental health institutions. This is a feature that is impossible with the FairTax or a VAT alone.

To extract cost savings under the NBRT, allow companies to offer services privately to both employees and retirees in exchange for a substantial tax benefit, provided that services are at least as generous as the current programs. Employers who fund catastrophic care would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates, but not so much that the free market is destroyed. Increasing Part B and Part D premiums also makes it more likely that an employer-based system will be supported by retirees.

Enacting the NBRT is probably the most promising way to decrease health care costs from their current upward spiral – as employers who would be financially responsible

for this care through taxes would have a real incentive to limit spending in a way that individual taxpayers simply do not have the means or incentive to exercise. While not all employers would participate, those who do would dramatically alter the market. In addition, a kind of beneficiary exchange could be established so that participating employers might trade credits for the funding of former employees who retired elsewhere, so that no one must pay unduly for the medical costs of workers who spent the majority of their careers in the service of other employers.

Conceivably, NBRT offsets could exceed revenue. In this case, employers would receive a VAT credit.

The Administration believes that the Affordable Care Act is failing. This is most likely not true, but it one day will be if funding is removed and coverage is gutted for the most vulnerable. The key question is whether the incentives for the uninsured are not adequate in the light of pre-existing condition reform to make them less risk averse than investors in the private insurance market, the whole house of cards may collapse – leading to either single payer or the enactment of a subsidized public option (which, given the nature of capitalism, will evolve into single payer). While no one knows how the uninsured will react over time, the investment markets will likely go south at the first sign of trouble.

We suggest to the Secretary that he have an option ready when this occurs. Enactment of a tax like the NBRT will likely be necessary in the unlikely event the ACA collapses. It could also be used to offset non-wage income tax cuts proposed by the House, rather than cutting coverage for older, poorer and sicker Americans. Single-payer is inevitable unless the President is simply blowing smoke about the ACA failing.

As to the Medicaid decision, if enough states refuse the additional funding for Medicaid to cover the uninsured, the likely consequence should be total federal funding (which would also please adherents to the Hyde Amendment).

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

Contact Sheet
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Committee on Ways and Means
The Department of Health and Human Services'
Fiscal Year 2018 Budget Request
Thursday, June 8, 2017, 1:00 PM
1100 Longworth House Office Building

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears:

This testimony is not submitted on behalf of any client, person or organization other than the Center itself, which is so far unfunded by any donations.

Congress of the United States
Washington, DC 20515

April 4, 2017

President Donald J. Trump
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Re: Use Existing Taxpayer Protection Rights Law to Lower Prescription Drug Prices Now

Dear President Trump,

We write regarding your oft-stated commitment to bring down pharmaceutical prices. You have said that the pharmaceutical industry is "getting away with murder" and called drug prices "astronomical." We urge you to use your existing statutory authority to respond to soaring drug costs harming so many American families.

Currently, the federal government grants companies (including foreign companies) monopoly pricing power to overcharge American taxpayers for life-saving medications developed through taxpayer-financed research. The government prevents competitors from entering the market, thus removing any market forces that might keep drugs affordable. Your Administration already has legal authority to prevent pricing excesses by promoting competition, while protecting taxpayer investments and addressing the failures of government-approved monopolies. This health and taxpayer protection issue is one that the prior Administration declined to address.

When taxpayer-funded federal research results in a new drug patent, the National Institutes of Health (NIH) is permitted to require the patent holder to license the federally-funded intellectual property to third parties, under certain circumstances. This power, granted in 1980 through the Bayh-Dole Act, authorizes federal agencies that fund private research to retain certain rights in patented inventions.

Under 35 U.S.C. §203(a)(2), when "action is necessary to alleviate health and safety needs which are not being reasonably satisfied" or, as noted in 35 U.S.C. §201(f), when the benefits of the patented product are not "available to the public on reasonable terms," the government can assert what are sometimes called "march-in rights," but would be better described as "taxpayer protection rights." By exercising these rights, the government can encourage competition and lower prices by allowing other manufacturers to produce and sell the taxpayer-funded drug. Unfortunately, NIH has never utilized this taxpayer protection law.

Drug manufacturers and patients need clarity. We urge you to direct NIH to issue public guidelines on the circumstances that will likely require it to invoke taxpayer protection rights. Reasonable and transparent guidelines would discourage drug price gouging and create a more competitive market for drugs developed using tax dollars. American taxpayers should be able to access publicly-funded medications on reasonable terms, instead of being burdened with unreasonable prices.

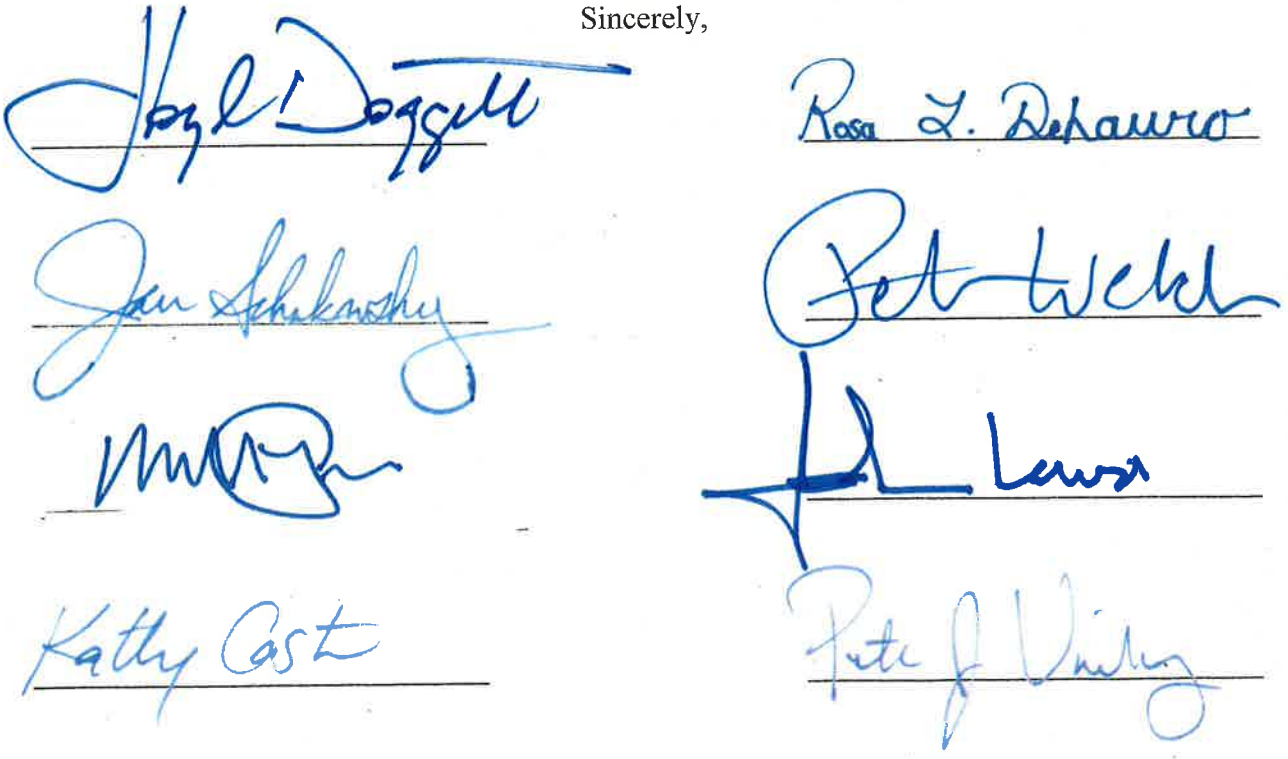
Last year, NIH also refused to hold a hearing on whether to exercise its statutory rights on Xtandi, a prostate cancer drug developed at the University of California, Los Angeles (UCLA) through taxpayer-supported research grants, but licensed to a Japanese company. As a result, Americans are still paying two to four times more than consumers in other high-income countries for a life-saving medication developed with our tax dollars—without even the benefit of a public hearing to determine why NIH refused to protect taxpayers.

