

**PRESIDENT'S FISCAL YEAR 2019
HEALTH CARE PROPOSALS**

HEARING
BEFORE THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
ONE HUNDRED FIFTEENTH CONGRESS
SECOND SESSION

—————
FEBRUARY 15, 2018
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PRESIDENT'S FISCAL YEAR 2019 HEALTH CARE PROPOSALS

THURSDAY, FEBRUARY 15, 2018

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 9:05 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Grassley, Crapo, Thune, Isakson, Portman, Toomey, Heller, Scott, Cassidy, Wyden, Stabenow, Cantwell, Nelson, Menendez, Carper, Cardin, Brown, Casey, McCaskill, and Whitehouse.

Also present: Republican staff: Jay Khosla, Staff Director; Chris Armstrong, Chief Oversight Counsel; Brett Baker, Health Policy Advisor; Ryan Martin, Senior Human Services Advisor; Stuart Portman, Health Policy Advisor; and Caitlin Soto, Oversight Counsel. Democratic staff: Joshua Sheinkman, Staff Director; Laura Berntsen, Senior Advisor for Health and Human Services; Anne Dwyer, Health-care Counsel; Michael Evans, General Counsel; Elizabeth Jurinka, Chief Health Advisor; Matt Kazan, Health Policy Advisor; and Arielle Woronoff, Senior Health Counsel.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order.

Before I begin, I want to express on behalf of the committee the sadness we all feel in light of yesterday's events in Florida.

I was firstly horrified as I watched the news unfold yesterday, though I was also moved to hear some of the stories of the heroism displayed by some of the students and teachers at the school.

In times like these, I know that thoughts expressed from those of us who are far away can sometimes seem empty and meaningless in the face of such a terrible tragedy. I will simply say that I am praying for all of those who were affected by these acts of senseless violence. That, of course, includes a member of our committee, who I know is mourning the loss and pain felt by those in his own State.

May they all find peace, healing, and a speedy recovery.

Now, I welcome everybody here to today's hearing, which will be our third and final hearing on the President's budget for fiscal year 2019. We have already had the Treasury Secretary and the Acting IRS Commissioner appear before us. And today we will be talking

with Secretary Azar from the Department of Health and Human Services.

Secretary Azar, I want to thank you for being here and cooperating with us, and welcome back. It has been just a little over a month since you last appeared before us. This could cause some nervous reactions, you never know.

Of course, you are still very new to your position, but we are glad to have you back, because we have a lot to discuss.

Since you were last here, this committee has amassed a number of legislative victories. I want to take a few minutes to highlight these accomplishments, as many are within HHS's jurisdiction.

Last month, as a result of countless hours of work by this committee, Congress passed and the President signed a 6-year CHIP extension. A few weeks later, we added another 4 years to that extension as part of a bipartisan budget act. That is 10 more years of CHIP funding, which is, quite frankly, really a historic accomplishment.

Senator Ted Kennedy and I created the CHIP program more than 2 decades ago. And despite always enjoying bipartisan support, at no point in the program's history have we been able to deliver this much certainty and security for the families and children who depend on CHIP.

I want to once again commend my colleagues on both sides who joined in this effort and who share in this success, and especially my colleague from Oregon. It was no small feat.

In addition to the CHIP extension, the CHRONIC Care Act, another bipartisan legislative product out of this committee, was also signed into law recently. This new law will improve care for Medicare beneficiaries living with chronic conditions, streamline care coordination, and improve quality outcomes without worsening Medicare's shaky fiscal status.

Again, I want to thank everyone on this committee who worked on this bill, most notably our ranking member, Senator Wyden, as well as Senators Isakson and Warner, who were key leaders in the drafting and passage of this very important bill.

And it does not end there. The budget bill also included the bipartisan Family First Prevention Services Act, which will help keep more children safely with their families specifically by funding substance abuse and mental health services that have been shown to prevent children from entering foster care.

All of this success is testament to bipartisanship and proves that it is possible for both parties to find common ground and work together. As always, there is more work to be done, and I am optimistic that we can be just as effective in the coming months.

Of course, these recent achievements will not mean much if they are not implemented properly.

Secretary Azar, I look forward to working with you as this process moves forward.

Now, I would like to take a moment to talk about some of the specifics in the President's budget which recognize the need to eliminate wasteful spending, rein in our national debt, and focus on protecting Americans at home.

I appreciate that the President's budget takes steps toward a course correction that will hopefully lead to a more economically

sound future, all while still ensuring high-quality and accessible health care.

One of the key and critical assumptions in the President's budget is the repeal of Obamacare. The budget bakes in this repeal and replaces it with a State-based grant system. All told, the administration estimates that would save more than \$675 billion—that is with a “b.”

Many of us on the committee, I think all of us on the Republican side, share this desire to repeal Obamacare. And we have actually done some great work on rolling back major elements of the so-called Affordable Care Act this Congress.

For starters, our tax reform bill zeroed out the individual mandate tax. The recent budget bill also included the so-called Medicare extenders and repealed the Independent Payment Advisory Board. And in that same bill, we extended previous delays on other Obamacare taxes, including the medical device tax, the health insurance, and the so-called “Cadillac tax.”

But as the budget points out, we are not quite there yet. I hope we can take additional steps in the future, and I look forward to continuing our discussions on how we can stop the skyrocketing costs of health care in a meaningful and a well-governed way.

Beyond the critical repeal-and-replace efforts with Obamacare, we also need to start getting serious about Medicare and Medicaid reforms. Both of these programs need to be put on more sustainable paths so that we can fulfill the promises of these programs for future generations.

I know that any time a Republican mentions the fiscal predicament of Medicare and Medicaid, we are essentially asking to be accused of robbing the elderly and low-income families of their health care. But none of these scare tactics will improve the outlook of our Federal health-care programs. That is going to take some hard work, and hopefully we can find a path forward there as well.

Secretary Azar, during your confirmation hearing, you emphasized that addressing rising drug prices would be one of your top priorities. As you know, I have spent quite a bit of time on this issue working to ensure that patients have access to innovative and high-quality medications.

It can be tricky to balance the need to encourage investment and development of new and effective drugs and treatments while also working to make sure those in need can obtain access to those potentially lifesaving and life-improving products.

Some have made a crusade out of scapegoating the companies that develop drugs and treatments. And when this almost singular focus prevails, the result is policy that tends to be less than perfect, to put it charitably. We saw an example of this in last week's bipartisan budget act that increased the discount that manufacturers were required to provide under the so-called “doughnut hole” in Medicare Part D. Now, I voiced my opposition to the inclusion of this provision in the budget agreement on the Senate floor last week. I am working with my colleagues who share my concern on the increased manufacturer discount provision to mitigate its impact.

And we should all strive further. As this budget has a number of other drug-related policy proposals, I implore the administration

to take care to strike a balance between access and innovation. It is a balance that I hope that we should all strive to achieve.

Now, Secretary Azar, you also emphasized that addressing America's opioid crisis is another one of your top priorities. I am happy to see that the President's budget stresses the importance of working together to fight this epidemic.

The CDC estimates that each day our country experiences more than 100 opioid-related deaths. My home State of Utah has been especially hard hit. And while the drug-overdose rate has risen over the past decade, we are starting to see a shifting tide thanks to the leadership of many officials in my State.

With that said, they need Federal help. And I know that many in Congress, including several members of this committee, have been outspoken leaders in this effort. And I commend them for their work.

We are committed to continuing our bipartisan committee process to address the opioid epidemic, especially through mandatory program proposals that can bring about meaningful and enduring change to a system plagued with issues.

Mr. Secretary, I look forward to working with you in the coming months as we look for solutions to address this crisis. And I hope that we, as a committee, can continue our bipartisan efforts to curtail this growing string of tragedies.

To close, let me just say that, as we all know, it is Congress's responsibility to pass a budget. The President's proposed budget merely sets the tone and provides us with the baseline for debate. I hope that we can work together to implement many of the common-sense reforms we have been debating for so long, and I hope that we can continue to work to set aside our differences in order to find beneficial solutions.

I look forward to having an open and frank discussion with Secretary Azar about these and other matters.

Before I close, I do want to note that because we were unable to get a quorum yesterday, if at any point during the hearing a suitable quorum is present, I intend to pause the hearing and move to votes on the nominations of Mr. Dennis Shea and Mr. C.J. Mahoney. Thereafter, we will resume our hearing.

With that, let me now turn to my friend, the ranking member, for his opening remarks.

[The prepared statement of Chairman Hatch appears in the appendix.]

The CHAIRMAN. Senator Wyden?

**OPENING STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON**

Senator WYDEN. Thank you very much, Mr. Chairman.

Mr. Chairman and colleagues, 18 school shootings this year. And I am just going to begin by saying, when is enough? And we watch these young people from the high schools, and I heard one in effect say, you know, we are kids, we cannot fix this. You adults get over it and deal with it. And that, to me, is central to what we are talking about this morning, because we are going to talk about health care.

And what we have been hearing on the news is, it sure sounds like there are a lot of young people who are frightened about what can happen at their school. So we deal with lots of bills and lots of amendments, but like those students said, it is time to get over it. It is time to act. And we have learned in the last 24 hours enough is enough.

And, Mr. Chairman, I want to pick up first on the point you made, because in the last couple of weeks on the health-care front, as you have noted, we have had some very positive developments here in the last few weeks.

If you had told me in the winter of 2017 that we would have 10-year CHIP reauthorization, everybody would have said, what planet is this person residing on?

The CHRONIC Care bill, and I see Senator Isakson, who was with me on day one—Senator Warner is not here—with Senator Isakson in this room, we launched it.

Chairman Hatch, to his credit, pulled together a bipartisan group of us.

Colleagues, let us make sure we understand what this CHRONIC Care bill is all about. The CHRONIC Care bill is about updating the Medicare guarantee and modernizing the program to deal with where most of the money is going to be spent: on cancer and diabetes and heart disease and strokes.

And when I was director of the Gray Panthers, it was a really different Medicare program. You had Part A for hospitals and you had Part B for doctors, and that was that. And colleagues like Senator Isakson and Senator Warner and our bipartisan group said, when you have 10,000 people turning 65 every day and it is going to happen for years and years to come, you have got to dig in.

Chairman Hatch made that possible. I want to thank the chairman.

And then, of course, a lot of people who work in the child welfare field are saying that the Family First bill was what they have been dreaming about for 3 full decades. And that came together here in the last couple of weeks, and I want to thank you for that, Mr. Chairman.

Now, on a not-so-positive note, the budget season is at hand again, so the Trump agenda of health-care discrimination is back. And I am going to go through the examples.

Start with discrimination against Americans with pre-existing conditions. People who have pre-existing conditions count on having a robust private insurance market with strong consumer protections. What the Trump budget offers is chaos in the private insurance market and the elimination of key consumer protections.

The budget embraces the old Graham-Cassidy proposal that lived a mercifully short life last fall because, in this room, we blew the whistle on the fact that it did not lock in protections for those who have pre-existing conditions.

On top of that, the administration is giving a green light to junk insurance policies that revive the worst insurance abuses of the past, such as skimpy coverage and dollar limits on care. So for millions of people with pre-existing conditions, the Trump administration seems dead-set on making the care they need unaffordable and inaccessible.

Next on the agenda of health-care discrimination is discrimination against women. When you get rid of the consumer protections in the Affordable Care Act, you return to an era when 75 percent of insurance plans in the individual market did not cover maternity care or birth control.

And under the Trump budget, which arbitrarily attacks key providers—Planned Parenthood and others—millions of women would lose the right to see the doctor they trust, the doctor of their choosing.

Then the Trump agenda of health-care discrimination goes after Americans who walk an economic tightrope. One-point-four trillion dollars cut from Medicaid, millions of Americans locked out of the program, a scheme to wipe out key nationwide protections and cap the program, essentially ending the guarantee of care for those who qualify for Medicaid. Now the administration reportedly is discussing lifetime limits for Americans on Medicaid.

Both sides used to agree that lifetime limits in health care were absolutely wrong, no exceptions. The ban on lifetime limits in the Affordable Care Act was one of the core protections that Republicans—Republicans—said ought to stay.

Introducing lifetime limits in Medicaid raises the frightening question of, what happens if somebody maxes out after cancer treatment at age 45? Are they going to be on the street in old age, capped out of nursing home benefits? We are going to be discussing that.

Finally, the Trump agenda of health-care discrimination turns against older Americans. Slashing Medicaid to the bone and transforming the program into a capped program is an extraordinary threat to the welfare of older people. Medicare helps to pay for two out of three seniors in nursing homes. And it is essential for seniors who count on home-based care.

Even for older people at age 62 or 63, there is bad news. The Trump budget hits them with an age tax, allowing insurance companies to charge them far-higher rates than they charge others.

Bottom line: the agenda of health-care discrimination is out in force in this Trump budget. And in my view, it is a comprehensive plan to drag the country back to the days when the health-care system was basically working for people who are healthy and wealthy and everybody else was on their own.

Finally, we are going to, I am sure, talk about the question of prescription drugs. The President famously talked about how drug companies were, quote, “getting away with murder.” Those are his words, not mine. And the President said they were getting away with murder by setting drug prices so high. The way he talked about the problem, Americans thought he was going to come out swinging with big solutions to the challenge.

In the plan released last week, I still do not see a solution to the fundamental issue: drug companies set prices that are way too high.

There is not a debate about the fact that the system is broken and it needs reform, but if pharmaceutical companies can come out of the gate with unaffordable prices, patients will suffer. And I do not see where you fix that with some efforts to play catch-up ball.

The Trump prescription drug plan lets pharmaceutical companies keep on—to borrow a phrase—getting away with murder.

Finally, a lot of what the administration put forward last week looks familiar. On the pharmaceutical side, some of it is borrowed from legislation I proposed or recommendations that came from outsiders. There is value in these ideas; there is an opportunity to move on a bipartisan basis. But that is not what the American people were promised.

The American people were promised a muscular approach, a position where the American people would know that their government was on their side and helping them deal with this issue of how they are getting clobbered at the pharmaceutical window when they go in to get their medicine.

I will wrap up by talking about a different part of the Secretary's agenda vital to kids. Chairman Hatch and I have both mentioned Family First. I am very proud of that effort, because for too long the child welfare system has basically been about splitting families apart. That is what Family First seeks to reform because, instead of just two lackluster options—leaving young people in a family setting where they were still going to face problems or sending them off to a future of uncertainty in foster care—we said we would allow States to find safe ways to keep families together and families healthier.

States could use foster care dollars to fund services like substance abuse treatment, mental health and parenting programs, with the goal of preventing a prolonged slide into the crises that end with families breaking apart.

I share Chairman Hatch's view about the opioid epidemic. It was good that additional funds were made available in the recent budget agreement. And now what we have to do is make sure that the Department moves quickly so that the States can get away from business as usual and deal with the epidemic.

We look forward to hearing from you, Secretary Azar.

As I have said publicly, the Secretary indicated in our pre-nomination hearing that he was going to take the initiative and be in touch on a regular basis to discuss the issues. And he has already shown he is serious about that with a call here recently. I appreciate it.

I look forward to our work together. And let us try to make more of it look like what has happened out of this committee in the last couple of weeks, and let us make less of it look like the agenda of health-care discrimination that I believe is what the budget is all about.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, thank you, Senator.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. Today we have the pleasure of being joined by Mr. Alex M. Azar, the Secretary for Health and Human Services.

Mr. Azar, I want to thank you for taking time out of what I know is a tremendous schedule and for your appearing here today.

Because we heard two very eloquent introductions for you just over a month ago, I will keep my introduction short and to the point.

After graduating with his law degree from Yale University, Mr. Azar also clerked for Justice Scalia on the Supreme Court and later became a partner at Wiley, Rein, and Fielding before being confirmed as General Counsel at HHS back in 2001.

Then in 2005, he was asked to serve as Deputy Secretary at HHS, where he served as the chief operations officer for the largest civilian Cabinet department in the United States of America, in our government, with over 66,000 employees and a budget of nearly \$700 billion.

Following his service at HHS, Secretary Azar rejoined the private sector as a senior vice president for corporate affairs and communications at Eli Lilly and Company. He eventually went on to become president of Lilly USA, LLC, the largest affiliate of Eli Lilly.

Then just last month, Secretary Azar was confirmed to his current role as Secretary of HHS.

So, Secretary Azar, we are grateful to have you here, grateful for your time, grateful for your expertise, and grateful for the service you have already given and continue to give.

Please proceed with your statement.

STATEMENT OF HON. ALEX M. AZAR II, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Secretary AZAR. Chairman Hatch, Ranking Member Wyden, and members of the committee, thank you for inviting me here today to discuss the President's budget for the Department of Health and Human Services for fiscal year 2019.

I would like to begin, though, by joining Chairman Hatch and Ranking Member Wyden in expressing our deepest sympathies and prayers for the victims and their families in Florida.

It is an honor to be here today, and it is an honor to be able to serve as Secretary of HHS thanks to the support of the members of this committee.

Our mission at HHS is to enhance and protect the health and well-being of all Americans. It is a vital mission, and the President's budget clearly recognizes that.

The budget makes significant strategic investments in HHS's work, boosting discretionary spending at the Department by 11 percent in fiscal year 2019 to \$95.4 billion. Among other targeted investments, that is an increase of \$747 million for the National Institutes of Health, a \$473-million increase for the Food and Drug Administration, and a \$157-million increase over 2018 funding for emergency preparedness across the Department.

The President's budget especially supports four particular priorities that we have laid out for the Department, issues that the men and women of HHS are hard at work on already: fighting the opioid crisis, increasing the affordability and accessibility of health insurance, tackling the high price of prescription drugs, and using Medicare to move our health-care system in a value-based direction.

First, the President's budget brings a new level of commitment to fighting the crisis of opioid addiction and overdose that is stealing more than 100 American lives from us every single day.

Under President Trump, HHS has already dispersed unprecedented resources to support access to addiction treatment. The budget would take total investment to \$10 billion in a joint allocation to address the opioid epidemic and related mental health challenges.

Second, we are committed to bringing down the skyrocketing cost of health insurance, especially in the individual and small-group markets, so more Americans can access quality, affordable health care. This budget recognizes that this will not be accomplished by one-size-fits-all solutions from Washington. It will require giving States room to experiment with models that work for them and allowing customers to purchase individualized plans that meet their needs.

That is why the budget proposes a historic transfer of resources and authority from the Federal Government back to the States, empowering those who are closest to the people and can best determine their needs. The budget would also restore balance to the Medicaid program, fixing a structure that has driven runaway costs without a commensurate increase in quality.

Third, prescription drug costs in our country are too high. President Trump recognizes this, I recognize this, and we are doing something about it. This budget has a raft of proposals to bring down drug prices, especially for America's seniors. We propose a five-part reform plan to further improve the already successful Medicare Part D prescription drug program.

These major changes will straighten out incentives that too often serve program middlemen more than they do our seniors, over the next 10 years adding to savings that we are already generating with reforms to Medicare Part B payments under the 340B drug discount program.

The budget also proposes further reforms in Medicaid and Medicare Part B to save patients money on drugs and provides strong support for FDA's efforts to spur innovation and competition in generic drug markets. We want programs like Medicare and Medicaid to work for the people they serve. That means empowering patients and providers with the right incentives to pay for health and outcomes rather than procedures and sickness.

Our fourth departmental priority is to use the tremendous power we have through Medicare as the largest purchaser of medical services in the United States to move our whole health-care system in this direction. This budget takes steps towards that by, for instance, eliminating price variation based on where post-acute care is delivered, rationalizing payments to physicians in hospital-owned outpatient facilities, supporting investments in telehealth, and advancing the work of Accountable Care Organizations.

The future of Medicare must be driven by value, quality, and outcomes, not the current thicket of opaque, unproductive incentives.

The President's budget will help accomplish three important goals at HHS: first, making the programs we run really work for the people they are meant to serve, including by making insurance affordable for all Americans; second, making sure that our programs are on a sound fiscal footing that will allow them to serve future generations too; and third, making the necessary invest-

ments to keep Americans safe from natural disasters and infectious threats.

Making our programs work for today's Americans, sustaining them for future generations, and keeping our country safe is a sound vision for the Department of Health and Human Services, and I am proud to support it.

Thank you, Mr. Chairman.

[The prepared statement of Secretary Azar appears in the appendix.]

The CHAIRMAN. As you may know, the Finance Committee is undertaking a bipartisan process to identify ways to address the opioid crisis or epidemic in Medicare and Medicaid so that the right incentives exist for addressing pain and addiction.

When you testified before this committee earlier this year, you mentioned that addressing the opioid epidemic would be one of your top priorities. Now, I am personally pleased to see a number of proposals included in the President's budget on this particular topic. And I am sure you have helped do that.

Will you commit to working with this committee to find bipartisan solutions to address this epidemic within Medicare and Medicaid?

Secretary AZAR. Absolutely, Mr. Chairman.

The CHAIRMAN. Well, I appreciate that.

I am not going to ask any further questions at this time, so we will turn to the ranking member, Senator Wyden.

Senator WYDEN. Thank you very much, Mr. Chairman.

And I am going to start, Mr. Secretary—and we have talked about this matter of junk insurance and particularly what seems to be an administration plan to greenlight it. And I recognize that this did not essentially commence on your watch, but you are there now and so I have to make sure we are going to have a sensible policy.

What junk insurance is all about is making sure that insurance companies can charge more for people with pre-existing conditions and include arbitrary caps on the amount of care.

And in a lot of ways, junk insurance just turns back the clock. And when I heard about this, the first thing I thought about is, when I was director of the Gray Panthers, it was common for an older person to have, like, 15, 20, 25 policies that were sold to supplement their Medicare. They were called Medigap.

And finally, we wrote a bipartisan law—Senator Dole, for example, was very helpful in it—which drained the swamp, an appropriate phrase for the time.

And now I look at what seems to be bubbling up again—different population group, not seniors, but the same sort of thing—that we are going to greenlight policies that are appropriately called junk because they are not worth the paper they are written on.

Idaho seems to have the most active effort: once again, people spending hard-earned money on a plan they need, only to find that they are being ripped off by an insurer.

So thus far, Blue Cross of Idaho is the only insurer that has applied to sell the junk plans. And I have the application here, and it seems all about finding out if people have pre-existing conditions so they can discriminate against them, charge them more. All the

questions in section 5A deal with that issue. Have you been pregnant? Have you been tested for allergies? Has anybody had a claim over \$5,000?

If an insurer is following the law banning discrimination against those with pre-existing conditions, what are all those questions about?

Secretary AZAR. So, Senator Wyden, I have seen the media reports about the Blue plan request and the actions in Idaho. I have not yet seen the plan or received any type of waiver request. I can assure you that if we do receive that and if that does progress forward, we will be looking at that very carefully and measuring it up against the standards of the law, as is our duty.

Senator WYDEN. I appreciate that. And I know this is new for you, so this is a first impression.

This, as I understand it, is not a waiver. In effect, Idaho is just saying, we are going to do this; we are going to do it because we are a State that wants to do it.

But there is a Federal law, something I fought very hard for. It was right in the heart of a bipartisan proposal, the Healthy Americans Act, the centerpiece—seven Democrats, seven Republicans—airtight protection, loophole-free, airtight protection for those who would have a pre-existing condition.

And now, what this is going to be all about—and when we talked in the office, I said you are not going to be sitting around reading paperbacks in your job—this is going to be a question of whether the Department is going to say Federal law, which protects people from discrimination against pre-existing conditions, controls or if Idaho can start something that just moves America back towards yesteryear where we can have insurers beat the stuffing out of people with a pre-existing condition.

So let us do this. This is new for you. I would like you to get back to me, let us say within 10 days, with respect to how the Department is going to pursue this. Because I think that this case is really being watched. This is the one that is really going to determine whether States can just on their own say, we are going back to yesteryear. So this has very, very substantial implications.

And what I would like to do—two things, Mr. Chairman. I would like to ask unanimous consent to enter the Blue Cross of Idaho application form into the record. That would be my first unanimous consent request.

[The application appears in the appendix on p. 101.]

Senator WYDEN. My second unanimous consent request is to enter in a letter to the Secretary from 15 organizations that represent millions of patients expressing serious concerns with essentially the points I am talking about, that Idaho is breaking a Federal law.

In other words, the first time I heard about it, I said, wow, maybe it is just a waiver, it will be complicated. I have been very interested in waivers—a lot of Senators have—but this is not a waiver. This is just saying, we are going to do it.

So I want to enter into the record the letter from the 15 organizations that represent millions of patients expressing the concerns I have with Idaho breaking the law, the harm it will have on patients, the implications as a precedent.

[The letter appears in the appendix on p. 104.]

Senator WYDEN. And then, is it acceptable to you that you will get back in some way to outline how the Department intends to pursue this within 10 days?

Secretary AZAR. I am very happy to get back. I do not want to commit on the 10 days because this has to run through a process of, first, I guess they are applying to Idaho, and Idaho will have to decide its own thing under its laws that it has. And then anything would presumably come to us.

I will be happy to work with you and be very transparent about that process. I just do not—I do not want to prematurely be involved before there is even a matter in controversy at the State level. So all we have seen is a press report that the Blues have submitted an application. I do not know whether it would even be approved by Idaho or certified as compliant under the ACA. So it is really just a question of timing.

I can assure you we will be looking, at the right time, looking very seriously at the legal requirements.

Senator WYDEN. I am over my time. Here is what concerns me. They are not planning to come to you and ask permission. They have made the argument that they can just do it on their own. So this idea that we are going to just sit in our offices back here and wait for somebody to tell us, oh, we are going to discriminate against people with pre-existing conditions, that will not cut it with me. It does not cut it.

Secretary AZAR. No, and that is not what I would propose.

Senator WYDEN. How about if we say I will be told how the Department is going to pursue this within 30 days?

Secretary AZAR. I hope—I believe that would be acceptable. My only issue is, I need a case in controversy; I need to know that there is actually action that is happening.

Senator WYDEN. I am over my time.

Secretary AZAR. But I do not think we—

Senator WYDEN. I think I have made my point. I am over my time.

Secretary AZAR. I do not think we have any difference about the need of the Department to be engaged here, Senator.

The CHAIRMAN. Well, if you will do that, that would be, I think, very helpful to the Senator.

Senator CRAPO?

Senator CRAPO. Thank you, Mr. Chairman.

And thank you for being here, Secretary Azar.

I am from Idaho, and I am very familiar with what Idaho is doing. And once again, we are in—this is like Groundhog Day. Every time a new idea for how to fix the health-care system comes out, it is accused of eliminating pre-existing conditions as well as every other possible attack that can be dreamed up against it.

I think it is appropriate for you, Mr. Secretary, to wait to see exactly what is developing and evaluate it carefully. And I would encourage all of my colleagues to review what is actually being done rather than just jumping right back in.

And my good friend from Oregon and I work very closely together on many, many issues. I look forward to working with you on this issue.

This plan, as I understand it, does not eliminate pre-existing issues. When the Graham-Cassidy proposal was made, the attack was that, as we give greater responsibilities to States to be that incubator of new ideas and of new approaches to health care, that it was going to get rid of pre-existing conditions, that it was going to drive people out of the marketplace, that it was going to cause people to lose their insurance.

The reality is, the effort being undertaken by the people in Idaho is one to protect and expand the opportunities and access people have to insurance of their choice, insurance that will work for them.

And yes, it does move away from the notion that the only insurance policy anyone in America should be able to buy is one that this committee or this Congress or this Federal Government decides they can buy.

Fortunately in the tax legislation that we just passed, we eliminated the tax penalty for people who do not want to buy the product the Federal Government wants to force on them. And now the States are seeking to have some flexibility.

In your testimony, Mr. Azar, you talked about the fact that we want to encourage the States to experiment and that additional resources are going to be provided to the States to allow them to experiment.

And I understand what the law is. And as I evaluate this, I do not see a violation at all. Idaho is still providing Obamacare-compliant plans for anyone who wants to purchase them, but they are allowing others to have options. And if the idea is that people in America can have options—comply with all the Obamacare mandates for anyone who wants that but allow others who want to buy a different kind of insurance policy to have an option—the idea that that is a direction that we should choke off right at the beginning is one that I resist.

And I would just like your—I know you cannot comment on the Idaho situation specifically. But I would just like your observation on the notion that we need to facilitate, incentivize, and provide additional resources to the States so that they can do exactly what many States are trying to do right now, which is to find a way to give their citizens greater choice and greater access.

Secretary AZAR. Thank you, Senator. And as you said, I think any consideration of a State proposal or any matter like this requires great deliberation and caution and care in assessing it. So I just simply cannot state a view based on media reports around a State's program.

But I think what we are seeing here is a cry for help. It is saying that where we are right now with our individual market, because of the structure we have, is not serving enough of our citizens and there are too many citizens who simply cannot afford the insurance packages that we have in our program because of the way the statute is designed and the way it has been implemented.

And so that is why it is so important that we work to give States flexibility so that we try to offer for those 28 million Americans who cannot afford access to the individual market—Affordable Care Act plans—that they can have other options to choose from that may meet their needs, and then also try to fix what is in the pro-

gram to help make that as affordable as possible, working together with the Congress.

Senator CRAPO. Well, thank you. And I will just conclude with an observation.

In addition to the program that my colleague from Oregon referenced, I expect that Idaho, like many other States, is probably going to apply for a waiver or two from HHS with regard to some aspect of Federal law, as States are starting, I think increasingly, to seek the flexibility that they can get from the Federal Government to do this kind of creative work on our health-care system to help us find the right path to provide the best and the most effective and efficient and inexpensive insurance that we can find.

And I would just encourage you—not just with regard to any applications that Idaho provides, but with regard to all 50 of the States as they seek to ask you, under the authorities you have to grant waivers, to allow them to do this kind of thing and to work to improve our health-care markets—to give those applications very careful consideration.

Thank you.

The CHAIRMAN. Thanks, Senator.

Senator Carper?

Senator CARPER. Thanks, Mr. Chairman.

Several of my colleagues have expressed their remorse and sorrow over the latest shooting, mass shooting, this time down in Parkland, FL. I share that.

I was born in West Virginia, but grew up in Virginia in a family of hunters. My dad introduced me to hunting at a very young age. I got my first BB gun when I was about 10. I got my first shotgun from my dad, and my grandfather died and he willed his shotgun to me. And I used it for many years hunting as I grew up in Virginia with my dad.

My dad was a gun collector and sold guns until near the end of his life down in Florida. I believe, my family believes in the Second Amendment to the Constitution, the right to bear arms.

I want to say, though, I am tired, sick and tired, of opening a hearing like this and we express our remorse, again another mass shooting. This has got to end.

My dad used to say we ought to use some common sense. In this case, we ought to use some common sense with respect to guns and gun legislation.

Senator Feinstein has legislation that has been introduced; it is called a “no-fly, no-buy” bill. If you are on a terrorist watch list, you should not be able to buy weapons. And we cannot even get that passed. It is a sad commentary.

And, colleagues, we have to use some common sense and use our hearts here. And enough of these expressions of remorse. I know they are heartfelt, but enough. That is not what we are here to talk about today.

I just want to say, Mr. Secretary, congratulations to you. Thank you for the dialogue and the conversations that we had during the nomination process. Thank you for the conversation we had earlier this week. And I look forward to more as well.

Sometimes we vote our hopes over our fears here, and I voted for you, for your confirmation, out of my hopes. And we have this

moral obligation I have talked to you about, to my colleagues about, until they are sick of hearing it. We have a moral obligation to the least of these, and that includes the moral obligation to make sure people have access to health care, everybody has access to health care.

We have a fiscal imperative to make sure we are doing it in a fiscally responsible way. Among the ways that we do that is Federally Qualified Health Centers, the CHIP program.

Congratulations, Mr. Chairman, on this latest extension of your creation, that with Ted Kennedy.

As a recovering Governor, former chairman of the National Governors Association, along with Mark Warner who was chairman of the NGA, I know a little bit about what States can do when they are given some flexibility.

By the same token, people can buy cheap insurance, and it is not worth the paper that it is written on. And so we have to be careful and be mindful of that.

I want to talk a little bit about our efforts to shift, move away from fee-for-service payment to a value-based system, Mr. Secretary. But before I do that, I want to just mention, despite the efforts of the administration to, I would say, undermine, even sabotage our insurance marketplaces, almost 9 million Americans, over 95 percent of the enrollment population in 2007, signed up for insurance plans for 2018.

Americans support it, they want to keep the Affordable Care Act. In contrast, the President's budget proposes to repeal the ACA, replaces it with a proposal that eliminates subsidies that make health insurance more affordable, and cuts more than \$1.4 trillion out of Medicaid.

I know you were not in the administration when this committee reviewed this proposal last year, so I just want to make sure you know that nearly every patient group, every physician group, every hospital group, health insurance group, strongly opposes the President's proposal.

More than two-thirds of Governors urged Congress not to pass that proposal. The Brookings Institution found that more than 20 million Americans could lose insurance if we go that path.

And individuals with pre-existing conditions could lose, would lose the guarantee of affordable health insurance. And with that, there is much concern from every corner of our health-care system in this country.

Do you think it might be worthwhile to first reexamine this proposal and work together with our patients, with our doctors, with our health-care providers to make some substantive changes before offering up this idea again?

Secretary AZAR. So on this proposal, our concept is, of course, to change it to a \$1.2-trillion grant program to the States that still retains protections for pre-existing conditions, maternal care, newborn care, reconstructive surgery after mastectomy, and certain coverage for those under the age of 26 on family plans.

So I am very happy to work with you on details to see if we can make this program work and have it make sense.

Where we are is not working for so many people, is the challenge. Now, I will work with whatever the Congress has given me

to try to make it as affordable as possible for individuals, with as much choice as possible. We would like to pursue legislative change to see if this can be the approach. Because insurance is so complex, I do not think, from the Federal level, we can do it all.

Your colleague, Senator Cardin, has a State that has taken a very different approach. Other States will take different approaches. I love the laboratory of States trying things in this very complex area.

Senator CARPER. All right. Good.

Mr. Chairman, the administration actually—and our Secretary has actually offered a couple of ways to stabilize the exchanges. This administration, up until now, has been just hell-bent on undermining the exchanges, destabilizing the exchanges. But I just want to thank you for some encouraging developments there.

And let us say—I think there are some things we can work together on, including reinsurance. But we will talk about that later. Thank you very much.

Secretary AZAR. Thank you.

The CHAIRMAN. Well, thank you, Senator.

The Senator from Georgia, Senator Isakson.

Senator ISAKSON. Thank you, Mr. Chairman.

Well, I can testify that you hit the ground running, because your first weekend on the job you were on the phone long-distance with me talking about the CDC. And I appreciate that very much.

I also know that you probably had no hand in the crafting of this budget, because you were not onboard when it was crafted, or at the least you saw it after it was done.

But with regard to the Centers for Disease Control and Prevention in Atlanta, I am deeply concerned this has a \$1-billion reduction in funding for CDC from 11.9 to \$10.9 billion at a critical time for our containment laboratories and the research and development that is done there, as well as our preparedness at CDC.

CDC was on the job, ready to go when Ebola hit. It did not need additional appropriations to hit the ground running. They hit the ground running, and appropriations came later. We stopped an epidemic which could have been a disaster, not just in Africa, but around the world.

CDC had the first people on the ground here when anthrax broke out after September 11, 2001 in Washington against members of the Senate and the House.

They are the world's health center. They are our protection, they are our safety blanket. It is the finest facility that there is. And to cut them by almost 10 percent, \$1 billion, in one fell swoop, to me is unconscionable.

Have you had time to look at the CDC's budget? Will you work to get it to an appropriate level to meet the needs that we place on it every single day?

Secretary AZAR. So, Senator, you know the care that I give to CDC and the value I place on it, both domestically and internationally.

As I look at the budget for CDC, the biggest part of change there really is our two transfers that are part of the reorganization that was begun at HHS. One is to move the leadership of the Strategic National Stockpile and the budgeting under the Assistant Sec-

retary for Preparedness and Response. So that just moves where it reports to; it does not even change the Atlanta aspect, but just moves where it reports to. That is one major chunk.

The other is the National Institute for Occupational Safety and Health, to integrate that—again, not moving it, but changing its leadership—to be reporting into the National Institutes of Health because of the research function.

So net-net, it is actually only about a \$100-million reduction on the operations of CDC.

What I am really proud of is that we were able to get the CDC budget regularized here in our proposal. So, you know, we have been operating out of the prevention fund. We have now moved that over to \$900 million of discretionary, moved that over so that the core operations of CDC are now regularized in the budget and do not just sit there as a pay-for as we look at other legislation. I think it is really critical to the long-term stability of CDC that we show that that is not variable each year, it is really built into the base of operations.

So I share the commitment and look forward to working with you on CDC.

Senator ISAKSON. Well, as we transition to a new Director—CDC is in a transitional leadership role right now—we need to not lose focus on the importance of that agency and see to it we are funding them to the level they need to be.

One other point on that funding: the containment laboratories, again, are facing economic obsolescence and practical obsolescence as early as next year.

Secretary AZAR. Yes.