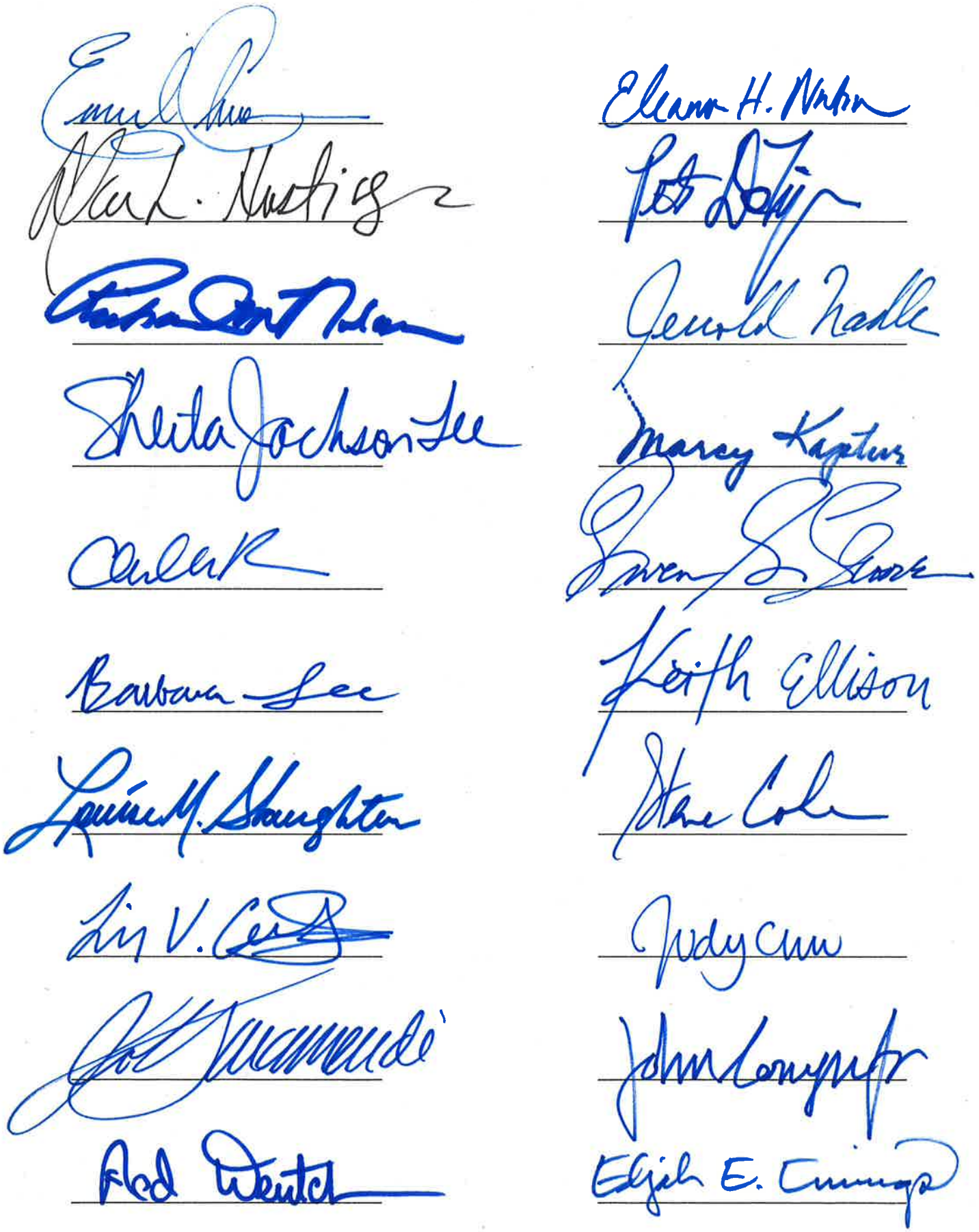
We are confident that reasonable guidance can be developed to address price gouging with transparency and fairness. We want pharmaceutical manufacturers to have the certainty of clear guidelines that indicate when taxpayer protection rights would apply, so that they can perform in a constructive way that avoids ever necessitating use of this extraordinary remedy. Since companies that do not engage in price gouging would not be affected, innovation and industry partnerships with public research institutions would not be threatened.

With adequate guidance, pharmaceutical companies should make better-informed pricing decisions that reflect the value of the taxpayer investment. High prescription drug prices are not limited to one treatment or one disease. Rising prices are reflected in ballooning Medicare and Medicaid drug budgets, and hit consumers through rising premiums, greater cost-sharing, and the higher prevalence of high-deductible plans. With drug prices continuing to soar and Americans continuing to struggle to access life-saving medications, your quick use of this taxpayer protection law will provide significant help to American families.

We look forward to your prompt response on this strategy to promote competition, target bad actors, and protect taxpayer investments.

Sincerely,





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IDSA
Infectious Diseases Society of America

June 8, 2017

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
United States House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
United States House of Representatives
1139E Longworth Office Building
Washington, DC 20515

Dear Chairman Brady and Ranking Member Neal:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for scheduling the hearing with Health and Human Services Secretary Tom Price to discuss the administration's FY2018 budget proposal, including the Centers for Medicare and Medicaid Services (CMS). As an update on the implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) and the Merit-Based Incentive Payment System (MIPS) was provided in the budget proposal, we wanted to focus several key concerns our members have raised regarding payment reform. Specifically, we wished to highlight the determination of evaluation and management codes, and MACRA implementation. We urge you to raise these issues with Secretary Price during and after the hearing.

The Value of Infectious Diseases Physicians

Infectious Diseases (ID) physicians make significant contributions to patient care, biomedical research, and public health. Their leadership and services save lives, prevent costly and debilitating diseases, and drive biomedical innovation. ID physician involvement in patient care is associated with significantly lower rates of mortality and 30-day readmission rates in hospitalized patients, shorter lengths of hospital stay, fewer intensive care unit (ICU) days, and lower Medicare charges and payments.

ID physicians provide life-saving care to patients with serious infections such as HIV and hepatitis C infections related to the opioid epidemic. ID doctors lead public health, public safety, and national biosecurity activities to prevent, control, and respond to outbreaks in healthcare settings and the community. They respond to emerging infections such as Ebola and Zika virus infections, and also to re-emerging infections such as the recent measles outbreak in Minnesota. ID physicians also lead antibiotic stewardship programs to optimally use antibiotics for the best clinical outcomes while limiting drivers of further antibiotic resistance. Routinely, ID clinicians care for highly complex patients with serious infections requiring refined management or they thoughtfully assist in preventing infection in at risk patients. ID physicians conduct research leading to breakthroughs in the understanding of emerging and re-emerging diseases leading to efforts at control and treatment. Finally, ID physicians help lead the way in the development of urgently needed new antimicrobial drugs, diagnostics, and vaccines.

The Practice of Infectious Diseases is Currently Under-valued and Jeopardizes the Next Generation of Infectious Disease Physicians

Despite the importance of ID physicians' work, the care they provide is undervalued by the current payment system. If not addressed, this fundamentally threatens the

future ID workforce and consequently their patients and the nation's health. When questioned about career choices, a 2014 IDSA survey of 600 Internal Medicine residents (in-training) found high interest in ID but decisions to ultimately chose another field instead. Low salary was the most often cited reason for not choosing ID as the average starting ID salary is less than positions taken that do not require additional training such as hospital medicine. Average salaries for ID physicians are significantly lower than those for most other specialties and only slightly higher than the average salary of general Internal Medicine physicians, even though ID training and certification requires an additional two to three years of training.

With this shift over recent years, the number of residents applying for ID fellowship declined steadily from 2013 to 2016, and the number of open training positions increased during the same period. While the number of residents applying for ID fellowships rose slightly in 2017, and open positions declined, these changes are attributable to administrative changes in the "match" program. Regardless, the data indicate a problem in the workforce pipeline.

Regarding compensation, over 90% of provided ID physician care is accounted by evaluation and management (E/M) services. These cognitive encounters are undervalued by the current payment systems compared to procedural practices (e.g., surgery, cardiology, and gastroenterology). This accounts for the significant compensation disparity between ID physicians and specialists who provide more procedure-based care, as well as physicians who provide similar E/M services but who have received payment increases because their specialty enrollment designation is as "primary care physicians." Based on CMS data, cognitive E/M services comprise a higher percentage of services provided by ID physicians than those provided by primary care physicians such as Internal Medicine, Family Medicine or Pediatrics.

The Need to Revalue Evaluation and Management Services

Current E/M codes fail to reflect the increasing patient complexity in both inpatient and outpatient E/M work that covers the vast majority of ID care. Without revising codes or other approaches, the payment system will not address this fundamental problem of wherein fair value is far from the work rendered in time-consuming complex care that cannot be hurried. This is driving fewer young physicians to enter the specialty of ID. ID physicians often care for more chronic illnesses, including HIV, hepatitis C, and recurrent or difficult infections. Such care involves preventing complications and avoiding the use of complicated and unnecessary diagnostic and therapeutic pathways. ID physicians also conduct post-visit work, such as care coordination including laboratory review, patient counseling, and other necessary follow up.

IDSA urges the Subcommittee to direct CMS to undertake the research needed to better identify and quantify inputs that accurately capture the elements of complex medical decision-making. We were pleased that report language in this regard was included in the FY2017 House and Senate Labor, Health, and Human Services Appropriations bills and affirmed in the FY2017 Consolidated Appropriations Act. We would appreciate the Committee's efforts to ask CMS to conduct these studies. Such studies should take into account the evolving health care delivery models that place growing reliance on team-based care. It should also consider patient case-mix or risk-adjustment as a component to determining complexity. Research activities should include the direct involvement of physicians who mostly provide only cognitive care. Specifically, this research should:

1. Describe in detail the full range of intensity for E/M services, placing a premium on the assessment of data and medical decision making;
2. Define discrete levels of service intensity based on observational and electronically stored data combined with expert opinion;
3. Develop documentation expectations for each service level;
4. Provide efficient and meaningful guidance for documentation and auditing; and
5. Ensure accurate relative valuation as part of the Physician Fee Schedule.

MACRA Implementation Challenges
When MACRA was enacted, IDSA and our members were hopeful that it would provide an opportunity to realign physician payment to truly incentivize high quality care while addressing the disparity in the compensation of ID physicians. We were hopeful that the Quality Payment Program (QPP) that incorporates both the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) options would offer significant improvements over the then existing quality programs. However, as implementation moves forward, we are concerned that the APM option, offering significant incentives, will not be accessible to physicians in small or mid-sized practices; and that the MIPS program, as currently structured, misses many opportunities to provide quality-based incentives.

The implementation of the new QPP will have a profound impact on ID physicians. CMS estimates that approximately 5,544 ID physicians will be participating in the MIPS program. Approximately 43% (2,300) of those physicians will experience a negative payment adjustment, equaling a $12 million loss in Medicare allowed charges across the specialty. Given this projection, IDSA has offered CMS a series of recommendations to strengthen the MIPS program geared toward providing the highest quality ID physician services, which we outline for the Committee.

Additional ID Quality Measures
First, while we are pleased that MACRA provides CMS with additional funding for measure development, current Physician Quality Reporting System (PQRS) measures are not well-aligned with infectious disease practices. We urge the Committee to encourage CMS to use part of this funding towards the development of ID quality measures.

We believe the lack of relevant ID quality measures within the MIPS is partly due to the time and the cost of measure development. The additional funding from the MACRA offers an invaluable opportunity for CMS to assist in the development of measures where gaps exist.

This is mostly due to the overwhelming proportion of ID clinical services delivered in the inpatient setting while most of the PQRS measures previously developed apply to face-to-face encounters in the outpatient setting. Aside from measures related to HIV, HCV, pneumonia vaccination and influenza immunization, there are no truly ID-specific measures on which ID specialists can report.

IDSA continues to propose relevant and meaningful ID measures for CMS to consider within the QPP. Last year, we submitted two additional measure concepts (Appropriate Use of anti-MRSA Antibiotics and 72-hour Review of Antibiotic Therapy for Sepsis) into the CMS Measures Under Consideration (MUC) process. Both related advancing quality measurement of antimicrobial stewardship at the physician-level. We hope the Committee will encourage CMS to advance these for inclusion on the list of applicable measures under the quality component of MIPS. Antibiotic stewardship is critical to prevent the misuse of antibiotics that drive the development of antibiotic resistance—a serious and growing public health crisis that claims at least 23,000 lives in the US a year according to the Centers for Disease Control and Prevention (CDC). Lack of good antibiotic prescribing also complicates a host of other medical services including the care of preterm infants, immunocompromised patients, solid organ and bone marrow transplants, cancer chemotherapy and many surgical procedures.

Improvement Activities (IAs) under MIPS
IDSA believes ID physicians will have the most impact in MIPS through IAs in the QPP. We encourage CMS ensure that a robust array of appropriate ID activities be available in list of clinical practice improvement activities.

IDSA is pleased that CMS is proposing the implementation of an antibiotic stewardship program (ASP) as an IA. We recommend CMS strengthen this approach by establishing ID physician leadership of an ASP as a high weight IA while maintaining participation in an ASP as a medium

weight IA. The CDC has recommended that all ASPs have a single leader who will be responsible for the program outcomes, noting that physicians—particularly those with formal training in infectious diseases—have been highly effective in this role. Further, the Joint Commission's Prepublication Standards for Antimicrobial Stewardship specifically cites the involvement of an infectious diseases physician in ASPs.

CMS has issued a proposed rule to require ASPs in acute care hospitals, and a final rule also requiring ASPs in long term care facilities, aligned with the goals and objectives of the National Action Plan for Combating Antibiotic Resistant Bacteria (CARB). The growing need for stewardship activities and expert leaders to ensure their success underscores the importance of making ID physician leadership of ASP leadership a high weight IA.

IDSA is also pleased that CMS has included emergency preparedness and response activities in the IA list. However, we strongly believe preparedness should go beyond volunteering for emergency response, disaster assistance, domestic and international humanitarian work. It is critical that our hospitals and health systems build the capacity to respond to public health emergencies, as recent examples include outbreaks of Ebola virus, Zika virus, MERS-CoV, pandemic influenza and other viral diseases. ID physicians are heavily involved in these intensive efforts that often involve coordination of care across multiple departments in a hospital or a health system coordinating with public health entities regarding needs assessments, protocol development, communications plans and other activities. IDSA recommends that CMS add additional IAs to encompass leadership and participation in a wide array of health care facility preparedness and response activities.

Conclusion

Once again, we thank the Committee for its attention to CMS and physician payment. We look forward to continuing work with you in order to meet the evolving needs of our patients.

Sincerely,

William G. Powderly, MD, FIDSA
President, IDSA

Majority to benefit from repeal of ACA

The repeal of Obamacare is a blessing to 94 percent of Americans who were or would be paying more for less coverage to provide insurance to 6 percent of Americans who allegedly would gain insurance coverage. More than 310 million Americans would be forced to pay higher premiums and accept larger deductibles and copays to provide coverage to these ³uninsured people.² The Senators and Congressmen demanding that the government be more generous with *your* tax dollars will not pay *one dime* extra out of their own pockets to provide this largess.

Their phony generosity and fake compassion is nauseating

Liberals in congress should dry their tears give up their pensions and Cadillac health care plans and give *their* money to the poor. They feign concern for constituents, while indemnifying themselves with generous health care benefits and pensions plans designed to indemnify themselves into perpetuity. Using taxpayers¹ money to protect themselves from the chaos they have created in our economy.

The repeal of the Affordable Care Act was inevitable. It was a bad idea poorly drafted and never really implemented. Some argued that the Republicans should have just stood by and let it implode. But that was never really an option. The majority of voters realized the ACA raised premiums, deductibles and copays to the point that most people in the middle class were essentially self-insured. They were purchasing catastrophic insurance at inflated prices, while increasing the cost of health care for everyone.