Senator ISAKSON. So it is time that we did some replacing. And that is where all the bad, bad, bad pathogens are out there. And a lot of young people risk their lives every day working with dangerous things, trying to protect us, so we want to make sure those laboratories are as safe as possible.

Secretary AZAR. Yes, sir.

Senator ISAKSON. In the legislation on chronic care, we also had another bill that went in that last night. When the train left the station, there were a lot of cabooses on that train. One of them was reimbursement for home infusion, which you are probably familiar with. This is legislation I worked on for a long time and has a deadline of January 1st of next year for you to develop reimbursement under Part B to see to it those reimbursements for home infusion therapy take place.

It is a real reduction in the cost to us, because home infusion is a lot better than hospital infusion in terms of its cost and what it costs the patient, as well as a better place for the patient to receive care.

Would you work with me to see to it that by January 1st of next year we get that in place so those reimbursements are done?

Secretary AZAR. Certainly. I am not familiar with that provision, but I will certainly work with you to make sure we get the job done on time.

Senator ISAKSON. I do not expect you to be familiar with it, but I would never leave here this morning without making you familiar with it.

Secretary AZAR. Yes.

Senator ISAKSON. And one last point on that. The graduate medical education programs were consolidated in the budget: Medicare, Medicaid, and the children's graduate medical education program into one program with a net decrease in appropriation. Those programs are fantastic for creating good physicians and new physicians in health care for children and the elderly.

Will you work with me to see if we can get the maximum appropriation appropriate to continue to meet the needs of the people of the United States for graduate medical education?

Secretary AZAR. Yes, absolutely, Senator. What we are doing with the proposal on graduate medical education is trying to pull the three different streams together and actually give flexibility to make sure that we are able to invest in specialties and underserved geographic areas that need it the most.

Right now, we are very ossified from 1996 program levels and sort of stuck there. This would grant flexibility to ensure that the money, that scarce money, is going where needed most for our health profession development, but I am happy to work with you on that.

Senator ISAKSON. I look forward to working with you and wish you the very best of luck in your new responsibility.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman.

Mr. Azar, a pleasure to see you here.

I want to talk about a few issues in the President's budget, following up on some of our conversations from your confirmation hearings and discussions that we have had.

You and I talked about our commitment in regards to minority health and health disparities, the Institute of Minority Health and Health Disparities at the National Institutes of Health, and the Office of Minority Health at HHS.

I was disappointed to see that where we have put newer resources into NIH—and I support that strongly—there was a reduction of resources at the National Institute for Minority Health and Health Disparities and a reduction of resources at the Office of Minority Health within HHS.

Can you just share with me the rationale of those budget cuts and reassure us of your commitment to the mission of minority health and health disparities?

Secretary AZAR. Yes, Senator Cardin. Thank you for raising that.

The NIH issue, if I could, I would like to get back to you on that, because I am not familiar—14 days on the job—with that granular level within the NIH budget. We are delighted we are able to actually keep NIH funding at the level it is, that we are proposing. So I do not know about some of the ups and downs there. I would like to get back to you on that if I could.

On the Office of Minority Health, you know, it is still a scarce and tight budget environment, and one thing that we tried to do was to really prioritize direct service delivery programs and actual scholarship, an underserved area, and promotional activities around health professions.

So as we looked across the budget, a thematic approach that was taken was, is this delivering direct care in minority communities or is this supporting the development of health professionals who will serve in underserved areas through scholarship and reimbursement programs?

So that was the thesis that we tried to operate from. And more general programmatic activities sometimes would have been deemphasized against those in just the budget tradeoffs that get made there.

So it is certainly not a minimization around minority health programs. It is really the tradeoff and focus on service delivery.

Senator CARDIN. Well, that is helpful. If you could work with our office so that we are aware of your strategies, because I think together we can be more effective. We want to make sure you have the resources that you need here and are able to deal with the mission that we believe in: reducing disparities in our communities. So if we could work together, I would appreciate it.

Secretary AZAR. Thank you.

Senator CARDIN. I would just caution on another area in regards to the budget and imposing some additional costs on emergency care, which turns out to be non-emergency conditions.

And my concern here is that we are seeing an attack on the prudent layperson's standard in the private insurance marketplace. Congress has passed legislation on this to make it clear that if it is prudent for you to seek emergency care, it is going to be reimbursed. And we are very happy if you end up in the emergency room and the condition is not life-threatening—that is good news. But then you might get a shock when you get the bill and recognize it is not being paid by your insurance company.

So the policies in the government programs become particularly important because they are used as goalposts by the private companies. And it looks like you are now imposing additional copayments and costs on emergency care, where the individual may have gone into the emergency room for proper reasons but now finds there is a cost issue, which could be used to deter people who need it from seeking care.

Secretary AZAR. So I believe you are referring to a suggested proposal that is in the budget that would allow for Medicaid copays for emergency room visits that are determined to have been misuse of emergency room visits. I agree with you, we have to be—

Senator CARDIN. I did not know it was misuse. I thought it was that it turned out not to be emergency care.

Secretary AZAR. Well, yes. We would need, we would want to work with you to make sure that any legislation there is done in a common-sense way. There is zero desire that it should deter anyone from going into emergency rooms for care that they ought to be seeking. And we need to make sure there is enough of a cushion there that is common-sense and that does not, as you said, create a situation where it deters people from going in when they ought to go in.

Senator CARDIN. Thank you, because we worked a long time on the prudent layperson's standards. We had horrible practices in the private sector, preauthorizations and things like that, that were jeopardizing people's health.

There is one last point I would like to make, and that is, I disagree with the budget on the Medicaid cuts and the basis behind the Medicaid cuts.

But I just want to raise one issue that I would urge you to be very careful about. We do not really have a long-term care policy in America. And the States have the lion's share of the burdens under the Medicaid system for long-term care. And to the extent that we put more pressure on the States on Medicaid programs, we jeopardize long-term care, which is critically important to our seniors in America.

And I just think it is important that, whatever policies we adopt here at the Federal level, we are mindful of the negative impact it could have on care for seniors.

We would like seniors to be able to pay for their long-term care; we would love them to have third-party coverage. Most do not and therefore fall under the Medicaid program. And if we put too much of a strap on the Medicaid program, we are going to jeopardize long-term care for our seniors.

The CHAIRMAN. Well, thank you, Senator.

Senator Portman?

Senator PORTMAN. Thank you, Mr. Chairman.

And, Secretary Azar, thank you for coming before us. I think you are now fully in place, and it is great to see the good work that you already started to do.

I know you are very interested in this issue of substance abuse and particularly the opioid crisis. You and I have talked about it at some length. And I would ask you a couple of questions about that.

First, with regard to the funding, I notice that in your budget you have additional funding for HHS, for SAMHSA. We also in this body in this fiscal year actually increased the funding for the Comprehensive Addiction and Recovery Act programs over the authorization level. We have \$267 million for fiscal year 2017, for instance, which was over the roughly \$181 million that was authorized, because we think these evidence-based programs are where we ought to be directing some of this funding, rather than just throwing money after the problem to find out what works.

And these are the right kinds of treatment programs: long-term recovery programs, prevention programs, helping our first responders.

My question to you is, with the President's budget indicating that HHS would have additional funding and with our recent budget indicating that there would be \$6 billion directed toward this effort over the next 2 years, would you support additional funding for these evidence-based programs under the Comprehensive Addiction and Recovery Act?

Secretary AZAR. So I do not know where our breakdown is on the additional \$3 billion in 2018 and \$3 billion that we are allocating in 2019. If I can get back to you, I just want to see if we have put in the allocation, the funding toward those particular programs.

But I am just delighted by the support of Congress and of the President here and the amount of funding. We are going to be able to support our addiction and treatment programs at historic levels. We also put more money out last year than ever before in history

to help with the opioid crisis. And then with these 2 years' funding and the \$10-billion total, I am excited to be able to work with all of you on these efforts.

Senator PORTMAN. Again, I would say that the \$267 million, which was unprecedented, that we appropriated for this fiscal year is a relatively small amount compared to the \$10-billion issue, say, that HHS was budgeted without specificity, as I see it, in your budget. And we just want to work with you to be sure that funding is used for evidence-based programs that really work.

We have an example of one, by the way, that works which I am concerned that your budget is going to make less effective, and that is the Drug Free Communities Act. And I was the author of this many years ago in the House, so maybe I have a little bit of a bias toward it, but I also spent 9 years as chair of our local coalition which was funded initially with some seed money from this program. Over 2,000 community coalitions have been formed around the country in response to the Drug Free Communities Act, which essentially provides some matching funds, almost seed money, for a short period of time.

We required that these coalitions, by the way, have performance measures so we know whether they are working or not. We think this is a very effective prevention and education program.

At the time of an opioid crisis, it seems to us to be exactly the wrong thing to do to take something that is working and risk its ability to be effective in the future by moving it from, in the case of your budget, ONDCP to HHS to combine with other prevention programs that are different in kind.

So I would ask you to take a look at that. If you can explain to me this morning why you think it ought to be moved, I would be interested to hear. But I would hope that you would not promote this idea.

I frankly do not think Congress is going to go along with it. If they do, I am going to fight against it. Again, when something is not broken, let us not try to fix it, and particularly at a time when we need desperately to have more prevention and education out there.

Secretary AZAR. So I hope that I am remembering the correct program, but I believe the change that you may be referring to is the movement of the program, the funding, from ONDCP to SAMHSA.

Senator PORTMAN. That is correct.

Secretary AZAR. We already at SAMHSA administer that program. And I think this is just regularizing where the funding is, since ONDCP is not a grant-making organization, does not have those capabilities and staffing around that we do already. And it is just putting the money where the function already is.

So I actually do not believe it is in any—I know it is in no way a deemphasis of the program. It was much more a regularizing of the function over to SAMHSA where the work was already getting done. I believe that is the case. And I will be happy to just confirm that.

Senator PORTMAN. Yes. Again, it, you know, has gone back and forth over the years. It was at DOJ for a while and HHS in terms of administering some of the actual grants, the grant-making that

goes out, as we talked about, but the direction comes from ONDCP, which has this ability to take an interagency approach. And it does involve a number of different departments and agencies ultimately, the prevention and education efforts.

So I would hope that you would take a look at that, because it is something that is actually working out there at a time when we need more help than ever.

So I thank you again for your service. My time is expired. I have a couple of other questions I am going to submit for the record. And again, I appreciate the fact that you have stepped up, and I look forward to working with you on the opioid crisis and other matters.

The CHAIRMAN. Okay. Senator Toomey?

Senator TOOMEY. Thank you, Mr. Chairman.

Secretary Azar, thank you for joining us. Good to see you again.

The administration's budget in your area, I think, strikes some constructive balances. You have emphasis in some important priority areas, like Senator Portman has alluded to: opioid abuse, research, and treatment. I do hope we will be doing more to understand the root causes of addiction as well as treatment of addiction. I think we have a long way to go there.

Also, ideas about lowering the costs of prescription drugs and continued investment in medical research generally are all good.

But I also want to commend you for addressing a huge, huge fiscal challenge that we have, which I think your budget does address, and which I am going to ask you to comment on in a moment, and that is dealing with the unsustainable spending of our entitlement programs.

I just think we cannot underscore enough that you cannot tax your way out of a problem. There is no revenue solution to Federal Government spending programs that are growing faster than our economy, as ultimately tax revenue can never, for long, grow at a rate faster than our economy.

It strikes me, it long has struck me, that one of the sensible places to begin to address this is with Medicaid, in part because it is the biggest net expenditure program in the Federal Government. There is no dedicated revenue stream, as with Social Security and Medicare.

So Medicaid has these huge, huge outlays. The growth has been staggering, right? In 1980, the Federal spending on Medicaid was 2.4 percent of our budget, half a percent of GDP. Today, it is 10 percent of our budget and 2 percentage points of GDP.

Yesterday, the CMS actuary report on national health expenditures projects that Medicaid will continue to grow at 6 percent per year—6 percent. Nobody believes that our economy is going to grow at 6 percent. So what that means is, this program is going to continue to consume an ever-greater share of Federal spending and the economy if we do not do something about it.

Well, one of the things we might consider doing about it is restructuring this program so that there are Federal caps on spending on a per-capita basis. And this, of course, is a completely bipartisan idea, first floated seriously by President Bill Clinton, supported by Donna Shalala and Howard Dean and the American Academy of Pediatrics. And at one point, every Democrat in the

United States Senate supported establishing these per-capita caps in a restructure of Medicaid.

And your budget, as I understand it, further would allow this per-capita cap to grow every year and you would tie it to a measure of inflation that we might actually be able to keep up with, the CPI-U.

And so the net effect of all that is that Medicaid spending every year would grow. Medicaid spending per beneficiary would grow. But it might just grow at a rate that we could afford, that we could keep up with.

Now, I think it is also critical that you tie this to giving States more flexibility to discover ever more efficient and effective ways to deliver services. My colleague from Rhode Island and I discussed just yesterday how many opportunities there are to encourage the development of more efficient ways to deliver health-care services.

So I am just wondering if you would elaborate a little bit on how you envision this reform idea, how it would still work for the people who need this program, as that is a necessary criterion for anything that could possibly be considered successful.

And if you would care to elaborate on how appropriate setting—I know you touched on that a moment earlier—how that might fit into this, I would welcome your thoughts.

Secretary AZAR. Well, thank you, Senator.

Actually, the President's budget goes exactly along the lines of the concerns and the solutions that you just expressed. And it adds into it, also helping to fix the concerns that we have around the individual marketplace. So it changes Medicaid to allow for these per-capita grants to the States that then they would have tremendous flexibility with to run their Medicaid program. They would have the skin in the game to run that program, but within a budget.

And it would combine money in a \$1.2-trillion program out to the States that would allow for coverage of what we currently call the Medicaid expansion folks as well as the individual markets—so money that could be used as States determine to try to create really effective mechanisms to provide affordable, flexible, tailored insurance for individuals in their State that would still have protections for pre-existing conditions, maternal care, newborn care, et cetera.

And so that is what actually, I think, is one of the really constructive aspects of this budget: putting all of those people together gives the State a real tool to create effective risk pools that can create sustainable, affordable insurance in the future.

And even core Medicaid would grow from \$400 billion to \$453 billion over 10 years. So even the core traditional Medicaid, as you said, would grow because of inflation adjustment.

So I am excited to work with Congress on this as a possible idea.

Senator TOOMEY. Thanks very much. I look forward to working with you.

Thank you, Mr. Chairman.

Senator PORTMAN [presiding]. Senator Whitehouse?

Senator WHITEHOUSE. Well, thank you, Mr. Chairman.

Senator PORTMAN. You looked lonely down there at the end of the panel.

Senator WHITEHOUSE. I know; it is a long way down here, and I am afraid Secretary Azar is going to get a crick in his neck that will require medical treatment from having to turn so far to see me. I appreciate it.

When we met in my office, I showed you, I think, one of my favorite charts, which is this one, which shows the CBO estimates for total Federal health-care expenditures. And the red line along the top was CBO's predicted total Federal health-care expenditures as of 2010.

The Affordable Care Act went into effect and time went on, and it turned out that instead of that red line, what actually happened was that green line. And then here in 2017, CBO did another forecast. So from this dot forward, the green line here is the newer forecast.

As you know from our budget process, we think in 10-year increments in the budget process. So this green area is the 10-year budget window from 2018 through 2027. And in that period, we estimate that anticipated Federal health-care spending is \$3.3 trillion lower.

Now, I do not know how that happened. And I have a terrific staff, but they are not like your staff. I think it should be a matter of urgency to try to really think hard about why that happened. And I hope that you will take a look, because if we can find \$3.3 trillion in Federal health-care savings without inflicting pain on seniors and other beneficiaries, that is a goal worth fighting for.

Now my sense of it, to go from the global scale down to local, is it has a lot to do with delivery system reform and payment reform. And I want to focus on the group that I mentioned to you, I think, also in our meeting, the Coastal Medical provider group, a primary care group in Rhode Island, which was one of the early ACOs.

In the 5 years that they have been an ACO, they have saved an average of \$558 per patient per year. And they were not high-flyers to begin with. In 2016, which is the year we have the last complete data for, they were down \$700 from their previous measure, but they were down a thousand dollars from the average. So it is not like they were one of the most expensive provider groups; they were actually doing better than average when they began, and they still saved an average of \$558 per patient per year.

And the patients could not be happier, I can tell you first-hand, because those savings came through better service and better care.

So it seems to me that if you take \$558 per patient per year and you spread that across the Federal health-care system, you start to look at numbers like \$3.3 trillion, that there is a connection perhaps between the payment reforms that empowered Coastal Medical to change their means of practice to save that money and better serve their patients and that big estimate of savings that we are seeing.

So I just want to flag that for you. We saved CMS \$28 million with what the Coastal Medical people did. Twenty-eight million dollars is not big bucks to you. You would probably have to put a "b" instead of an "m" in that. But in small Rhode Island from one provider group, to save 28 million bucks is pretty significant. And you start adding in the multipliers nationally, and I think there is a big gain here.

So I really want to work with you on this. I would urge that the more that we talk about repealing Obamacare and having those fights, fine if that is what you want to do. I do not think that is good policy. I do not think that is good for the recipients. I do not think that is good at all.

But what I do not want is for you to get so involved in that fight that you will not work on the delivery system reform piece, which I think is strongly bipartisan, is completely beside the Obamacare wars. I do not think the people who want to repeal and replace Obamacare the most want to go back and repeal and replace the ACOs. They would have an explosion from their home-State doctors and providers if they tried. So I think this is a safe bipartisan place where real progress can be made.

And I just want to take my time with you today to urge that. And we are counting on a visit from you at some point to meet Dr. Kurose and his Coastal Medical team up in Rhode Island. We have other primary care physicians who are producing similar results. And there is a lot of excitement and satisfaction around that.

Secretary AZAR. Well, if I could say, I totally agree about the need for the value-based transformation. I think it is a bipartisan issue that we can improve quality, we can decrease costs, and we can make all of our programs more sustainable the more we can do that.

Senator WHITEHOUSE. And I will just give you fair warning, but I am going to be harassing your folks at the staff level for more information out of, like, the MACRA program, the MIPS program, the Center for Medicare and Medicaid Innovation, all those things. So I hope I will get good answers to my questions.

Thank you.

Senator PORTMAN. Senator Cantwell?

Senator CANTWELL. Thank you.

Welcome, Secretary Azar.

You mentioned GME in the discussion with our colleagues. How would the proposal encourage medical training in community clinics where most physicians actually care for patients? And how would it help the community clinics that are not under the current cap?

Secretary AZAR. So in terms of the—is this the community health center program on GME that you are referring to, Senator?

Senator CANTWELL. Your proposal to change the structure, so I am just trying to understand how would it address a couple of things that are in the need area—

Secretary Azar. Right.

Senator CANTWELL [continuing]. Which is community-based clinic training and teaching hospitals that are not under the current cap program.

Secretary AZAR. So we are not proposing a change to the community health center-based training programs that we have. Those are separate. These are the Medicare, Medicaid, and then the HRSA-run children's hospital programs on GME. And it puts those together so that we do not operate under these artificial 1996-based caps and instead can really focus on the providers that can help train our physicians and get them to both make sure we are fund-

ing in the underserved specialties and areas where we need physicians the most to make—

Senator CANTWELL. Including primary care.

Secretary AZAR. Absolutely, absolutely, as well as underserved areas. How can we make sure that we are dedicating the money to get training to physicians that are or will serve in areas that are lacking in appropriate physician care.

Senator CANTWELL. Okay. So if you are saying you are willing to take on the big behemoth of east coast teaching institutions having most of the capacity, I am all with you, okay? Because I think with the divergence of medicine and where we are going, we need to train physicians in all sorts of ways. So I am all for that.

I do not like the fact that you have actually then cut the program. Because from my estimation and what I see in the Pacific Northwest and our shortage and the whole notion of everybody having a medical home—and we are very excited about P4 medicine, you know, predictive, preventive, personalized, participatory, so that physicians are being trained on what you would, I hope, describe as a way to drive value into the system and get off of fee-for-service.

So what about that number? Why cut the program when I am pretty sure we need probably, like, four or five times that amount?

Secretary AZAR. Well, overall, one of the philosophies that we had was to try to move some of our programs, where right now we are having Medicare carry the burden across the whole health-care profession. As we looked at how can we make Medicare be more sustainable, you know, our proposals actually stretch out the life of the program for another 8 years as a result of it. And they are tough choices, I will admit that.

But right now, we are having Medicare and Medicaid fund graduate medical education that private insurers, commercial people get the benefit of. And so there is a bit of recalibrating in there, from the Federal taxpayer perspective and Medicare and Medicaid, that transition to cut that back a bit. As a result, I think it is \$48 billion off of where we stand right now over 10 years.

Senator CANTWELL. But if we examined the shortage and the need, you would not cry if Congress basically boosted that number.

Secretary AZAR. I would have to do so within our budget targets. So if that goes up, something else has to go down. That is the age-old challenge of these budgets.

Senator CANTWELL. Okay. Well, please mark me down as very counter to what Senator Toomey just said.

I believe that we have a growth in our Medicare and Medicaid population because we have a burgeoning baby boomer population that is reaching retirement. So the notion that somehow people think that you should cut Medicaid and Medicare or block-grant Medicaid as a way to save dollars just because the population is growing, because of the demographics in our population, I just think is wrongheaded.

Now, do I think there are efficiencies? You and I have had a chance to talk about rebalancing as one of those. That is a huge, huge savings. But the notion that somebody, after giving away billions of dollars in tax breaks to big corporations, would want to come here and say, now we have to block-grant Medicaid as the

only solution because it is growing in numbers because of demographics is just—I just do not agree with it. As my providers have told me—hospitals—they view the block-granting proposal as nothing but a budget mechanism to cut Medicaid.

So what they do support are the efficiencies that we are driving in the Northwest and implementing those in the system. You know, who doesn't want to stay at home and get long-term care, as my colleague just mentioned? Who doesn't want to do that? That is one-third the cost.

And so, if you could, comment on rebalancing from nursing home care to community-based care as a big savings.

Secretary AZAR. For some individuals, institutional nursing home care meets their needs and is what they need. But I am, as I said at my confirmation hearings, a firm supporter of the notion of home-based care and these alternative ways that I believe can save us money.

I believe that for many it can be the best solution. It can be the way to age with dignity. So I am very supportive and very much want to work with you on ways we can generalize that more across the United States.

Senator CANTWELL. Well, I appreciate that. I am just very concerned about some of my colleagues. We have been very suspicious that this is what might happen now after the tax bill passed, that people are going to go back to trying to block-grant Medicaid. And just mark me down as very opposed.

And basically, a much better—we are already doing the job. We are already doing the job of reducing the costs. So the notion that somebody wants to create a budget mechanism to cut people off Medicaid, my providers—the community services, the children's hospitals—they are just not going to support it.

Thank you, Mr. Chairman.

Senator PORTMAN. Senator Nelson?

Senator NELSON. Mr. Chairman, thank you for the kind comments of several of you with regard to the slaughter of 17 students and teachers.

And Senator Rubio and I will be addressing this issue on the floor of the Senate at noon today.

Mr. Secretary, I want you to know that you are a very prepared individual. You are a fine person.

When you were here on your confirmation hearing, I asked you several questions about Medicaid and Medicare. And you sidestepped the questions about cuts. And now, coming forth just a few weeks later with the budget, sure enough you have about \$1.4 trillion over 10 years in cuts to Medicaid. And that is going to shift costs to the States, and the States will have to plug the holes by raising taxes or cutting other parts of the budget that they are responsible for, like education.

A State alternatively could choose to cut Medicaid benefits or drop people from the program or cut payments to providers.

How would you expect a State, like Florida, that has a big population to afford to cover the higher cost, Mr. Secretary?

Secretary AZAR. So on Medicare, one thing that I would want to emphasize is, you know, we are proposing to Congress to make some changes there in how we do various payments to providers.

We are actually not suggesting changes that would impact the beneficiary. The only ones that we have that would impact beneficiaries are around drug pricing that we think would have a very positive effect for beneficiaries in terms of their out-of-pocket spending.

What we do is, the net change to Medicare that we propose, it is \$250 billion over 10 years, which is about a 2.8-percent reduction. But just to give a sense of perspective, that takes Medicare, which is growing at a 9.1-percent annual rate of growth over that 10-year period, and changes that to an 8.5-percent rate of growth.

Senator NELSON. Now, you are talking about Medicare.

Secretary AZAR. Yes, in Medicare.

Senator NELSON. Well, my question was Medicaid. My question was Medicaid.

Well, let me ask you then on Medicaid—for example, veterans rely on Medicaid. Seventy percent of seniors in nursing homes rely on Medicaid in Florida. So capping Medicaid benefits could lead to States cutting these veterans' benefits and the seniors'. What do you say to that?

Secretary AZAR. Well, we believe that States are in the best position to decide how to use the money to allocate among various populations.

So for instance, the core Medicaid continues and actually grows from \$400 billion to \$453 billion over the 10-year period. And then we replace the Medicaid expansion and the Affordable Care Act individual markets program with a \$1.2-trillion grant out to States that is very flexible, that actually, on the expansion population, the States then do not have that 10 percent of copayment Federal matching that they would have to come up with to do that. So it actually gives them flexibility, and it is sort of found money for them in that sense.

Senator NELSON. That is what is typically the case with a block-grant program or turning it over to the States.

My State is subject to hurricanes. Puerto Rico is subject to hurricanes. We saw what has happened with Medicaid. It has to respond to a public health emergency in a natural disaster. And if your response is that, oh, further Medicaid funding would be provided after a hurricane, the fact is that Congress waited nearly 5 months before passing disaster aid for hurricane victims in Florida—5 months—and 32 months after Flint, Michigan's lead poisoning.

I know what your answer is—you have provided it—and we have a significant difference of opinion.

Let me ask you this specific question. States faced \$1.3 billion in higher Medicaid drug costs with the introduction of the then-new hepatitis C drug Sovaldi in 2014. By cutting Medicaid, are you suggesting that States should not cover these kind of breakthrough treatments that cure chronic conditions and come with high costs?

Secretary AZAR. Absolutely not. In fact, the Sovaldi case is a really good example of how all of our payment systems are really not equipped to deal with what we would call curative therapies. And that is an area I would look forward to working with you and the committee on.

Our payment systems just cannot handle the notion of a high-cost drug that we would pay for but get the benefit then over the

course of somebody's entire lifetime, from a single year's expenditure. We need to be creative and we have to think about ways all of our programs, including the commercial marketplace, can handle, in the future, products like that.

Senator NELSON. Mr. Chairman, in closing I just want to point out that in a growth State like your State, especially my State that is growing at a thousand people a day, where we educate the doctors and then we do not have the residency programs, they end up going and doing their residency outside of the State of Florida, and they usually stay and practice there. And yet we have borne the cost of educating them.

And when you start cutting \$48 billion over 10 years to the graduate medical education payments, it is going to severely hurt a State like ours that is a growth State that desperately needs those residency programs to keep our doctors.

Senator SCOTT [presiding]. Senator Casey?

Senator CASEY. Thank you, Mr. Chairman.

Mr. Secretary, good to be with you. I guess you have been on the job about a month.

Secretary AZAR. Fourteen days.

Senator CASEY. Fourteen days; okay, less than a month. We are grateful you are here.

And you and I have had discussions before, and certainly in this setting about Medicaid. Our approaches to it differ, so I want to raise it with you in the context not just of the program, but also what I believe the administration has been trying to do with regard to Medicaid, and secondly some kind of Pennsylvania-specific challenges.

When I think about the program, both the core Medicaid and then the expansion, I try to think about it in terms of the people who are impacted.

In our State—there are lots of ways to describe it, but more than 2 million people are covered. But also, you could think about it with three numbers: 40, 50, 60. Forty percent of the children in Pennsylvania, 50 percent of individuals with disabilities in our State, and 60 percent of individuals who are in fact nursing home residents. So that is, as you can tell, a big, big number—or three big numbers.

In our State, we have 48 rural counties out of 67. And just in those rural counties, 180,000 people got the benefit of Medicaid expansion for their health care.

And then another way of looking at it is the horror, which you know well—the horror of the opioid epidemic and the overdoses that come with that as well as related overdoses. Just in Pennsylvania, when we look at it between 2015 and 2016, the overdose death rate is up some 37 percent. It is higher actually, in the low 40s, I guess, for rural areas.

You are a native; you have roots in Cambria County. That is one of those counties, among many, not among a few, where the overdose death rate has gone way up: 94 deaths just in Cambria County in 2016.

So I raise all that because Medicaid is critically important to our State. It is especially important, the Medicaid expansion part of the

story, to deal with the opioid crisis, because it is basically the number-one payer for those who need treatment and services.

My real concern is twofold. Number one is that the administration, I believe, in a little more than a year now, has been sabotaging the Affordable Care Act, taking administrative actions, doing everything it can to undermine the Affordable Care Act in the absence of getting full repeal by way of legislation. I would hope that you would put an end to that.

And then secondly, there appears to be an effort in the budget to use the budget process over time not only to cut Medicaid dramatically, but to end the Medicaid expansion.

So I would ask you two questions. Number one is, will you commit to ending the sabotage through the efforts of an agency like yours?

And secondly, tell us about the impact of the budget on Medicaid and, in particular, Medicaid expansion.

Secretary AZAR. Yes, thank you, Senator.

On the first point, as we have talked about before, you have my commitment that I and my department will work to make health insurance as affordable as possible, have as much choice for people and meet their needs as much as we can, and do so faithfully within the law of whatever programs we have.

I am about making our programs work as best they can. And I can tell you, the team around me has that same commitment to do so.

Now, you and I will often disagree ideologically about what might work and what will not work, our understanding about economics or insurance benefits and how they will function. Our desire is the same. I want as many people as possible, as do you, to have access to affordable health insurance and to help those who cannot afford it get access within our fiscal constraints. So I think we certainly share those goals.

On the second point of Medicaid—

Senator CASEY. Just parenthetically to add, I hope your goal also would be that no one loses coverage who is covered by Medicaid now.

Secretary AZAR. So our goal is to make sure people have access to affordable insurance and that they have a choice of those packages.

On Medicaid, you actually mentioned some populations that I do care a lot about—and we care about all—but children, the disabled, the elderly in nursing homes. One of the really odd incentives of the way the expansion was done is, it created a perverse incentive, because of the differential matching from the Federal Government, to actually prioritize the expansion to able-bodied, new-entry populations, over those traditional Medicaid populations.

So I am actually concerned, and I hope that, through our proposals and our work together, we can reorient Medicaid to fix a lot of those counter-incentives there that are in what we might call the traditional Medicaid populations. So I do worry about that group.

Senator CASEY. Well, I just hope that we are not at a point where we are talking about access, that we are talking about ensuring that people covered by Medicaid do not lose it, all those

folks who have a disability, all the children, all the folks in nursing homes.

Let me just, Mr. Chairman, with your indulgence, have one more minute.

You probably have not seen this yet because it was just sent yesterday, but I have a letter that I have sent you about what States are applying for in their waivers. I will just read one sentence from the letter I sent you. I hope you will take a close look at this and provide a response.

At the end of the first paragraph, I say, "I urge you to reject Medicaid waiver applications from States that would further three things: limit, restrict, or block Americans' guaranteed access to affordable coverage."

So I just hope you take a close look at that and provide a response.

Secretary AZAR. I will. Thank you.

Senator CASEY. Thank you.

Senator CASSIDY [presiding]. Hi, Mr. Azar.

You know, as one of the authors of Graham-Cassidy—I was not intending to, but I will at least open up with some comments regarding that.

And as I have heard some of my Democratic colleagues speak to this, it becomes clear that what I suspected is true, that they really do not understand the legislation. Because what we have been speaking to, Graham-Cassidy addressed.

For example, one of my colleagues said that there has been a problem after natural disasters, that there were not dollars made immediately available for Medicaid for those who were impoverished because of the disaster. And of course, under Graham-Cassidy, we have either every 3 or 6 months a registration in which the State would say, hey, these people are now eligible so, therefore, we get money for them. And they would get money on a risk-adjusted, per-person enrollment. And so indeed, the State only gets money if they enroll somebody, aligning the incentive to enroll.

It acknowledges something, which I have to say I was a little surprised others are now acknowledging who were in the Obama administration, which is that the status quo is not working.

I just got an email from Bill Frist, if you will, one of those emails everyone gets, the United States of Care, which is a group of people including Andy Slavitt, Melanie Bella, Pat Conway, Tom Daschle, a constellation of Democrats who were concerned with or in the Obama administration—either nominated or who actually served—saying that the status quo is not working.

So it is interesting, people are defending a status quo which is not working. And I would digress just a minute more to speak about how it is not.

One, States in the individual market, if they are not getting a subsidy, can no longer afford insurance. Folks in Louisiana are paying as much as \$40,000 a year for premiums. Get that, \$40,000 a year. Now, people like Andy Slavitt and Melanie Bella are acknowledging that, but some folks up here are not. This is not sustainable.

It is not sustainable for States. Oregon is having to pass new taxes in order to pay for the State's share of Medicaid expansion. I heard one person say who opposed it, she said, hmm, we are excluding unions, but we are taxing individuals and small businesses. They are the only ones without lobbyists. And so those without lobbyists will pay the tax for everyone else. Oregon is having to pass new taxes to afford the Medicaid expansion.

So what Graham-Cassidy did is, it told States that if you cannot afford the match, you do not have to put it up.

One other thing I will note. Senator Nelson from Florida was concerned about the impact on his State. Under Graham-Cassidy, Florida would have gotten \$15 billion more than under current law to care for those who are poor or poorly insured in their State.

Why somebody would oppose—as a doctor who took care of the uninsured for 25 years, why somebody would oppose \$15 billion more over 10 years to care for the poorly insured in their State, I have no clue, no clue whatsoever, except a dogged determination to support the status quo.

That said, now I will get to my question.

I had an intriguing conversation yesterday—I do not know if it is true, but I would like your thoughts—that Medicaid best price actually drives up the cost of medicines for everybody else. Medicaid best price was put into place—only one out of 11 Americans was covered by Medicaid, but now one out of four Americans are.

By the way, this is not because of demographics, as suggested earlier, because this is not age-based. It is rather because of an expansion of Medicaid under Obamacare.

And just one-quarter of the population getting the best price has a hydraulic effect, which, sure, if you lower the price here—it does for Medicaid, but in turn, it raises the costs for everybody else.

What are your thoughts about that?

Secretary AZAR. Senator, I think that is a very perceptive observation. And I think it is something that we have to be careful of, not just when we talk about drug pricing, but when we talk about our hospital physician services.

With Medicare and Medicaid, if we end up underpaying what sort of natural market forces would lead to, we will see higher rates in the commercial space, for instance, and we end up having this, it is called the cross-subsidization problem, with Medicare and Medicaid.

Senator CASSIDY. I get that. Specifically on drug costs, though—because that was obviously a major emphasis of the Obama administration—does Medicaid pricing increase that cost?

Secretary AZAR. If we underpay in Medicaid, it will increase costs elsewhere; it will increase pricing elsewhere.

Senator CASSIDY. Then let me ask you one more thing. Related to that, I was also told some States have carved out the pharmacy benefit from their managed-care contracts, and carving out that allows them to get the rebates. And they are preferentially going to name-brand drugs, the higher-priced drug, because it increases their rebate. As long as the Federal taxpayer is paying 90 percent in the Medicaid expansion, it is a good deal for them. Sure, it increases what the Federal taxpayer pays, but the State gets more in rebate. Have you observed that?

Secretary AZAR. I have seen that on the carve-outs. And there is a bit of a perverse incentive in the Medicaid system to carry branded drugs because the rebates are so high compared to generic drugs. And so from the program perspective, it can actually be beneficial to the State Medicaid program to receive the branded rebate as opposed to paying the reimbursement to the pharmacy, which is acquiring a generic drug at quite a low price. It is an oddity in the system.

Senator CASSIDY. So we have misaligned incentives, do we not?

Secretary AZAR. Yes. We need to work on that.

Senator CASSIDY. Yes, and what I will say, as I close, is that Graham-Cassidy aligns incentives. It does not incentivize States to do that sort of trickery, to hose, if you will, the Federal taxpayer in order to make money for the general fund of the State, but frankly, ultimately driving up costs for everybody else.

Thank you. I may have a second round.

Senator Stabenow?

Senator STABENOW. Well, thank you very much, Mr. Chairman.

I do not know where to start. I greatly respect my colleague who just spoke. We have such a different view of the world in terms of health care. You know, it is not a commodity; I think it ought to be a basic human right. We all get sick. It is not like the way you can choose to buy a car or not buy a car. And I would love everybody to buy a new car made in Michigan, but if you do not, you know, it is not going to affect everybody else's rates going up and so on. But health care is just very different, because we are all human and we all get sick.

So let me just say one other thing I had not originally intended, which is when folks say "status quo" now, this is the new status quo under the Trump administration where there are no cost-sharing payments, no reinsurance, no requirements that people share in their own health care in terms of responsibility.