From the time the ACA (Obamacare) was passed, it never met any of its ³goals² it was too expensive and unattractive to younger patients who were better off going without coverage. As with all insurance, a very small group of patients benefit at the expense of the majority of premium payers.

Additionally, Obamacare sought to provide insurance coverage for routine care. That is not insurance, but simply a subsidy. This subsidy, like most of the features in the ACA, drove up prices. The Affordable Care Act was not affordable and did not provide care for the vast majority of Americans.

From its inception, the goal of the ACA was to make liberals look and feel like they were being generous with other peoples money. Government run programs are notoriously inefficient. By design they are structured to add administrative costs that eventually smother the real reason for the program. The term ³cost overrun² was invented to describe

government programs. It encouraged the development of tax exempt, non-profit organizations that use their status to mask exorbitantly expensive charges.

This new legislation could provide Americans with the last clear chance to cut health care spending in half. While the rest of the world spends less than 8 percent of its GDP for health care, America is spending double that amount. This effectively increases the cost of all goods sold by American manufacturers, making it a long-term recipe for disaster.

Restructuring health care delivery is essential to reducing costs.

Medical oligopolies have no incentives to save money. They will actively seek to destroy innovation and technologies that could lower the total cost of health care. We can no longer tolerate their ³benevolent² bullying. The problem in America is too much government involvement in business and health care. The solutions will come from the private sector and not the government.

These oligopolies were created by the *Stark Laws* that prohibited doctors from owning their own hospitals and then referring patients to these facilities for care. Hospital administrators, who are not providers, quickly stepped in and agreed to make these doctors employees of the facilities and encouraged them to refer patients to their employer¹s facilities. This actually compounded the problem and made it worse. The facilities executives are rarely providers and have no contact with the patient. Their only concern is the bottom line and maximizing billing. They seek to appear charitable, while raking in excessive payments to fund overpriced executives who add nothing to health care delivery. Their business model requires patients to over-utilize health care services and goods.

New legislation will provide perhaps the last opportunity to improve care and reduce costs. Eliminating the Stark provisions and divesting the oligopolies of the tax-exempt status is essential. Allowing physicians to own their own facilities and compete directly will reduce costs. The oligopolies never produced any economies of scale. In fact, it has produced just the opposite, because they focused on maximizing their payments from the government to increase their revenue and swallow their competition.

Although promoted by the FTC for ³managed competition,² they were in fact structured to obfuscate the truth and maximize their profit. If you have ever tried to read your hospital bill, you know that clarity and economy were not the goals.

Conservatives need to do a better job explaining that lowering corporate tax rates and health care costs will create more jobs. Private sector corporations employ many

Americans and their stocks fund employee pension plans, all of which is tied to the success of these private corporations.

Liberals want you to believe patients will die because of the repeal of Obamacare. That is not true. But unless we get government spending under control, we will kill off private sector jobs and destroy what¹s left of manufacturing in America. Socialism has never worked and is unsustainable. We need to wake up and shrink our government.

Repealing the ACA is the essential first step.

NACDD
National Association of Councils on Developmental Disabilities

Statement for the Record Submitted By:
Cindy Smith, MS, CAS, JD
Director of Public Policy
National Association of Councils on Developmental Disabilities
202-506-5813
csmith@nacdd.org

Dear Chairman Brady and Ranking Member Neal:

The National Association of Councils on Developmental Disabilities (NACDD) is pleased to submit this statement for the record to you and the Members of the Committee in advance of the hearing on the Department of Health and Human Services' Fiscal Year 2018 Budget Request scheduled for June 8, 2017. NACDD is the national membership organization for the Councils on Developmental Disabilities (DD Councils) appointed by Governors, and located in every state and territory. NACDD respectfully requests that Congress appropriate $76 million for the DD Councils in FY 2018 and makes no changes to the structure or funding level of the DD Councils as proposed in in the President's Fiscal Year 2018. The DD Councils are funded through the U.S. Dept. of Health and Human Services, Administration for Community Living: Administration on Intellectual and Developmental Disabilities.

NACDD's funding history includes:

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016/2017
NACDD's Request	$75,000,000	$75,000,000	$75,000,000	$75,000,000	$76,000,000
Actual Appropriations	$74,774,000	$70,661,000*	$70,876,000	$71,692,000	$73,000,000

*After sequestration

The DD Councils were first authorized in 1970. They are currently part of the Developmental Disabilities Assistance and Bill of Rights Act (DD Act). The DD Act has always been a bipartisan piece of legislation. The DD Councils are catalysts that create effective solutions and fulfill the mandate to improve service and systems with and for people with developmental disabilities (DD). The central purpose of the DD Act is to "is to assure that individuals with developmental disabilities and their families participate in the design of and have access to needed community services, individualized supports, and other forms of assistance that promote self-determination, independence, productivity, and integration and inclusion in all

facets of community life, through culturally competent programs."[1] DD Councils consist of people with DD, their families, representatives of other programs funded under the DD Act, other stakeholders in the community, and representatives of state agencies. The President's FY 2018 budget proposal to restructure the DD Councils would remove the voices of persons with DD from the DD Act. Losing the direct input of persons with DD about how to create and improve services and systems to support them will dilute the entire essence of the DD Act. The DD Councils are charged with investing in dynamic and innovative programs that improve state services and systems with the limited funding they receive. By statute, the DD Councils are required to expend 70 percent of their funding on programs that serve people with DD in the community. The DD Councils, through their innovative programming and investments, ensure persons with DD can realize the same goals we all have, to receive a quality education, live in their communities, and be taxpayers.

For 47 years, the DD Councils, in partnership with the University Centers for Excellence in Developmental Disabilities (UCEDDs) and Protection and Advocacy program for Developmental Disabilities (P&As) have provided critical services and supports for those with DD and their families. The concept of the triumvirate in the DD Act was designed by and for individuals with DD and was masterful in its partnering together of three distinctly different programs that together work collaboratively to meet the overall intended purpose of the DD Act through their individual responsibilities. The DD Councils, P&As, and UCEDDs are linked in their responsibilities ensuring a well-trained cadre of experts providing services to individuals with DD and their families, protecting the rights of individuals with DD, and ensuring that people with DD are fully included in the work to improve services and systems to make them fully inclusive.

The DD Act requires DD Councils to assess and review federal and state programs for people with DD and develop a comprehensive five-year state plan to address the needs of persons with DD. The state plan is carried out by a series of identified goals, objectives and activities designed to address the identified needs. The DD Councils are unique in that people with DD, who are encountering barriers and challenges, are the majority of the people creating the state's plan for how it can address those barriers and challenges through investing in dynamic and innovative programs. The DD Councils just began their first year of a new five-year state plan that lays out the goals, objectives, and activities of the DD Council, and what each DD Council will accomplish in the next five years with its funding.

Employment is a key component of community living. Given the high unemployment, underemployment and low employment retention rates for persons with DD, the majority of DD Councils have prioritized efforts in their state plans to improve employment outcomes for persons with DD. More than half of the DD Councils have led in implementing an innovative program, *Project Search*, which immerses students in employment opportunities during their final years of special education. The projects teach independence and work skills that meet the needs of both the individuals and the employers. About 80 percent of graduates of *Project Search* go on to hold regular, paid, integrated employment with employers. For example, five years ago, the Kansas Developmental Disabilities Council implemented *Project Search* and the management and support of the program was transferred to a Managed Care Company. As of 2017, the *Project Search* program has expanded three times without any financial support from the DD Council.

[1] 42 U.S.C. 15001(b).

The Mississippi Developmental Disabilities Council graduated its first Project Search class in May of 2016. In addition, the Council funded the Farm Entrepreneurship and Independence Initiative at $70,000. This initiative uses an employment model of youth inclusiveness in the Delta, which pairs youth with and without disabilities to train and employ young farmers. Students are grouped in threes (one with a disability and two without disabilities), who are then familiarized with farming. Students have the opportunity to learn new skills associated with processing, sorting, packaging, quality control, food safety transportation and record keeping. Students in the program also gain the skills and knowledge to help farmers meet the Good Agricultural Practice (GAP) food safety standards.