So we are back to junk plans, people buying insurance that may not cover basics and they do not know it until they get sick, and folks walking into emergency rooms without insurance and everybody else is going to pay for it. That is what we called uncompensated care. That is what it used to be.

Because of the Affordable Care Act and people being involved and responsible in terms of being able to pay for their health insurance, the State of Michigan actually saved hundreds of millions of dollars last year, and group market rates were flattened for a lot of small businesses in Michigan, and so on.

So a very different view of the world; I look forward to debating that as we go on.

I do want to start with something, though, a positive that I have seen in the budget. A lot of things I disagree with certainly, certainly as it relates to the view on Medicaid and what that means for seniors and families and children in Michigan when we see these kinds of cuts.

But part of the recent budget agreement, the caps agreement, included a much-needed \$6-billion investment over 2 years in combating the opioid crisis and mental illness, which is a major focus for me and has been.

And I want to acknowledge the fact that in the budget, the HHS budget actually recommends expanding what Senator Blunt and I have been working on as certified behavioral health clinics and being able to do with behavioral health what we have done for health centers.

And so, one of my big frustrations has been the fact that we literally pay for service, we pay providers that provide physical health care, but for mental health or addiction services we do something we would never do, which is, you know, we provide service until the grant runs out.

So I cannot imagine, if somebody needs heart surgery, that the doctor would say, gosh, I would love to provide your surgery, but the grant ran out. And we do that every day for mental illness and opioid addiction.

And we know this is part of multiple things that need to happen around violence and even what we saw yesterday. So this is, I believe, an all-hands-on-deck moment.

So I want to first say that I appreciate that that is in the budget, that we have begun. Eight States have been fully funded as demonstrations across the country: Minnesota, Missouri, New Jersey, New York, Nevada, Oklahoma, Oregon, and Pennsylvania. We are working to expand that.

I would like very much to work with you as we move forward to expand comprehensive services in the community, including 24-hour psychiatric services and facilities so people are not going either to the emergency room or to the jail, which is exactly what is happening for folks right now. So I look forward to working with you on that.

I am concerned, though, that if we go on to talk about opioids and mental health, that when we look at the change, the cuts in Medicaid, this time about \$1.4 trillion—and we can talk about grants again, I mean the sort of big grants rather than small grants—I am very concerned that the Medicaid cuts would really make it more difficult for us in Michigan and across the country to fight the opioid crisis as well as expand what we need to do in mental health.

In fact, expanding what we call Healthy Michigan—if we were to end Healthy Michigan, the addiction treatment gap would increase by 50 percent. And substance abuse disorders and mental health funding would be cut over \$5 billion across the country.

So has HHS modeled the effect of the Medicaid cuts on individuals with substance abuse or mental health disorders?

Secretary AZAR. Not to my knowledge, but certainly the points you raise are important concerns that we would want to work with in any legislative package around Medicaid reform, obviously ensuring that what we are doing there provides adequate resourcing around substance abuse treatment.

Senator STABENOW. Do you believe that mental health and substance abuse treatments should be included in all health-care plans?

Secretary AZAR. I believe so, but I think mental health—I think our mental health parity requirements would provide that. I would need to look at the statutes, but I believe that is part of that.

Senator STABENOW. We do have mental health parity; I authored the language in the ACA to make sure that this was included in everything, because it had not been happening up until then. And so it is part of the essential benefits package that would, as I understand it, be eliminated under the kind of approach, the large block-grant approach, that is being talked about. So I am very concerned about that.

What would you suggest, I mean, if people lose coverage under the budget? If these Medicaid cuts go through, what would you recommend to the State of Michigan and those right now who desperately need services?

Secretary AZAR. So of course, the challenge we have now is that, for 28 million Americans, what we have is simply not affordable for them. As Senator Cassidy was speaking about earlier, the status quo is leaving tens of millions out through unaffordable options.

So we want to work together to try to see, what can we do to build stable, good, affordable, flexible, tailored options for individuals out there? Because that status quo is not working for as many people as it ought to.

Senator STABENOW. And I would just close, Mr. Chairman, by saying it has been a year and a half under a new administration with a very aggressive approach, some would say a war, on health care, and multiple changes that are raising costs. And so the status quo today is a new status quo based on actions that have been done and ramifications that will continue to be felt as new insurance rates come out based on what has been done as part of the tax bill as well as other decisions to roll back efforts to keep health care affordable.

And I do want to say also, at some point we can debate how Medicaid pricing is the reason drug companies are dramatically raising their prices. If that was part of what you were saying in terms of the pricing, I would have major concerns about that.

Secretary AZAR. I certainly did not mean to say that that is the reason. Certainly, it is an economic incentive. And what we have to do in addressing drug pricing is, how do we flip those incentives around across the board?

Senator STABENOW. I understand.

Thank you, Mr. Chairman.

Senator CASSIDY. Yes.

Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman.

Mr. Secretary, welcome.

In New Jersey, one in 41 children is diagnosed as having autism spectrum disorder, much higher than the national average of one in 68. Is it true that the fiscal year 2019 budget zeroes out a program that is of great interest to those in the autism community, the Autism CARES Act program in HRSA?

Secretary AZAR. I do not know that program in particular, Senator. As you know, I am 14 days into this. And so I know we have several programs that, as part of just prioritizing direct-care delivery, direct-service delivery and underserved care-service delivery, there are programs that simply we had to recommend not funding because of the tradeoffs—

Senator MENENDEZ. Well, let me help you out. You may be on the job only 14 days. I have been here a little longer. It is zero in the budget.

And in fiscal year 2018, the congressional justification was that the Department believed that the same services could be provided to the States through the Maternal and Child Health Services Block Grant. Do you know if that is the same reasoning today?

Secretary AZAR. As I said, the challenge that we have is, we are prioritizing direct-care service delivery, not—

Senator MENENDEZ. I am asking a specific question. Is it your view that the congressional justification in fiscal year 2018 that the services can be provided by States through the Maternal and Child Health Services Block Grant is the reason that you have zero in this budget?

Secretary AZAR. No. I do not know if that is the reason why the budget was prepared with that program zeroed out. It more likely is the fact that if it is not a direct-care service delivery program or was viewed as being less effective than other expenditures of money in a scarce fiscal environment, tough choices had to be made.

Senator MENENDEZ. Well, yes. The autism community does not need those tough choices. They have a tough life as it is already, with their children who are trying to fulfill their God-given capabilities and families that are enormously challenged with that reality.

Well, I have a feeling that that is the justification. The problem with that is that you also cut funding for the Maternal and Child Health Services Block Grants as well. So I do not know how—explain to me how you think that States are best positioned to replace the education, training, and research authorized by the Autism CARES Act with reduced funding for the programs that you claim replicate HRSA's progress?

Secretary AZAR. I did not claim that. What I have told you is that we prioritized our direct care-delivery programs, and these programs that are back-door support programs we had to deprioritize against others or those direct service-delivery programs would have been cut.

Senator MENENDEZ. I can assure you, Mr. Secretary, they are not back-door to these communities; they are front-door.

Secretary AZAR. No, but it is actual direct care, providing clinical care and service to individuals, is what we had to prioritize in the budget to—

Senator MENENDEZ. Well, let me ask you something. How is it when I wrote QFRs in your confirmation, I specifically asked you about working with me on reauthorizing the Autism CARES Act and you provided a vague answer saying you were fully committed to implementing the laws passed by Congress and improving access in disadvantaged communities. That was your answer.

So explain to me, how does zero-out funding to implement a law passed by Congress and signed into law by the President allow you to do that?

Secretary AZAR. In a budget—you are a member of the Senate and part of setting the targets that we have to operate within. And

we operate within that and have to propose a budget. If you have a tradeoff of another program you are willing to defund—

Senator MENENDEZ. You are not fulfilling the law. The law is clear.

Secretary AZAR. There is not limitless money, Senator. I am sorry.

Senator MENENDEZ. I know. That is why we should not have spent \$1.5 trillion on tax cuts to the wealthiest people in this country. Maybe we would not be having this debate now. And maybe we would not be having this debate if we were not spending tons of money in other things outside of our health-care system.

But it is simply inexcusable to take a community that is so challenged, that the law specifically directs the Department to engage in, and then you zero that out. And how do you think eliminating the Medicaid disproportionate share payments at the same time you strip Medicaid funding to States—are hospitals going to be able to deal with that?

Secretary AZAR. That is a continuation of the Medicare disproportionate share hospital payment reductions that are part of the Affordable Care Act. And we continue to scale down there as we have many other programs.

Senator MENENDEZ. It is not a scale-down, it is an elimination.

Secretary AZAR. And we will be putting out \$1.2 trillion in the budget of the America's Health Care Grant program so that we have alternative insurance vehicles that should be the alternative, as with the Affordable Care Act, to disproportionate share hospital subsidies.

Senator MENENDEZ. Mr. Secretary, it is not a scaling down. It is an elimination—elimination, zero, cero, nada. That is not a scaling down. And I expect you to enforce the law. And the law on autism is very clear. And I am going to challenge this administration to respect the law and enforce it.

Thank you, Mr. Chairman.

Senator CASSIDY. Senator Brown?

Senator BROWN. Thanks, Mr. Chairman.

Mr. Secretary, welcome.

I concur with Senator Menendez and what he is saying about the trillion-and-a-half-dollar tax cut, and then how you are just taking away so much for so many people who are a whole lot less privileged than CEOs and Cabinet Secretaries and members of the Senate, starting about January 20th a year ago, going after the health care law.

And you know, I mean the Republican approach of this Congress has been to increase the deficit by billions of dollars. You know, this is the party that cares so much about deficits when there are Democratic Presidents, but not so much now—tax relief to the richest individuals, and then you cut programs that millions of working families rely on to pay for those tax cuts. I mean, it is just morally reprehensible. I would assume you think the same thing.

A few months ago, Mr. Secretary, the first lady and Kellyanne Conway visited a facility in West Virginia, Lily's Place, which provides treatment for babies born with neonatal abstinence syndrome. We have a similar facility in Kettering, OH right outside Dayton called Brigid's Path that is focused on keeping families to-

gether and helping both moms and babies overcome addiction and withdrawal.

I introduced a bill last year with a number of members of this committee, including my colleague from Ohio, called the CRIB Act. Our legislation would provide State Medicaid programs with flexibility to reimburse residential pediatric recovery facilities like Brigid's Path.

I understand yesterday you all announced it is approved, you have approved reimbursement for this type of residential treatment service in West Virginia. We should not have to do this State by State. I would like to ask for your commitment, Mr. Secretary, to ensure that babies in Ohio in a place like Kettering have the same opportunities as those in West Virginia, whether it be through administrative action or through helping the five of us pass the CRIB Act. Would you commit to doing that?

Secretary AZAR. Senator, I do not know that particular waiver approval, but I am happy to work with you and Governor Kasich if that is a request that they have, to make sure it goes through our process as expeditiously as possible if it complies with our waiver requirements. Absolutely, it seems a very noble purpose to me.

Senator BROWN. Okay, thank you.

Another issue. I appreciate the efforts you have put in to proposing some initiatives that would help lower the cost of prescription drugs in Medicare and Medicaid as part of this year's budget proposal. Some of them I agree with and support.

Can you, as you do this, point to a single proposal in this budget that would force a pharmaceutical company to lower the list price of a drug in a way where all Americans who rely on that drug will benefit?

Secretary AZAR. So actually, one of the things we are trying to do in the budget proposal is to create the incentives so that it will put downward pressure on the list price of drugs. So one of the things that we are recommending, in that catastrophic coverage in Part D, is changing the incentive structure.

Right now, the government is on the hook for most of the cost once a senior citizen gets to catastrophic coverage. We propose to progressively switch that so that the insurer is on the hook for that and will then have even more incentive to fight against the branded drug companies to keep those list prices down, as opposed to now where they have a lot of incentive for those higher prices, to just drive into the catastrophic coverage and offload that expense onto us. So that is certainly one of them.

And this is just one step in working on the issue of drug pricing. And this is the one that is in the context of the budget and Medicare and Medicaid, many more things that we are working on. And if you have ideas around list price, ways that we can reverse those incentives on list, I would love to work with you and hear them, because it is the most difficult challenge as opposed to even net pricing.

Senator BROWN. And I appreciate that, but it sounds to me like relying on a middleman here—and none of these policies actually goes after the pharmaceutical industry, your former employers, the folks who set these prices in the first place. None of these policies

guarantees—I understand you work with insurance companies to sort of incent them to push, but none of these policies guarantees lower drug prices for individuals who rely on drugs like insulin, who are not insured by Medicare or Medicaid. Nothing that we can see so far will help individuals who pay for drugs out of pocket and cannot benefit from a rebate policy.

It seems the administration—an administration that promised that it would make the drug companies pay, until the President met with the drug company executives and came out singing a very different song as he met with his CEO friends—left out of its budget proposal any policy that would directly target big pharma and hold them responsible for the prices they set.

Rely on insurance companies, to be sure, but we need to do better. We are ready to partner with the President. I note Ranking Member Wyden from Oregon is willing to do that, to go after pharmaceutical companies in ways that will not reduce patient choice. I hope you will take us up on our willingness and join us.

Secretary AZAR. Well, I hope I will have the chance to meet with you to brief you on our budget proposals, because in fact there is a suite of proposals here that will dramatically reduce senior citizens' out-of-pocket costs, which I would be happy to walk you through.

In addition, in Part B, we are proposing an inflation cap on list prices. So if you increase the price above inflation, just like in Medicaid, the pharma company, there will be lower reimbursement paid out through our Medicare Part B program. But we have a whole suite that we believe will dramatically reduce senior citizens' out-of-pocket costs when they walk into the pharmacy for medicines and get their Part D drugs, which are the physician-administered drugs.

And I would love to brief you and talk with you about that, because I am quite proud—I think there is a lot that you actually could get behind on this.

Senator BROWN. That is good news, but that is Medicare. What about everyone else? So we have lots to do.

Senator CASSIDY. Senator Thune?

Senator THUNE. Thank you, Mr. Chairman.

Mr. Secretary, thank you for being here today. I appreciate the priorities you have laid out in the President's budget, particularly the emphasis on addressing drug prices, opioids, and reducing regulatory burdens.

And while it is not the jurisdiction of this committee, I also want to point out that I appreciate the attention to the Indian Health Service in your written testimony today.

And on that topic, it was great to see the proposed 8-percent increase in funding for IHS and resources to help facilities in the Great Plains area meet CMS's quality and accreditation standards.

However, as I have said before, money alone cannot solve those problems. And one thing I had hoped to see included in the budget was a legislative proposal signaling the administration's interest in working to reform the IHS structurally, like the Restoring Accountability in the IHS Act that we have discussed previously.

So my question is, is that legislative solution something that the administration will continue to work with us on?

Secretary AZAR. We will certainly work with you on that. I have not been able to get deep into it yet myself, but I am happy to work with you on that, Senator.

Senator THUNE. Thank you.

As you recall, we talked at your confirmation hearing about the pending interim final rule regarding the application of competitive bidding rates in non-competitively bid areas for durable medical equipment. And I realize you have only been sworn in for a couple weeks, so I get that.

But I wanted to ask you to please provide a status update on when that rule will be finalized and whether the President's budget proposal on competitive bidding, which projects more than \$6 billion in savings, takes that rule into account.

Secretary AZAR. I will be happy to do that. The proposal that we have in the budget, I hope is sensitive to the concerns. I am very focused on the concern of rural providers' and rural citizens' access to durable medical equipment. And so the proposal we have would have the DME bidding be targeted towards the area in which it is bid, so rural, and also so that the winners get compensated at what their bid was as opposed to being pulled down to a median if you happen to win and be entered into the process.

But I am concerned about access and affordability in rural areas through the DME program. So I hope that, as we work on legislative approaches here, that we can solve that problem.

Senator THUNE. Okay, good. Well, that is what we like. The issues you talked about are where we would like to see you focus with respect to that issue.

While it was listed as having no budget impact, I am encouraged by CMS's proposal to reduce reporting burdens and eliminate low-value metrics of meaningful use.

I do think that there will be a positive impact on health-care providers. And I have been working with others here on the Finance Committee to address these challenges for many years.

In fact, one of the provisions to eliminate the requirement for meaningful use standards to become more stringent over time was just signed into law as part of the budget deal. Is this change incorporated into your budget proposal? And what other reforms do you expect to make in this space?

Secretary AZAR. Senator, I do not know if the most recent change on meaningful use has made it in. The budget is a rather fast-moving target, so I do not know if that was fully integrated yet into that.

But the other aspect that you mentioned I am very proud of, which is for physicians who are being paid under MACRA, the incentive program for quality, what we are doing is taking a whole host of physicians who not only will have reduced reporting burdens, but maybe none under the MIPS part of that program, where we would be able to independently look at data ourselves to decide their compliance with the quality programs rather than their having to even report anything. So I think it is one of many significant regulatory burden relief efforts that Administrator Seema Verma has been taking charge of.

Senator THUNE. Okay. And so with respect to that as sort of a follow-on, could you speak to or at least address the sort of current

all-or-nothing approach to meaningful use? You kind of spoke to that a little bit in your answer.

Secretary AZAR. Yes. So I want to delve more into the current status of where we stand on meaningful use. For me, the important thing is becoming not so much meaningful use but actual interoperability. And it is not going to do us a lot of good if we have everybody electrified and have simply converted our records to electric format if they do not actually communicate with each other.

Senator THUNE. Right.

Secretary AZAR. So my energies and focus are, how do we now get those connected to each other? But I will be happy to get back to you, if that is okay, on your meaningful use question. I just want to make sure I answer that accurately for you.

Senator THUNE. Got it. Okay. Thank you. We will look forward to continuing to work with you on that and with your team.

Mr. Chairman, thank you.

Senator CASSIDY. Senator Scott?

Senator SCOTT. Thank you, Mr. Secretary. Thank you for being here this morning.

I know that you have had a number of questions on opioids and the abuse and the challenges that we face as a Nation. And I will ask you another question that you may have answered in a different way before.

The last time you and I had an opportunity to discuss opioids was at your first hearing. Congratulations and condolences as well.

We talked about the importance of addressing the growing opioid abuse epidemic from the bottom up, from the local level.

In South Carolina, Horry County is a place where a lot of folks come to vacation, the Myrtle Beach area, but it is also the place where we have seen the highest opioid-related overdoses in the State. More than a hundred folks have lost their lives in Horry County, accounting for 16 percent of the State's challenges on the opioid epidemic front.

In your response to my questions on the crisis, you mentioned that there is not a one-size-fits-all approach to opioid treatment and prevention programs. How does your department plan to use the \$6 billion to customize and to create more flexibility for local jurisdictions to play a more important role in addressing the challenges that we see?

Secretary AZAR. So just by way of example, the \$3 billion initially that we have allocated in the 2019 funding that we are proposing, we would have \$1 billion in grants under the State Targeted Response grant program, which is very flexible for the States to be able to customize and target that money. That is a doubling of the current funding of \$500 million a year.

So that is very flexible, and so the State of South Carolina, for instance, could really work with communities on coming up with community-based, very customized approaches.

Another program that we are really interested in is, at HRSA we are going to be investing \$150 million in rural substance abuse programs to try to develop novel methods of care and of treatment for addiction and dependence in more rural communities because of the access issues and distribution of resource issues, to focus there in the rural communities.

Senator SCOTT. Yes.

Secretary AZAR. And then another \$400 million of that goes to quality incentive work with our community health centers, again, localized.

Senator SCOTT. Excellent. Thank you very much.

I am not sure that you have answered a question on wellness so far during this hearing.

I spent, as you may recall, a few years in the insurance industry. And one of the things that we have done over the last year is talk about the access to health insurance; we have talked about the cost of health insurance. We have talked about who is insured, who is not insured, who is underinsured. We have talked about a lot of topics around the exploding costs of health insurance.

But the underlying driver is obviously the exploding costs of health care. And unless we spend more time talking about the explosive costs of health care, we will not be able to address the actual challenge of the explosive costs of health insurance.

And many of the issues that we face from a health-care cost perspective—and the costs continue to rise—are around issues of the morbidities of diabetes and obesity as well as the challenges around cancer. These are explosive drivers of our health-care costs.

When it comes to encouraging healthy habits so that we can prevent some of the challenges that we see, that too requires a local, bottom-up approach to creating more flexibility in the alternatives.

I know in South Carolina we have a unique population. Some of the programs that we see that are very effective in the State are programs that work with nonprofits, whether it is churches or synagogues, whether it is the ability to create wellness programs at your local community nonprofit, or planting community gardens. We have found that these programs have been quite successful in South Carolina.

What do you plan to do this year to empower and encourage States to invest in this space of wellness programs so that we can attempt to get control of future costs, perhaps before they happen?

Secretary AZAR. So, Senator Scott, I think you have put your finger on some of the important drivers of health-care costs in our system, which are the social and behavioral determinants of health. And I am very committed in that space that we help to provide alternatives to minimize both medical spend and health-care spend if we can do so in alternative ways.

But also, on the behavioral side, can we create adequate incentives or create flexibility for adequate incentives on the behavioral side?

Actually, when I was at HHS in the 2000s, we were involved in helping to create greater flexibility through HIPAA, the statute to allow employers and insurance plans to create greater financial incentives for healthy behaviors. If you have other ideas of things that we could work to address, barriers where our programs or authorities are in the way, I would love to learn more about that, because I think it can be very constructive.

Senator SCOTT. Certainly, I look forward to having that conversation with you perhaps at another time. There have been a number of programs that focus on healthy alternatives and how you avoid what it is that we find to be incredibly tasty but may not long-term

be very helpful for your arteries. So I look forward to having that conversation.

Secretary AZAR. Thank you.

Senator SCOTT. Thank you, Mr. Chairman.

Senator CASSIDY. Mr. Secretary, we have these two folks, me and the ranking member, to ask another set of questions, and then you will be through.

Let me first observe—not related to you, but someone earlier criticized the Tax Cuts and Jobs Act provision which does not allow the deduction of State and local taxes. Excuse me, they were criticizing the Tax Cuts and Jobs Act as a benefit for the upper-income. But the same Senators who say that also complain about the SALT tax provision. They complain about that.

Well, the SALT tax provision disproportionately affects the wealthy. So on the one hand, you cannot have the wealthy getting taxed more and on the other hand having a bill which benefits the wealthy. But that is one of the incongruities of our debates up here.

Secondly, there were a couple of assertions about Graham-Cassidy that I have to address.

One, we, under Graham-Cassidy, maintained the mental health benefit. We encouraged provisions such as auto-enrollment, which could increase enrollment relative to now. We allowed pooling of the individual market and the Medicaid pools, which I am told would lower premiums by 20 percent, therefore making insurance more affordable.

Again, folks on the left just do not seem to care about those middle-class families paying \$40,000 a year.

And I will say, the criticism of the status quo, the status quo still includes the individual mandate. And I suppose all of this is the reason that folks, like Andy Slavitt, Tom Daschle, and Melanie Bella, are saying that we need to do something different.

Now, to another question. You spoke earlier of the Part D provision, I presume decreasing the out-of-pocket exposure for a beneficiary. And I gather that is by increasing the mandates pharmaceutical companies must pay. My concern is that these rebates that they pay count towards the true out-of-pocket cost. And so, if you will, it is pushing the senior more rapidly into the catastrophic portion of the Medicare Part D benefit, which means that the taxpayer is paying even more.

The other thing I have observed, and I think I have read this as well, is that when drug companies have to increase the rebate, they just increase the cost of the drug.

So if we are, going back to our earlier discussion, forcing them to increase the cost of the drug if you are not on Medicare and you are not on Medicaid, you are going to pay a lot more. And if we are counting these rebates towards the true out-of-pocket cost, then we are pushing people up into that provision, the catastrophic coverage where the taxpayer is paying more.

I am not sure I am seeing this as a great benefit for society writ large. What are your comments, please?

Secretary AZAR. So the proposals that we have in the budget around drug pricing, really I think we need to look at them as a

holistic set of all five parts there, because they work together in a related way.

First, we would require that the rebates that the drug companies are paying the drug plans be offered to the senior citizen, at least one-third of that benefit, when they arrive at the pharmacy, at point of sale—so a real out-of-pocket benefit for them on that.

Second, we would have a genuine out-of-pocket maximum in Part D for the first time. Right now, even in catastrophic coverage, the senior citizen has to pay 5 percent, which can be a lot of money. That would now be zero.

We also would fix this incentive we have where the Federal Government is picking up that catastrophic care to the tune of 80 percent and reverse that so that the insurance company pays 80 percent and we pay 20 in the future.

We would also have—to that true out-of-pocket-cost question that you raised, Senator, we propose that we would not count the coverage gap discount payments from the drug companies against true out-of-pocket costs, again creating a continued incentive for the plans to not hustle the beneficiary to catastrophic, to unload them on us, and also to have higher list prices to get them there.

And finally, for our low-income-subsidy seniors, free generics.

Senator CASSIDY. All that sounds fantastic. I am glad you explained it. And as a package, it sounds better. But let us go back to what we discussed in my earlier questioning about the hydraulic effect upon those who are not on Medicare or Medicaid.

Now they have Medicare and Medicaid, both of which are getting large rebates and/or discounted pricing and/or taxes upon the cost of the drug going back to the State, causing the drug company to raise the price to make that up. Is that going to increase the price that the person who is either paying cash through a small-business group plan or through the individual market pays for their drug?

Secretary AZAR. I do not believe the mechanisms that we are proposing would have that effect, because what we are trying to get at in particular is the out-of-pocket to the patient, which is much more a matter between them, the insurance company, and us. And so we want to get that out-of-pocket from the patient down and then reverse the incentives on list price. The net could even remain the same to the program level.

I do hope that we will keep good incentives to keep driving our net prices down, as we do quite effectively. It is that list price that we have to reverse. As you have said, every incentive towards that higher list price, we have to try to flip those incentives backwards on that.

And this is a starting point on that, and I am going to keep working with you all to come up with other ideas that can either contain or actually pull back those list prices, create financial incentives, create market forces that will actually get those list prices down.

Senator CASSIDY. I was following you on everything up until the last 45 seconds, but we will have a follow-up conversation on that.

Senator WYDEN?

Senator WYDEN. Thank you, Mr. Chairman.

Mr. Secretary, I want to come back to what Senator Brown said and do it very quickly. Because as we have talked about, we are going to have to spend a lot of time to really dig into these issues.

So seniors, people in organizations, like the work I have done with the Gray Panthers over the years; they talk about how they are getting clobbered when they go to the pharmaceutical window.

Senator Brown asked you about that, because I was with him in Ohio and I heard seniors talking about it. And you said, you know, what we are going to do is, we are going to change the incentives, we are going to change the incentives for the middlemen.

As you know, I have legislation to do that. That is a key part of the puzzle. But what Senator Brown was saying and what I am saying is—we will talk some more about it in the future—you cannot solve this problem if you let the manufacturers off the hook. And that is what the budget does, and that will be a topic for another day.

My question for you deals with something our colleague and someone I admire, Congressman Davis, talked to you about yesterday in Ways and Means: this question of AFCARS, this important rule, AFCARS, the adoption, the foster care kids.

This rule has, as far as I can tell, been blocked or put on hold or something of this nature. This gives us critical data, like how many foster kids get really terrorized in the sex-trafficking system. We really want to get this out.

Are you supportive of this? Will you work with us? This is what Congressman Davis was talking to you about yesterday.

Secretary AZAR. And I did not have a chance yet to follow up from his comment. That was the first I had heard of this issue.

Obviously, I want to learn more from you about that and work on this. If that is the impact, we want to be doing everything in our power to solve that problem.

Senator WYDEN. Good. The reason this is so important is, as you know, a number of us are supportive of the idea of States having a bigger role in these kinds of areas, but we have to know what is going on at the State level and have this kind of information to have this partnership. So that is that.

And then, because my friend is here, I am going to put something into the record, because we have talked a fair amount about Graham-Cassidy, and sometimes people do not know this, but the two of us talk often about health policy. I think Senator Hatch thought at one point we were going to punch each other out in the middle of the Graham-Cassidy debate.

Here is where it was left on the pre-existing condition issue. And I am going to actually put it in the record, because I suspect we are going to come back to that.

[The information on preexisting conditions appears in the appendix on p. 106.]

Senator WYDEN. When we had the hearing, I had received voluminous amounts of information from doctors and hospitals who were concerned that Graham-Cassidy did not protect people with pre-existing conditions. My colleague said, "That is not right; those people mean well, but they are not right."

So sitting on the far end of the table was a representative from the Cancer Society. And the representative from the Cancer Society

looked at me and looked at my colleague and said, "We know something about pre-existing conditions, and this does not," this being Graham-Cassidy, "protect people with pre-existing conditions."

The reason I am going to put it in the record is I want my colleague and others to have a chance to comment and be part of the debate. But since Graham-Cassidy has come up several times and I am particularly concerned about the trend apparently started by Idaho to go back to junk insurance and, again, no protection for people with pre-existing conditions, I want all sides to have a fair chance to comment on this.

And we will put into the record what I have just given, a shorthand description. I am sure my colleague sees this issue differently. But at least we are going to be picking up where it was left when we actually had our hearing.

Thank you, Mr. Chairman.

Senator CASSIDY. Yes. And hopefully it will be noted that that is rhetoric; it is not based upon fact.

By the way, Mr. Secretary, thank you for being here.

Thank you, my colleague, and all others who participated. A very good hearing.

Since it appears we will not obtain a quorum, we will postpone the markup scheduled for today to occur during a rollcall vote of the Senate at a location to be determined that will be off the floor.

I want to thank Secretary Azar for attending today.

I thank all my colleagues for participating.

For any of my colleagues who have written questions, I ask that you submit them by the close of business next Thursday, February 22nd.

With that, this hearing is adjourned.

[Whereupon, at 11:25 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. ALEX M. AZAR II, SECRETARY,
DEPARTMENT OF HEALTH AND HUMAN SERVICES

The mission of the Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of the American people.

President Trump and all of us at HHS take that charge seriously. So, when programs are not as effective as they can be, or cost more than they ought to, or fail to deliver on their promise, change and reform are necessary.

The President's fiscal year (FY) 2019 budget applies this reform mindset to the work of the Department, making thoughtful and strategic investments to protect the health and well-being of the American people, while addressing the opioid crisis, promoting patient-centered health care, strengthening services for American Indians and Alaska Natives, encouraging innovation in America's health-care future, addressing high drug prices, reforming the Department's regulations, and generally focusing resources toward proven and effective initiatives. The budget also recognizes the fiscal challenges our country faces today, and the need to focus our investments and update them to meet the needs of a rapidly changing world.

The President's budget for HHS also reflects proposals to meet the President's comprehensive government-wide reform plan through a Department initiative called "ReImagine HHS." ReImagine HHS, through a range of initiatives, aims to identify opportunities to improve the work HHS does for the American people, in terms of its efficiency, quality, and cost-effectiveness. In particular, ReImagine HHS offers a unique opportunity for the experienced career staff of the Department to lead initiatives that will advance the work of the Department and revamp outdated processes and structures.

Across all of HHS's priorities, the budget makes clear that business-as-usual will not suffice, and that the substantial investments made every year at HHS ought to be allocated with efficiency and toward programs that work.

TACKLING THE OPIOID EPIDEMIC

One of the Department's top priorities is fighting the scourge of opioid addiction facing our country.

Due to skyrocketing numbers of opioid overdoses, deaths by drug overdose have become the leading cause of injury death in the United States. In 2016, 174 Americans died each day from drug overdoses. American life expectancy has dropped for the second year in a row—a tragic development not seen in more than a half century.

The President's budget recognizes the devastation caused by this crisis in communities across America, by providing a historic new investment of \$10 billion in HHS funding to address the opioid crisis and serious mental illness, and building upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five part strategy, which complements work being done elsewhere in the administration and covers:

- Access: improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Overdoses: targeting availability and distribution of overdose-reversing drugs;

- Data: strengthening our understanding of the epidemic through better public health data and reporting;
- Research: supporting cutting edge research on pain and addiction; and
- Pain: advancing better practices for pain management.

The budget proposes to improve ways in which the Federal Government helps communities respond to the opioid epidemic. As just one example, the budget directs resources to the Substance Abuse and Mental Health Services Administration to improve access to medication-assisted treatment services, boost State capacity to establish and operate comprehensive prevention systems, and disseminate high-quality resources on best practices for treatment.

The budget includes a total of \$126 million to support efforts by the Centers for Disease Control and Prevention (CDC) to prevent the abuse and overdose of opioids. This investment supports key public health and surveillance activities at the State level, recognizing that States can best determine their unique needs. CDC will also continue to increase the awareness and adoption of the CDC Guideline for Prescribing Opioids for Chronic Pain. In all of these activities, CDC will endeavor to support and execute programs that have a proven track record of success.

We recognize that government at the Federal, State, and local levels cannot defeat the opioid crisis alone, so HHS will continue to leverage the resources and expertise of the private sector and academia to develop new tools to end the epidemic. This includes a \$500 million investment in a National Institutes of Health (NIH) public-private partnership to accelerate the development of new treatments for pain and addiction.

To help address the drivers of the epidemic, current practices for pain management must also be rethought, including in the work of Federal agencies that prescribe painkillers. The FY 2019 budget will support the Pain Management Best Practices Inter-Agency Task Force, which will determine whether there are gaps or inconsistencies in pain management best practices among Federal agencies; propose recommendations on addressing gaps or inconsistencies; provide the public with an opportunity to comment on any proposed recommendations; and develop a strategy for disseminating information about these best practices.

EFFECTIVELY TREATING SERIOUS MENTAL ILLNESS

Serious mental illness, such as a psychotic or major depressive disorder, afflicts nearly 10 million American adults each year, and remains one of the Nation's most difficult health-care challenges. Without treatment, many of these individuals cycle repeatedly among the health, behavioral health, and criminal or juvenile justice systems, with each system insufficiently prepared to meet their needs. According to one report, 10 times as many Americans with serious mental illness are in jail or prison than in inpatient psychiatric treatment, and tragically, Americans with serious mental illness live lives at least 10 years shorter, on average, than others.

The budget recognizes that there are effective, proven forms of treatment for those struggling with serious mental illness, which have not always received the necessary support. One is "assertive community treatment," which places individuals in the care of a multidisciplinary behavioral health staff to deliver comprehensive services and treatment and has been shown to reduce hospitalization and improve patient satisfaction compared with other interventions of the same cost. The budget fully funds a new Assertive Community Treatment for Individuals with Serious Mental Illness program, authorized by the 21st Century Cures Act.

Another effective approach to serious mental illness is the budget's support of Certified Community Behavioral Clinics, funded as part of the new \$10 billion investment to address the opioid epidemic and serious mental illness. The budget also continues to direct 10 percent of State allocations from the Community Mental Health Services Block Grant to bring care more quickly to those experiencing a first episode of psychosis, a proven intervention.

ADVANCING HEALTH REFORM THAT WORKS

A Washington-centric, one-size-fits-all approach to health care—especially in insurance markets most affected by Obamacare—is simply not working and must change. The President's budget proposes a bold plan to redirect a significant amount of health-care funding back to the States and individuals, where health-care decisions should be made, while also taking major steps to encourage innovation and better quality of care.

The budget supports repealing Obamacare and replacing the law with flexibility for States to create a free and open health-care market tailored to their citizens' needs. The two-part approach is modeled closely after the Graham-Cassidy-Heller-Johnson amendment to H.R. 1628, the American Health Care Act of 2017, and also includes additional reforms to put health-care spending on a sustainable fiscal path.

The proposed Market-Based Health Care Grant Program will help States stabilize their insurance markets and provide for a smooth transition away from Obamacare. The budget would also fix the perverse incentive structures created by Obamacare, by ending the disparity between States that expanded Medicaid to new populations and those that did not and providing States with a choice between a per capita cap and a block grant.

The budget also proposes reforming our broken medical liability system, to ensure it is not driving excess costs. Finally, the budget proposes consolidating the byzantine system of graduate medical education funding into a single, direct grant program that will streamline incentives and better serve patients and providers.

Bringing Down Drug Prices

As President Trump has repeatedly made clear, the prices Americans pay for prescription drugs are simply too high. The budget proposes a range of legislative measures to build on the proven success of the Medicare Part D prescription drug program, including through giving drug plans more tools to negotiate with manufacturers and encourage use of higher value drugs. In addition, the budget discourages rebate and pricing strategies that increase spending for both beneficiaries and the government and, for the first time in the program's history, provides beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap for seniors with especially high drug costs.

Sustainable Medicaid and Medicare Reforms

Millions of Americans rely on Medicaid and Medicare to meet their everyday health-care needs. Together, Federal health care programs comprise the largest portion of the Federal budget. The President's budget proposes several legislative solutions to improve the programs, promote greater efficiencies, advance patient-centered care, and reduce government-imposed burden on providers.

The administration recognizes that the over-50-year-old structure of the Medicaid program has failed to create a sustainable Federal-State partnership that is capable of controlling costs. In fact, its outdated design incentivizes cost increases without delivering commensurate benefits or allowing for much-needed local health innovation.

Our budget proposes a new future for Medicaid that will restructure Medicaid financing, provide States with new flexibilities to better serve their communities, improve the State plan and waiver processes, and provide the right incentives to preserve the program for future generations.

BOOSTING UPWARD ECONOMIC MOBILITY

There is no more effective anti-poverty program than helping someone find a job. Recognizing this common-sense approach, the President's budget re-focuses HHS's public assistance programs on helping low-income Americans find gainful employment, providing them with a sense of purpose, personal dignity, and independence.

Importantly, the budget proposes key reforms to the Temporary Assistance for Needy Families program that reinforce its focus on promoting work as the best pathway to self-sufficiency. Specifically, the budget strengthens the program's accountability framework related to work requirements and ensures that States allocate sufficient funds to work, education, and training activities.

The budget also proposes establishing Welfare to Work Projects that will allow States to streamline funding from multiple public assistance programs and redesign service delivery to meet their constituents' specific needs. Importantly, these Welfare to Work Projects would be rigorously evaluated, expanding the evidence base that informs how assistance programs can be most effectively structured to help Americans achieve self-sufficiency.

In January, for the first time in the history of the Medicaid program, the Federal Government indicated openness to State-led innovations that promote work or community engagement activities for working age, able-bodied enrollees. Productive work and community engagement is associated with improved health and well-being, meaning this reform can achieve the goals of the Medicaid program while

also supporting independence and economic self-sufficiency for millions of able-bodied adults.

PROMOTING EFFICIENCY AND INNOVATION IN SCIENTIFIC WORK

Supporting and encouraging scientific research is a longstanding Federal priority, one that results in both a growing economy and longer lives. Executing this responsibility demands that the Federal Government regularly consider how to organize such support in the most efficient manner possible.

The administration believes it is a priority to support NIH, a crown jewel of American science, and proposes to do so not just through continued financial investments but also through innovative partnerships with non-federal entities, administrative reforms, and better coordination and planning.

Among other efforts to derive maximum benefit from the substantial Federal investments made in NIH research, the budget supports expanding public-private partnerships that will challenge private sector partners to match Federal investments; increasing coordination across NIH's Institutes and Centers; focusing grant awards on projects with the highest potential to accrue benefits for public health; assessing new and current strategic investments in research; curtailing the rate at which high researcher salaries at private institutions are reimbursed with taxpayer dollars; and implementing burden reduction measures to reduce costs for grant recipients.

The budget also supports administrative reforms for NIH, including efforts to harmonize operational functions and break down silos within the agency. In addition, the budget proposes to consolidate three other major HHS research institutions in NIH to maximize the effectiveness of their research.

The Food and Drug Administration (FDA) is another crown jewel of American science. But its needs and priorities must change as the face of medical innovation changes, too. The budget includes investments for FDA to speed the development and approval of new drugs and medical devices, and to increase the quality and safety of next generation manufacturing practices, including approximately \$500 million to strengthen medical product safety development and access.

INVESTING IN OUR BIODEFENSE, PREPAREDNESS, AND GLOBAL HEALTH SECURITY PROGRAMS

The President's budget aims to improve our Nation's preparedness for, and capabilities to respond to, chemical, biological, radiological, and nuclear threats; pandemic influenza; natural disasters; emerging infectious diseases; and cybersecurity challenges.

In each area, smart investments that empower the private sector and our global partners will help keep our country safe.

Chemical, Biological, Radiological, and Nuclear Threat Preparedness

The budget includes \$512 million for the Biomedical Advanced Research and Development Authority (BARDA) and \$510 million for Project BioShield, which fund successful public-private partnerships that support the development and procurement of new medical products crucial to defending our country against chemical, biological, radiological, nuclear, and infectious disease threats. Prior HHS investments in these programs have resulted in more than 190 medical countermeasure candidates, 34 FDA-approved products from BARDA, and the procurement of 14 new products for the Strategic National Stockpile. Funding will also be available for exercises to build preparedness for threats such as emerging infectious diseases, natural disasters, and manmade biological, chemical, nuclear, and radiation threats.

The budget proposes to transfer the Strategic National Stockpile to the Office of the Assistant Secretary for Preparedness and Response, to boost operational efficiencies and streamline development and procurement of medical countermeasures. It also provides \$575 million to maintain and replenish the stockpile, the Nation's largest supply of life-saving medical countermeasures that can be deployed in the event of a public health emergency.

Natural Disaster Preparedness

Following the powerful hurricanes and historic wildfires of 2017, HHS remains ready to respond to any and all hazards when disaster strikes. The budget ensures the Department is able to support essential emergency preparedness activities to refine our disaster responses. In particular, Hospital Preparedness Program resources will continue to be allocated to States and localities according to risk, ensuring com-

munities with more risk have the necessary coordination and resources. The budget also continues to provide \$50 million to support the National Disaster Medical System. Through this cost-effective and successful program, HHS trains and deploys teams of American health-care professionals from across the country to provide medical care to our fellow Americans in the event of an emergency.

Global Health Security

One of the most effective ways to protect Americans from the threat of infectious diseases is to enable other countries to follow through on their own commitments to contain and respond to disease threats. Such investments are far less expensive than mounting an international public health response to control an epidemic.

To support this goal, the budget provides a total of \$409 million for CDC's global health activities, which strengthens CDC's international preparedness and response capabilities. The budget would also build on substantial progress that has been made toward global health security goals under the Global Health Security Agenda (GHTSA), including a \$59 million investment that provides funding for CDC to continue this work into FY 2020.

Cybersecurity

The budget recognizes that HHS must continue robust operations to meet today's cybersecurity needs and includes \$68 million to ensure the Department is able to protect sensitive and critical information in an ever-changing threat landscape. The Department will also focus on support for and coordination with the health care and public health sectors in close coordination with the Department of Homeland Security, to promote information and resource sharing across levels of government and the private sector.

STRENGTHENING THE INDIAN HEALTH SERVICE

Through the Indian Health Service (IHS), HHS is responsible for providing quality health-care services to more than 2.2 million eligible American Indians and Alaska Natives. The budget prioritizes funding for this agency, and in particular for direct health services. The budget also makes significant investments to assist IHS facilities with meeting CMS quality health standards.

Looking forward, and consistent with our statutory authorities, we recognize that how we provide quality health care in Indian Country and beyond must change to achieve and ensure the high quality of these services. More Tribes have assumed the responsibilities of providing health care for their members with support from the IHS, and investments in the budget reflect our support for the growth of tribal self-governance in the provision of health care.

The President's 2019 budget for HHS recognizes the importance of focusing government spending on programs that work and reforming our Nation's health-care programs for a fast-changing world. This budget recognizes that securing America's future demands sound fiscal management and responsible decisions about our priorities. If we are serious about fulfilling HHS's mission of enhancing and protecting the well-being of all Americans, we must adopt the bold innovation and direction espoused by the President's budget.

QUESTIONS SUBMITTED FOR THE RECORD TO HON. ALEX M. AZAR II

QUESTIONS SUBMITTED BY HON. ORRIN G. HATCH

Question. Mr. Azar, In the Medicare program, providers like doctors and hospitals are experiencing extremely long wait times to resolve appeals of Medicare payment decisions. These providers sometimes have to wait months or years to resolve cases and get reimbursed. This situation is mostly attributable to the backlog in appeals at the Office of Medicare Hearings and Appeals. The Senate Finance Committee passed the Audit and Appeals Fairness, Integrity, and Reforms in Medicare Act, known as AFIRM out of committee in the last Congress, and I believe the need for this legislation is just as important today. Mr. Azar, please describe how the changes to the appeals process in the President's budget will fix this backlog.

Answer. The budget includes several proposals to reform the Medicare appeals process across all four levels within the Department, at CMS, the Office of Medicare Hearings and Appeals, and the Departmental Appeals Board. These proposals will improve the efficiency and efficacy of the administrative appeals process. The strategies include taking administrative actions to reduce the number of pending appeals

and encourage resolution of cases earlier in the process and proposing legislative reforms that provide additional funding and new authorities to address the appeals volume. The FY 2019 budget includes significant funding increases for OMHA and the DAB along with a package of legislative proposals that would provide the flexibilities needed for both agencies to process their appeals workload more efficiently and allow OMHA to resolve a portion of its appeal receipts at lower cost.

In addition to increased financial resources for greater adjudication of claims, the President's budget proposes legislative authority to:

- Remand appeals to the redetermination level with the introduction of new evidence.
- Increase the minimum amount in controversy for ALJ adjudication of claims to equal amount required for judicial review.
- Establish Magistrate adjudication for claims with amount in controversy below new ALJ amount in controversy threshold.
- Expedite procedures for claims with no material fact in dispute.
- Change the Medicare Appeal Council's standard of review from *de novo* to an appellate-level standard of review (which would increase its adjudication capacity by up to 30 percent, without increasing costs).
- Limit appeals when no documentation is submitted.
- Require a good-faith attestation on all appeals.
- Establish a post-adjudication user fee for unfavorable appeals at the 3rd and 4th levels of appeal.

Taken together, these common sense reforms would significantly reduce the backlog and ultimately allow suppliers and health-care providers to more efficiently deliver services and goods to patients. I look forward to working with you to help realize our shared goals in this area.

Question. Mr. Azar, as you may know, this committee held a round table discussion in 2015, as well as a hearing in 2016, to hear from industry stakeholders on proposals to reform the Stark Law. Many of the proposals and challenges faced by providers under the law are still very relevant today. The President's budget contains a request for additional authority to create exemptions from the self-referral law to facilitate participation in alternative payment models and apply Stark to physician-owned distributors.

How will additional exemptions and authorities under the Stark Law help facilitate the transition to value-based care and assist in implementation of Advanced Alternative Payment Models under MACRA?

Answer. We agree that the physician self-referral law must better support and align with alternative payment models. The FY 2019 President's budget proposes establishment of a new exception to the physician self-referral law for arrangements that arise due to participation in Advanced Alternative Payment Models. The Department, in consultation with the HHS Office of Inspector General, will identify the types of arrangements and the minimum risk levels and level of participation in the model required for such exceptions.

Question. I am concerned about the viability of independent, especially small, physician practices. The past decade has seen a significant uptick in hospital acquisitions of independent physician practices. According to the Physician Advocacy Institute, hospital acquisitions of physician practices rose 86 percent between 2012 and 2015, and physician employment by hospitals increased over 50 percent. Is HHS actively evaluating how to better support independent practices and develop policies that allow solo providers to compete on a level playing field with hospitals and large health systems?

Answer. We bear in mind whether new burdens created by models or programs or the scale they require for viability may be driving consolidation in the health-care market. As a matter of principle, we want to move to a system where we can be agnostic about ownership structures, a system that will allow independent providers to group together to drive innovation, quality, and competition. Independent, small physician practices play an important role in the health-care system. Technical assistance is available to help small practices participate successfully in the Quality Payment Program, including assistance with all aspects of the program and optimizing the use of technology. This assistance is provided through the Small, Underserved and Rural Support initiative, the Transforming Clinical Practice Initiative and the Quality Improvement Organization program. I look forward to examining this issue further and working with Congress to support these practices.

Question. A 2014 law requires that ordering physicians consult imaging appropriate use criteria (AUC) that are developed by national medical specialty society or other provider-led entities prior to referring Medicare patients for advanced diagnostic imaging services, such as CTs, MRIs, and PET scans. In addition to facilitating improved health-care outcomes through the use of physician-developed guidelines and minimizing patient exposure to unnecessary radiation, this approach was thought to be more physician-friendly than establishing an advanced imaging prior authorization program that is typical among other payers. Although the law called for ordering physicians to begin consulting AUC for advanced diagnostic imaging procedures beginning on January 1, 2017, CMS, working iteratively through the rulemaking process, has set a January 1, 2020 start date for the program. Can you affirm the decision to start the program on this date?

Answer. The Medicare Appropriate Use Criteria (AUC) Program for Advanced Diagnostic Imaging will begin in a manner that allows practitioners more time to focus on and adjust to the Quality Payment Program before being required to participate in the AUC program. The Medicare AUC program will begin with an educational and operations testing year in 2020, which means physicians are required to start using AUCs and reporting this information on their claims. During this first year, however, CMS will pay claims for advanced diagnostic imaging services regardless of whether they correctly contain information on the required AUC consultation. This allows both clinicians and the agency to prepare for this new program.

In addition, physicians may begin exploring the AUC Program and the use of clinical decision support mechanisms well in advance of the start of the Medicare AUC program through the voluntary participation period that will begin mid-2018 and run through 2019. During this time CMS will collect limited information on Medicare claims to identify advanced imaging services for which consultation with appropriate use criteria took place.

Question. Mr. Azar, this budget puts forward a demonstration related to the Medicaid Drug Rebate Program and State flexibility. I, and many members on the dais, have long shared the goal of providing States with flexibility to administer Medicaid programs in the most appropriate way for their populations. However, this demonstration should give us a moment of pause.

How will CMS evaluate these demonstrations to ensure that beneficiaries will have access to the best therapies available? It is very important that we have strong evaluations of such ideas before making broader policy decisions.

Answer. The budget includes a new statutory demonstration authority to allow up to five States more flexibility in negotiating prices with manufacturers, rather than participate in the Medicaid Drug Rebate Program, and to make drug coverage decisions that meet State needs. Participating States will be required to include an appeals process so beneficiaries can access non-covered drugs based on medical need. By structuring the proposal as a limited demonstration opportunity, HHS and participating States will have the tools to rigorously evaluate these demonstrations, providing an assessment of the demonstrations' impacts on cost and access to medications.

Question. Mr. Azar, I'm glad the budget proposes changes to the financing of the child welfare system to help States keep more families safely together instead of bringing more children into foster care. I'm pleased to note that last week the President signed into law the Family First Prevention Services Act as part of the government funding bill, and this legislation is focused on achieving the same goals set out in the President's budget. Will you commit to working with Senator Wyden and I—and other members of this committee—to be sure this new law is implemented quickly, so we can achieve our shared goal of keeping more kids safely with their families and out of foster care?

Answer. We are committed to the implementation of the Family First Prevention Services Act. As the act makes numerous significant changes to Federal financing for child welfare, we must ensure that we take into consideration the needs of children and families, State and tribal challenges, and the landscape of available services as we implement the law. Changes of this magnitude cannot be rushed, but we are working as quickly as possible while continuing to work towards our goals of permanency, safety and well-being for all children.

Question. Mr. Azar, as you may know, the Finance Committee is undertaking a bipartisan process to identify ways to address the opioid epidemic in Medicare and Medicaid so that the right incentives exist for addressing pain and addiction. When

you testified before this committee earlier this year, you mentioned that addressing the opioid epidemic would be one of your top priorities, and I'm pleased to see a number of proposals included in the President's budget on this topic. Will you commit to working with this committee to find bipartisan solutions to address this epidemic within Medicare and Medicaid? Can you please elaborate on the mandatory program changes included in the President's budget to help move Medicare and Medicaid forward to better confront this epidemic?

Answer. The budget includes several proposals that work to address the impact that the opioid epidemic has on our Nation's seniors. The Medicare population has among the highest and fastest-growing rates of opioid use disorders, currently at more than six of every 1,000 beneficiaries. Many Medicare beneficiaries take multiple medications and receive prescriptions from multiple doctors, making tracking and controlling any misuse of these prescriptions a substantial challenge. HHS has made tackling this issue, and the opioid epidemic more broadly, a top priority.

The budget proposes to conduct a demonstration to expand access to comprehensive substance abuse treatment for Medicare beneficiaries, including medication-assisted treatment. This demonstration would be expanded nationwide if successful. A corresponding expansion of medication-assisted treatment is also proposed for Medicaid beneficiaries, who likewise have rates of opioid use disorder beyond those of other populations.

The budget also proposes to address opioid misuse in Medicare by giving the Secretary authority to require plan participation in a program to prevent prescription drug abuse in Part D, essentially strengthening the statutory authority already provided through the Comprehensive Addiction Recovery Act of 2016 to "lock" an at-risk beneficiary into a single prescriber or pharmacy. To address potentially abusive prescribing practices the budget proposes to allow the Secretary to work with the Drug Enforcement Administration (DEA) to revoke a provider's DEA Certificate of Registration after CMS revokes a provider's Medicare enrollment based on a pattern of abusive prescribing.

Question. The President's budget includes a proposal to authorize the Secretary to consolidate certain drugs covered under Part B into Part D. As the details would be helpful to evaluate this proposal, I ask some initial questions. Has HHS identified certain conditions or treatments that lend themselves to a transition from Part B to Part D? What would be the implications for moving a drug from Part B to Part D for beneficiaries, physicians, and the Medicare program?

Answer. Senator Hatch, thank you for raising this crucial issue and bringing attention to an important proposal in the President's budget to lower drug costs for American seniors. While I am unable to discuss specific drugs or conditions that would be targeted, at this time, if given this authority, HHS would carefully analyze the projected impacts on beneficiary access and cost-sharing, as well as costs to the Medicare program, before pursuing any drug consolidation approaches. We look forward to working with you, your staff, and other interested members of Congress on this proposal, and we would seek any opportunity to find ways to reach our shared goal of bringing down the cost of prescription drugs for all Americans.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. As a strong supporter of Medicare Part D and as someone who cares about those who will count on these programs today and for many years to come, I have a responsibility to ensure the survival of this program for future generations.

Please tell me how you will bring down drug prices and ensure the Medicare Part D will continue to work as a free market solution for the seniors who depend upon the program.

Is there need for more transparency in the Part D program? How would you achieve that?

Answer. The budget modernizes the Part D drug benefit, based upon 12 years of program experience, to improve plans' ability to deliver affordable drug coverage for seniors and reduce their costs at the pharmacy counter. Seniors will benefit from the budget's proposals, which are designed to better protect beneficiaries from high drug prices, give plans more tools to manage spending, and address the misaligned incentives of the Part D drug benefit structure. The proposed changes enhance Part D plans' negotiating power with manufacturers, encourage utilization of higher value drugs, discourage drug manufacturers' price and rebate strategies that in-

crease spending for both beneficiaries and the Government, and provide beneficiaries with more predictable annual drug expenses through the creation of a new annual out-of-pocket spending cap.

Question. In the HHS budget justification, there is a proposal to use centralized CMS screening for enrollment of providers who receive Medicare, Medicaid, or CHIP funding.

Current regulations currently allow State Medicaid Agencies to rely on CMS screening, but providers are still subject to duplicative screening in many situations. I want to draw your attention to bipartisan legislation that Senator Bennet and I introduced this week. S. 2415, the Accelerating Kids Access to Care Act would streamline the enrollment process for some pediatric providers while protecting program integrity. I became aware of the need for this legislation when I heard a child's heart surgery was delayed because a provider—who was already credentialed in Medicaid in one state—could not be credentialed by the referring State because he could not find his original social security card. Thankfully, most children are well. But, there are a few who need care for their complex medical needs. We should not have artificial barriers to that care. Mr. Secretary, will your office work with staff from my office and Senator Bennet's to get this proposal off the ground?

Answer. We are available to work with your staff and review any legislative language you may have in order to provide technical assistance.

Question. Recent news investigators have reported on a wide variety of generic medications that on certain insurance plans could be cheaper when patients pay out of pocket instead of using their insurance benefits, but a so-called Pharmacy Benefit Manager "gag clause" can prevent some pharmacists from telling patients that they may be overpaying for their prescription. Are you aware of these concerns regarding "gag clauses" on pharmacies? Do you believe this is helpful in promoting a competitive free market? What changes do you believe need to be made in regard to PBM transparency?

Answer. Senator Grassley, as you know, we share the mutual desire to ensure that Americans are paying the lowest possible price at the pharmacy counter, and I have made it a top priority in my tenure as Secretary to meet that goal, so I thank you for raising this important issue. We are committed to looking further into this, and any other issues that relate to Medicare Part D or other HHS programs that impact the price of pharmaceuticals, and we look forward to working with you and your staff to identify government policies which impede consumer access to drugs and to develop patient-driven solutions to empower patients.

Question. Community pharmacists in Iowa have reported increasing use of price concessions and fees imposed by pharmacy benefit managers months after prescriptions are filled, called Direct and Indirect Remuneration (DIR) fees. CMS has now for several years recognized issues with how DIR fees are reported by part D plan sponsors, how these fees impact pharmacy business, and the resulting challenges they create for Part D beneficiaries, including addressing it in the President's budget. CMS recently proposed requiring that all DIR fees would be reflected at the point of sale, and I joined with 20 of my colleagues urging CMS to move forward with this proposal, which would lower out of pocket costs for beneficiaries. Given the fact that these "fees" are detrimental to the Federal Government, Part D beneficiaries and Part D pharmacy care providers, how will you work to resolve these concerns?

Answer. In the proposed Parts C and D rule (CMS-4182-P), we included a Request for Information in which we discussed considerations related to and solicited comment on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. Feedback received will be used for consideration in future rulemaking on this topic. HHS is committed to enacting reforms to ensure our health-care programs work for the American people, provide Americans with access to care that meets their needs, increase options for patients and providers, and build financial stability and responsibility.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

Question. Secretary Azar, you've talked about bringing more competition into the market in Medicare Part B. What would that look like?

Answer. I look forward to working with Congress to explore ways that we can bring the negotiation strategies that are currently working in Medicare Part D, where we receive the best deals of any payer in the commercial marketplace, into Part B, which does not negotiate prices. Additionally, the budget proposes to leverage Medicare Part D Plans' negotiating power by providing HHS the authority to consolidate certain drugs covered under Part B into Part D, when there are savings to be gained from price competition.

Question. The Senate Finance Committee has consistently exhibited broad bipartisan support to fix the competitive bidding program, and in particular, the component in need of our immediate attention: the payment rate cuts for DME supplied to rural areas or "non-CBAs" must be reversed. While I appreciate the Medicare Program's goal to save taxpayer money, I am greatly concerned that the payment reductions for DME supplied to rural America are negatively impacting suppliers' ability to reach Medicare's most needy beneficiaries. Congress shares my concern, having established a temporary reprieve through The 21st Century Cures Act, which reversed these cuts for 6 months through the end of 2016. The cuts, however, were reinstated on January 1, 2017 and remain in place today. Adversely impacting durable medical equipment suppliers' ability to do their jobs is creating very real patient access issues for Medicare beneficiaries in rural America, which in turn undermines the quality of health care they rightfully depend upon.

We know that CMS leadership shares our concern, having prepared an Interim Final Rule (IFR) for publication last year, known as the "Durable Medical Equipment Fee Schedule; Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas" (RIN: 0938-AT21). The IFR has been stalled at the Office of Management and budget since last summer. This is both an unfortunate and unacceptable way to treat our Medicare beneficiaries.

Please describe in detail the steps you have taken and will take to ensure that OMB promptly releases the IFR to allow CMS to publish it promptly. If there are any obstacles to the prompt publication of the IFR, then please describe them to the committee, why they haven't been removed, and what you will do to remove them.

Answer. Senator Cornyn, thank you for raising this important issue. While this regulation is under review by the administration, and I am unable to answer in specific details as you request at this time, I do want to stress that I share your interest and commitment to ensuring access to durable medical equipment for Medicare beneficiaries. The Department is prioritizing actions to address the concerns you have expressed.

Question. The Affordable Care Act included an effective ban on the expansion of physician-owned hospitals, as well as a ban on the construction of new hospitals. As you are aware, Hurricane Harvey caused massive damage to hospitals in Texas, including the permanent closure of one in Pasadena. This has resulted in a community of over 300,000 individuals having access to only one physician-owned hospital with 65 beds. Do you support an exception that would allow physician-owned hospitals in regions impacted by major disasters?

Answer. I understand that HHS and CMS staff have been providing technical assistance on bill text that would lift the ban on the expansion of physician-owned hospitals. I am happy to continue working with your office to learn more about this issue.

Question. Most people would be surprised to know that State Medicaid programs cannot negotiate—or get someone to negotiate on their behalf—with drug manufacturers. Do you foresee State Medicaid programs banding together to get the kind of scale that would drive even greater rebates than the statutory rebates already required?

Answer. Under current Federal law, drug manufacturers must provide Medicaid programs the best prices for prescription drugs that they offer to any private payer. As part of an administration-wide effort to address the high costs of prescription drugs and provide States more purchasing flexibility, the budget proposes a new statutory demonstration authority that will allow up to five States to test a closed formulary under which they negotiate prices directly with manufacturers, rather than participating in the Medicaid Drug Rebate Program. I am happy to work with Congress regarding this legislation.

Question. Many agencies within HHS are pursuing the right things to incentivize innovation in health care. For example, the FDA has a pilot program that moves

health-care technology into a 21st-century paradigm by certifying a company and its development processes as a whole, as opposed to each individual product. This shift enables rapid, iterative development processes for lower-risk medical device software and aligns with the rest of the consumer technology industry. How will the Secretary work to align all of HHS policy on health IT and digital health tools to foster private sector innovation in a similar manner to the FDA's forward thinking approach in its pre-certification pilot?

Answer. The 21st Century Cures Act provided FDA some additional important tools to help the agency ensure adequate and timely implementation so that patients can realize the benefits, companies have a clear and predictable path to bring these new advances to the United States, and patients and consumers can realize the benefits of new products while maintaining confidence that products will be reasonably safe and effective. In the area of digital health, FDA has released an action plan that includes the agency's precertification pilot program (FDA Pre-Cert), which seeks to apply a tailored approach toward digital health technology by looking at the software developer or digital health technology developer, rather than primarily at the product. The 21st Century Cures Act expands on policies advanced by the Center for Devices and Radiological Health (CDRH) generally to make clear that certain digital health technologies—such as clinical administrative support software and mobile apps that are intended only for maintaining or encouraging a healthy lifestyle—generally fall outside the scope of FDA regulation. Such technologies tend to pose low risk to patients but can provide great value to the health-care system. I look forward to reviewing our current policies on health IT and digital health tools to see where there may be other areas we can expand this approach. Our policies should protect consumers, but at the same time be flexible enough to allow innovation.

Question. The administration proposes creating savings in Medicare Part D by allowing Part D plans more flexibility in managing their formularies. Could the agency implement allowing plans to cover one drug per class or would you need Congress to change the statute? What other tools can CMS provide plans NOW under current authority?

Answer. CMS is committed to supporting flexibility and efficiency throughout the MA and Part D programs. The MA and Part D programs have been successful in allowing for innovative approaches for providing Medicare and Part D benefits to millions of Americans. Our budget includes this proposal for legislative authority because the statute does not allow for plans to cover one drug per class. In the proposed Parts C and D rule (CMS-4182-P) released in November 2017, CMS proposed to provide more formulary flexibility to plan sponsors by, for instance, permitting Part D sponsors to immediately substitute newly released equivalent generics for brand name drugs at the same or lower cost-sharing tier, if they meet revised requirements, including generally advising enrollees beforehand that such changes can occur without a specific advance notice and later providing information to affected enrollees about any specific generic substitutions that occur.

QUESTION SUBMITTED BY HON. JOHN THUNE

Question. As discussed at your confirmation hearing, I have concerns regarding how the Department of Veterans Affairs' (VA) change in its electronic health record system would impact the Indian Health Service (IHS), which relies on the same system. Last week, Secretary Shulkin testified that he expects the VA's transition may require maintaining the existing system for several years to come. While that would likely be helpful to IHS for the short-term, I want to ensure attention continues to be paid to this issue. I've been told that a working group was formed to examine the current platform and how VA and IHS will continue to collaborate when a transition occurs. Then-Secretary Price expected that recommendations from the group would be made by fall 2017. Have these recommendations been completed, and if so, what are they?

Answer. The Indian Health Service (IHS) continues to work with the Department of Veterans Affairs (VA) about the VA's plans and anticipated timelines. Similarly, the IHS remains engaged in discussions with its stakeholder groups such as the Tribal Self-Governance Advisory Committee, Direct Services Tribal Advisory Committee, and Information Systems Advisory Committee. Monthly updates are provided during the IHS All Tribes Call.

IHS published a Request for Information (RFI) in FedBizOps in December 2017 seeking new and innovative solutions to the goals and challenges which Federal and Tribal health programs seek to address in the delivery of care. Over 40 vendors of commercial electronic health record systems responded to the RFI describing a variety of software platforms and various services. IHS will continue a robust dialogue with a number of the respondents throughout Spring of 2018. Future steps will be determined based on the developments resulting from our work with all stakeholders.

QUESTIONS SUBMITTED BY HON. JOHNNY ISAKSON

Question. We know and I suspect agree that Hospital Acquired Pressure Ulcers (HAPUs) are an important problem that contributes to morbidity, mortality, and cost for Medicare, Medicaid, and commercially insured and uninsured beneficiaries. My question pertains to pain management protocols and the prevalence and impact to human suffering and associated medical costs of HAPUs, a national epidemic that kills approximately 60,000 patients/year while impacting over 2 million Americans and costing between \$9–\$11 billion (mid 2000's data from AHRQ).

The data from the National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data From National Efforts To Make Health Care Safer states that pressure ulcers had the lowest reduction of hospital acquired conditions in the United States in that time span. Specifically, more recent data from the Office of Enterprise Data and Analytics at CMS shown in October 2017 identified pressure ulcer discharges increased by 58.4% between Q1 2016 and Q1 2017, a concerning trend. These data sets demonstrate the need to work together to determine how we can improve our Nation's health-care outcomes by reducing pressure ulcers and saving the government significant costs.

The aforementioned provides concerns for the lowest reduction and rising state of one of the most preventable unintended consequences of the Hospital-Acquired Condition (HAC) score used by CMS. The HAC Reduction Program (HACRP) requires the Secretary of the Department of Health and Human Services to adjust payments through the domain formula with respect to risk-adjusted HAC quality measures. The CMS has the ability to re-balance the domain formula in the HACRP to incentivize the reduction of hospital acquired Pressure ulcers.

I would like to understand what HHS is doing to promote the prevention of pressure ulcers. Specifically:

- (1) What steps is CMS taking to implement an improved care protocol to ensure the Hospital-Acquired Condition (HAC) Reduction Program incentivizes hospitals to reduce HAPUs?
- (2) Does HHS have statutory authority to test or implement new scientifically based HAPU prevention protocols?
- (3) Please describe how CMS can use existing tools like re-balancing the domain formula in the Hospital-Acquired Condition Reduction Program (HACRP) to reverse the trend and reduce HAPUs and the time line for any such action?

Answer. We agree that pressure ulcers are a critical area to address. We now have pressure ulcer quality measures for all of the post-acute care providers (long-term care hospitals, inpatient rehabilitation hospitals, skilled nursing facilities, and home health agencies). The measure looks at the percent of patients with pressure ulcers that are new or have worsened. In the acute care hospital setting, there is not such an individual pressure ulcer measure; however, there is a patient safety composite measure (the Patient Safety and Adverse Events Composite) that includes pressure ulcers as one of the eight components of this composite measure. In FY 2018, this measure will comprise 15 percent of a hospital's score under the Hospital Acquired Condition (HAC) Reduction program. In the HAC Reduction Program, we solicit comments in our rulemaking on future potential safety measures that could be added to the program. We are always re-evaluating the measure set as well as the weights of the measures and domains in the program, and are able to add and remove measures, as needed. In addition, the Quality Improvement Organization (QIO) Program has worked over the past several years to bring together hospitals, nursing homes, physician practices, and patient advocates to work on patient safety issues, including the reduction of pressure ulcers. The Hospital Improvement Inno-

vation Networks are part of the QIO program, and pressure ulcers are one of the 11 areas of harm they have been focused on.

Question. In the updated Unified Agenda, FDA Commissioner Gottlieb identifies more than 70 actions the FDA will pursue this year to deliver on its critical mission of protecting and promoting the public health.

Across the FDA's broad regulatory portfolios, Commissioner Gottlieb is prioritizing innovation, committing the FDA to:

. . . "evaluating all aspects of its policies to make sure we're protecting consumers, while promoting beneficial innovation that has the potential to . . . improve public health" and taking "steps to foster innovation and regulating areas of promising new technology in ways that don't raise the cost of development or reduce innovation."

Examples of these steps include modernizing medical device pathways to be more "transparent, consistent, and objectively defined," supporting innovation in digital health products, establishing a new regulatory framework for regenerative medicine policy to provide "efficient access to potentially transformative products, while ensuring safety and efficacy," and announcing a new regulatory framework for nicotine that seeks to "reduce(e) the addictiveness of combustible cigarettes" and supports "innovation to lead to less harmful products, which under FDA's oversight, could be part of a solution."

Will you commit to supporting Commissioner Gottlieb's vision for fostering innovation in industries regulated by the FDA through sensible regulatory pathways that don't raise costs or stifle technological advancements? If yes, please provide examples of how you will be supportive at the full agency level.

Answer. Yes, I am committed to supporting Commissioner Gottlieb's vision for fostering innovation in industries regulated by FDA through sensible regulatory pathways that do not raise costs or stifle technological advancements. For example, I will support actions that FDA has planned for 2018 in the areas of food safety, drug safety, and broadening access to nonprescription drugs.

Question. Will you commit to supporting Commissioner Gottlieb's efforts to modernize the FDA by focusing on making the FDA more efficient, innovative, and transparent? If yes, please provide examples of how you will be supportive at the full agency level.

Answer. Yes, I am committed to supporting Commissioner Gottlieb's efforts to modernize FDA by focusing on making FDA more efficient, innovative, and transparent. I support the following goals of FDA for 2018.

FDA is working to ensure efficiency of existing regulations—a key focus of the Unified Agenda—by making sure that FDA's standards are clearly defined, that they advance our public health goals and help promote the protection of consumers, and achieve these goals in an efficient way that does not place unnecessary burdens on those FDA regulates. FDA also wants to ensure that our standards and regulations are modern and reflect the latest science, and have not become outdated, obsolete, or otherwise not applicable to the current environment.

- Harmonizing global standards: FDA will be updating its requirements for accepting foreign clinical data used to bring new medical devices to market. While helping to ensure the quality and integrity of clinical trial data and the protection of study participants, this rule should also reduce the burden on industry because it will harmonize with the standards currently used in drug regulation.
- Modernizing mammography standards: FDA will be proposing a rule to modernize mammography quality standards that will improve women's health. FDA's aim is to recognize advances in technology and help to ensure women get the most relevant, up-to-date information about their breast density, which is now recognized as a risk factor for breast cancer. This information can help doctors and patients make more informed decisions about further imaging.
- Embracing electronic submissions: FDA will propose a new framework that will allow FDA and product developers to take greater advantage of the efficiency of electronic, rather than paper, submissions for devices and veterinary drugs.
- Removing outdated rules: FDA will remove an outdated inspection provision for biologics and outdated drug sterilization requirements to remove barriers to the use of certain sterilization techniques.

Question. Do you also believe that FDA regulatory pathways should be modernized to be transparent, consistent, and objectively defined? If yes, please describe what specific steps will you take to ensure this happens at the FDA under your and Commissioner Gottlieb's watch?

Answer. Yes, I believe we should always look for ways to modernize our regulatory approach. For example, FDA's new comprehensive tobacco regulation plan (announced in July 2017) builds on current endeavors and is part of an overall effort to reduce the adverse effects of tobacco products, create clearer guideposts for the regulation of all tobacco products, and account for the role of noncombustible products.

The components of the plan work together as a package to help achieve our public health goals of reducing tobacco-related disease and death. The agency's new tobacco regulatory framework has two primary parts: exploring the reduction of the addictiveness of combustible cigarettes while recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health. Several steps and components make up each part, and to be successful, all these measures must be pursued together to allow FDA to address known harms while establishing a framework for sustainable regulation of all products going forward, including by encouraging innovations that have the potential to help smokers quit cigarettes. FDA is taking a fresh look at noncombustible tobacco products and recognizing the potential for innovation to lead to less harmful products, which under FDA's oversight could reduce risk while delivering satisfying levels of nicotine for adults who still need or want it.

To encourage innovations that have the potential to make a notable public health difference and to put foundational rules in place to provide increased clarity and efficiency for industry, the agency extended the premarket application compliance deadlines described in the deeming rule for certain products. Specifically, FDA is deferring enforcement of requirements to submit premarket applications for newly regulated tobacco products that were on the market as of August 8, 2016. Under these revised timelines, applications for such newly regulated combustible products, such as cigars, pipe tobacco, and hookah tobacco, would be submitted by August 8, 2021, and applications for such non-combustible products such as ENDS would be submitted by August 8, 2022.

As another example, FDA continues to work to advance the field of regenerative medicine and, in November 2017, issued a comprehensive framework for the development and oversight of regenerative medicine products, including novel cellular therapies.

Congress advanced the promise of this cutting-edge field when it passed the 21st Century Cures Act which includes several provisions that build upon FDA's previous efforts in the field of regenerative medicine and provides the agency with tools to facilitate the development and review of these important products. FDA's Center for Biologics Evaluation and Research implementation of the regenerative medicine-related provisions of the Cures Act, including the new Regenerative Medicine Advanced Therapy (RMAT) designation program, is a key part of the agency's efforts to encourage the development of innovative, safe, and effective regenerative medicine products.