DD Councils also fund programs that support quality education for people with DD. Education is critical to securing competitive community-based employment, launching and advancing one's career, being independent and economically self-sufficient, and achieving personal goals. The Massachusetts Developmental Disabilities Council undertook a pilot initiative to provide a unique educational opportunity to teach teenagers and young adults with intellectual and other developmental disabilities skills that will assist them in gaining independence as adults. The program includes a core curriculum and elective options, and a practicum that must be completed in order to graduate. Thirty-one students successfully graduated from Independence College in 2016, and over 50 students have applied for enrollment in 2017.

The Maryland Developmental Disabilities Council funded the development of an online training for childcare providers about serving children with disabilities that offers Continuing Education Units. It is the second most requested training on a national website for providers. Available nation-wide, over 500 people have enrolled in the program. The Council also has produced two videos for $5000 about the inclusion of children with disabilities, which they use to train over 14,000 childcare providers.

Many DD Councils work to ensure that people with DD are able to safely and fully access all aspects of life in the community. For example, the Florida Developmental Disabilities Council (FDDC) in partnership with the Florida Department of Transportation (FDOT) implemented two transportation voucher pilot programs in 2016. FDDC and FDOT funded $75,000 to each project for a total of $150,000 per site: one urban and one rural. The voucher pilot enabled HARTPlus to contract with Yellow Cab of Tampa. Prior to the voucher pilot, HARTPlus required a three-day notice to provide rides to its 3,000 clients, only serving individuals within ¾ mile of the standard bus schedule and each trip cost HARTPlus $36. The voucher pilot allowed HARTPlus to secure trips for $16 per person for up to a 7.6-mile ride. As a result, HARTPlus was able to offer 27,813 trips at a cost of $445,008, rather than the typical cost of $1,001,268, saving $556,260. Riders now receive 24-hour service and are able to book trips for a multitude of purposes. This availability to efficient transportation positively affected safety and satisfaction while opening the door to a wider variety of community access, including employment and recreational events.

HARTPlus credits the voucher pilot with its 8% growth, improved on-time performance and its ability to exceed expectations in accessibility to wheelchair users. The urban model is self-supporting after one year of funding, and the rural model is working towards independent sustainability with a second year of funding. Preliminary reports from the rural model include an individual who transitioned from working at McDonald's earning $8.05 per hour to welding,

now earning $16.00 per hour and another individual who initially had to turn down a job offer was able to become an employee at Walmart.

The Missouri Developmental Disabilities Council has led a Victimization Task Force that includes several state agencies, DD service providers, the UCEDD, the P&A, various victim services stakeholders, (FBI Victim's Unit, rape crisis centers, abuse hotlines, forensic interviewers, law enforcement, the Attorney General's Office), persons with disabilities who had been victimized, parents of children with DD, MO Ombudsman and other stakeholders. The task force identified gaps and barriers in the various systems and as a result, developed approximately 40 recommendations for the state to work to implement to improve safety and ensure victims are protected from abuse. To educate people about the issue, the DD Council provided a $200,000 grant to the Arc in MO to implement an awareness campaign with the tag line, "It's Happening." A website (www.andwecanstopit.org) was established that provides information, and resources for community members to recognize when someone is being victimized, and how it can be reported.

Unfortunately, the timely need for the establishment of the Victimization Task Force and implementation of the recommendations was seen in April 2017. A man with intellectual and developmental disabilities was reported missing when a new service provider took over management of the group home where he was living. The police discovered the man's body in a storage container that was filled with concrete. The discovery of the man's body indicated that he had likely died several months before he was reported as missing by the provider. To address this serious failure of the system, once the outcome of the investigation is known, the Council plans to re-convene the Victimization Task Force and work with stakeholders to identify and recommend additional changes to policies that must be made to keep people with DD safe.

As you can see in the examples above, the funding provided to the DD Councils ensures that people with DD have the opportunity to achieve what we all want, to receive a quality education, live in and fully access all parts of the community, and be taxpayers. The President's budget proposal to combine the DD Councils with two other entities that represent different parts of the disability community, are not national in scope, have different authorizing statutes and mandates, will result in a significant loss of the voices of and focus on those living with DD. Under this proposed structure and funding reduction, the DD Councils will not be able to meet the stated goals of the DD Act that has led to significant improvements in the lives of persons with DD in the last 47 years.

In summary, the DD Councils are highly accountable for their outcomes and bring the voice of individuals with DD to the forefront in making decisions of how to improve services and systems. NACDD requests that the DD Councils be provided their requested funding for Fiscal Year 2018 and are not restructured into a brand new program called *Partnerships for Innovation, Inclusion, and Independence*, just as they begin their important work in their new five-year state plan.

National
Family Planning
& Reproductive Health Association

Testimony of Clare Coleman, President & CEO
National Family Planning & Reproductive Health Association

Submitted to the House Committee on Ways and Means

Statement for the Record Re: The President's Fiscal Year 2018 Budget
Held June 8, 2017

My name is Clare Coleman; I am the President & CEO of the National Family Planning & Reproductive Health Association (NFPRHA), a national membership association representing providers and administrators committed to helping people get the family planning education and care they need to make the best choices for themselves and their loved ones. Many of NFPRHA's members receive federal funding from Medicaid and through Title X of the federal Public Health Service Act, the only federally funded, dedicated family planning program for low-income and uninsured people. These cornerstones of the nation's public health safety net are essential resources for those providing access to high-quality services in communities across the country. As a result, NFPRHA respectfully disagrees with the administration's priorities laid out in its fiscal year (FY) 2018 budget.

Publicly funded family planning services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers, and other private nonprofit organizations. For decades, these diverse provider networks have helped ensure that millions of poor and low-income individuals as well as those who are underinsured or uninsured receive access to high-quality family planning and other preventive health services in all 50 states, the District of Columbia, and US territories.

Oppose Cuts to Medicaid
The president's proposal advances congressional proposals that, if enacted, would cut more than $627 billion from Medicaid, alter the structure and financing of the program, and dismantle the provider network, deepening a crisis in public health. NFPRHA opposes the end to or rollback of Medicaid expansion, either of which would reduce the number of people with access to Medicaid, thereby leading to fewer people getting health care, even-greater increases in rates of sexually transmitted diseases, and a reversal of the reduction in rates of unintended pregnancy.

Furthermore, these proposed changes to the structure and financing of Medicaid will compound the demands being place on the publicly funded family planning safety net. NFPRHA opposes both per capita caps and block grants. Both proposals would inevitably shift costs to states, forcing them to make choices about program eligibility, benefits, and provider payments in order to adapt to new funding constraints. Medicaid beneficiaries would also likely face new barriers to coverage, such as premiums and other cost-sharing requirements.

Increase Support for Title X
An analysis published in the *American Journal of Public Health* last year found that, in order for publicly funded providers to meet the needs of all low-income, uninsured women of reproductive age for family planning services, the Title X program would need to be supported with approximately $737 million annually. This estimate is based on the presumption that the Medicaid expansion resulting from the Affordable Care Act remains unchanged. The president's budget requests only level funding ($286.5 million), a fraction of what is needed to serve low-income, uninsured women across the country. It is also important to note that the Title X program also supports men, so the resource needs identified in the analysis are extremely conservative. Since FY 2010, Title X has dropped from $317.5 million annually to $286.5 million annually, leading to a loss of approximately 1.2 million patients from the network.

The ongoing threat of the Zika virus has only increased demand on Title X providers. The CDC-confirmed causal linkage between babies born with microcephaly and pregnant women infected with the Zika virus reinforced the simple concept that in a time of public health emergency, women will turn to Title X-funded providers for thorough counseling, risk assessment, and access to family planning services. As summer returns throughout the United States, public health experts expect the Zika virus to continue to spread domestically and demand for education and services to rise again.