QUESTION SUBMITTED BY HON. ROB PORTMAN

Question. Secretary Azar, you noted that the President's budget calls for \$10 billion in funding to address the epidemic, but it does not obligate any of these funds to specific programs. Because of this, you stated that you could not commit at the time to seeing these funds used to support existing programs, like those under the Comprehensive Addiction and Recovery Act (CARA). What would the intended strategy be for utilizing these proposed funds? Would HHS rely on existing programs and infrastructure like those established under CARA, or would HHS seek to establish new opportunities for addressing the epidemic?

Answer. The President's budget request for \$10 billion reflects the administration's strong commitment to addressing the opioid epidemic and mental health. Of the \$10 billion, an initial allocation provides \$1.2 billion to SAMHSA for a variety of new and expanded efforts to fight the crisis. Of that amount, \$1 billion is included to expand the State Targeted Response Grants. Additional funds will also help States provide services to reduce injection drug use and related HIV/AIDS and Hepatitis C infection rates, allow communities to purchase naloxone for first responders,

and expand the use of drug courts, as well as services to pregnant and postpartum women.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. During the Finance Committee hearing on your nomination to be HHS Secretary, you proposed applying principles from Medicare Part D to how Medicare pays for Part B drugs. In response to my Question for the Record (QFR) on this topic, you reiterated your interest in working with Congress on this proposal to ensure the Medicare program pays the most appropriate rate for Part B drugs (and, as a result, beneficiaries pay the lowest possible cost-sharing).

The FY 2019 President's budget includes a proposal to provide you, as the Secretary of Health and Human Services (HHS), "with the authority to consolidate certain drugs currently covered under Medicare Part B into Part D." Please provide detailed answers to the following questions regarding this proposal.

If given this new authority, how would you, as HHS Secretary, determine which Part B drugs to shift to Part D? What categories of Part B drugs does HHS consider good candidates for shifting to Part D? Are there any specific categories of Part B drugs that HHS does not consider appropriate to shift to Part D?

The President's budget proposal states that the HHS Secretary would exercise this authority when "there are savings to be gained from price competition." If given this new authority, how would you, as HHS Secretary, determine whether there are savings to be gained from shifting a specific Part B drug to Part D? In exercising this new authority, how would HHS determine the savings gained from shifting a drug from Part B to Part D would result from a lower price of the drug rather than reduced utilization due to any access concerns? Would HHS consider any factors other than potential savings when determining whether to shift a Part B drug to Part D? If so, what other factors would be considered?

Please describe in detail how HHS would implement this policy if Congress were to adopt the President's budget proposal, including how the policy would impact Medicare beneficiaries, physicians and other health care providers, drug plan sponsors, and pharmacies. Do you anticipate changes in Part D Plan premiums as a result of shifting drugs to Part D? Would changes in beneficiary premiums as a result of shifting drugs from Part B to Part D factor into savings estimates?

Answer. I look forward to working with Congress to explore ways that we can bring the negotiation strategies that are currently working in Medicare Part D, where we receive the best deals of any payer in the commercial marketplace, into Part B, which does not negotiate prices. I hope to work with you and your colleagues to develop legislation that will provide us with the authority to re-classify Part B drugs into Part D when appropriate, while taking into consideration the projected impacts on beneficiary access and cost-sharing, as well as costs to the Medicare program.

Question. The President's FY 2019 budget proposes to eliminate the Medicaid expansion and impose a per capita cap or block grant on the remainder of the Medicaid program, the combination of which would cut an estimated \$1.4 trillion from Medicaid just over the next 10 years. When asked about these proposals during a hearing before the Senate Finance Committee, you testified that these policies would help "reorient Medicaid" to fix what you called a "perverse incentive" in the Medicaid expansion program to "prioritize the expansion able-bodied new entry populations over those traditional Medicaid populations," including children, the elderly, and individuals with disabilities.

As demonstrated by the independent, nonpartisan Kaiser Family Foundation in a report entitled "Data Note: Data Do Not Support Relationship between States' Medicaid Expansion Status and Home and Community-Based Services Waiver Waiting Lists," expansion of the Medicaid program has not lead to increased waiting lists for services for those with disabilities. In fact, according to the analysis, among States that saw their waiting lists grow over that time period, the average increase was more than 2.5 times greater in non-expansion States compared to expansion States. In fact, in 2015, the two States with the largest HCBS waiver waiting lists—Texas and Florida—were non-expansion States.

Given these data demonstrating that the claim that the decision to expand Medicaid comes at the expense of access to HCBS for traditional Medicaid beneficiaries

is inaccurate, please explain how the Medicaid expansion program creates a “perverse incentive” in this case.

Answer. Thank you for the opportunity to further explain the structural defects in the PPACA which prioritize able-bodied adults over the traditional Medicaid population, including Americans with disabilities. As you know, States receive a larger Federal match (94 percent in 2018 which declines to 90 percent by 2020 and beyond) to cover the able-bodied, but a Federal match ranging from 50–75 percent to cover individuals with disabilities. Unfortunately, the report cited above does not take into account a number of important factors which might impact a State’s decision to expand Medicaid or reduce its waiting lists for individuals with disabilities such as the relative size, wealth or tax base of a State, the differing demographics of States, or other fiscal challenges within the States. In addition to the study not controlling for critical differences among the States, it is an undeniable feature of the Medicaid expansion to provide States a significantly greater financial incentive to cover the able-bodied expansion population (94 percent Federal share) instead of individuals with disabilities (as low as 50 percent Federal share). Whether and how to prioritize Medicaid coverage for their citizens varies significantly among States due to a number of factors, but a significantly larger Federal share of spending for one population over another is a clear financial incentive to cover one group of citizens over another.

Question. Studies conducted by the independent Robert Wood Johnson Foundation, Kaiser Family Foundation, and others have also demonstrated that extending Medicaid coverage to low-income adults produces savings for State governments. In fact, over 2015 and 2016, States that opted not to expand their programs saw Medicaid costs rise at a faster rate than the costs reported by expansion States. Such data suggests that the Medicaid expansion program supports, rather than limits, the ability of States to fund and support services for traditional Medicaid beneficiaries and other individuals in State health care programs.

In light of these data, how does repealing the Medicaid expansion program support State efforts to provide health-care coverage and services?

Answer. The FY 2019 budget establishes a block grant or per capita cap for the traditional Medicaid populations and repeals the PPACA Medicaid expansion. States would have the option to cover the former Medicaid expansion population through the new Market-Based Health Care Grants included in the Graham-Cassidy-Heller-Johnson legislation. These new financing mechanisms will harmonize the treatment of States over time and allow States to better target resources to their most needy citizens. To that end, we need reforms to provide States flexibility to design their Medicaid programs to meet the spectrum of diverse needs of their Medicaid populations. Currently, 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. Reforms like block grants, when paired with additional authority and flexibility, can incentivize and empower States to develop innovative solutions to challenges like high drug costs and fraud, waste and abuse. We must make health care more tailored to what individuals want and need in their care. The President’s FY 2019 budget takes a significant step in that direction by putting the Medicaid program on a sustainable course and returning local health-care decisions back to where they should be made.

Question. Repealing the Medicaid expansion and capping the traditional Medicaid program would have severe consequences for State budgets by increasing the number of uninsured residents and leaving State Medicaid programs with billions fewer dollars in Federal support. Such cuts would force States to compensate by modifying their traditional Medicaid programs by limiting enrollment, rolling back optional benefits—including HCBS—and reducing provider payments, as the non-partisan Congressional budget Office reported in 2017.

In light of these projections, how does this budget’s proposal to cut and cap the traditional Medicaid program ensure that low-income children, seniors, and individuals with disabilities do not lose access to the services and coverage they need?

Answer. The budget’s Medicaid proposal is modeled after the Graham-Cassidy-Heller-Johnson bill, which includes a modernization of Medicaid financing and repeal of the Obamacare’s Medicaid expansion. Medicaid financing reform will empower States to design individual, State-based solutions that prioritize Medicaid dollars for traditional Medicaid populations and support innovations like community engagement initiatives for able-bodied adults. Additionally, the Market-Based Health Care Grant Program included in the Graham-Cassidy-Heller-Johnson legis-

lation will provide more equitable and sustainable funding to States to develop affordable health-care options for their citizens. The block grant program will empower States to improve the functioning of their own health-care market through greater choice and competition, with States and consumers in charge. Putting States back in charge of their health-care decisions will allow them to better target resources to low-income children, seniors and individuals with disabilities.

Question. In January, OCR and HHS issued a proposed rule regarding protecting the conscience rights of providers that have objections to certain activities based on their values or religious beliefs.

There is no language included in this proposed rule regarding discrimination against gay, lesbian, bisexual or transgender individuals.

Will you commit to including language in the final draft of this rule to State that the rule does not permit discrimination against LGBT populations or allow a provider to refuse care or services to an individual that identifies as LGBT?

Answer. We are currently reviewing public comments on the proposed rule, and we cannot predetermine the outcome of the notice and comment process. The Federal conscience laws were passed by Congress with bi-partisan support in order to prohibit discrimination and to further diversity in health care. The proposed conscience regulation would provide mechanisms for enforcement of current Federal laws that have been under-enforced in the past. HHS is committed to faithfully applying the facts to the law, and to treating all complainants fairly under every statute it enforces.

Question. Mental illness affects millions of Americans, regardless of culture, race, ethnicity, gender, or sexual orientation. As the primary Federal agency for research on mental illness, the National Institute of Mental Health (NIMH) is tasked with conducting clinical research that advances prevention, treatments, and cures for mental disorders. There is an urgent need for clinical research that addresses immediate public health needs and reduces disparities among underrepresented communities. At NIMH, clinical trials are vital to discovering interventions that are culturally appropriate for each community.

The Fiscal Year 2019 President's budget would increase funding to the National Institute of Mental Health (NIMH) by \$21 million.

How would NIMH balance the allocation of new resources between basic and clinical research priorities?

Answer. NIMH strives to maintain a diverse portfolio of short-, medium-, and long-term investments to maximize impact on public mental health. Short-term investments include applied research, such as clinical trials and implementation research; medium-term investments involve research aimed at understanding mechanisms of illness; and long-term investments focus on basic research to understand how the brain works, how it is influenced by environment, and how it guides behavior. By supporting this diversity of research across timeframes, NIMH helps those who have mental illnesses now, and funds research that leads to more effective treatment and prevention programs in the future. Increased funding would enable NIMH to fund excellent science across all timeframes that might otherwise go unfunded.

Question. How would NIMH use the additional funding to focus on clinical research trials that test the effectiveness of mental health interventions for minority groups and other underserved communities?

Answer. NIMH recognizes the compelling need to assess treatment efficacy among minority groups and other underserved communities. NIMH is committed to research focused on decreasing disparities, as exemplified by the inclusion of mental health disparities as a theme that cross-cuts its entire NIMH Strategic Plan for Research. NIMH strives to include adequate numbers of men and women and members of diverse racial/ethnic groups in research studies—from genomics to services and clinical research—in order to detect and mitigate these disparities. In addition, studies of diverse populations can contribute to our understanding of risks for mental illnesses, responsiveness to prevention and treatment interventions, and access to, and engagement in, care.

Through current funding opportunity announcements, NIMH is seeking research applications to specifically target the reduction and elimination of mental health disparities. In addition, notable NIMH clinical research trials directed toward underserved populations include a safety study of the antipsychotic drug clozapine,

and a community-based study examining adherence to an HIV intervention. NIMH will continue to support efforts to test effectiveness of mental health interventions for minority groups. Research on sex, gender, age, racial, and ethnic differences related to mental disorders will provide information essential to the development of precision medicine and personalized interventions.

Question. What steps will NIMH take to increase the diversity of clinical trial participants across all NIMH funded clinical research studies?

Answer. NIMH applies NIH policies on the inclusion of women, minorities, and individuals across the lifespan in clinical research.^{1,2} The NIH Grants Policy Statement (4.1.15.7–8) requires that applicants address the inclusion of individuals based on sex/gender, race, and ethnicity in research designs as appropriate to the scientific objectives of the study.³ In addition, the NIMH Recruitment of Participants in Clinical Research Policy requires recruitment plans for all NIMH extramural-funded clinical research studies proposing to enroll 150 or more subjects per study, and all clinical trials, regardless of size. Consideration must be given to recruitment plans for females and males, members of racial and ethnic minority groups, and children. Grantees are encouraged to propose outreach plans for research participation.⁴

To increase awareness of opportunities to participate in research, NIMH provides an online resource for studies conducted at the NIH Clinical Center.⁵ NIMH also engages with mental health professional and advocacy groups that focus on health disparities communities.⁶ These efforts provide a unique opportunity to reach diverse groups, increase awareness about the opportunities to benefit from participation in mental health research, and increase public access to science-based mental health information.

Question. The President's FY 2019 budget proposes policies that will undermine access to essential health services for millions of women across the country.

The budget calls for Congress to exclude providers of abortion, including Planned Parenthood from the Medicaid program. However, Planned Parenthood provides preventive care to roughly 2.7 million patients, at least 60 percent of whom rely on Medicaid or title X to access care. Excluding Planned Parenthood and other providers from Medicaid would block these beneficiaries from accessing primary care and reproductive health services, including contraception, breast and cervical cancer screenings, vaccines, and testing for sexually transmitted diseases. As a result, these women could face higher rates of unintended pregnancy or maternal mortality.

In over 20 percent of counties across America, a Planned Parenthood health center is that county's only safety-net family planning provider. How will you ensure access to health care for the women in these counties?

Experts agree that community health centers do not have the capacity to provide care to the millions of patients who rely on Planned Parenthood. What steps will you take to protect access to care for the 4 in 10 women who rely on Planned Parenthood and similar providers as their only source of health care?

Answer. Preventing unintended pregnancy is important to women's health. As I said in my opening statement to the committee, we must make health care more affordable, more available, and more tailored to the medical care individuals need. I look forward to working with Congress to ensure that such a system is in place.

Question. Over 54 percent of Planned Parenthood health centers are in health professional shortage or medically underserved areas. What steps will you take to ensure that women in rural and underserved regions of the country continue to have access to family planning services?

Answer. Women should have access to the health care and services they need. The Department is committed to ensuring that women in rural and underserved regions

¹ https://grants.nih.gov/grants/funding/women_min/guidelines.htm.

² <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>.

³ https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm?toopath=4%20Public%20Policy%20Requirements%2C%20Objectives%20and%20Other%20Appropriation%20Mandates%7C4.1%20Public%20Policy%20Requirements%20and%20Objectives%7C4.1.15%20Human%20Subjects%20Protections%7C7#4.1.15.7 Inclusion of Children as Subjects in Clinical Research.

⁴ <https://www.nimh.nih.gov/funding/grant-writing-and-application-process/nimh-recruitment-of-participants-in-clinical-research-policy.shtml>.

⁵ <https://www.nimh.nih.gov/labs-at-nimh/join-a-study/index.shtml>.

⁶ <https://www.nimh.nih.gov/outreach/partnership-program/index.shtml>.

have access to quality family planning services. Accordingly, the most recent title X family planning services funding opportunity announcement (FOA) encourages new applicants to submit quality and innovative proposals, to expand subrecipient partnerships in novel ways, and to extend services to those areas and clients previously unserved or underserved.

Question. The budget also calls for Congress to bring back the Graham-Cassidy-Heller proposal, which proposed establishing a new State block grant program. This program would have permitted States to waive certain consumer protection mandates for insurers, including the requirement that insurers cover maternity care as an essential health benefit. The non-partisan Congressional Budget Office projected that if insurers are permitted to waive essential health benefits, many will forgo coverage to maternity care given its high cost. Consistent with this projection, prior to the Affordable Care Act, only 11 States required maternity coverage on the individual and small-group markets.

Reducing access to coverage for maternity care will make it more difficult for women to find plans that cover these services, and will likely drive up the cost of plans that offer such services. Does this administration believe women should have to pay more for coverage to access care essential to women's health?

Does this administration support allowing States to decide whether women should be guaranteed access to coverage for maternity care?

Answer. I support ensuring access to health care for all Americans. I will work to promote a health-care system that will provide access to quality care, while ensuring patients are able to make decisions that work best for them. I will also work with States to help them achieve their goals within the parameters and confines of the law.

Question. On January 25th, the Associate Attorney General for the Department of Justice (DOJ) issued a memorandum to the DOJ's civil litigating components instructing United States attorneys on the legal enforceability of guidance for administrative enforcement actions. This memorandum stated that going forward, non-compliance with guidance could not create new legal obligations on regulated parties and could not be used as a basis for proving legal violations, including in cases brought under the False Claims Act.

Please explain how this Department of Justice memorandum will impact the Department of Health and Human Services' efforts to combat fraud and abuse in programs under the Senate Finance Committee's jurisdiction, including the Medicare and Medicaid programs.

Answer. The Department of Justice memorandum instructs Department civil litigators that they are prohibited from using guidance documents to establish violations of law in affirmative civil enforcement actions. While guidance documents can be helpful, too often administrations have used them to circumvent the rulemaking process. The Department of Justice's memorandum helps clarify that guidance documents cannot create additional legal obligations. The relevant laws covering fraud and abuse within Department programs, including Medicare and Medicaid, are still in effect. I remain committed to fighting all fraud, waste, and abuse in our programs and I look forward to discussing with you how we can work together to do this.

Question. Please describe the justification for converting the Maternal, Infant and Early Childhood Home Visiting program from a mandatory to discretionary program.

Answer. The administration viewed the higher spending caps as an opportunity to resolve some long-standing budget challenges across the Federal budget, including the use of funding for types of activities that would more typically be supported with discretionary resources.

Question. Medicaid is the single largest payer of substance use disorder (SUD) services in the Nation and pays for a third of all medication-assisted treatment (MAT) in the United States. Many States with the highest opioid overdose death rates have employed the Medicaid expansion to increase access to MAT including Kentucky, Pennsylvania, Ohio, and West Virginia as well as many other States being devastated by the opioid epidemic like my home State of Oregon. Under the ACA's Medicaid expansion, one out of three people covered through the Medicaid expansion have a mental illness, substance use disorder, or both. In fact, independent researchers estimate that repealing the Medicaid expansion would cut \$4.5 billion from mental health and substance use services for low-income Americans. According to SAMHSA, the Affordable Care Act, including the expansion of Medicaid, is ex-

pected to increase total spending on behavioral health by more than \$7 billion per year by 2020. Unfortunately, the President's budget aims to directly undermine much of this progress by gutting the Medicaid program.

As Secretary of HHS, how do you intend to protect the gains in access to SUD treatment achieved through Medicaid expansion if Medicaid is cut by \$1.4 trillion and the Medicaid expansion is repealed?

One of the critical ways in which we see the importance of access to SUD treatment is by looking to the spread of the opioid epidemic, particularly in rural regions of the country. The Congressional Budget Office projected millions of Americans would lose coverage under the Graham-Cassidy-Heller-Johnson proposal. How do you plan to combat this epidemic if millions of Americans lose coverage for mental health and SUD treatment? Given the fact that this epidemic is particularly devastating for rural communities, do you have plans to combat opioid abuse that will target individuals in these regions?

Answer. Our Medicaid program is an important tool in providing health care to many Americans but we must put it on a stable, long-term sustainable footing for it to be there for this and future generations. That's the challenge that we have as we seek to empower the States with the right incentives to deliver quality service. The FY 2019 budget provides additional flexibilities to States, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from \$421 billion in FY19 to \$702 billion in FY28 over the budget window. The FY 2019 budget also repeals the Medicaid expansion and the Exchange program subsidies and replaces these programs with the \$1.2 trillion Market-Based Health Care Grant program through the Graham-Cassidy-Heller-Johnson legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

Question. Earlier this fall, ACF blocked for 2 years the implementation of the AFCARS rule which would have provided decision makers with new key information on children in the child welfare system including children at-risk of sex trafficking. This information is used to inform policy and help us understand what is happening with children who are removed from their homes. The questions asked of States about their children in foster care have NOT been updated since 1993. Since then, several major laws have been enacted that statutorily mandate that these upgrades take place and charge HHS with using new enforcement tools.

Earlier this month I sent a letter to your department outlining these issues. In my view, this 2-year delay is completely unreasonable.

Please explain the policy rationale for this 2-year delay.

Answer. HHS is publishing an Advance Notice of Proposed Rulemaking (ANPRM) seeking public suggestions for streamlining the AFCARS data elements and removing any undue burden related to reporting AFCARS. The HHS Regulatory Reform Task Force identified the extensive additions to the reporting system included in the December 2016 AFCARS final rule as an area where there may be areas for reducing reporting burden and where costs may exceed benefits. The proposed 2-year delay in implementation of the new requirements would allow HHS time to consider the comments to the ANPRM and use them to draft a NPRM proposing revisions to the AFCARS consistent with the objectives and direction of E.O. 13777. It would

also allow title IV–E agencies ample time to consider the full impact the data reporting from the 2016 AFCARS rule and provide HHS with specific comments on the burden associated with the 2016 rule.

Question. Do you believe delaying congressionally mandated data collection is consistent with HHS's authority?

Answer. Section 479 of the Social Security Act requires us to regulate the AFCARS requirements. There is no legislative deadline established in the act for updating or issuing regulations. Therefore, it is within our authority to issue regulations and revise the regulations. Title IV–E agencies will continue to submit AFCARS data per the requirements in regulations 45 CFR 1355.40 and the appendix to part 1355.

Question. How do you square HHS's decision to delay this improvement to child welfare data with your stated priorities related to improving Federal data and program management?

Answer. The delay provides HHS with time to consider the best approach to improving child welfare data that balances the need for improved data with the burden of reporting by title IV–E agencies. Our effort is to ensure that we are collecting the data required by law and needed for program management, and not creating an unnecessary burden for agencies when their time and resources could instead be used to directly help children.

Question. In your questions for the record for your nominations hearing, you cited data indicating support of the 1996 welfare reform law in demonstrating increased employment rates for single mother-led families and decreased poverty rates among single mother-led families. It seems that you are supportive of TANF and how it has impacted welfare in the United States. The President's budget included a 10% cut in funding for TANF.

If TANF has been a successful program, why would the budget propose to cut it?

Answer. TANF's success comes from its restructuring of a welfare system to create a program that provides time-limited assistance, promotes empowerment through work, and fosters innovation, and, not from the amount of dollars spent. Moreover, since TANF's inception, cash assistance caseloads have fallen about 70 percent. 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.

Question. As a general matter, do you support cutting funding for successful programs?

Answer. This administration supports using taxpayer funds as efficiently as possible for the purposes they are intended. For example, in the TANF program, many States are not sufficiently investing their current dollars in TANF's key welfare-to-work activities. In fiscal year 2016, States spent only about 31 percent of their total TANF and State maintenance-of-effort funds on the combination of work, work supports like child care and transportation services, and case management services. States do not need more money in the TANF program; they need to target the money more effectively to help move individuals to stable work that can lead to self-sufficiency.

We are confident States could find ways to use more of their block grant funds to increase engagement in work, and would be encouraged to do so with the proposed spending floor. States use a significant amount of TANF funds to fill State budget gaps in areas that are tangential, at best, to the core purposes of TANF. This includes spending on college scholarships for students from families who earn incomes well above the Federal poverty level.

Question. In the President's proposed FY 2019 budget, the administration makes clear that it intends to bring back the failed Graham-Cassidy-Heller-Johnson proposal, legislation that would gut the Affordable Care Act's consumer protections—legislation that the American people clearly rejected last year. Indeed during the committee's hearing on the Graham-Cassidy-Heller-Johnson proposal last fall, the witness from the American Cancer Society confirmed that this proposal would allow insurance companies to discriminate against Americans with pre-existing conditions and impose annual caps on coverage.

Does the administration believe insurers should be able to discriminate against individuals with pre-existing conditions by charging them more for their health insurance coverage or not covering essential services?

Answer. The ACA statutory requirements here are very strict and burdensome. While this may help some consumers, it also prevents States from developing innovative solutions that are tailored to their populations. I believe that when States are not permitted to innovate, everyone is worse off. Affordability, accessibility, benefit options, and procedural safeguards are all valuable, but our current top-down, Federally driven approach is not working well for Americans. I will work with States to allow innovation within the confines of the ACA.

Question. Does the administration believe that insurers should be able to refuse to cover maternity care or birth control, as many States allowed before the Affordable Care Act?

Answer. I look forward to working across the administration and with Congress to ensure that women have access to the care they need—that may include care for cancer, diabetes, maternity care, family planning, cardiovascular health and many other issues affecting women, men and families—while simultaneously implementing the many conscience-protections that Congress has enacted.

Question. Does the administration believe that insurers should be able to charge older Americans even more for their insurance premiums than they are able to today, as AARP confirmed would happen under the Graham-Cassidy-Heller-Johnson proposal?

Answer. There is an emerging bipartisan consensus that the ACA's structure is fundamentally flawed in this area. The age rating structure as currently in statute does not allow for functional risk pooling. Under the ACA age rating requirements, insurance is unaffordable for younger and healthier individuals. That is why older enrollees currently represent the largest share of enrollees. As a result, premiums have risen for older and younger Americans far beyond anything that would have occurred in a stable risk pool even with a more realistic age rating structure. This is a problem we must all work together to solve, as effective and predictable risk pools are critical to the success of any health insurance system. I pledge to work with Congress on health-care reforms that create effective risk pools.

Question. During your confirmation hearing last month, you pledged to be responsive to members of the Finance Committee. Following the hearing, in response to questions for the record from Senator Casey, you wrote that you would be responsive to all members of Congress. Therefore, I was extremely concerned by the inadequate reply that three congressional colleagues and I received in response to a January 31st letter to you and Administrator Verma regarding changes to Idaho's insurance regulations. On February 9th, Administrator Verma responded to that letter without even attempting to answer the questions that had been posed, before doubling down by saying that CMS "does not have any additional information to share." Absent any other correspondence, Administrator Verma's letter appears to represent the Department's position, which is simply unacceptable. It also appears to continue the Department's general lack of responsiveness to Congress that has become commonplace since the beginning of the Trump administration, and been subject to criticism from both parties, most recently by Congressman Gowdy in a letter to you. As such, let me take this opportunity to restate Senator Casey's written question from your confirmation hearing—do you commit to providing thorough, complete, and timely responses to requests for information from all members of Congress, including requests from members in the minority? Will you review the letter that I and other colleagues sent you on January 31st and Administrator Verma's response and let us know whether you will provide answers to the questions we asked?

Answer. Thank you for bringing this matter to my attention. Regarding this particular communication, it is my understanding that in an effort to provide timely responses to incoming congressional inquiries, and given that the Department had not yet received any communication from the State, there was no additional information to provide in response to the questions at that time.

I continue to pledge that I will work with my staff to ensure that the Department's responses to requests from Congress are timely, appropriate, and reasonable. However, at the time of this response, the Department did not have information to share regarding the Idaho bulletin.

Question. The Idaho Department of Insurance issued a Bulletin on January 24th allowing insurers in Idaho to submit so-called "State-based health benefit plans" or "State-based plans." Idaho would allow these plans to ignore many of the Affordable Care Act's consumer protections including prohibitions on charging individuals more for pre-existing conditions, annual limits, geography, as well as expanding age rat-

ing ratios to 5:1. Recently, Blue Cross of Idaho announced that they would be the first plan to submit insurance plans under this new program. The application for these plans includes numerous questions about the applicant's health status and family history, presumably to medically underwrite the applicant.

Do you think it violates Federal law for an insurance company to ask these kinds of very personal questions? If an insurer is following the law barring discrimination against those with pre-existing conditions, why would they need this information?

In your confirmation hearing, you committed to upholding the law. Major patient groups and legal experts believe that Idaho is violating the law. What specific actions are you taking and do you plan to take to ensure that Idaho follows Federal law?

Why, if what Idaho is doing is illegal or wrong, is the administration's proposal that allows issuers to sell similar or even lower quality plans renamed as "short-term plans," legal or not wrong?

Answer. I am committed to working with States to grant flexibility wherever appropriate to provide their citizens the best possible access to health care. However, the Affordable Care Act remains the law. CMS informed the State that its State-based plan proposal, as originally issued, is inconsistent with the law.

The Department looks forward to working to explore ways in which Idaho can achieve its policy goals ensuring that health insurance coverage sold within the State complies with all applicable Federal laws and requirements.

QUESTIONS SUBMITTED BY HON. MARIA CANTWELL

Question. I understand the President's budget proposes statutory changes similar to the so-called Graham-Cassidy legislation. Numerous nonpartisan evaluations, including those performed by the Congressional Budget Office, have found that Graham-Cassidy would reduce insurance coverage and sharply lower Federal Medicaid investment, relative to current law. I am concerned that Graham-Cassidy would consequently lead to large spikes in hospital uncompensated care levels. Does the administration project that enacting the Graham-Cassidy legislation will not increase levels of hospital uncompensated care, and if so, what is the administration's rationale for that projection?

Answer. The administration is committed to rescuing States, consumers, and taxpayers from the failures of Obamacare and to supporting States as they transition to more sustainable health-care programs that provide appropriate choices for their citizens. The budget supports a two-step approach to repealing and replacing Obamacare, starting with enactment of legislation modeled closely after the Graham-Cassidy-Heller-Johnson bill, as soon as possible. The administration supports the comprehensive Medicaid reform in the Graham-Cassidy-Heller-Johnson bill, including modernization of Medicaid financing and repeal of the Obamacare's Medicaid expansion. Medicaid financing reform will empower States to design individual, State-based solutions that prioritize Medicaid dollars for traditional Medicaid populations and support innovations like community engagement initiatives for able-bodied adults. Additionally, the Market-Based Health Care Grant Program included in the Graham-Cassidy-Heller-Johnson legislation will provide more equitable and sustainable funding to States to develop affordable health-care options for their citizens. The block grant program will empower States to improve the functioning of their own health-care market through greater choice and competition, with States and consumers in charge. The second step of the repeal and replace proposal builds upon the Graham-Cassidy-Heller-Johnson bill to make the system more efficient by including proposals to align the Market-Based Health Care Grant Program, Medicaid per capita cap, and block grant growth rates with the Consumer Price Index for all Urban Consumers.

Question. In addition to proposing the Graham-Cassidy legislation, I understand the President's budget calls for a net reduction of \$69.5 billion in Medicare uncompensated care payments to hospitals over a 10 year period. What is the administration's policy rationale for this proposal?

Answer. This proposal would remove uncompensated care payments from the Inpatient Prospective Payment System and establishes a new process to distribute uncompensated care payments to hospitals based on share of charity care and non-Medicare bad debt. This proposal more closely aligns Medicare payment policy with private insurers, who do not typically cover uncompensated care.

Question. I appreciate that your budget includes a proposal to expand beneficiary assignment rules for Medicare Accountable Care Organizations (ACOs) to include primary care visits furnished by non-physician providers. Your budget also projects that this statutory change would yield \$140 million in savings over 10 years, presumably to the Medicare program. What are the administration's assumptions for this cost-saving estimate, and does the administration believe that more Medicare beneficiaries would participate in an ACO under this proposal?

Answer. Effective CY 2019, this proposal allows the Secretary to base beneficiary assignment on a broader set of primary care providers, to include nurse practitioners, physician assistants, and clinical nurse specialists, in addition to physicians. This option broadens the scope of Accountable Care Organizations to better reflect the types of professionals that deliver primary care services to fee-for-service beneficiaries. Potentially assignable beneficiaries could increase for ACOs that rely on non-physician practitioners for a majority of primary care services, such as those in rural or underserved areas. As the program's goals are to improve quality of care received by Medicare fee-for-service beneficiaries while reducing overall growth in costs, broader participation could help improve care received by beneficiaries and lower Medicare expenditures.

By expanding the basis for beneficiary assignment to better reflect the types of professionals that deliver primary care services, the proposal would move more beneficiaries to value-based care.

Question. In the past, we have discussed the importance of accelerating Medicare's transition from fee-for-service to a value-based payment system. I understand that your budget proposes a statutory change to the 5 percent bonus for participation in an Advanced Alternative Payment Model (A-APM) under Medicare's new physician payment framework. The HHS budget in brief document states that this change will better incent clinicians to participate in A-APMs. Could you further explain the mechanisms of this proposed change? Specifically, could you explain whether HHS projects that, under this proposal, the aggregate level of A-APM bonus payments would rise, fall, or stay the same compared to current law? Additionally, why is HHS unable to make a cost or savings estimate for this proposal?

Answer. The President's budget proposes to modify how the 5-percent incentive payment is determined in order to better reward clinicians who participate in Advanced Alternative Payment Models (APMs). Instead of receiving a 5-percent incentive payment on all physician fee schedule (PFS) payments if they meet or exceed certain payment or patient thresholds, clinicians will receive a 5-percent incentive payment on PFS revenues received through the Advanced APMs in which they participate.

This proposal changes two major aspects of the QP determination process and how the 5-percent incentive is calculated: it eliminates the payment and patient thresholds for becoming a QP. All clinicians in Advanced APMs would be eligible for incentive payments. It also alters how the 5-percent incentive payment is calculated. Instead of being calculated based on the total PFS payments from the previous year, it is based on the payments clinicians received through the Advanced APM.

QUESTIONS SUBMITTED BY HON. BILL NELSON

Question. Last week at the House Budget Committee hearing, the Office of Management and Budget Director said the FDA will apply a new set of standards to the cost-benefit analyses involved in the review of premium cigar regulations. He also expressed a willingness to work with Congress and all stakeholders on this issue moving forward. In light of these commitments from the OMB, would HHS consider delaying upcoming deadlines pending the release of the Advanced Notice of Proposed Rulemaking (ANPRM)?

Answer. Thank you for the opportunity to clarify FDA's work in this area. Due to the continued interest in the regulation of "premium" cigars, FDA intends to provide an opportunity for the public to provide new information for the agency to consider. In particular, FDA is seeking comments and scientific data related to how to define a "premium" cigar and the patterns of use and resulting public health impacts from these products. This has taken the form of a new Advance Notice of Proposed Rulemaking (ANPRM). While ANPRMs do not contain cost-benefit analyses, the agency is seeking any information that may inform regulatory actions FDA might take with respect to premium cigars. The agency will explore any new and

different questions raised and consider additional data that is relevant to the regulatory status of premium cigars.

In the meantime, the tobacco deeming rule, including upcoming compliance dates, will remain in effect based on FDA's previous determination that there was no appropriate public health justification to exclude "premium" cigars from regulation.

Question. Last week, a former student at Marjory Stoneman Douglas High School in northern Broward County, Parkland, Florida, walked on to campus carrying an AR-15 assault rifle and opened fire killing 17 students and teachers.

This incident marked the 30th mass shooting in 2018 alone. The victims of this act of gun violence were children—high school students with promising futures. How many more lives must be lost until we say enough is enough?

Sandy Hook elementary, 20 students killed. That wasn't enough. The Pulse nightclub in Orlando, 49 people killed. That wasn't enough. Las Vegas, 58 people killed, that wasn't enough. Or just a year ago also in Broward county, Fort Lauderdale airport, five people killed. That wasn't enough. In his speech addressing the Parkland shooting, President Trump pledged to work with State and local leaders to "tackle the difficult issue of mental health." Yet, the budget proposal guts billions from programs critical to increasing access to mental health treatment, including Medicaid—the single largest payer of mental health services in the United States. It also slashes spending for established programs within the Substance Abuse and Mental Health Administration by over \$600 million, and revives a tried and failed approach to repealing the Affordable Care Act through the Graham-Cassidy bill. This is the same bill that the National Alliance on Mental Illness has said would allow States to drop the requirement to cover mental health care.

Tell me, do you stand by your cuts to critical mental health programs in light of the President's call to "tackle" mental health?

Answer. The FY 2019 budget includes funding for State and local programs to help individuals with serious mental illness (SMI) and serious emotional disturbances (SED), including: \$563 million for the Community Mental Health Services Block Grant, \$15 million for a new Assertive Community Treatment for Individuals with SMI program to help communities establish, maintain, or expand evidence-based efforts to avoid the ineffective cycling of patients with SMI, and directs up to 10 percent or \$12 million of the Children's Mental Health Program to new, evidence-based demonstration grants for earlier intervention in a first episode psychosis. The President's budget also includes \$10 billion to address the opioid crisis and SMI.

Question. Under the last administration, the National Institutes of Health sponsored a new funding opportunity under the National Institute of Mental Health and the National Institute on Alcohol Abuse and Alcoholism for "Research on the Health Determinants and Consequences of Violence and its Prevention, Particularly Firearm Violence." The gun violence research initiative has funded 14 firearm related research projects for \$11.4 million from January 2014 to January 2017 to help us identify the causes and factors for the prevalence of gun violence in our country. According to news reports, the NIH initiative expired in January 2017 and has yet to be renewed.

Do you support the renewal of the gun violence research program at the National Institutes of Health?

Answer. A key component of NIH's mission is to enhance health, lengthen life, and reduce illness and disability. In the spirit of this mission, NIH is committed to understanding effective public health interventions to prevent violence, including firearm violence, and the trauma, injuries, and mortality resulting from violence. NIH-funded research on the causes and prevention of firearm violence addresses a range of topics, such as parental roles in preventing injury—including injuries from firearms—in the home and in other settings, the relationship between alcohol abuse and gun violence, risk factors for gun violence, appropriate containment measures to reduce risk of suicide or accidental deaths among children and adolescents, as well as determinants that make war veterans at higher risk for suicide with guns.

NIH has supported research on firearm violence for many years, and it will continue to support this area of research in the future.

Question. Amyotrophic Lateral Sclerosis (ALS) is a progressive disease that results in the loss of muscle control and leads to death within 2 to 5 years after diagnosis. They may stop walking, speaking, eating, moving, or even breathing. The inci-

dence of ALS in the military is twice that of civilians, but it can affect anyone. There is no cure, and treatments are extremely limited.

The National ALS Registry, at the Centers for Disease Prevention and Control, is a unique patient and research asset for this devastating disorder. The Registry connects people living with ALS with information for clinical trials. To date, more than 100,000 email notifications have been sent to people with ALS alerting them of clinical trials and studies.

The Registry also includes a biorepository which collects biological samples, which are a critical resource for researchers who are investigating treatments and a cure for ALS. The Registry has collaborated and assisted more than 35 institutions, both pharmaceutical and academic, with recruitment for their clinical trials and epidemiological studies. In addition, the ALS Registry has funded 13 research institutions to identify risk factors and possible causes for ALS. The ALS Registry has received bipartisan support and is typically funded with an appropriation of \$10 million. Without the registry, research on ALS would be set back considerably.

Please describe how the administration's FY 2019 budget request will advance the operation of this essential initiative.

Answer. While the FY 2019 President's budget eliminates the Amyotrophic Lateral Sclerosis (ALS) registry and related research program, NIH-funded research on ALS will continue. External researchers would still be able to use biospecimens previously obtained from the ALS biorepository.

Question. The opioid crisis is devastating families across the Nation. In Florida alone, 5,275 opioid-related deaths were reported in 2016—35 percent more than reported in 2015. Fentanyl killed 1,390 Floridians, nearly double the 705 Floridians killed by fentanyl a year before. I've long called for a comprehensive solution that includes new resources to prevent and treat the opioid epidemic before more lives are lost. The President's budget proposes a \$10-billion investment into combating the opioid epidemic. I share this goal, but this modest increase in funding is coupled with a massive cut to Medicaid—to the tune of nearly \$1.4 trillion in cuts. Medicaid is the largest payer of substance abuse services in the country.

Explain how States like Florida can help communities fight the opioid epidemic if you cut billions from Medicaid.

Answer. Our Medicaid program is an important tool in providing health care to many Americans but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That's the challenge that we have as we seek to empower the States with the right incentives to deliver quality service. The FY 2019 budget provides additional flexibilities to States, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from \$421 billion in FY19 to \$702 billion in FY28 over the budget window. The FY 2019 budget also repeals the Medicaid expansion and the Exchange subsidies and replaces these programs with the \$1.2 trillion Market-Based Healthcare Grant program through the Graham-Cassidy-Heller-Johnson legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

Question. Over 5,658 cases of Zika virus have been reported across the U.S. States and territories. No State has been hit harder by the Zika outbreak than Florida. The State has seen more than 1,735 reported cases of the Zika virus to date and reported 255 new cases of Zika in 2017. In 2016, I fought to secure funding to address the Zika crisis. Congress ultimately approved \$1.1 billion to combat the threat. These funds made critical investments into agencies to support vaccine development and better understand the virus; to bolster vector control and enhance laboratory capacity; and to support Zika-related health care, to name a few.

The administration's proposed budget slashes the very programs Congress voted to fund in 2016 so they could help prevent, control and research the spread of Zika. The cuts are numerous, but here are a few highlights. Compared to 2017, it cuts \$27 million from the CDC's National Center on Birth Defects and Developmental Disabilities, \$68 million from the CDC's Center for Emerging and Zoonotic Infectious Disease, \$58 million from CDC's National Center for Environmental Health, and \$602 million from the CDC's Office of Public Health Preparedness and Response, all of which are central to Zika surveillance and control.

Given these cuts, do you believe the administration is doing everything it can to prepare for public health threats, like a Zika outbreak?

How would you justify the cuts to Zika control programs to my constituents in Florida with mosquito season right around the corner?

Answer. Preparedness for public health threats is of critical importance to us at the Department. Specifically, the Centers for Disease Control and Prevention (CDC) helps to protect America's health, safety, and security by working to prevent, detect, and respond to a wide range of public health threats, from anthrax and Ebola to Salmonella food poisoning and Zika.

A large portion of the proposed cut to CDC includes a \$575 million reduction representing the transfer of the Strategic National Stockpile from CDC to ASPR. Those funds will continue to be used to maintain and replenish the Nation's largest supply of life-saving medical countermeasures that can be deployed in the event of a public health emergency. This transfer will streamline the medical countermeasure development and procurement enterprise and will increase operational efficiencies during emergency response by fully integrating the Stockpile with other preparedness and response capabilities.

With the remaining funding requested by the administration, CDC will prioritize efforts to maintain its critical preparedness and response infrastructure. CDC may reduce ongoing core preparedness activities (*e.g.*, preparedness exercises, timeliness of reporting critical information, applied research for first responders, select agent training, etc.) and prioritize funds to address the most urgent needs.

CDC's vector-borne diseases program is the core of our Nation's capacity to detect, control, and prevent pathogens transmitted by ticks and insects. The FY 2019 President's budget maintains the elevated level of funding proposed in the FY 2018 President's budget for vector-borne diseases at \$49.459 million, which is \$12.601 million above the FY 2018 Annualized Continuing Resolution. At this funding level, CDC would provide enhanced support for up to nine States at the greatest risk for vector-borne disease outbreaks. Each vector program would include increasing State entomological expertise, as well as support for laboratory activities, case and outbreak investigation activities, and vector control and management activities.

CDC's FY 2019 President's budget, also proposes a \$10 million investment to continue the Zika Pregnancy and Infant Registry in four to eight high risk U.S. jurisdictions. With this investment, CDC will be able to continue to follow the outcomes of babies exposed to Zika during pregnancy in these jurisdictions, and provide on-the-ground support to a small number of cities or counties at highest risk from either local transmission or travel. Overall, this investment would allow the CDC to understand the full spectrum of Zika-associated birth defects, and maintain capacity at a small number of health departments to identify and track emerging threats that potentially cause birth defects or developmental disabilities.

Question. The Federal Government supports patient care and physician training at the Nation's teaching hospitals through Medicare Graduate Medical Education (GME) payments. The United States is facing a massive physician shortage of up to 104,900 physicians by 2030.

Yet, the President's budget makes more than \$48 billion in cuts over the next 10 years to GME by consolidating GME spending from Medicare, Medicaid, and the Children's Hospital GME program into a single grant program. The budget proposes

to adjust FY 2016 spending levels each year by the Consumer Price Index (CPI-U) minus 1 percent. This would cause enormous harm to the future physician supply in our country, and threaten what is usually stable Medicare funding for training doctors.

For the past several Congresses, I have introduced the Resident Physician Shortage Reduction Act, this year with Senator Heller, to increase the number of residency slots eligible for Medicare GME support. Investing in the training of the next generation of physicians will not only address our country's growing health-care needs, but it will keep us as a leader in health-care innovation. We should pass my bill and expand support of GME in this Nation, not enact draconian cuts.

Please explain how the administration reconciles the need to address the physician shortage while also proposing \$50 billion in cuts to GME funding?

How should teaching hospitals absorb these cuts?

Answer. The budget proposes to better focus Federal spending on GME by consolidating spending that is currently in the Medicare, Medicaid, and Children's Hospital GME Payment Program into a new capped Federal grant program. In an effort to improve the distribution of specialties in health care, to address health-care professional shortage areas, and to incentive better training of professionals, funding would be distributed to hospitals that are committed to building a strong medical workforce and would be targeted to address medically underserved communities and health professional shortages.

Payments would be distributed to hospitals based on the number of residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. Funding for this consolidated, single grant program for teaching hospitals would be equal to the sum of Medicare and Medicaid's 2016 payments for graduate medical education, plus 2016 spending on children's hospitals graduate medical education, adjusted for inflation. Funding would increase at a rate of inflation minus 1 percentage point each year.

In addition, the National Health Service Corps (NHSC) and Teaching Health Center GME (THCGME) programs will continue to address health professions shortages. NHSC serves as a vitally important recruitment tool for community health centers and other health-care entities nation-wide operating in underserved areas where shortages of health-care professionals exist. In FY 2017, the NHSC had over 2,000 physicians providing health-care services in NHSC-approved sites. In addition, the THCGME program supports primary care medical and dental residency programs in community-based ambulatory patient care settings. In Academic Year 2017-2018, the THCGME program supports the training of 732 residents in 57 primary care residency programs.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. The FDA received additional funding for FY 2019. How much of this money do you anticipate going to promote investment into production of older generics that have only one or two producers to keep costs low?

Answer. I understand the importance of having multiple generic applications approved, including for older generics, to help provide American consumers with lower-cost medicines. Under FDA's Manual of Policy and Procedure (MAPP) on Prioritization of the Review of Original ANDAs, Amendments, and Supplements (Prioritization MAPP), the agency prioritizes the review of generic applications: (1) for "sole source" drug products, where there is only one approved drug product listed in the Prescription Drug Product List (*i.e.*, the "active section") of FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book) and for which there are no blocking patents or exclusivities; and (2) for drug products for which there are not more than three approved drug products listed in the Orange Book and for which there are no blocking patents or exclusivities listed for reference listed drug.

In addition, under the Commissioner's Drug Competition Action Plan (DCAP), the agency has taken substantial steps to facilitate increased competition through the approval of lower-cost generics medicines. In the coming months, FDA will continue to take actions to enhance the efficiency of the generic drug review process, to maximize scientific and regulatory clarity with respect to generic drugs, and to reduce "gaming tactics" by brand name drug companies that delay the generic competition Congress intended when it enacted the Hatch-Waxman Amendments. All these ac-

tions are intended to help ensure consumers can get the medicines they need at affordable prices.

FDA cannot determine the precise amount of funding that will go toward older generics, as we do not ultimately control which drugs the generics industry chooses to submit marketing applications for, but the actions we are taking should help encourage industry to invest in the development of older generics that have minimal competition.

Question. Will the FDA's New Medical Data Enterprise take into account the current lack of true representation of all patient populations in clinical trials and address the need for greater inclusion of women and minorities in clinical trials?

Answer. The FDA will advance the use of real-world evidence to better inform patient care and provide more efficient, robust, and potentially lower-cost ways to develop clinical data that can inform product review and promote innovation. The FDA will establish new capabilities, including the development of data and analytical tools, to conduct near-real-time evidence evaluation down to the level of individual electronic health records for at least 10 million individuals in a broad range of U.S. health-care settings and populations beyond those who typically participate in clinical trials.

Toward these ends, an expanded use of natural language processing for the assessment of information submitted to the agency would be developed in an effort to markedly speed recognition and remediation of emerging safety concerns in a variety of populations. The effort would cover a broad range of medical products, including drugs, biologics, and medical devices. The health-care settings would be carefully selected to cover data gaps in the Sentinel and National Evaluation System for health Technology (NEST) systems for FDA-regulated products not currently easily assessed with existing systems.

Expanding the FDA's capacity to utilize real-world evidence to evaluate the pre- and post-market safety and effectiveness of medical products would generate processes that could improve the efficiency of the regulatory process, better inform patients and providers about pre- and post-market safety, reduce some of the burdens that drive up the time and cost required to bring beneficial innovations to the market and address barriers that can make certain important safety and effectiveness information around the real-world use of products hard to collect and evaluate (*e.g.*, subpopulation evaluations based on sex, gender, race, ethnicity, age). The use of real-world evidence may allow subpopulation evaluations beyond those conducted in the controlled setting of a clinical trial and expand our knowledge base to further reflect actual usage and experience by a wider population.

The agency has already leveraged the use of real-world data to reduce the time and cost of clinical evidence development resulting in more timely and informative post-market data collection and more timely and efficient approvals of new devices and expanded indications of already marketed drugs and devices, including for drug-eluting stents, pacing leads, companion diagnostics, a spinal cord stimulator, and a pediatric ventricular assist device. In the case of transcatheter heart valves, leveraging real-world evidence has already resulted in a greater than 400-percent cost savings for industry, improved post-market surveillance, and moved the United States from 42nd to, in some cases, first-in-the-world approvals for life-saving technologies.

Question. The CDC's ability to study gun violence has been limited by a 1996 amendment (the "Dickey Amendment") that prevents the agency from collecting data to "advocate or promote gun control." On February 15, 2018, you told a House Energy and Commerce subcommittee that a provision passed 2 decades ago limiting the CDC's work on gun violence only prevents it from taking an advocacy position—not from doing research. Specifically, you said, "[m]y understanding is that the [Dickey] rider does not in any way impede our ability to conduct our research mission. . . . We believe we've got a very important mission with our work with serious mental illness as well as our ability to do research on the causes of violence and the causes behind tragedies like [Parkland]. So that is a priority for us."

As Secretary of Health and Human Services, will you direct the CDC to conduct research into gun violence? If yes, please be specific as to the steps you will take.

Answer. At HHS, we are always working to keep Americans safe from public health threats including violence. CDC currently conducts and funds research on a variety of related topics, including youth violence, child abuse and neglect, domestic violence, and sexual violence. These are the topical line items that are supported

through CDC's annual appropriation for both research and non-research activities. In order to fund new research, we must make decisions about moving funds from other important areas. We will continue to support surveillance activities, epi-aid investigations, and analyses of surveillance and other data to document the public health burden of firearm injuries in the United States.

Question. Do you believe that gun violence is a public health issue?

Answer. Violence is certainly a public health issue of importance and one that HHS continues to study. We are committed to researching and evaluating what causes individuals to commit violence. Public health works to prevent health problems and to extend better care and safety to entire populations. An important function of public health is to prevent injuries and violence or to lessen their impact when they occur.

Question. In your written responses during your confirmation hearing, you seemed to acknowledge the importance of the CDC's work in global health. The budget cuts \$23 million from global health programs at the CDC and reserves \$59 million for the Global Health Security Agenda. Coupled with cuts to the emerging and zoonotic of \$60 million, this is an overall reduction in investment against global health threats.

How do you envision maintaining HHS's leadership on global health policy in light of these cuts?

Answer. As announced by administration officials in Uganda in October 2017 at the high-level ministerial meeting on the Global Health Security Agenda (GHSA), the United States supports the extension of that initiative through 2024. President Trump has himself emphasized the importance of the GHSA, including at the UN General Assembly in September 2017, by highlighting that the GHSA is one of several programs that promotes better health and opportunities all over the world.

President Trump's FY 2019 budget of \$59 million in funding for activities in support of the GHSA for FY 2019 for CDC demonstrates the administration's commitment to global health leadership. If enacted, this funding would also provide an important bridge to the extension of the GHSA announced by the administration in October 2017 in Uganda. CDC is engaged in a deliberative process regarding U.S. Government support for the next phase of GHSA, led by the National Security Council.

At the reduced level proposed for Global Health activities overall in the FY 2019 President's budget, CDC will continue supporting scientific and technical experts at headquarters and in the field, but will prioritize efforts across its disease specific programs including global HIV and tuberculosis programs and polio and measles eradication efforts. CDC will provide technical support to optimize staffing and resources to address the highest disease burden areas. At this funding level, CDC will also strategically limit reference laboratory services and viral sequencing to priority areas, including CDC's polio, measles, and rubella reference laboratories' diagnostic services, and HIV reference lab services.

Question. Last month, several news outlets indicated that the CDC may have to dramatically scale back operations undertaken as part of the Global Health Security Agenda to help countries prevent and respond to health threats such as infectious-disease epidemics from 49 countries to just 10 in 2019.

Will that drawdown still be necessary under this budget request?

Answer. With regard to the recent news about CDC reducing its global presence, CDC is in the process of planning, as the \$1.2 billion supplemental Ebola/Global Health Security funding awarded to CDC in FY 2015 sunsets at the end of FY 2019. However, the U.S. commitment to global health security and the Global Health Security Agenda (GHSA) specifically, remains steadfast.

The FY 2019 President's budget includes \$59 million for CDC to continue activities that support Global Health Security Agenda implementation—evidence of the continued commitment. The \$59 million for GHSA in the President's FY 2019 budget are bridging funds that would be used to support the continued development of core public health capabilities in GHSA priority countries as CDC transitions from the funding surge provided by the emergency supplemental funding to the next phase of GHSA implementation.

The U.S. Government strongly supports the GHSA and its objectives to build capacity to prevent, detect, and respond to infectious disease threats at their source. As President Trump has publicly stated, and as reaffirmed by U.S. administration

officials at the GHSA Ministerial Meeting in Uganda in October 2017, the U.S. Government strongly supports the extension of GHSA through 2024.

Question. If so, what countries will CDC staff be withdrawing from?

Answer. CDC is in the process of planning, as the \$1.2 billion supplemental Ebola/Global Health Security funding awarded to CDC in FY 2015 sunsets at the end of FY 2019. CDC is engaged in a deliberative process regarding U.S. Government support for the next phase of GHSA, led by the National Security Council. CDC's goals are to maximize global impact and to plan responsibly. CDC will continue to respond to outbreaks and build long-term capacity around the globe, utilizing assets both in host countries and from headquarters.

Question. When will the drawdown take place?

Answer. CDC remains committed to the U.S. Government's July 2015 pledge to support the Global Health Security Agenda in 17 partner countries through FY 2019. CDC is engaged in a deliberative process regarding U.S. Government support for the next phase of GHSA, led by the National Security Council. This process will inform decisions about CDC's country presence and activities.

Question. What will be the capability of HHS to respond to the next Ebola or Zika crisis with these budget cuts?

Answer. CDC's global programs, utilizing assets in countries and at headquarters, build the capabilities required for countries to meet the International Health Regulations and are essential to our national defense, forming critical links in the U.S. prevention, detection, and response chain for outbreaks—in collaboration with the Departments of Defense and State, as well as the U.S. Agency for International Development and other partners.

CDC, working with other partners, is making America safer from public health threats. For the first time, countries are closing health security gaps using standardized metrics. This has allowed for the mobilization of significant contributions from other donor nations and the private sector, as well as increased host government support from low- and middle-income countries themselves. For example, in 2014–2016, Liberia experienced more than 10,000 cases of Ebola and more than 4,800 deaths, as the initial response took more than 90 days from virus detection to the initiation of a coordinated response. In April 2017, in response to an outbreak of meningococcal disease, Liberia was able to mobilize 14 U.S.-trained Liberian disease detectives, activate a new public health emergency operations center, deploy a national rapid response team, and, through local laboratory testing, rule out Ebola within 24 hours. Rapid and coordinated response interventions helped contain the outbreak within days, limiting it to 31 cases and 13 deaths. Rapid and high-quality response prevents an isolated outbreak from spreading and potentially becoming a global catastrophe. Similarly, CDC's health security personnel and resources were indispensable in averting crisis during the 2017 responses to Ebola in the Democratic Republic of the Congo and Marburg virus in Uganda.

CDC's global investments and continued domestic investments along with other activities across HHS (including through ASPR) support infrastructure that will allow HHS to respond to future public health issues.

Question. It has been reported closures of CDC offices are planned for some of the world's hot spots for emerging infectious diseases: Congo, Haiti, Pakistan, etc. When will those closures take place?

Answer. HHS remains committed to the U.S. Government's July 2015 pledge to support implementation of the Global Health Security Agenda in 17 partner countries through FY 2019. CDC is engaged in a deliberative process regarding U.S. government support for the next phase of GHSA, led by the National Security Council. This process will inform decisions about CDC's country presence and activities.

In addition to Global Health Security-funded work, CDC's global health work in polio eradication, HIV, and malaria, will continue in many of the world's hot spots and CDC will continue to monitor and respond to emerging and reemerging diseases and outbreaks where they occur. CDC's global health security work in Haiti is funded through earthquake supplemental reconstruction funds which will end in FY 2020.

Question. How would you characterize the change in risk and vulnerability for these diseases reaching U.S. shores with the closure of these 30 country programs?

Answer. With regard to the recent news about CDC reducing its global presence, CDC is in the process of planning, as the \$1.2 billion supplemental Ebola/Global Health Security funding awarded to CDC in FY 2015 sunsets at the end of FY 2019. However, the U.S. commitment to global health security and the Global Health Security Agenda (GHSA) specifically, remains steadfast.

CDC, working with other Global Health Security Agenda partners, is making America safer today. For the first time, countries are closing health security gaps using standardized metrics. This has allowed for the mobilization of significant contributions from other donor nations and the private sector, as well as increased host government support from low- and middle-income countries themselves. For example, in 2014–2016, Liberia experienced more than 10,000 cases of Ebola and more than 4,800 deaths, as the initial response took more than 90 days from virus detection to the initiation of a coordinated response. In April 2017, in response to an outbreak of meningococcal disease, Liberia was able to mobilize 14 U.S. trained Liberian disease detectives, activate a new public health emergency operations center, deploy a national rapid response team and through local laboratory testing rule out Ebola within 24 hours. Rapid and coordinated response interventions helped contain the outbreak within days, limiting it to 31 cases and 13 deaths. Rapid and high-quality response prevents an isolated outbreak from spreading and potentially becoming a global catastrophe. Similarly, CDC's health security personnel and resources were indispensable in averting crisis during the 2017 responses to Ebola in the Democratic Republic of the Congo and Marburg virus in Uganda.

CDC's global disease detection programs are designed to build the capabilities required for countries to meet the International Health Regulations. These programs support U.S. national defense, forming critical links in the U.S. prevention, detection, and response chain for outbreaks. CDC's global investments and continued domestic investments along with other activities across HHS (including through ASPR) support infrastructure that will allow HHS to respond to future public health issues.

Question. How much of an investment is being made into the research of pain and alternate forms of pain management?

Answer. Addressing the opioid crisis is one of my top four priorities at the Department. One prong of our five-part opioid strategy is to support cutting-edge research into pain and alternative forms of pain management. Specifically, the budget provides \$500 million to NIH for a public-private partnership to accelerate the development of safe, non-addictive, and effective strategies to prevent and treat pain, opioid misuse, and overdose. NIH holds a broad research portfolio on pain, ranging from basic research into the molecular, genetic, and bio-behavioral basis of chronic pain to large-scale clinical studies of potential treatments, including an array of non-pharmacological approaches. In addition, a long-term plan to coordinate and advance pain research across the government, the Federal Pain Research Strategy, was developed recently. It includes important research priorities spanning basic to clinical research across the continuum of acute to chronic pain, including development of non-opioid pain medications and an expanded evidence base for non-pharmacological treatments. These recommendations are being considered as funding priorities by NIH and other Federal agencies and departments that support pain research, including AHRQ, CDC, FDA, DoD, and VA.

Question. The FY19 budget provides \$10 billion to fight the opioid epidemic. However, the budget significantly reduces the availability of resources to fight opioids and coordinate a national effort by repealing the ACA and capitating Medicaid. How do you envision stretching the \$10 billion for all of the administration's aims?

Answer. Our Medicaid program is an important tool in providing health care to many Americans but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That's the challenge that we have as we seek to empower the States with the right incentives to deliver quality service. The FY 2019 budget provides additional flexibilities to States, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from \$421 billion in FY19 to \$702 billion in FY28 over the budget window. The FY 2019 budget also repeals the Medicaid expansion and the Exchange program subsidies and replaces these programs with the \$1.2 trillion Market-Based Health Care Grant program through the Graham-Cassidy-Heller-Johnson legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

Question. The HHS FY 2019 budget proposes to both eliminate the Medicaid Disproportionate Share payments and capitate Medicaid funding to States. What will be the impact on hospitals?

Answer. The budget's Medicaid proposal is modeled after the Graham-Cassidy-Heller-Johnson bill, which includes a modernization of Medicaid financing and repeal of the Obamacare's Medicaid expansion. Medicaid financing reform will empower States to design individual, State-based solutions that prioritize Medicaid dollars for traditional Medicaid populations and support innovations like community engagement initiatives for able-bodied adults. Additionally, the Market-Based Health Care Grant Program included in the Graham-Cassidy-Heller-Johnson legislation will provide more equitable and sustainable funding to States to develop affordable health-care options for their citizens. The block grant program will empower States to improve the functioning of their own health-care market through greater choice and competition, with States and consumers in charge. By putting States back in charge of their Medicaid dollars and decisions, hospitals will benefit from the ability to locally partner with the State to innovate and target resources to the most needy citizens and health-care providers.

QUESTION SUBMITTED BY HON. SHERROD BROWN

Question. Last year, the President made the decision to stop paying mandatory cost-sharing reduction (CSR) payments to Affordable Care Act (ACA) insurers, saying that “the gravy train end(s) the day I knocked out the insurance companies' money.” As a result of his decision, insurers and State regulators in more than 40 States adjusted their plan offerings by dramatically increasing the cost of their silver plans—or “silver loading.” As a result, taxpayers are now supporting larger payments to insurers through tax credits and subsidies than would have been provided through the CSRs.

The President's budget proposal includes a provision that would provide a mandatory appropriation for cost-sharing reduction (CSR) payments for FY18 through the end of FY19. This means that insurers that have been benefitting from higher premium payments for silver plans will also now receive CSR payments on top of the taxpayer support they are already receiving. In other words, the President's budget proposal proposes to use taxpayer dollars to compensate insurers twice: first through higher tax credits because of silver loading, and second through the additional CSRs proposed in the budget. This seems to be proposing two gravy trains.

Why is this administration reversing course on CSR payments?

Do you support paying insurance companies twice for FY18, as the budget proposes?

Answer. In 2017, the administration conducted a legal review and concluded that because Congress did not appropriate the money for Cost Sharing Reductions, the administration could no longer legally make the payments.

I am party to related litigation and am limited in what comments I can make. The government's litigation position on cost sharing reduction payments has not changed, and I refer any questions about the litigation to the Department of Justice.

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER

Question. In October, the President issued an executive order to expand so-called “short-term, limited-duration plans,” which are plans that can still discriminate based on pre-existing conditions, charge older people more, exclude coverage for services such as maternity care and treatment for opioid addiction, and impose annual and lifetime limits. Furthermore, you recently proposed a new rule that would expand short-term plan durations to 3 months to 12 months. Health insurers and patient groups, including the American Cancer Society and the American Heart Association, have said short term plans could “lead to higher premiums for consumers, particularly those with pre-existing conditions” and “destabilize the health insurance markets.” With these concerns in mind, how will HHS ensure that these plans are transparent with consumers about their lack of comprehensive benefits and coverage?

Answer. Short-term limited duration insurance plans are flexible, adaptable insurance products that can be particularly useful for those entering the job market, those transitioning between jobs and other forms of insurance, or who are otherwise priced out of unaffordable ACA insurance markets. Americans need more insurance options with less Federal micromanagement of those insurance options.

The status quo is not working for millions of Americans—whether it is those who are in the insurance market or those who have been left out of it. Although there are many Americans who may not be best served by a short-term, limited-duration plan, expanding the availability of such plans creates affordable options for those who understand how to choose and use these flexible, short-term products. HHS will work with the Departments of Labor and the Treasury, and across the executive branch, to create a health insurance system that is more affordable and accessible, where individuals and families can choose the type of insurance coverage that works best for them, including the option of short-term, limited-duration insurance. As part of the short-term, limited-duration proposed rule, the Departments proposed standard language that issuers of short-term, limited-duration insurance would have to provide to applicants and enrollees that describes the potential limitations of the short-term, limited-duration insurance and how it is not Minimum Essential Coverage. I will also work to ensure the least disruptive approach to implementing these policies, and to appropriately consider the concerns expressed by stakeholders during the rulemaking process.

Question. Secretary Sylvia Burwell, one of your predecessors at HHS, laid out an ambitious goal of tying 90 percent of Medicare fee-for-service payments to quality and value by the end of 2018, and linking 50 percent of Medicare payments to innovative payment models such as accountable care organizations by the end of 2018. Unfortunately, CMS has indicated that it will no longer operate on the timeline laid out by Secretary Burwell.

Without this goal in place, how specifically does CMS intend to improve Medicare payments and better coordinate care for patients and on what timeline will Medicare move away from fee-for-service payments towards outcomes-based reimbursement? How can we include Medicare and Medicaid’s payment for drugs in the movement towards value and outcomes-based payments? More broadly, how can HHS better work with the private sector to encourage delivery system reforms and bring down the cost of health coverage for Americans?

Answer. Senator, thank you for your questions. As you know, upon taking office at HHS, I identified the value-based transformation of our entire health-care system as one of the top priorities for our Department. Value-based transformation in particular is not a new passion for me. It became a top priority for Secretary Mike Leavitt when I was working for him as deputy secretary, and it was taken seriously by President Obama’s administration as well.

It has been, at times, a frustrating process. But there is no turning back to an unsustainable system that pays for procedures rather than value. In fact, the only option is to charge forward—for HHS to take bolder action, and for payers and providers to join with us.

Millions of Americans rely on Medicaid and Medicare to meet their everyday health-care needs, and together these Federal health-care programs comprise the largest portion of the Federal budget. As such, the budget proposes several legislative solutions to improve the programs, promote greater efficiencies, advance patient-centered care, and reduce government-imposed burden on providers.

The budget makes significant strides toward addressing and reining in drug prices. The legislative solutions would benefit seniors by protecting Medicare beneficiaries from high drug prices, giving plans more tools to manage spending, and re-aligning incentives in the Part D drug benefit structure. The proposed changes enhance Part D plans' negotiating power with manufacturers; encourage utilization of higher value drugs; discourage drug manufacturers' price and rebate strategies that increase spending for both beneficiaries and the government; and provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap.

I look forward to working with you, and any other stakeholders, who will work with us toward our shared goal of transforming our health-care system to make sure we are paying for quality, rather than quantity.

Question. Mr. Secretary, the affordability of health-care coverage continues to be a problem across our health-care system. One of the ways the public and private sectors have been trying to address this challenge is through value-based purchasing models. For example, employers have been offering Accountable Care Organizations and we have seen their growth and success in the Medicare Program. How can HHS better work with the private sector to encourage delivery system reforms and bring down the cost of health coverage for Americans?

For example, companies such as Boeing are operating accountable care programs in cities across the country to improve the quality of care their employees receive, enhance employees' experience with the health-care system, and reduce costs. Over the last several years, Boeing has seen improvement in their employees' health, including a significant uptake in depression screenings and better control of blood pressure and diabetes. Employees also like the customer-focus of these programs and re-enroll at high rates. How will you increase this type of innovation in Medicare, Medicaid, CHIP, and our other government health-care programs?

Answer. One of the key commitments President Trump has made across this administration has been to see the private sector as our partners, not just as entities to be regulated or overseen. Upon taking office at HHS, I identified the value-based transformation of our entire health-care system as one of the top priorities for our department. Value-based transformation in particular is not a new passion for me. It became a top priority for Secretary Mike Leavitt when I was working for him as Deputy Secretary, and it was taken seriously by President Obama's administration as well. It has been, at times, a frustrating process. But there is no turning back to an unsustainable system that pays for procedures rather than value. In fact, the only option is to charge forward—for HHS to take bolder action, and for payers and providers to join with us.

There are four particular areas of emphasis that will be vital to laying down new rules of the road, accelerating value-based transformation, and creating a true market for health care. The four areas of emphasis are: giving consumers greater control over health information through interoperable and accessible health information technology; encouraging transparency from payers and providers; using experimental models in Medicare and Medicaid to drive value and quality throughout the entire system; and removing government burdens that impede this transformation.

Question. Obesity, tobacco, and lack of medication adherence cost our health-care system more than \$1 trillion each year. Part of the challenge is our doctors don't know how to talk to patients about their weight and Medicare and Medicaid beneficiaries don't understand how to access services to treat obesity and addiction to tobacco products.

Will you commit to working together with me to redouble our efforts to address these root causes of poor health outcomes and high costs?

Answer. The conditions that you mentioned are all complex public health issues that deserve our attention. I believe we must implement evidence-based programs and policies that are proven to make an impact in these areas. I commit to ensuring that we are leveraging our resources to the greatest extent possible to make advances in these areas. The President's Fiscal Year (FY) 2019 budget supports the mission of the Department of Health and Human Services (HHS) by making thoughtful and strategic investments to protect the health and well-being of the American people.

QUESTIONS SUBMITTED BY HON. THOMAS R. CARPER
AND HON. PAT ROBERTS

Question. Secretary Azar, we applaud the inclusion of the provision in CMS' Proposed Part D Rule revising the MLR requirements, which clarifies that Part D medication therapy management (MTM) programs fall under quality improving activities (QIA). This is the right approach and policy, and we would strongly urge CMS to finalize this important provision to increase proper medication adherence through better utilization of MTM services.

How is CMS working to ensure multiple delivery options for MTM services, either in person at retail or community pharmacies as well as remotely, are included in the demo and available to beneficiaries?

When does CMS intend to expand the Enhanced MTM demo to Medicare Advantage plans?

Answer. That said, the provision of Enhanced MTM items or services may not be tied to use of specific network pharmacies for dispensing of Part D drugs. The model does not waive Part D network access requirements or any other Part D requirement not specifically listed in the Enhanced MTM Request for Applications. CMS believes that a successful participant in this model will design an MTM program that effectively engages enrollees at risk for medication-related issues "where they are" as opposed to requiring the enrollee to come to the plan or plan preferred providers for assistance in overcoming a barrier to improved medication use.

The Enhanced MTM model tests design elements that give standalone PDPs many tools that MA-PD plans already have (such as sharing Parts A and B data with Part D sponsors), which would not make such plans appropriate for the model as it is currently designed.

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The Enhanced MTM model tests design elements that give standalone PDPs many tools that MA-PD plans already have (such as sharing Parts A and B data with Part D sponsors), which would not make such plans appropriate for the model as it is currently designed.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

Question. I am following up on the conversation we had regarding the budget for the Office of Minority Health and the National Institute on Minority Health and Health Disparities (NIMHD). I raised a concern about the President's budget cutting the Office of Minority Health by \$2 million from the FY18 continuing resolution, and the NIMHD by \$7 million. You stated that because you did not have a granular knowledge of the budget that you would get back to me on the cuts to NIMHD. Would you please share your rationale for these budget cuts?

Answer. The cuts you point out do not signify a lack of commitment by this Department to minority health issues. Many programs throughout HHS received small cuts to ensure that funding is more targeted towards direct service delivery. Our

strategy is to focus in on existing programs that provide these services. The President's budget continues to show its commitment to minority health by requesting \$281 million for the National Institute on Minority Health and Health Disparities and \$54 million for the Office of Minority Health.

Question. You offered a rationale regarding the cuts to the Office of Minority Health. You stated that there is not a minimization around minority health programs, rather a tradeoff and focus on service delivery. Would you please share your strategies to increase the focus on service delivery, where those resources are being reallocated from, and the programs or initiatives that are having their funding reduced?

Answer. The cuts you point out do not signify a lack of commitment by this Department to minority health issues. Many programs throughout HHS received small cuts to ensure that funding is more targeted towards direct service delivery. Our strategy is to focus in on existing programs that provide these services. The President's budget continues to show its commitment to minority health by requesting \$281 million for the National Institute on Minority Health and Health Disparities and \$54 million for the Office of Minority Health.

Question. The President's budget wishes to provide \$10 billion in funding to address the opioid epidemic. Nearly 12 percent of Medicaid beneficiaries over the age of 18 have a substance use disorder. To me, there seems to be a disconnect between trying to fund programs that address the opioid epidemic, while also cutting Medicaid, a program which so many people with substance use disorders rely on to get the treatment and the care they need. Can you discuss how cutting Medicaid and eliminating the Medicaid expansion under the Affordable Care Act helps those with a substance use disorder?

Answer. Our Medicaid program is an important tool in providing health care to many Americans but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That's the challenge that we have as we seek to empower the States with the right incentives to deliver quality service. The FY 2019 budget provides additional flexibilities to States, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from \$421 billion in FY19 to \$702 billion in FY28 over the budget window. The FY 2019 budget also repeals the Medicaid expansion and the Exchange subsidies and replaces these programs with the \$1.2 trillion Market-Based Health Care Grant program through the Graham-Cassidy-Heller-Johnson legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

Question. In our conversation regarding the prudent layperson standard, you mentioned the proposal in the budget that would allow for Medicaid to impose copayments on beneficiaries for emergency room visits that are determined to be "misuse of emergency room visits." You suggested that any legislation would need to be done in a common sense way, and it should not deter anyone from going to the emergency room for the care that they ought to be going in for. Would you please provide your proposed language that would make this change in policy, as well as provide your definition for "misuse of emergency room visits"?

Answer. Currently, States are required to obtain waiver authority to charge copayments above the nominal statutory amounts for non-emergency use of the emergency department. I am happy to work with Congress to define the exact parameters of this proposal.

Question. Would there be a limit as to what States could charge for ER copayments or surcharges for non-emergency use of the ER? Would States be able to charge these individuals—many of which are making less than \$15,000 a year whatever amount they want?