Oppose Cuts to Other Safety Net Programs
NFPRHA is further troubled by proposals to eliminate several maternal-child health programs, the Social Services Block Grant, and the Teen Pregnancy Prevention Program. Each of these programs is a vital part of the federal government's role in fostering healthy women, children, and families. NFPRHA also opposes the harmful reductions to the National Center for HIV/AIDS, Viral Hepatitis, STIs, and TB Prevention; Temporary Assistance for Needy Families; Special Supplemental Nutrition Program for Women, Infants, and Children; Ryan White HIV/AIDS program; and rural health programs. Budgets for each of these programs are already stretched thin, and these further reductions will harm the patients our providers serve.

Oppose Harmful Budget Riders
NFPRHA is deeply concerned by the harms to the Title X network and other health care programs that would be caused by the budget rider that seeks to prohibit any funding in the Labor-HHS appropriations bill from going to essential community providers that provide abortions or contract with abortion providers and that received more than $23 million in Title X funding in FY 2016. The implicit intention of this proposed rider is to exclude Planned Parenthood affiliates, which are key networks within the publicly funded family planning safety net. A recent analysis by the Guttmacher Institute found that Planned Parenthood serves 32% of all safety-net contraceptive clients despite having just 6% of the nation's safety-net family planning providers. Our members, from federally qualified health centers to local public health departments to universities and school-based programs to private non-profits, rely on Planned Parenthood to offer patients high quality services and share the patient load in communities with high levels of need for publicly funded family planning.

Conclusion

Millions of low-income women and men depend on the safety-net programs for affordable access to the family planning and preventive health services that help them stay healthy. However, this budget would jeopardize the capacity of our nation's public health infrastructure to help these vulnerable individuals and families as well as the broader social services and health care safety net. **NFPRHA urges the Committee to reject the president's budget proposal.**

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Testimony of the National Rural Health Association (NRHA)
Concerning HRSA's Programs Impacting Rural Health
Submitted for the Record to the Committee on Ways and Means – FY 2018

The National Rural Health Association (NRHA) is pleased to provide the Committee on Ways and Means with a statement for the record on Fiscal Year 2018 funding levels for programs with a significant impact on the health of rural Americans.

NRHA is a national nonprofit membership organization with a diverse collection of 21,000 individuals and organizations who share a common interest in rural health. The Association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research.

NRHA is advocating support for a group of rural health program that assist rural communities in maintaining and building a strong health care delivery system into the future. Most importantly, these programs help increase the capacity of the rural health care delivery system and true safety net providers. Rural Americans, on average, are poorer, sicker and older than their urban counterparts. Programs in the rural health safety net increase access to health care, help communities create new health programs for those in need and train the future health professionals that will care for the 62 million rural Americans. With modest investments, these programs evaluate, study and implement quality improvement programs and health information technology systems.

Funding for the rural health safety net is more important than ever as rural America is facing a hospital closure crisis. Seventy-nine rural hospitals have closed, 10,000 rural jobs lost and 1.2 million rural patients have lost access to their nearest hospital since 2010. Even more concerning is that 673 rural hospitals are at risk of closure, meaning sustained Medicare cuts threaten the financial viability of 1 in 3 rural hospitals. The loss of these hospitals would mean 11.7 million patients would lose access to care in their community. Continued cuts to rural providers have taken their toll, forcing far too many closures. Medical deserts are appearing across rural America, leaving many of our nation's most vulnerable populations without timely access to care.

Important rural health programs supported by NRHA are outlined below.

State Offices of Rural Health (SORH) provide state specific infrastructure for rural health policy. SORH is the counterpart to the federal rural health research and policy framework. SORH forms an essential link between small rural communities and the state and federal resources to develop long term solutions to rural health problems. These funds provide necessary capacity to states for the administration of critical rural health programs, assist in strengthening rural health care delivery systems, and maintaining rural health as a focal point within each state. SORH plays a key role in assisting rural health clinics, community health centers, and small, rural hospitals assess community health care needs. This program creates a state focus for rural health interests, brings technical assistance to rural areas, and helps frontier communities tap state and national resources available for health care and economic development. SORH forms an essential connection to other state agencies and local communities; allowing federal resources to best address the unique needs of rural communities. Request: $12.5 million.

Rural Health Research and Policy program forms the federal infrastructure for rural health policy and the Federal Office of Rural Health Policy (FORHP). FORHP administrates important rural health programs, coordinates activities related to rural health care, and analyzes the possible effects of

policy on the 60 million rural Americans and advises the Department of Health and Human Services (HHS) Secretary on access to care, the viability of rural hospitals, and the availability of physicians and other health professionals. These grants provide policy makers with policy-relevant research on problems facing rural communities in providing access to quality affordable care and to improving population health in rural America. By funding rural health research centers across the country, these grants produce a mix of health services research, epidemiology, public health, geography, medicine, and mental health. This program allows rural America to have a coordinated voice in HHS, in addition to providing expertise to agencies such as the Centers for Medicare and Medicaid Services. Request: $10.4 million.

The **National Health Service Corps (NHSC)** plays an important role in maintaining the health care safety net by placing primary health care providers in the most undeserved rural communities. NHSC is a network of 8,000 primary health care professionals, and 10,000 sites (September 2010). However, the demand for primary care providers far exceeds the supply, and the needs of rural communities continue to grow. Seventy-seven percent of the 2,050 rural counties in the United States are designated as primary care Health Professional Shortage Areas (HPSAs) and 60 percent of rural Americans live in a mental health professional shortage area. Rural areas have fewer than half as many primary care physicians per 100,000 people as urban areas. Rural communities must have the resources necessary to hire primary care, dental and behavioral health providers. Request: $337 million.

Rural Health Outreach and Network Grants provide capital investment for planning and launching innovative projects in rural communities that will become self-sufficient. These grants are unique federal grants in that they allow a great deal of flexibility for the community to build a program around their community's specific needs. Grant funds are awarded for communities to develop needed formal, integrated networks of providers that deliver primary and acute care services. The grants have led to successful projects including information technology networks, oral screenings, and preventative care. Due to the community nature of the grants and the focus on sustainability after the grant term has run out – 85 percent of the grantees continue to deliver services a full five years after federal funding ends. Request: $72.4 million.

Rural Hospital Flexibility Grants fund quality improvement and emergency medical service projects at Critical Access Hospitals (CAHs). These grants allow rural communities to improve access to care, develop increased efficiencies, and improved quality of care by leveraging the services of CAHs, Emergency Medical Services (EMS), clinics, and health practitioners. These grants serve an important function in increasing information technology activities in rural America. Also funded in this line is the Small Hospital Improvement Program (SHIP), which provides grants to more than 1,500 small rural hospitals (50 beds or less) across the country to improve business operations, focus on quality improvement, and ensure compliance with health information privacy regulations. Request: $50.4 million.

The Office for the Advancement of Telehealth (OAT) supports the provision of clinical services at a distance, reduces rural provider isolation, fosters integrated delivery systems through network development, and tests a broad range of telehealth applications. Long-term, telehealth promises to improve the health of millions of Americans, save money by reducing unnecessary office visits and hospital stays, and provide continuing education to isolated rural providers. OAT coordinates and promotes the use of telehealth technologies by fostering partnerships between federal and state agencies and private sector groups. Since telehealth is still an emerging field with new approaches and technologies; continued investment in the infrastructure and development is needed. Request: $21 million.

The Rural Opioid Overdose Reversal Grant helps reduce the occurrences of morbidity and mortality related to opioid overdoses in rural communities through the purchase and placement of emergency devices used to rapidly reverse the effects of opioid overdoses. The grant also helps train licensed health care professionals and emergency responders on the use of opioid reversals. Rural

communities are struggling with prescription opioids and heroin abuse. While opioid use generally is on the rise nationwide, the rate of overdose deaths in non-metro counties is 45% higher than in metro counties. Request: $11.1 million.