Answer. The budget proposes to provide States the option to use State plan authority to increase these copayments to encourage personal financial responsibility and proper use of health-care resources.

Question. Under this proposal, how would the administration ensure individuals have access to other, more appropriate care settings, especially if the State no longer has to offer non-emergency transportation?

Answer. We would want to work with you to make sure that any legislation is done in a common sense way that does not deter anyone from going to the emergency room for care when appropriate.

Question. As you know, working Americans may be unable to go receive medical care in a less expensive setting because the ER is the only provider open when they can go—whether that’s late at night or on the weekend. How will the administration work with States to ensure that individuals who are not able to get time off or cannot afford child care will be able to access these providers?

Answer. I am happy to work with Congress to develop this legislation in a way that ensures that individuals maintain access to emergency care when appropriate.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

Question. The President’s HHS budget lists “tackling the opioid epidemic” as its first priority, yet the proposal eliminates Medicaid expansion and proposes additional cuts to Medicaid, the number one source of addiction treatment services in Ohio.

During your testimony in front of the House Ways and Means Committee, you mentioned that you had recently spoken with Governor Kasich about Ohio’s struggle with the addiction epidemic. You said that we need to take best practices from one State and ensure other States can benefit from those innovative practices in tackling this epidemic.

Yet the President’s budget proposes the exact opposite—it would actually eliminate Medicaid expansion, a program that is already working in Ohio that could help other States across the country who have yet to expand their programs. It would take this option away from States. Medicaid expansion is an issue that Governor Kasich and I agree on—without Medicaid expansion, hundreds of thousands of Ohioans currently struggling with addiction and mental illness would lack access to treatment. It’s Ohio’s number one tool in our fight against addiction. Taking this option away from States and then making additional cuts to Medicaid is not supporting our local communities—it’s abandoning them. We should be giving States the flexibility to provide more services, not less.

If this administration is going to make the argument that States are the best decision-makers when it comes to the health-care options their constituents need, then why eliminate a program that States like Ohio have said are working?

Answer. Our Medicaid program is an important tool in providing health care to many Americans, but we must put it on a stable long-term sustainable footing for it to be there for this and future generations. That’s the challenge that we have as we seek to empower the States with the right incentives to deliver quality service. The FY 2019 budget provides additional flexibilities to States, puts Medicaid on a path to fiscal stability by restructuring Medicaid financing, and refocuses on the populations Medicaid was intended to serve—the elderly, people with disabilities, children, and pregnant women. Annual Federal Medicaid spending will grow from \$421 billion in FY19 to \$702 billion in FY28 over the budget window. The FY 2019 budget also repeals the Medicaid expansion and the Exchange program subsidies and replaces these programs with the \$1.2 trillion Market-Based Health Care Grant program through the Graham-Cassidy-Heller-Johnson legislation.

Opioid misuse, abuse, and overdose impose immense costs on the Nation, contributing to two-thirds of deaths by drug overdose. Deaths by drug overdose are the leading cause of injury death in the United States. The FY 2019 President's budget recognizes the devastation caused by the opioid crisis in communities across America and fulfills the President's promise to mobilize resources across the Federal Government to address the epidemic. The budget provides a historic level of new resources across HHS to combat the opioid epidemic and serious mental illness—\$10 billion—to build upon the work started under the 21st Century Cures Act.

The budget's targeted investments advance the Department's five part strategy, which involves:

- Improving access to prevention, treatment, and recovery services, including medication-assisted treatment;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health data and reporting;
- Supporting cutting edge research on pain and addiction; and
- Advancing better practices for pain management.

Question. During your nomination process, I submitted a QFR about the Low-Income Heating Assistance Program (LIHEAP). I want to share my question and your answer with you again in light of the new FY19 budget proposal, and then rephrase my question to you.

As you know, the Low-Income Heating Assistance Program, or LIHEAP, plays a key role in helping the elderly and low-income families stay warm in the winter and avoid dangerous heat in the summer. With the sustained cold in Ohio this winter, we see firsthand how critical it is to the nearly 450,000 households in my State that would otherwise be forced to choose between keeping warm or going hungry. When your predecessor was before the committee, he indicated that he supported this program, then he proceeded to eliminate it in the FY18 budget request.

If confirmed, would you propose to once again eliminate the program?

Answer. If confirmed, I will prioritize programs that demonstrate results for the populations they intend to serve. If resources for LIHEAP continue to be appropriated by Congress, I will continue to implement the program in the most effective and efficient manner possible.

Question. The President's budget would eliminate LIHEAP in FY19. How do you intend to "implement the program in the most effective and efficient manner possible" without any funding? How do you justify the elimination of this program?

Answer. After careful examination, the administration believes that LIHEAP is unable to demonstrate strong performance outcomes. In addition, we reviewed programs and policies of utility companies and State and local governments and found that they provide significant heating and cooling assistance to individuals and families, including policies in the majority of States prohibit utilities from discontinuing heating during the winter months. With our limited resources and based on that review, we determined that continued funding of the LIHEAP program is not the best use of taxpayer dollars and have proposed eliminating future funding for this program. While this is the administration's proposal, as long as there continues to be an appropriation of resources for this program I will continue to implement the program in as effective and efficient manner as possible.

Question. As I said during last week's hearing, I appreciate the efforts the administration has put into proposing some initiatives that would help lower the cost of prescription drugs in Medicare and Medicaid as part of this year's budget proposal, some of which I agree with and support. During the hearing last week I asked you about proposals to lower the list price of drugs for all Americans, not just those who rely on Medicare or Medicaid, by putting pressure directly on the pharmaceutical industry—not just through leveraging other entities on the drug supply chain. In order to truly address the high cost of drugs we can't just put pressure on insurers and pharmacy benefit managers, we must also put pressure directly on manufacturers.

In your answer to one of my QFRs from your confirmation hearing, you said: "I believe that we need to institute policies that lower the list prices of drugs while also maintaining innovative new research and development."

Are there any proposals in the proposed budget that will force a pharmaceutical company to lower the list price of a drug in a way where all Americans who rely on that drug will benefit?

Do you plan on pursuing any policies that go after pharmaceutical manufacturers, in addition to these policies in the budget that target insurance companies and pharmacy benefit managers? If so, what are those policies?

Answer. The budget includes proposals to create incentives that will put downward pressure on the list price of drugs. One proposal involves changing the incentive structure in the catastrophic coverage in Part D. Currently, the government is on the hook for most of the cost once a senior citizen gets to catastrophic coverage phase. We propose to progressively move to a system where the insurer bears the risk for the catastrophic coverage phase, and will then have even more incentive to negotiate with branded drug companies to keep those list prices down. Currently, plan sponsors have incentives to accept higher prices so that their enrollees reach the catastrophic coverage phase sooner and that expense is offloaded on to the Federal government. In addition, in Part B, the budget proposes an inflation cap on the average sales price, so that the increase of the average sales price above inflation will receive lower reimbursement paid out through Medicare Part B. Another proposal requires Part D sponsors to apply at least one-third of total rebates and price concessions at the point of sale. This will improve price transparency and allow beneficiaries to share more directly in the savings from discounts negotiated by plans. Yet another proposal will improve manufacturers' reporting of average sales prices to set accurate payment rates. This proposal would provide the Secretary with the authority to apply penalties for manufacturers who do not report required data. And finally, the budget proposes increased plan formulary flexibility and negotiation power with manufacturers. Increased competition for formulary placement will provide plans with enhanced ability to negotiate lower prices with manufacturers.

QUESTION SUBMITTED BY HON. SHERROD BROWN
AND HON. ROBERT P. CASEY, JR.

Question. This year's budget represents a drastic change from last year's budget in how it treats the Children's Hospitals Graduate Medical Education (CHGME) payment program. Last year, the President's budget proposed to maintain funding for the CHGME program at \$295 million. This year, the budget proposes to eliminate the program and combine it with other graduate medical education funding streams, while reducing total Federal support for graduate medical education by almost \$50 billion over a decade.

Eliminating programs like CHGME that have helped to grow our pediatric subspecialty workforce, and that currently train nearly half the pediatric physician workforce, will weaken our training pipeline and ultimately hurt access to care for children across the country. We urge the Department and the White House to focus its attention on working with Congress on finding ways to strengthen our commitment to producing the next generation of doctors, both for children and adults.

What caused the President to reverse course on CHGME in this year's budget proposal, as compared to last year's budget proposal?

If CHGME is eliminated, how will HHS ensure that our pediatric workforce pipeline is protected and kids have access to the care we need?

Answer. The President's budget supports continued funding for GME in children's hospitals through a mandatory appropriation. The budget proposes to better focus Federal spending on GME by consolidating spending that is currently in the Medicare, Medicaid, and Children's Hospital GME Payment Program into a new capped Federal grant program. In an effort to improve the distribution of specialties in health care, to address health care professional shortage areas, and to incentive better training of professionals, funding would be distributed to hospitals that are committed to building a strong medical workforce and would be targeted to address medically underserved communities and health professional shortages. Children's hospitals would remain eligible for funding.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. The President's budget proposes moving control of the Strategic National Stockpile from the Centers for Disease Control and Prevention to the Office of the Assistant Secretary for Preparedness and Response. My staff has been informed by HHS that this move is already under way, and will be completed by the end of the current fiscal year. I am concerned that such a significant change could disrupt our public health emergency preparedness. Could you please explain how this move will contribute to protecting the public health and increase our capacity to respond to public health emergencies?

Answer. HHS is transferring the SNS from CDC to ASPR to improve emergency response effectiveness. While placing the SNS at CDC made historical sense, the creation and maturation of ASPR provides an opportunity to better align the direct oversight and management of SNS under ASPR. When disasters occur, ASPR leads the National Response Framework, Emergency Support Function #8 as delegated by the Secretary, thereby coordinating Federal public health and medical responses, such as the recent string of high consequence hurricanes. (ASPR also coordinates HHS's recovery functions under the Health and Social Services Recovery Support Function of the National Disaster Recovery Framework.) ASPR has a robust medical logistics capability that supports the National Disaster Medical System (NDMS), moving medical personnel, equipment, and supplies across the Nation within hours.

ASPR works closely with State and local emergency management professionals, clinicians, health-care facilities, public health officials and NDMS response teams who may be called upon to dispense SNS medical products. ASPR plans to exercise different SNS dispensing mechanisms and implement innovative approaches to improve stockpiling and distribution practices, and to ensure SNS contents can continue to be quickly dispensed and used locally in natural or manmade emergencies. This reorganization also streamlines the medical countermeasure development and procurement enterprise by fully integrating the Stockpile with other preparedness and response capabilities within ASPR.

The transfer of the SNS from CDC to ASPR is fully underway, and we expect to complete this transition by October 1, 2018. Workgroups are meeting often to ensure that all of the details of the move are addressed. CDC personnel employed by the SNS will remain employed by the SNS and will stay in Atlanta. In addition, CDC subject matter experts will remain actively involved in the MCM enterprise, and ASPR will continue to rely on CDC relationships with State and local public health officials and the agency's scientific expertise.

Question. In recent years, policymakers and multiple administrations have indicated an increased desire to pursue evidence-based policies and programs, the hallmarks of which are providing an objective set of criteria for evaluating programs, and an open and transparent process for publishing the results of these evaluations. The Teen Pregnancy Prevention Evidence Review does exactly that—it identifies effective programs, based on rigorous evaluation, that reduce teenage pregnancy, the behavioral risk factors underlying teenage pregnancy and other associated risk factors. The Assistant Secretary for Planning and Evaluation oversees this work. While the review is supposed to be updated regularly, the last update was made in June 2016 reflecting studies published through August 2015, and the new evidence submitted by researchers in November 2016 has yet to be incorporated into the review. This lack of action denies programs, policymakers, and researchers access to the most up-to-date information about what works. Please provide details on when the updated evidence review will be published.

Answer. HHS is committed to research that informs programs. The Office of the Assistant Secretary for Planning and Evaluation continues to undertake review of the Teen Pregnancy Prevention program, and I will ensure HHS shares any results with you and your office.

Question. January 4, 2017 was last year's submission date for home visiting models to seek review for inclusion on the Home Visiting Evidence of Effectiveness (HomeVEE) list under the Maternal, Infant, and Early Childhood Home Visiting Program. As of today, submissions from that round have not been reviewed. What is the timeline for reviewing these submissions and responding to the models who have been waiting for over a year to learn whether or not they will be included on the HomeVEE list?

Answer. In September 2017, we released the results of HomeVEE's annual review for 2017, which took into consideration submissions of studies through January 4, 2017. HomeVEE will release the results of 2018's review in the fall of 2018.

Hundreds of models are considered in HomVEE's annual prioritization process; many more models than there are resources to review. The process is not first-come-first-served. Instead, HomVEE follows a systematic and transparent process for selecting the models that will be reviewed in a given year.

Specifically, each year, HomVEE screens all new research for eligibility, according to its screening criteria (for details, see <https://homvee.acf.hhs.gov/Review-Process/4/Screening-Studies/19/3>). To determine which models HomVEE will review each year, points are assigned to models based on published criteria (for details, see <http://homvee.acf.hhs.gov/Review-Process/4/Prioritizing-Program-Models-for-Review/19/4>). The number of models selected for review each year depends on (1) the number of studies each of the models with the most points has, (2) available resources, and (3) HHS policy and programmatic needs. Studies identified for models not selected for review in a given year remain in the queue and are considered in each subsequent year's prioritization decisions. However, studies are not reviewed until the model they are associated with is selected for prioritization.

Models that HomVEE has studied on (including those received last year during the call for studies which closed in January 2017) are considered for prioritization each year until they are prioritized for review. If a model is not prioritized for review, it means that other models had higher points on the prioritization list based on their available research. Studies on models that were not prioritized for review in a particular year will be included in the prioritization process until the model has enough studies and points (relative to other models) to be prioritized for review.

HomVEE releases an annual update every fall. The annual release announces the models that were reviewed that year and the results of the review. Results may include adding new models to the list of models HomVEE has reviewed (both evidence-based models and those that do not meet evidence-based criteria) and/or updating findings on previously reviewed models. As of September 2017, HomVEE had prioritized 45 program models for review, and completed reviews of 363 impact studies and 274 implementation studies of these 45 models. These reviews have resulted in HomVEE identifying 20 home visiting models that meet the HHS criteria for an evidence-based early childhood home visiting service delivery model.

Question. In the administration's fiscal year 2019 budget, you have called for an extensive cut to Medicaid. Such a cut would disproportionately affect people with disabilities. In the 2017 State of the States in Developmental Intellectual and Developmental Disabilities report, 76 percent of the public intellectual and developmental disability funding goes to home and community based services and supports making it possible for people with disabilities to live in their own home, be independent, and be full participants in their communities. A cut of the size you recommend would drastically reduce Medicaid funding for States. How will you ensure that people with disabilities who wish to live in their own homes and be part of their communities will not be forced to return to nursing homes or institutions if these cuts go into effect?

Answer. The budget's Medicaid proposal is modeled after the Graham-Cassidy-Heller-Johnson bill, which includes a modernization of Medicaid financing and repeal of the Obamacare's Medicaid expansion. Medicaid financing reform will empower States to design individual, State-based solutions that prioritize Medicaid dollars for traditional Medicaid populations and support innovations like community engagement initiatives for able-bodied adults. Additionally, the Market-Based Health Care Grant Program included in the Graham-Cassidy-Heller-Johnson legislation will provide more equitable and sustainable funding to States to develop affordable health-care options for their citizens. The block grant program will empower States to improve the functioning of their own health-care market through greater choice and competition, with States and consumers in charge. Putting States back in charge of their Medicaid dollars and decisions will allow them to better serve and target resources for needy citizens, such as individuals with disabilities who wish to live in their own homes.

QUESTION SUBMITTED BY HON. ROBERT P. CASEY, JR.
AND HON. ROB PORTMAN

Question. We introduced legislation last year, S. 486, the Protecting Beneficiary Access to Complex Rehab Technology Act, that is designed to permanently protect complex rehab wheelchairs from the application of Medicare's Durable Medical Equipment (DME) Competitive Bidding program. The legislation reiterates the lan-

guage in the Medicare Improvements for Patients and Providers Act of 2008 that exempts complex rehab wheelchairs and accessories from the DME competitive bidding program that was designed for standard DME items.

Last year, HHS reinterpreted a previous CMS response to a “Frequently Asked Questions” document from December of 2014 that would have applied DME bid pricing for standard wheelchair accessories to complex rehab wheelchair accessories. The problem is the HHS reinterpretation only applies to those accessories provided on complex power wheelchairs and not all complex wheelchairs.

While we appreciate the agency’s reinterpretation on power accessories, there needs to be a similar fix for manual accessories. Why did the agency limit its regulatory relief to complex rehab power wheelchair accessories and not all complex rehab wheelchair accessories rather than use its authority to broaden the regulatory relief to also include complex manual wheelchair accessories? It is our hope that can happen in the future.

Answer. Section 1847(a)(2)(A) of the Social Security Act provides the categories of items that are subject to the DME Competitive Bidding Program and excludes certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs). We believe that this statutory exclusion should inform our implementation of section 1834(a)(1)(F) of the Act such that the fee schedule amounts for wheelchair accessories and back and seat cushions used in conjunction with group 3 complex rehabilitative power wheelchairs would not be adjusted based on DME competitive bidding information. The fee schedule amounts for all other accessories used with different types of base wheelchair equipment would be calculated in accordance with the adjusted DME fee schedule methodology using DME competitive bidding information.

QUESTIONS SUBMITTED BY HON. MARK R. WARNER

Question. Gabriella Miller, a 10-year old girl from Leesburg, VA who suffered from pediatric brain cancer, became an extremely impressive activist on behalf of childhood cancer awareness before her untimely death. Her work led to the passage of the Gabriella Miller Kids First Act in 2014, and NIH has been moving forward to implement this law and expand pediatric research.

I have appreciated the steps NIH has taken to continue prioritizing pediatric research, including brain tumor research. However, still the amount of funding for research on adults far outpaces that for children. I am hopeful that under your leadership there can be more focus.

Will you commit to continuing to implement efforts to focus on pediatric medical research—including focus on the Gabriella Miller research fund?

Answer. We are committed to continuing support for pediatric medical research, including childhood cancer research.

Pediatric research will continue to be an NIH priority. In fiscal year (FY) 2017, the NIH funded over \$4.1 billion in research grants and projects directed specifically at pediatric research. The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) funds the largest portion of pediatric research among the 27 NIH Institutes, Centers, and Offices (ICOs), taking a leadership role in many pediatric research efforts that involve trans-NIH collaborations. However, all ICOs support aspects of pediatric research; the NICHD accounts for only 19 percent of the total NIH support for pediatric research. This reflects the breadth of the research portfolio at the NIH dedicated to improving the health of children everywhere.

The National Cancer Institute (NCI) is committed to addressing the unique scientific challenges and opportunities that pediatric cancers pose in ways that lead to better outcomes for children with cancer. Conducting and supporting childhood cancer research remains a high priority for NCI, and each year the Institute identifies the best research opportunities to build upon the foundation of basic science, expand scientific understanding of genetic drivers of childhood cancers, identify promising new therapies, and improve the outlook for pediatric cancer survivors. In addition to soliciting applications in areas of scientific focus, NCI also remains committed to supporting a number of key research efforts focused specifically on childhood cancers. NCI has been renewing many of these programs for numerous 5-year funding periods.

With regard to childhood cancer research, in addition to NCI-supported efforts described above, NCI will also continue to implement childhood cancer research efforts through two high priority pediatric research opportunities within the Cancer MoonshotSM. The first is fusion oncoproteins in pediatric cancers, as these distinctive proteins are unique to childhood cancers and drive cancer growth and survival. The second priority area is pediatric immunotherapy, and specifically creating a translational science network devoted to pediatric immunotherapy research. This is a critical research area as it is likely that many immunotherapy treatments being developed for adult cancers will not be applicable to childhood cancers.

The NIH is also committed to continuing support for the Gabriella Miller Kids First Pediatric Research program, pending continued appropriation of funds from the Pediatric Research Initiative Fund created for this purpose.

Question. The National Alzheimer's Project Act became law in January 2011. From that legislation came a national strategic plan to address the rapidly escalating Alzheimer's disease crisis and the coordination of Alzheimer's disease efforts across the Federal Government. Additional data show that more than 5 million Americans are suffering from Alzheimer's and dementia today with total costs exceeding \$200 billion annually and on the way to exceeding \$1 trillion annually by mid-century.

How are we measuring and tracking progress towards this goal? Do we have the necessary resources and tools to achieve if it? If not, what are we lacking? What more can Congress do to help achieve the goals of the plan, including the 2025 goal as well as improving care and supporting caregivers?

Answer. In order to track progress made at the Federal level on Alzheimer's disease and related dementias, HHS continues to annually update the National Plan to Address Alzheimer's Disease, with the 2018 Update expected later this summer. The National Plan establishes five ambitious goals:

- Prevent and effectively treat Alzheimer's disease and related dementias by 2025;
- Optimize care quality and efficiency;
- Expand supports for people with Alzheimer's disease and related dementias and their families;
- Enhance public awareness and engagement; and
- Track progress and drive improvement.

The activities outlined in the National Plan Update vary in scope and impact and include: immediate actions that the Federal Government has taken and will take; actions toward the goals that can be initiated by the Federal Government or its public and private partners in the near term; and longer-range activities that will require numerous actions by Federal and non-Federal partners to achieve. Progress is tracked through these annual updates of the Plan, as well as through quarterly meetings of the Advisory Council on Alzheimer's Research, Care, and Services. The Advisory Council receives updates from Federal partners at each meeting and provides annual recommendations to HHS, Congress, and other stakeholders about areas where they feel additional work is necessary to achieve the goals of the National Plan.

Progress has been made on a number of fronts, particularly in biomedical research, where NIH has been able to translate its yearly increases in funding to nearly double the number of individual research grants it has awarded, and continues to make strides towards the goal of finding a cure for dementia. In the care and services sphere, CMS's National Partnership to Improve Dementia Care in Nursing Homes established a national goal in 2014 of reducing the use of antipsychotic medications in long-stay nursing home residents by 25 percent by the end of 2015, and 30 percent by the end of 2016. Both goals were achieved and new goals are currently under development.

One of the greatest successes of the past year was the National Research Summit on Care and Services, held in October of 2017, and sponsored by the Advisory Council. The goal of the Summit was to bring together experts from across the country to focus on research that is needed to improve quality of care and outcomes across care settings, including quality of life and the lived experience of persons with dementia and their caregivers. The Summit was a resounding success, attended by over 500 people, and many others viewed the webcast online. The Summit also produced a number of recommendations for Federal agencies and non-Federal partners to pursue. These recommendations are already being considered by the Federal

members of the Advisory Council as they pursue research projects and policy alterations in the coming fiscal year.

Congress's continued engagement and commitment to the goals set out in the National Plan are very helpful in spurring progress. The Advisory Council has articulated a desire for congressional response to their annual recommendations, particularly those directed at legislative change and improvement. Implementation of caregiver support programs and other services outlined in the President's budget will help HHS make further progress on providing quality care for people living with dementia and their caregivers.

Question. I have worked with bipartisan members of the Finance Committee to expand the use of telehealth, especially in Medicare. Recently, provisions were signed into law that expand telehealth services offered through different providers of care that will benefit seniors in rural areas and increase access to primary care services and telestroke care. During your previous hearings before the committee you have called telehealth an "exciting innovation for rural and underserved areas."

As Secretary, I am hopeful that you will prioritize implementing the important provisions that Congress just passed. I am also interested in seeing you utilize HHS's existing authority to lower barriers for telehealth and remote patient monitoring in Medicare. Do you have any updates on projects that you are working on?

Answer. Telehealth can provide innovative means of making health care more flexible and patient-centric. Innovation within the telehealth space could help to expand access to care in rural and underserved areas. We are working to implement the provisions of the Bipartisan Budget Act of 2018 addressing telehealth, such as the provisions increasing access to home dialysis-related care and stroke care in Medicare, as well as providing certain Part B covered benefits to Medicare Advantage enrollees, through telehealth.

Furthermore, the Centers for Medicare and Medicaid Services (CMS) has previously sought information regarding ways that it might further expand access to telehealth services within the current statutory authority and pay appropriately for services that take full advantage of communication technologies. CMS is carefully reviewing comments and considering commenters' suggestions for future rulemaking and any appropriate sub-regulatory changes.

I look forward to continued discussions on telehealth, including on the best means to offer patients increased access, greater control, and more choices that fit their medical needs.

Question. The declining cost of digital storage and Internet connectivity have made it possible to connect a vast range of products and services to the Internet, with medical devices and medical data at the forefront of this trend.

However, manufacturers are often bringing insecure devices to market, with few incentives to design the products with security in mind, or to provide ongoing support to address vulnerabilities. For example, there have been cases where implantable devices are susceptible to unauthorized or malicious commands that are sent remotely.

While I am pleased to see a spending boost for cybersecurity efforts within HHS, I am concerned that the administration is proposing to cut the Office of the National Coordinator for Health IT, ONC's, budget by more than a third, from \$60 million to \$38 million, for FY 2019.

ONC has been some of the most technically adept, along with FDA in taking important steps to addressing cybersecurity in the Internet of things. During your confirmation you said that you would continue efforts to strengthen cybersecurity with the industry.

How does your Department have the expertise to fight and protect cyber threats if those who have the appropriate knowledge and expertise don't have the requisite resources? Does the HHS have a perspective on how best to improve our Nation's cybersecurity posture?

Answer. The HHS Deputy Secretary (currently Eric D. Hargan) serves as the senior official responsible for coordinating cybersecurity activities across the Department. Mr. Hargan convenes the HHS Cybersecurity Working Group, which brings together representatives from all Operating and Staff Divisions with cybersecurity responsibilities for senior-level coordination on policy and program matters. The Department takes seriously its role as the sector specific agency for the Health care

and Public Health Sectors with respect to cybersecurity under, among other things, PPDs 21 and 41.

Various components of the Department, including the Office of the National Coordinator for Health IT (ONC), the HHS Office for Civil Rights (OCR), Assistant Secretary for Preparedness and Response (ASPR), and the Department's Office of the Chief Information Officer (OCIO) have formed strong partnerships within the Department—and with other Federal partners such as the Department of Homeland Security and National Institute for Standards and Technology. Through these partnerships, HHS provides cybersecurity expertise with a health care (including health IT) and public health focus. This also includes participation in public-private initiatives, such as those related to the National Health Information Sharing and Analysis Center (NH-ISAC) and helping to communicate identified security threats to the health IT community (*e.g.*, ransomware attacks).

Question. The administration halved this year's Open Enrollment period and significantly reduced funding for nonpartisan health-care Navigators. Cuts to this important program greatly diminished their ability to reach consumers during the enrollment period. The information these Navigators and outreach efforts would have provided would have been especially valuable given the high amount of confusion surrounding the marketplace.

Now that you are leading the Department, what are you going to do to ensure that consumers are well informed about the opportunity to enroll? Are you committed to ensuring Americans wishing to enroll in coverage, have access to unbiased application assistance from the navigator program in years to come?

Answer. Please note that the previous administration proposed that the open enrollment period be shortened to the current length starting for the 2019 plan year, and that this policy aligns more closely with the 1 month open enrollment periods we typically see in the employer-sponsored insurance market and the 7 week Medicare open enrollment period, the two markets where the vast majority of Americans are successfully enrolled, year after year.

I will examine the data and work with the Administrator to make the best, evidence-based decisions, balancing prudent use of resources with faithful execution of the law. As it relates to advertising expenditures, it is my understanding that the current level of spending is consistent with what is spent on promotion for Medicare Advantage and Part D, and that Navigators were funded at levels based partly on their ability to meet their enrollment goals from the prior year so as to inject accountability into that program.

Question. As you may know, included in the Bipartisan Budget Agreement of 2018 is a provision that reduces hospital payments when a patient is transferred to hospice. I have concerns that this financial penalty could discourage hospitals from giving patients a timely referral to hospice. One way to help address this concern is for the administration to develop new quality metrics that will allow individuals as well as policymakers to identify models that honor patient choice and provide high-quality care.

Can you provide an update on how the administration is approaching quality measurement, especially with regard to honoring patient choice at end of life?

Answer. This is an area of significant importance to our health-care system and every family who ultimately faces challenging end of life care questions. To your specific question, as required under section 1814(i)(5) of the Social Security Act, CMS administers a Hospice Quality Reporting Program. Section 1814(i)(5)(A)(i) of the act requires that beginning with FY 2014 and each subsequent FY, the Secretary shall reduce the market basket update by 2 percentage points for any hospice that does not comply with the quality data submission requirements for that FY. The Hospice Quality Reporting Program includes data submitted by hospices through the Hospice Item Set (HIS) data collection tool, and an experience of care survey, the Hospice Consumer Assessment of Healthcare Providers and Systems (CAHPS).

The HIS captures information about patient choice at the end of life through two of its National Quality Forum (NQF)-endorsed quality measures: the Treatment Preferences measure, and the Beliefs/Values Addressed measure. The CAHPS Hospice Survey is used to collect data on the experiences of hospice patients and the primary caregivers listed in their hospice records and is the first standardized national survey available to collect information on patients' and informal caregivers' experience of hospice care. Several of the CAHPS Hospice Survey NQF-endorsed

measures address patient choice at the end of life, including the Communication with Family measure, the Treating Patients With Respect measure, and the Emotional and Spiritual Support measure.

QUESTIONS SUBMITTED BY HON. CLAIRE MCCASKILL

Question. Mr. Azar, please describe any provisions in the President's FY 2019 budget that would directly limit increases in prescription drug list price. Additionally, please describe any provisions in the President's FY 2019 budget that directly limit increases in reimbursement for prescription drugs.

Answer. The budget includes proposals to create incentives that will put downward pressure on the list price of drugs. One proposal involves changing the incentive structure of the Part D benefit by modifying the distribution of liability in the catastrophic phase. Specifically, the proposal increases Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over 4 years from 15 percent to 80 percent, and simultaneously decreasing Medicare's reinsurance liability from 80 to 20 percent. Additionally, beneficiary coinsurance would decrease from 5 to 0 percent, creating a true out-of-pocket maximum in Part D for the first time in the program's history. Collectively, these changes provide beneficiaries with more predictable annual drug expenses and incentivize plans to better manage spending throughout the entirety of the benefit. Currently, plan sponsors have incentives to accept higher prices so that their enrollees reach the catastrophic coverage phase sooner and that expense is offloaded on to the Federal Government. These proposed modifications additionally incentivize plans to negotiate with drug manufacturers to keep list prices down as they now bear the majority of the financial risk in the catastrophic phase. In addition, in Part B, the budget proposes an inflation cap on the average sales price, so that the increase of the average sales price above inflation will receive lower reimbursement paid out through Medicare Part B. Another proposal to improve manufacturers' reporting of average sales prices would provide the Secretary with the authority to apply penalties to manufacturers who do not report required data. Incomplete or inaccurate data leads to Medicare paying more for drugs. Additionally, increased plan formulary flexibility and negotiation power with manufacturers will provide plans with enhanced ability to negotiate lower prices. This will improve price transparency and allow beneficiaries to share more directly in the savings from discounts negotiated by plans.

Question. Mr. Azar, there was nothing in the budget specifically aimed at reining in the increases in direct-to-consumer prescription drug advertising. Are there steps that the administration can take to address the rise in direct-to-consumer prescription drug advertising? If so, please describe.

Answer. I am working with Commissioner Gottlieb to examine whether our approach to how we authorize and approve direct-to-consumer prescription drug advertising, consistent with the law, including the First Amendment.

When considering a change to the FDA's policy on direct-to-consumer drug advertisements, the agency often examines and conducts research to ensure that any changes are grounded in science and will have the greatest benefit to public health. For this reason, the FDA conducts research about the content and delivery of drug advertisements to ensure it is delivered in a way that will optimize health-care professional and patient understanding of the benefits and risks of prescription drugs.

QUESTIONS SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. As you know, Secretary Burwell announced specific payment reform goals of tying 30 percent of Medicare fee-for-service payments to quality or value through alternative payment models by the end of 2016 and 50 percent by 2018. These goals sent a strong signal that galvanized the public and private sectors to participate in the movement away from fee-for-service payment.

During your nomination hearing before the Health, Education, Labor, and Pensions Committee, you acknowledged the importance of this work, saying: It is, I think, one of the great legacies of Secretary Burwell's tenure was launching off so many of the alternative payment models that we have out there, and I would like to keep driving that forward.

Should the Federal Government take a leadership role in moving our health-care system away from fee-for-service payment?

On February 20th, *The Washington Post* reported that the Centers for Medicare and Medicaid Services is no longer focused on achieving the Medicare payment reform goals announced by Secretary Burwell in 2015 but instead on “evaluating the impact of new payment models on patients and providers.” Do you plan to announce different goals and targets for participation in value-based payment and alternative payment models? Why can’t evaluation of the past administration’s efforts be done at the same time CMS works toward those payment reform goals?

How do you intend to monitor and measure overall progress related to payment reform and implementation of new delivery models?

What is your plan for driving forward participation in alternative payment models across public and private health-care sectors?

Answer. Upon taking office at HHS, I identified the value-based transformation of our entire health-care system as one of the top priorities for our department. Value-based transformation in particular is not a new passion for me. It became a top priority for Secretary Mike Leavitt when I was working for him as Deputy Secretary, and it was taken seriously by President Obama’s administration as well, including under the leadership of Secretary Burwell.

It has been, at times, a frustrating process. But there is no turning back to an unsustainable system that pays for procedures rather than value. In fact, the only option is to charge forward—for HHS to take bolder action, and for payers and providers to join with us.

There are four particular areas of emphasis that will be vital to laying down new rules of the road, accelerating value-based transformation, and creating a true market for health care. The four areas of emphasis are: giving consumers greater control over health information through interoperable and accessible health information technology; encouraging transparency from payers and providers; using experimental models in Medicare and Medicaid to drive value and quality throughout the entire system; and removing government burdens that impede this transformation.

The key theme uniting these four priorities is the recognition that value is not accurately determined by outside authorities or central planners.

Question. At your Health, Education, Labor, and Pensions Committee nomination hearing, you said, “As I indicated in my opening statement, one of my top priorities as Secretary, if confirmed, will be to use the power of Medicare and Medicaid to drive transformation of our health-care system from a procedure-based system that pays for sickness to a value-based system that pays for quality and outcomes. If given the opportunity to serve I will use the appropriate tools within the Department to meet this goal and measure our progress in reaching it.”

What specific tools in the Department of Health and Human Services will you use to meet and measure progress on transforming our health-care system from a procedure-based system to a value-based system?

Answer. I am committed to value-based transformation of the health-care system. We have a range of tools for using the Medicare and Medicaid programs to pay for value, many created by the 2015 MACRA legislation. The Center for Medicare and Medicaid Innovation, alongside these tools, vests HHS with tremendous power to experiment with new payment models. In addition, the President’s budget especially supports particular priorities that we have laid out for the Department, including using Medicare to move our health system to a more value-based direction.

Question. As we’ve previously discussed, I have observed a recurring bias within the HHS for taking care of the middle of the pack on major health initiatives. This type of policymaking makes political sense because that is where most health-care providers are. But it fails to drive and reward the health-care providers who take financial and reputational risks by engaging early in new payment and delivery models and investing in the tools and personnel needed to improve the quality of care while reducing costs.

In a response to a question for the record on this topic, you responded that we need to “ensure that our programs do not penalize or create any disincentives for those providers who are at the forefront of leading us toward the desired future State of our health-care system.” What steps have you taken, and what steps do you intend to take, to ensure HHS programs do not penalize or create disincentives for the “lead dogs,” the providers at the forefront of payment and delivery system reform?

Answer. I am committed to value-based transformation of the entire health-care system and will work to ensure that providers at the forefront of payment and delivery system reform are not penalized. One example of a step that has been taken is the changes CMS has made to the Medicare Shared Savings Program to encourage continued participation from high performing ACOs. In addition, we are looking at our efforts regarding ACOs to determine how we can improve results, and we are looking at all alternative payment models to determine what is and what is not working. Furthermore, under the Merit-based Incentive Payment System (MIPS), one of two avenues under the Quality Payment Program, the structure of the program incentivizes performance by “lead dogs” or high performers. The higher a clinician’s or a group practice’s score, the higher the payment adjustment under MIPS. For exceptional performance above an even higher performance threshold, an additional MIPS payment adjustment factor is also available for the first 6 years of the program.

Question. As you know, the framework for MACRA is laid out in statute, but the administration has significant flexibility to adjust the metrics by which clinician performance is measured and to exempt clinicians from MACRA requirements.

What is your goal for the number of clinicians participating in the advanced alternative payment model pathway in 2019 and 2020?

What is your goal for the number of clinicians participating in the Merit-Based Incentive Payment System in 2019 and 2020?

Will you commit to pursuing higher performance standards in the Merit-Based Incentive Payment System over time?

Answer. Although we do not have numerical participation goals for clinicians in either the Merit-Based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (APMs), we have done extensive outreach with clinicians, patients and other stakeholders, and created seven strategic objectives for these programs. These objectives help to guide our policies and future rulemaking so that we can design, implement, and advance a program that aims to improve health outcomes, promote efficiency, minimize burden of participation, and provide fairness and transparency in operations.