Title VII Health Professions Training Programs (with a significant rural focus):

• **Area Health Education and Centers (AHECs)** encourage and provide financial support to those training to become health care professionals in rural areas. Without this experience and support in medical school, far fewer professionals would be aware of the needs of rural communities and even fewer would make the commitment to practice in rural areas. AHECs support the recruitment and retention of physicians, students, faculty and other primary care providers in rural and medically underserved areas. It has been estimated that nearly half of AHECs would shut down without federal funding, placing future access to health care in rural communities at risk. Request: $33.5 million.

• **Rural Physician Pipeline Grants** help medical colleges develop rural specific curriculum and to recruit students from rural communities that are likely to return to their home regions to practice. This "grow-your-own" approach is one of the best and most cost-effective ways to ensure a robust rural workforce into the future. Request: $5.3 million.

• **Geriatric Programs** train health professionals in geriatrics, including funding for Geriatric Education Centers (GEC). There are currently 47 GECs nationwide that ensure access to appropriate and quality health care for seniors. Rural America has a disproportionate share of our nation's elderly and is more likely to have physician shortages than urban locations. Without this program, rural health care provider shortages would grow. Request: $42.8 million.

The National Rural Health Association appreciates the opportunity to provide our recommendations to the Committee. These programs are critical to the rural health delivery system and help maintain access to high quality care in rural communities. We greatly appreciate the support of the Committee and look forward to working with Members of the Committee to continue making these important investments in rural health.

JOHN B. LARSON
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Congress of the United States
House of Representatives
Washington, DC 20515-0701

June 22, 2017

The Honorable Tom Price, MD
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Price:

Thank you for your testimony before the Ways & Means Committee on the President's FY2018 budget proposal for the Department of Health and Human Services. In order to complete the record for the hearing, please respond to the following questions regarding several important bipartisan bills addressing patient access issues with upcoming deadlines:

1) When you were a member of the House, you cosponsored legislation to protect access to complex rehab wheelchairs and related accessories for Medicare beneficiaries with high level needs due to ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury, and traumatic brain injury. Despite clear Congressional intent to exclude CRT wheelchair and accessories from the Competitive Bid Program, CMS decided to apply Competitive Bid Program pricing information to reduce the rates for critical CRT wheelchair accessories. Congress acted twice to delay this rule, one in 2015 and again in 2016. The most recent delay passed by Congress will expire at the end of June. Will HHS address this patient access issue immediately using its authority?

2) On May 26, 2017, a letter was sent to you to request that you use statutory authority to implement an appropriate inflationary update measure to ambulatory surgery centers. The current update factor threatens patient access to high quality, cost-effective surgical and preventative care by limiting access to ASCs. It was signed by 25 bipartisan members. As a member of the House, you previously supported this policy. Will HHS respond and outline HHS' plan to help patients who receive care at ASCs?

3) In 2015, the House and Senate passed into law the Steve Gleason Act of 2015 (P.L. 114-40) to improve Medicare regulations and protect patient access to medically necessary Speech Generating Devices (SGDs) for individuals with communication disabilities by removing SGDs from the "Capped Rental" category until October 1, 2018. The bill was a direct response to steps taken by the Centers for Medicare and Medicaid Services in April 2014, which categorized SGDs as "Capped Rental" under Medicare. This prohibited

payments for devices when patients entered a hospital, nursing facility, or hospice care jeopardizing the ability for patients to communicate with their doctors, loved ones, and caregivers. Will HHS work with CMS in order to make this exclusion from "Capped Rental" permanent before the October 2018 expiration?

Please send your response to the attention of Sylvia Lee on my staff at 1501 Longworth House Office Building, Washington, DC 20515. In addition to a hard copy, please submit an electronic copy of your response to Sylvia.lee@mail.house.gov.

Thank you again for your testimony and your attention to these questions.

Sincerely,

John B. Larson
Member of Congress
(CT01)

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

For

United States House of Representatives
Committee on Ways and Means

On

Department of Health and
Human Services' Fiscal Year 2018 Budget Request

June 8, 2017
1:00 p.m.

1100 Longworth House Office Building

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Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Brady, Ranking Member Neal, and the Members of the Committee on Ways and Means for the opportunity to submit a statement for the hearing on "Department of Health and Human Services' (HHS) Fiscal Year 2018 Budget Request."

NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to improve the quality and affordability of health care services. NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 178,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 21 countries. Please visit nacds.org.

As the face of neighborhood health care, chain pharmacies and pharmacists work on a daily basis to provide the best possible care and the greatest value to their patients with respect to access to critical medications and pharmacy services. We help to assure that patients are able to access their medications and take them properly. NACDS believes retail pharmacists can play a vital role in improving and sustaining the Medicare and Medicaid programs by greatly improving beneficiary health while reducing program spending including better health through improved medication adherence, and through improving access for underserved beneficiaries with chronic conditions in the Medicare Part B Program. As this Committee examines the HHS budget request for 2018 we offer the following for its consideration.

Pharmacist Provider Status

As the U.S. healthcare system continues to evolve, a prevailing issue will be the adequacy of access to affordable, quality healthcare. The national physician shortage coupled with the evolution of health insurance coverage will have serious implications for the nation's healthcare system. Access, quality, cost, and efficiency in healthcare are all critical factors—especially to the medically underserved. The medically-underserved population includes seniors with cultural or linguistic access barriers, residents of public housing, persons with HIV/AIDS, as well as rural populations and many others. Many of these beneficiaries suffer from multiple chronic conditions. Significant consideration should be given to policies and initiatives that enhance healthcare capacity and strengthen community partnerships to offset provider shortages, particularly in communities with medically-underserved populations.

Pharmacists play an increasingly important role in the delivery of services, including key roles in new models of care beyond the traditional fee-for-service structure. In addition to medication adherence services such as medication therapy management (MTM), pharmacists are capable of providing many other cost-saving services, subject to state scope of practice laws. Examples include access to health tests, helping to manage chronic conditions such as diabetes and heart disease, and expanded immunization services. However, the lack of pharmacist recognition as a provider by third-party payors, including Medicare and Medicaid, limits the number and types of services pharmacists can provide, even though they are fully qualified to do so. Retail pharmacies are often the most readily accessible healthcare provider. Research shows that nearly all Americans (91 percent) live within five miles of a retail pharmacy. Such access is vital in reaching the medically underserved.

We urge you to increase access to much-needed services for underserved Medicare beneficiaries by supporting H.R. 592/S. 109, the *Pharmacy and Medically Underserved Areas Enhancement Act*, which will allow Medicare Part B to utilize pharmacists to their full capability by providing those underserved beneficiaries with services, subject to state scope of practice laws, not currently reaching them. This important legislation would lead not only to reduced overall healthcare costs, but also to increased access to healthcare services and improved healthcare quality, all of which are vital to ensuring a strong Medicare program.

Value of Medication Adherence and MTM

Medications are the primary intervention to treat chronic disease and are involved in 80% of all treatment regimens.[1] Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, have 50 different prescriptions filled per year, account for 76% of all hospital admissions, and are 100 times more likely to have a preventable hospitalization.[2] Yet medication management services are poorly integrated into existing healthcare systems. Poor medication adherence alone costs the nation approximately $290 billion annually—13% of total healthcare expenditures—and results in avoidable and costly health complications.[3] Thus, given the importance of medications in achieving patient care outcomes and lowering overall healthcare costs, it is critical that policies are implemented to encourage greater care integration across the healthcare continuum and promote financial accountability for safe and appropriate medication use.

[1] http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf
[2] Ibid.
[3] "Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease;" New England Healthcare Institute, Cambridge, MA, 2009.

A growing body of evidence suggests that when physicians, nurses, pharmacists, and other healthcare professionals work collaboratively, better health outcomes are achieved. Pharmacies in particular provide access to highly-trained and highly-trusted health professionals. The unique reach and access points of pharmacy provide a means of continuous care and oversight between scheduled visits. Medication related services provided by community pharmacists improve patient care, enhance communication between providers and patients, improve collaboration among providers, optimize medication use for improved patient outcomes, contribute to medication error prevention, assist with hospital readmission cost avoidance goals, and enable patients to be more actively involved in medication self-management. Examples of the value of these services include:

- A 2013 CMS report found that Medicare Part D MTM programs consistently and substantially improved medication adherence for beneficiaries with chronic diseases. This included savings of nearly $400 to $525 in lower overall hospitalization costs.[4]

- A study of published research on medication adherence conducted by Avalere Health in 2013 concluded that the evidence largely shows that patients who are adherent to their medications have more favorable health outcomes such as reduced mortality and use fewer healthcare services, especially hospital readmissions and ER visits. Such outcomes lead to less expensive healthcare costs, relative to non-adherent patients.[5]

- How and where MTM services are provided also impact its effectiveness. A study published in the January 2012 edition of *Health Affairs* found that a pharmacy-based intervention program increased adherence for patients with diabetes and that the benefits were greater for those who received counseling in a retail, face-to-face setting as opposed to a phone call from a mail-order pharmacist. The interventions were cost-effective, with a return on investment of approximately $3 for every $1 spent. These findings highlight the central role that pharmacists can play in promoting the appropriate initiation of and adherence to therapy for chronic diseases.[6]

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[4] "Medication Therapy Management in Chronically Ill Populations: Final Report;" Centers for Medicare and Medicaid Services (CMS); August 2013 (http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf).
[5] "The Role of Medication Adherence in the U.S. Healthcare System;" Avalere Health; June 2013 (http://www.avalerehealth.net/research/docs/20130612_NACDS_Medication_Adherence.pdf).
[6] "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients;" *Health Affairs,* January 2012 (http://content.healthaffairs.org/content/31/1/120.full).

Despite the proven value of medication adherence and MTM, the Medicare Part D MTM Program historically has seen low enrollment and utilization rates. Over the years, CMS has made programmatic changes they believed would increase eligibility and enrollment. However, these changes have not led to increased MTM eligibility and utilization. In 2012, there were approximately 27.2 million people enrolled in either a MA-PD (9.9 million) or a PDP (17.3 million). Of the more than 27 million beneficiaries, only 3.1 million were enrolled in an MTM program (11.4%). These figures fall well short of the CMS estimate that approximately 25% of the beneficiaries would be eligible for MTM.

NACDS has long been supportive of exploring new and innovative approaches to improve the Part D MTM program. One of the approaches we believe can be successful is the Enhanced MTM Model pilot being conducted by the Center for Medicare and Medicaid Innovation. This pilot gives Part D plans the opportunity to utilize new and innovative approaches to MTM, such as more efficient outreach and targeting strategies and tailoring the level of services to the beneficiary's needs. NACDS believes the Enhanced MTM Pilot program presents an opportunity to create better alignment of program incentives and has the potential to lead to improved access to MTM services for beneficiaries and greater medication adherence.

To ensure the success of the Enhanced MTM model, NACDS believes retail pharmacists must be included in the Enhanced Model Pilot programs. As preparations are made for the second year of the pilot, ways to maximize utilization of retail community pharmacists and their unique ability to improve medication adherence should be considered.

Transparency in Use of Fees in the Part D Program

NACDS supports transparency between Medicare Part D plans and retail pharmacies in the use of direct and indirect remuneration (DIR) fees, post-adjudication fees, and quality and performance-based network fees by prescription drug plans in the Medicare program.

The Centers for Medicare and Medicaid Services (CMS) recently released a fact sheet on the use and impact of DIR fees by plan sponsors in the Medicare Part D program. The fact sheet reported that the use of DIR by Part D sponsors has been "growing significantly in recent years" and has led to an increase in beneficiary cost-sharing and an increase in subsidy payments made by Medicare.

The increasing use of fees in the Part D program is also a growing problem for retail pharmacies. Retail pharmacies have to conduct business in an environment where they are unsure if a reimbursement they received is the "final reimbursement" or if a fee will be applied at some future point. This may lead some pharmacies to question their ability to continue to participate in certain Part D networks, which ultimately endangers beneficiary access to prescription drugs.

The Social Security Act clearly gives CMS the authority to regulate the use of fees in the Medicare program. We believe that CMS should issue guidance clarifying the appropriate use, submission, and approximation of fees in the Medicare program, including in quality and performance-based payment structures. Such guidance should also clarify the components of DIR fees, such as direct product and service reimbursement, as well as quality and performance-based program reimbursement. DIR fees must be separately tracked and reported by plans to ensure their transparent use. In seeking guidance, NACDS is not asking CMS to regulate the types of fees plans can use, how or when plans can use fees, or the dollar amounts for such fees. Rather, we are seeking guidance that would require clarity and consistency in how fees are used and applied.

We urge Congress to advise CMS on the importance of issuing guidance to improve transparency between plans and pharmacies in prescription drug reimbursement structures. Specifically, we urge Congress to advise CMS on the importance of issuing guidance to improve consistency in disclosures to pharmacies on how fees are defined, how they will be calculated, the timing for fee collection, how fees will be reported to pharmacies at the claim level detail (thus allowing reconciliation of reimbursement), and the parameters for pharmacies to "earn" back the fee post reconciliation. Increased transparency in the Medicare program will benefit CMS, participating pharmacies, and beneficiaries alike.

Lowering Prescription Drug Costs

NACDS shares the goal of reducing the cost of prescription drugs and believes community pharmacies are ideally situated to help through services designed to improve medication adherence and the promotion of generic drugs as safe, cost-effective alternatives. Retail community pharmacies are the closest healthcare providers to patients with respect to prescription medications. A March 2017 survey of registered voters conducted by *Morning Consult* and commissioned by NACDS found that eight-in-ten respondents believe that pharmacists are credible sources of information about how to save money on prescription drugs—the highest rating of healthcare professionals tested. In addition to the ability of improved adherence and increased transparency (as detailed above) to impact drug costs, NACDS recommends other beneficial changes, such as:

- Generic Utilization: Pharmacies have long promoted generic drugs as safe, cost-effective alternatives. Increasing the use of generic drugs is one of the most effective ways to reduce prescription costs**.** For every one percent increase in generic utilization, the Medicaid program could save $558 million. For example, if all other states could match the generic utilization rate of Hawaii (82.7%), the Medicaid program could save $6.56 billion annually. Community pharmacies have a higher generic dispensing rate (71%) than any other practice setting.

- Risk Evaluation and Mitigation Strategy (REMS): The REMS program requires manufacturers to ensure the benefits of a drug or biological product outweigh its risks. However, some manufacturers unfortunately are using the REMS Elements to Assure Safe Use (ETASU) requirements to prevent competition for products. Specifically, certain companies are employing restricted distribution networks to deny manufacturers of generics and biosimilars access to product samples they need to compete. An analysis by Matrix Global Advisors found that utilizing these networks to prevent generic competition costs the health care system $5.4 billion annually, including $1.8 billion to the federal government. Also, it could result in approximately $140 million in lost savings for every $1 billion in biologics sales. NACDS supports closing loopholes to boost generic-medication access and lower costs.

- Biosimilars: NACDS supports policies that promote confidence in and encourage increased use of more cost-effective biosimilar medications. FDA should adopt naming policies for biosimilar drugs and biologics that are consistent with the naming conventions for brand and generic small molecule drugs, that is assigning the same individual nonproprietary name ("INN") to a biosimilar drug product that is assigned to the reference biologic drug counterpart. Special naming policies for biosimilar drugs (and other biological drugs) that deviate from the traditional naming scheme can undermine prescriber and patient confidence in biosimilar products, thereby discouraging their use and jeopardizing the savings that could otherwise be achieved through increased use of more cost-effective biosimilar products. Without robust generic competition, brand biological products could cost the United States healthcare system $120 billion by 2024, according to projections from Express Scripts. However, a 2014 report published by the Rand Corporation found that the use of biosimilars could provide a $44.2 billion reduction in direct spending on biologic medications over the next ten years.

Conclusion

NACDS thanks the Committee for your consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.