These strategic objectives are: (1) To improve beneficiary outcomes and engage patients through patient-centered Advanced APM and MIPS policies; (2) to enhance clinician experience through flexible and transparent program design and interactions with easy-to-use program tools; (3) to increase the availability and adoption of robust Advanced APMs; (4) to promote program understanding and maximize participation through customized communication, education, outreach and support that meet the needs of the diversity of physician practices and patients, especially the unique needs of small practices; (5) to improve data and information sharing on program performance to provide accurate, timely, and actionable feedback to clinicians and other stakeholders; (6) to deliver IT systems capabilities that meet the needs of users for data submission, reporting, and improvement and are seamless, efficient and valuable on the front and back-end; and (7) to ensure operation excellence in program implementation and ongoing development; and to design the program in a manner that allows smaller independent and rural practices to be successful.

The first year of MIPS was established as a transition year, and in the second year, we continued the transition and provided a gradual ramp-up of the program and of the performance threshold. To allow the Quality Payment Program to work for all stakeholders, we also recognize that we must provide ongoing education, support, and technical assistance so that clinicians can understand program requirements, use available tools to enhance their practices, and improve quality and progress toward participation in APMs if that is the best choice for their practice.

Question. In response to a question for the record, you wrote, “Of course, we must exercise the power of CMMI and other authorities in ways that are open and transparent, and that seek out collaboration and input as much as possible.” Last year, the Centers for Medicare and Medicaid Services collected public comments on a Request for Information on a new direction for the CMS Innovation Center. To date, none of those comments have been released publicly.

Give your emphasis on openness and transparency, why hasn’t CMS released all of the public comments submitted to its “new direction” Request for Information?

Do you have a timeline for releasing all of the comments?

Answer. As you highlight, Senator Whitehouse, we share a commitment to harnessing the power of the Center for Medicare and Medicaid Innovation (Innovation Center) to advance and enhance the way health care is provided in America. Our existing partnerships with health-care providers, clinicians, States, payers and stakeholders have generated important value and lessons and CMS is setting a new direction for the Innovation Center. That is why, in September 2017, CMS released a Request for Information⁷ (RFI) seeking public feedback on ways to promote patient-driven care and test market-driven reforms that empower beneficiaries as consumers, provide price transparency, increase choices and competition to drive quality, reduce costs, and improve outcomes. We are grateful for the comments and thoughtful ideas that we received in response to the RFI. Overall, through the close of the comment period in November, CMS received approximately 1,000 submissions. CMS continues to review these submissions, and they will be an integral source of information as CMS moves forward with the agency-wide efforts to promote innovation, including through the design and testing of additional Advanced APMs that will aim to improve the patient-provider experience. However, our engagement with stakeholders has not ended with this RFI and we look forward to continuing to work with all stakeholders to make sure we are delivering results and putting the patient in the driver's seat.

We are committed to following the Administrative Procedures Act (APA) and while the comments were not solicited as part of any proposed rule, and therefore CMS is not obligated to publish the comments, we plan to make the comments available on the Innovation Center's website and are happy to work with you and relevant stakeholders to share any additional information as needed.

Question. How is CMS disseminating best practices from payment and delivery models identified as working and lessons learned from those that are not?

Answer. As required by section 1115A of the Social Security Act, CMS conducts an evaluation of each model tested under such section. The Innovation Center, using independent evaluators, routinely and rigorously assesses the impact of each model on quality and cost. Each evaluation report is posted on the Innovation Center's website. The Innovation Center has also created model-specific learning collaboratives that promote broad and rapid dissemination among model participants of evidence-based best practices that have the potential to deliver high quality and lower cost care for Medicare, Medicaid, and CHIP beneficiaries. In addition, CMS has incorporated lessons from models in other programs. For example, after the Pioneer Accountable Care Organization (ACO) Model was determined to meet the statutory requirements for expansion, CMS incorporated elements of the Pioneer ACO Model into the Medicare Shared Savings Program.

Question. Please provide the following information about CMS Innovation Center operations:

- The number of FTEs working at the Center in 2016, 2017, and 2018 (to date).
- Annual Center expenditures in 2016, 2017, and 2018 (to date).
- A list of alternative payment models and initiatives that, since 2016:
 - Have been announced or introduced by the Center;
 - Are being tested;
 - Have been terminated by the Center; and
 - Have been deemed eligible for expansion by the Center.
- A list of alternative payment models for which there are interim or final evaluations.

Answer. As of September 30, 2017, the Innovation Center had 581 staff. The Innovation Center's net outlays in FY 2016, 2017, and 2018 (to date) are \$1,156 million, \$1,136 million, and \$1,278 million, respectively. To date, the Innovation Center has tested or announced 39 models. A list of the models and information about their status is available at <https://innovation.cms.gov/initiatives/index.html#views=models>. Every Innovation Center model is independently evaluated, and all evaluation reports are available at: <https://innovation.cms.gov/Data-and-Reports/index.html>.

Question. I have heard from stakeholders that CMS does not have a coherent, systematic strategy for resolving issues that arise—e.g., attribution of beneficiaries, expenditures, and savings—when health care providers and beneficiaries participate in overlapping alternative payment models. Instead, resolution of these issues is done on a one-off, model-by-model basis, and that guidance is not made widely available to the public. This lack of transparency and haphazard approach creates uncer-

⁷ <https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>.

tainty and confusion about the rules of the road for participating in alternative payment models.

What is CMS's framework for resolving issues that rise related to overlapping alternative payment models?

Will you direct CMS to make publicly available policy decisions related to overlapping alternative payment models?

Answer. Transparent model design is one of the guiding principles for models tested by CMS. Overlap between current and anticipated alternative payment models is a factor that CMS considers in the design of models. CMS has a system for aligning beneficiaries to models and programs and ensuring that shared savings and performance-based payments are only paid once for an individual beneficiary. Generally, policies for overlap between models and other initiatives are included in the Requests for Applications for models.

Question. An evaluation published in *Health Affairs* of the 2016 Medicare Shared Savings Program results showed that the longer providers participate in the program, the more likely they were to achieve shared savings. In addition, the data shows that physician-led ACOs are more likely to achieve shared-savings payments than ACOs whose membership includes hospitals. What is CMS's strategy for ensuring physician-led ACOs are able to sustain their participation in the Medicare Shared Savings Program?

Answer. I agree that physician-only ACOs continue to outperform ACOs that include a hospital and that ACOs continue to show greater improvement in financial and quality performance as they gain experience in the program. We are looking at our efforts regarding ACOs to determine how we can improve results. CMS has made changes to the Medicare Shared Savings Program to encourage continued participation from high performing ACOs, and we continue to consider ways to enhance the program.

PREPARED STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R-Utah) today delivered the following opening statement at a Finance Committee hearing to consider the administration's fiscal year (FY) 2019 budget request for the Department of Health and Human Services (HHS).

Before I begin, I want to express, on behalf of the committee, the sadness we all feel in light of yesterday's events in Florida. I was personally horrified as I watched the news unfold yesterday, though I was also moved to hear some of the stories of the heroism displayed by some of the students and teachers at the school.

In times like these, I know that thoughts expressed from those of us who are far away can sometimes seem empty and meaningless in the face of such a terrible tragedy. I will simply say that I am praying for all of those who were affected by these acts of senseless violence.

That, of course, includes a member of our committee who I know is mourning the loss and pain felt by those in his home State. May they all find peace, healing, and a speedy recovery.

I welcome everyone to today's hearing, which will be our third and final hearing on the President's budget for fiscal year 2019.

We've already had the Treasury Secretary and the Acting IRS Commissioner appear before us. And today, we'll be talking with Secretary Azar from the Department of Health and Human Services.

Secretary Azar, thank you for being here and welcome back. It has been just a little over a month since you last appeared before us. Of course, you are still very new to your position, but we are glad to have you back because we have a lot to discuss.

Since you were last here, this committee has amassed a number of legislative victories. I want to take a few minutes to highlight these accomplishments as many are within HHS's jurisdiction.

Last month, as a result of countless hours of work by this committee, Congress passed and the President signed a 6-year CHIP extension. A few weeks later, we added another 4 years to that extension as part of the Bipartisan Budget Act.

That is 10 more years of CHIP funding, which is, quite frankly, a historic accomplishment.

Senator Ted Kennedy and I created the CHIP program more than 2 decades ago. And, despite always enjoying bipartisan support, at no point in the program's history have we been able to deliver this much certainty and security for the families and children who depend on CHIP. I want to once again commend my colleagues on both sides who joined in this effort and who share in this success.

It was no small feat.

In addition to the CHIP extension, the CHRONIC Care Act, another bipartisan legislative product out of this committee, was also signed into law recently. This new law will improve care for Medicare beneficiaries living with chronic conditions, streamline care coordination, and improve quality outcomes without worsening Medicare's shaky fiscal status. Again, I want to thank everyone on this committee who worked on this bill, most notably our ranking member, Senator Wyden, as well as Senators Isakson and Warner, who were key leaders in the drafting and passage of this important bill.

And it doesn't end there. The budget bill also included the bipartisan Family First Prevention Services Act, which will help keep more children safely with their families—specifically by funding substance abuse and mental health services that have been shown to prevent children from entering foster care.

All of this success is testament to bipartisanship and proves that it is possible for both parties to find common ground and work together. As always, there is more work to be done and I am optimistic that we can be just as effective in the coming months.

Of course, these recent achievements won't mean much if they are not implemented properly. Secretary Azar, I look forward to working with you as this process moves forward.

Now, I'd like to take a moment to talk about some of the specifics in the President's budget, which recognizes the need to eliminate wasteful spending, rein in our national debt, and focus on protecting Americans at home. I appreciate that the President's budget takes steps toward a course correction that will hopefully lead to a more economically sound future, all while still ensuring high-quality, and accessible health care.

One of the key and critical assumptions in the President's budget is the repeal of Obamacare. The budget bakes in this repeal, and replaces it with a State-based grant system. All told, the administration estimates that this would save more than \$675 billion.

Many of us on the committee—I think all of us on the Republican side—share this desire to repeal Obamacare, and we've actually done some great work on rolling back major elements of the so-called Affordable Care Act this Congress. For starters, our tax reform bill zeroed out the individual mandate tax.

The recent budget bill also included the so-called Medicare extenders and repealed the Independent Payment Advisory Board. And, in that same bill, we extended previous delays on other Obamacare taxes, including the medical device tax, the health insurance, and the so-called Cadillac tax. But, as the budget points out, we are not quite there yet. I hope we can take additional steps in the future and I look forward to continuing our discussions on how we can stop the skyrocketing cost of health care in a meaningful and well-governed way.

Beyond the critical repeal and replace efforts with Obamacare, we also need to start getting serious about Medicare and Medicaid reforms. Both of these programs need to be put on a more sustainable path, so that we can fulfill the promises of these programs for future generations.

I know that any time a Republican mentions the fiscal predicament of Medicare and Medicaid, we're essentially asking to be accused of robbing the elderly and low-income families of their health care. But, none of these scare tactics will improve the outlook of our Federal health-care programs. That's going to take some hard work and, hopefully, we can find a path forward there as well.

Secretary Azar, during your confirmation hearing, you emphasized that addressing rising drug prices would be one of your top priorities. As you know, I've spent quite a bit of time on this issue, working to ensure that patients have access to innovative and high-quality medications. It can be tricky to balance the need to encourage investment and development of new and effective drugs and treatments while also working to make sure those in need can obtain access to those potentially life-saving and life-improving products.

Some have made a crusade out of scapegoating the companies that develop drugs and treatments.

And, when this almost singular focus prevails, the result is policy that tends to be less than perfect, to put it charitably. We saw an example of this in last week's Bipartisan Budget Act that increased the discount that manufacturers are required to provide under the so-called donut hole in Medicare Part D.

I voiced my opposition to the inclusion of this provision in the budget agreement on the Senate floor last week. I am working with my colleagues who share my concern on the increased manufacturer discount provision to mitigate its impact.

Further, as this budget has a number of other drug-related policy proposals, I implore the administration to take care to strike a balance between access and innovation. It is a balance that I hope that we should all strive to achieve.

Secretary Azar, you also emphasized that addressing America's opioid crisis is another one of your top priorities. I am happy to see that the President's budget stresses the importance of working together to fight this epidemic.

The CDC estimates that, each day, our country experiences more than 100 opioid-related deaths.

My home State of Utah has been especially hard hit. And while the drug overdose rate has risen over the past decade, we are starting to see a shifting tide thanks to the leadership of many officials in my State. With that said, they need Federal help.

And, I know that many in Congress, including several members of this committee, have been outspoken leaders in this effort, and I commend them for their work.

We are committed to continuing our bipartisan committee process to address the opioid epidemic, especially through mandatory program proposals that can bring about meaningful and enduring change to a system plagued with issues.

Mr. Secretary, I look forward to working with you in the coming months as we look for solutions to address this crisis, and I hope that we, as a committee, can continue our bipartisan efforts to curtail this growing string of tragedies.

To close, let me just say that, as we all know, it is Congress's responsibility to pass a budget. The President's proposed budget merely sets the tone and provides us with a baseline for debate. I hope that we can work together to implement many of the common-sense reforms we've been debating for so long. And I hope that we can continue to work to set aside our differences in order to find beneficial solutions.

I look forward to having an open and frank discussion with Secretary Azar about these and other matters.

Before I close, I do want to note that because we were unable to get a quorum yesterday, if, at any point during the hearing, a suitable quorum is present, I intend to pause the hearing and move to votes on the nominations of Mr. Dennis Shea and Mr. C.J. Mahoney. Thereafter, we'll resume our hearing.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

It's budget season in Washington, which means the Trump agenda of health care discrimination is back. This morning I'll run through the plan example by example.

Let's start off with discrimination against Americans with pre-existing conditions. People who have pre-existing conditions count on having a robust private insurance market with strong consumer protections. What the Trump budget offers is chaos in the private insurance market and the elimination of key consumer protections.

The budget embraces the old Graham-Cassidy proposal, which lived a mercifully short life last fall before it was blocked on a bipartisan basis. But here it is once

again, warts and all, another crack at repealing the Affordable Care Act and forcing Americans to pay more for less care. On top of that, the administration is giving a green light to junk insurance policies that revive the worst industry abuses of the past, such as skimpy coverage and dollar limits on care. So for millions of people with pre-existing conditions, the Trump administration seems dead-set on making the care they need unaffordable and inaccessible.

Next up in the agenda of health-care discrimination is discrimination against women. When you get rid of the consumer protections in the Affordable Care Act, you're turning the clock back to an era when 75 percent of insurance plans in the individual market didn't cover maternity care or birth control. And under the Trump budget, which arbitrarily attacks Planned Parenthood and other key providers, millions of women would lose the right to see the doctor of their choosing.

Then the Trump agenda of health-care discrimination goes after Americans who are walking an economic tightrope: \$1.4 trillion cut from Medicaid. Millions of working Americans locked out of the program. A scheme to wipe out key nationwide protections and cap the program, essentially ending the guarantee of care for those who qualify for Medicaid. Now the Trump administration is reportedly discussing lifetime limits for Americans in Medicaid. Both sides used to agree that lifetime limits in health care were absolutely wrong, no exceptions. The ban on lifetime limits in the Affordable Care Act was one of the core protections even Republicans said should stay. Introducing lifetime limits in Medicaid raises the frightening question of what happens if somebody maxes out after cancer treatment at age 45. Are they going to be on the street in old age, capped out of the nursing home benefit, for example?

Finally, the Trump agenda of health care discrimination turns against older Americans. Slashing Medicaid to the bone and transforming the program into a capped program is an enormous threat to the welfare of seniors. Medicaid helps pay for two out of three seniors in nursing homes, and it's essential for seniors who count on home-based care. Even for Americans at age 62 or 63, there's bad news. The Trump budget would hit them with an age tax, allowing insurance companies to charge them at far higher rates than they charge others.

Bottom line, the agenda of health care discrimination is out in force in this Trump budget. It is a comprehensive plan to drag America back to the dark days when health care worked only for the healthy and the wealthy.

Another issue the committee needs to address this morning is the cost of prescription drugs. Donald Trump famously talked about how drug companies were "getting away with murder" by setting drug prices so high. The way he talked about the problem, Americans believed he was going to come out swinging with big solutions to this challenge.

In the plan released late last week, I still don't see a solution to the fundamental issue: drug companies set prices that are way too high. Yes, the whole system is broken and needs reform. But if drug companies can still come right out of the gate with unaffordable prices, patients will still suffer. I'll put this simply. The Trump prescription drug plan lets pharmaceutical companies keep on, to borrow a phrase, getting away with murder.

That said, much of what the administration put forward last week looks awfully familiar. That might be because a lot of it borrowed directly from legislation I've proposed, or recommendations that came from outside groups. There's value in these ideas, and much of it could move forward on a bipartisan basis. But the American people are still looking for the kind of muscular policies the President promised he'd bring forward, and it's still not there.

Finally, I want to discuss a different part of Secretary Azar's jurisdiction at HHS, but one that's vital to the well-being of kids across the country. Last week, the Congress passed a bill Chairman Hatch and I wrote called the Family First Prevention Services Act, which amounts to the most consequential improvements to the child welfare system in decades.

For too long, the child welfare system has defaulted to splitting families apart. The Family First Act is all about finding safe ways to keep families together and healthy. For the first time, States will get to use foster care dollars to fund services like substance use treatment, mental health treatment, and parenting programs with the goal of preventing the kind of prolonged slide into crisis that ends with families breaking apart.

Particularly with the opioid epidemic raging across the country, this is a smart, new approach that can go a long way to helping hundreds of thousands of families and kids. But now that Congress passed the bill, it's up to HHS to implement it the right way. With bipartisan legislation that has this much potential for good, it would be criminal for HHS to stand pat and let States continue the status quo.

BLUE CROSS OF IDAHO APPLICATION FORM



State-Based Plans – Idaho Individual Application
FOR ENROLLMENT OUTSIDE OF THE IDAHO EXCHANGE

Please type or print legibly in black ink and complete all applicable sections.

SECTION 1 ENROLLMENT INFORMATION (check all that apply)

- Are you: A new applicant Adding dependents
- Are you a resident* of the state of Idaho? Yes No
*The primary applicant must be a resident of the state of Idaho on or before the effective date of and during the term of this policy to be eligible for coverage. Coverage under the policy will be terminated if the primary applicant was not a resident upon the effective date of this policy and/or failed to maintain residency in the state of Idaho.
- Do you have a current Idaho driver's license or Idaho identification card? Yes No
 Idaho driver's license or identification card number _____ Expiration date _____
If you are unable to provide an Idaho driver's license or identification card number, to establish residency you must provide copies of two other forms of documentation that contain your name and residential address with this completed application. Examples include home mortgage statement; lease or loan agreement; homeowner's, renter's, or car insurance policy (within the last 60 days). These documents must contain the applicant's name and residential address.
- Requested effective date (Subject to insurance carrier approval): (mm/dd/yyyy)

SECTION 2 APPLICANT INFORMATION

First Name, Middle Name, Last Name							
Physical Address						City, County, State, Zip Code	
Mailing Address (if different than physical address)						City, County, State, Zip Code	
Billing Address (if different than mailing address)						City, County, State, Zip Code	
Preferred Phone Number			Cell Phone Number			Email Address	
Marital Status <input type="radio"/> Single <input type="radio"/> Married <input type="radio"/> Other (explain) _____	Date of Birth	Age	Gender <input type="radio"/> Male <input type="radio"/> Female	Weight	Height	Tobacco Use* <input type="radio"/> Yes <input type="radio"/> No	Social Security Number

SECTION 3 DEPENDENT INFORMATION List all eligible dependents you want to enroll, including any child who is under the age of 26; or who is medically certified as disabled and dependent on parent for support (copy of certification required). Use extra paper if necessary.

Dependent's Names (first, middle, last)	Relationship to Applicant (spouse, child, etc.)	Date of Birth (mm/dd/yyyy)	Age	Gender <input type="radio"/> Male <input type="radio"/> Female	Weight	Height	Tobacco Use* <input type="radio"/> Yes <input type="radio"/> No	Social Security Number
				<input type="radio"/> Male <input type="radio"/> Female			<input type="radio"/> Yes <input type="radio"/> No	
				<input type="radio"/> Male <input type="radio"/> Female			<input type="radio"/> Yes <input type="radio"/> No	
				<input type="radio"/> Male <input type="radio"/> Female			<input type="radio"/> Yes <input type="radio"/> No	
				<input type="radio"/> Male <input type="radio"/> Female			<input type="radio"/> Yes <input type="radio"/> No	
				<input type="radio"/> Male <input type="radio"/> Female			<input type="radio"/> Yes <input type="radio"/> No	

*Has any person listed on this application used a tobacco product on average four or more times a week within the last six months (anyone age 18 or older)?

SECTION 4 OTHER COVERAGE INFORMATION (For proper crediting of preexisting condition waiting periods AND Coordination of Benefits, please complete the section below.) Use extra paper if necessary.

Please indicate for EACH person listed on this application any health insurance coverage (including Medicare, Medicaid, FEHBP/uniformed services, Indian Health Service, high risk pool or other creditable coverage) in effect within 12 months prior to the proposed effective date of this coverage. Each person applying for coverage must be listed below. If no health insurance coverage was in effect within the past 12 months, please indicate **NONE**.
 If you have had coverage within 63 days of this coverage effective date, proof of existing coverage may be requested to accurately credit your waiting periods. If you have canceled High Risk Pool (Basic, Standard, Catastrophic A or B, HSA) coverage within the past 12 months, please read the **Notice of Federal Eligibility** in Section 6 of this application to see if you are eligible for this insurance.

FOR OFFICE USE ONLY	Electronic System ID
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Other Insurance Carrier Information: Insurance Carrier Name, Policy Number, Phone Number	Policyholder Name	Names of Covered Members: Self and Dependent(s)	Coverage Start Date (mm/dd/yy)	Coverage End Date (mm/dd/yy)	Type of Coverage	Will this coverage continue?
					<input type="radio"/> Group <input type="radio"/> HRP <input type="radio"/> Indiv <input type="radio"/> COBRA	<input type="radio"/> Yes <input type="radio"/> No
					<input type="radio"/> Group <input type="radio"/> HRP <input type="radio"/> Indiv <input type="radio"/> COBRA	<input type="radio"/> Yes <input type="radio"/> No
					<input type="radio"/> Group <input type="radio"/> HRP <input type="radio"/> Indiv <input type="radio"/> COBRA	<input type="radio"/> Yes <input type="radio"/> No
					<input type="radio"/> Group <input type="radio"/> HRP <input type="radio"/> Indiv <input type="radio"/> COBRA	<input type="radio"/> Yes <input type="radio"/> No
					<input type="radio"/> Group <input type="radio"/> HRP <input type="radio"/> Indiv <input type="radio"/> COBRA	<input type="radio"/> Yes <input type="radio"/> No
					<input type="radio"/> Group <input type="radio"/> HRP <input type="radio"/> Indiv <input type="radio"/> COBRA	<input type="radio"/> Yes <input type="radio"/> No

Are you or any dependent listed on this application receiving Worker's Compensation payments or are not eligible to receive such payments?
 Yes No If YES, give person's name, specific type and details.

Medicare Coverage Information (If any person listed on this application is covered by Medicare, please complete the following)

Name _____ Medicare Beneficiary Number _____ Reason for Medical Department (age, disability or ESRD) _____

Date of Medicare Entitlement: Part A _____ / _____ / _____ Part B _____ / _____ / _____

SECTION 5A	HEALTH STATEMENT
PLEASE ANSWER BELOW	Have you or any family member listed on this application ever seen a doctor, been diagnosed with, had treatment, hospitalization, medications, tests or been advised to have treatment or surgery for any of the following? If YES, please provide details on grid below. NOTE: The list of specific conditions is not comprehensive.
A. Cancer/Tumor <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Brain <input type="checkbox"/> Breast <input type="checkbox"/> Cervical <input type="checkbox"/> Colon <input type="checkbox"/> Leukemia <input type="checkbox"/> Liver <input type="checkbox"/> Lung <input type="checkbox"/> Lymphoma <input type="checkbox"/> Melanoma <input type="checkbox"/> Non-Malignant Tumor <input type="checkbox"/> Ovarian <input type="checkbox"/> Prostate <input type="checkbox"/> Testicular <input type="checkbox"/> Other Cancer
B. Heart/Circulatory <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Aneurysm <input type="checkbox"/> Angina <input type="checkbox"/> Angioplasty/Stent <input type="checkbox"/> Blood Clots/Disorders <input type="checkbox"/> Bypass <input type="checkbox"/> Cholesterol/Triglycerides <input type="checkbox"/> Congestive Heart Failure <input type="checkbox"/> Hemophilia <input type="checkbox"/> High Blood Pressure <input type="checkbox"/> Pacemakers/ICD <input type="checkbox"/> Stroke
C. Reproductive <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Breast Disorders <input type="checkbox"/> Endometriosis <input type="checkbox"/> Fibroids <input type="checkbox"/> Infertility <input type="checkbox"/> Menstrual Disorders
D. Intestinal/Endocrine/Liver <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Chronic Pancreatitis Cirrhosis <input type="checkbox"/> Colon Disorder <input type="checkbox"/> Crohn's <input type="checkbox"/> Diabetes <input type="checkbox"/> Gall Bladder <input type="checkbox"/> Gastric Bypass <input type="checkbox"/> Hepatitis B/C <input type="checkbox"/> Liver Disorder <input type="checkbox"/> Pituitary Disorder <input type="checkbox"/> Reflux <input type="checkbox"/> Ulcer <input type="checkbox"/> Ulcerative Colitis
E. Brain/Nervous <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> ALS <input type="checkbox"/> Alzheimer's <input type="checkbox"/> Cerebral Palsy Cyst <input type="checkbox"/> Head Injury <input type="checkbox"/> Migraines <input type="checkbox"/> Multiple Sclerosis <input type="checkbox"/> Paralysis <input type="checkbox"/> Parkinson's Disease <input type="checkbox"/> Seizures/Epilepsy
F. Immune <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> AIDS <input type="checkbox"/> Arthritis (Rheumatoid/Psoriatic) HIV+ <input type="checkbox"/> Immunodeficiency <input type="checkbox"/> Lupus <input type="checkbox"/> Psoriasis <input type="checkbox"/> Scleroderma
G. Lung/Respiratory <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Allergies <input type="checkbox"/> Asthma <input type="checkbox"/> Chronic Bronchitis <input type="checkbox"/> COPD <input type="checkbox"/> Cystic Fibrosis <input type="checkbox"/> Emphysema <input type="checkbox"/> Lung Disorders <input type="checkbox"/> Pneumonia <input type="checkbox"/> Sarcoidosis <input type="checkbox"/> Sleep Apnea <input type="checkbox"/> Tuberculosis
H. Eyes/Ears/Nose/Throat <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Acoustic Neuroma <input type="checkbox"/> Cataracts <input type="checkbox"/> Chronic Ear Infections <input type="checkbox"/> Chronic Sinusitis <input type="checkbox"/> Cleft Lip/Palette <input type="checkbox"/> Deviated Septum <input type="checkbox"/> Glaucoma <input type="checkbox"/> Retinopathy
I. Urinary/Kidney <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Bladder Disorders <input type="checkbox"/> Kidney Disorders <input type="checkbox"/> Kidney Stones <input type="checkbox"/> Polycystic Kidney Disease <input type="checkbox"/> Prostate Disorder <input type="checkbox"/> Renal Failure
J. Bones/Muscles <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Back Disorder <input type="checkbox"/> Bulging/Herniated Disc <input type="checkbox"/> Chronic Pain Syndrome <input type="checkbox"/> Fibromyalgia/Chronic Fatigue Syndrome <input type="checkbox"/> Joint Injury <input type="checkbox"/> Knee Disorder <input type="checkbox"/> Neck Disorder <input type="checkbox"/> Osteoarthritis <input type="checkbox"/> Shoulder Disorder <input type="checkbox"/> Spina Bifida
K. Behavioral Health <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> ADHD <input type="checkbox"/> Alcohol/Drug <input type="checkbox"/> Anxiety/Depression <input type="checkbox"/> Autism <input type="checkbox"/> Bipolar Depression <input type="checkbox"/> Eating Disorder <input type="checkbox"/> Inpatient Mental Health <input type="checkbox"/> Manic Depression <input type="checkbox"/> Substance Abuse <input type="checkbox"/> Suicide Attempt
L. Transplant <input type="radio"/> Yes <input type="radio"/> No	<input type="checkbox"/> Bone Marrow <input type="checkbox"/> Discussed Possible Future Transplant <input type="checkbox"/> Organ <input type="checkbox"/> Stem Cell <input type="checkbox"/> Transplant Complications
M. Pregnant <input type="radio"/> Yes <input type="radio"/> No	Are you or any family member listed on this application currently pregnant? If so, then on the grid below include due date, details about any complications, surrogacy information (if applicable), etc.
N. Hospital/Surgery <input type="radio"/> Yes <input type="radio"/> No	Have you or any family member listed on this application been hospitalized, or had surgery, during the last 5 years?
O. Future Treatment/Surgery <input type="radio"/> Yes <input type="radio"/> No	Have you or any family member listed on this application ever been advised to have any treatment and/or surgical operation(s) that you or any family member have not yet had?
P. Congenital Conditions <input type="radio"/> Yes <input type="radio"/> No	Do you or any family member listed on this application have any congenital conditions that have not previously been disclosed on the detail grid below for a previous question?
Q. \$5,000+ Claims <input type="radio"/> Yes <input type="radio"/> No	Have you or any family member listed on this application had claims in excess of \$5,000 that have not previously been disclosed on the detail grid below for a previous question?

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PLEASE ANSWER BELOW	Have you or any family member listed on this application ever seen a doctor, been diagnosed with, had treatment, hospitalization, medications, tests or been advised to have treatment or surgery for any of the following? If YES , please provide details on grid below. NOTE: The list of specific conditions is not comprehensive.
R. Other <input type="radio"/> Yes <input type="radio"/> No	Do you or any family member listed on this application suffer from any chronic or recurring ailments, illnesses or other departures from good health, regardless of whether a physician or other healthcare professional has been consulted that has not previously been disclosed on the detail grid below for a previous question?
S. Prescriptions <input type="radio"/> Yes <input type="radio"/> No	During the past 12 months, have you or any family member listed on this application received a prescription for medication from a healthcare provider or taken any prescribed medication not previously been disclosed on the detail grid below for a previous question?
T. Denied/Refused Coverage <input type="radio"/> Yes <input type="radio"/> No	Have you or any family member listed on this application ever been refused or issued restricted health insurance coverage?

SECTION 5B HEALTH STATEMENT (If you answered Yes to any question in Section 5A, please complete the information in this section. Use extra paper if necessary.)

Item (A-T) from previous page	Person Affected	Name of Condition – Include Type of Treatment	Date Condition Began MM/YYYY	Date Last Treated MM/YYYY	Name of Healthcare Provider	Name of Hospital and Number of Days, if any	Medications – Include type or name, dosage, length of time used and how often taken	Was Recovery Complete?

SECTION 6 FEDERALLY ELIGIBLE INDIVIDUAL INFORMATION

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), guaranteed availability of individual coverage means that if you are HIPAA eligible, you cannot be denied the right to buy individual coverage. In addition, a pre-existing condition exclusion cannot be applied to your coverage.

You are HIPAA eligible, also called an "eligible individual," if **ALL** of the following are true at the time you apply for individual coverage in Idaho.

- You have at least 12 months of continuous creditable coverage without any break in coverage greater than 63 days
- Your most recent coverage was under a group health plan, a governmental plan or a church plan (or health insurance offered in connection with such a plan)
- You are not covered under another group health plan
- Your most recent coverage was not cancelled because you did not pay your premiums or because you committed fraud
- You are not currently eligible for Medicare or Medicaid

If you are HIPAA eligible, you will lose your right to get individual coverage offered through this application without an exclusion unless you submit an application for individual coverage within 63 days after the day your group coverage or continuation coverage ends. Act promptly to protect your rights.

SECTION 7 AFFIRMATION

I affirm the answers given in this "Blue Cross of Idaho State-Based Plans Individual Application" are complete and correct. I am providing these answers as part of the application procedure required by this insurance carrier to enroll in its insurance coverage. I understand that the insurance carrier will rely on each answer in making its determination to extend coverage and to determine the type of coverage offered. I understand if this application contains any material misstatements or omissions, the insurance carrier may, within the first 24 months of coverage, take any legal action available by law.

I will promptly inform the insurance carrier in writing if anything happens before my coverage takes effect that makes any answer in this application incomplete or incorrect. I understand that a 12-month waiting period for coverage of pre-existing conditions may apply. I understand and agree no coverage shall be in force until approved by the insurance carrier.

FOR OFFICE USE ONLY	Electronic System ID
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SECTION 8 STATEMENT OF UNDERSTANDING

By signing this application, I represent that all my answers are complete and accurate to the best of my knowledge and belief and that I understand and agree to the following conditions:

a. No independent producer, agent or employee of the insurance carrier can change any part of this application or waive the requirement that I answer all questions completely and accurately.

b. The insurance carrier may terminate insured's coverage for any misrepresentation, omission of fact by, concerning, or on behalf of any insured that was or would have been material to the insurance carrier's acceptance of a risk, extension of coverage, provision of benefits or payment of any claim.

c. Coverage for me and any eligible persons named on this application will begin on the effective date assigned by the insurance carrier.

d. I understand that this application will become part of the contract between the insurance carrier and me.

e. I affirm that I have reviewed all answers given on this application and, regardless of whether an independent producer or other person has filled out the answers for me, I verify that the answers are true and complete.

f. NOTE:

A preexisting condition is (i) a condition that would have caused an ordinarily prudent person to seek medical advice, diagnosis, care or treatment during the six(6) months immediately preceding the effective date of coverage; (ii) a condition for which medical advice, diagnosis, care or treatment was recommended or received during the six (6) months immediately preceding the effective date of coverage; or (iii) a pregnancy existing on the effective date of coverage. This exclusion may last up to 12 months from your first day of coverage; however, the exclusion period will be reduced by the number of days of your prior "creditable coverage." Most prior health insurance coverage is considered creditable coverage and can be used to reduce the preexisting condition exclusion period if you have not experienced a break in health insurance coverage of 63 days or more. This preexisting condition exclusion does not apply to a child who is enrolled in the plan within 60 days after birth, adoption or placement for adoption.

SECTION 9 ACKNOWLEDGEMENT AND AUTHORIZATION TO OBTAIN MEDICAL RECORDS

I acknowledge and understand my health plan may request or disclose health information about me or my dependents (persons who are eligible for benefits coverage and are listed on the application) for the purpose of facilitating healthcare treatment, payment or for the purpose of business operations necessary to administer healthcare benefits, or as required by law.

- Health information requested or disclosed may be related to treatment or services performed by:
 - A physician, dentist, pharmacist or other physical or behavioral healthcare practitioner;
 - A clinic, hospital, long-term care or other medical facility;
 - Any other institution providing care, treatment, consultation, pharmaceuticals or supplies or;
 - An insurance carrier or group health plan.

Health information requested or disclosed may include, but is not limited to: claims records, correspondence, medical records, billing statements, diagnostic imaging reports, laboratory reports, dental records, or hospital records (including nursing records and progress notes).

This acknowledgement does not apply to obtaining information regarding psychotherapy notes. A separate authorization will be used for psychotherapy notes.

Authorization to Obtain Records: I authorize any physician, medical professional, hospital, clinic, pharmacy, pharmacy benefit manager or other pharmacy related services organization, health plan, insurance company, claims administrator, employer, governmental agency or other person or firm, to disclose to Blue Cross of Idaho or its authorized representative, my personal information, including copies of records concerning physical or mental illness, advice, diagnosis, prognosis, prescription information, care or treatment provided to me. I understand that such information will be used by Blue Cross of Idaho for the purpose of evaluating my application for insurance. Health information obtained will not be re-disclosed without my authorization unless permitted by law, in which case it may not be protected under federal privacy rules. This authorization shall be valid for six months from this date and may be revoked by sending written notice to Blue Cross of Idaho.

Signature of Applicant _____ Signature Date (mm/dd/yyyy) _____

Signature of Spouse _____ Signature Date (mm/dd/yyyy) _____

(if applying for coverage)

SECTION 10 PARENTAL OR GUARDIAN CONSENT TO APPLICATION

I, the undersigned, represent that the person listed as the applicant on this application is under 18 years of age and is making application for health coverage with my full knowledge and consent. I hereby accept full responsibility for the payment of premiums and the answers and information provided in this application.

Signature _____ Print Name _____ Date (mm/dd/yyyy) _____

SECTION 11 AGENT INFORMATION

Agent's Name _____ ID No. _____

Signature of Agent _____ Date _____

LETTER SUBMITTED BY HON. RON WYDEN

February 14, 2018
 Honorable Alex Azar
 Secretary of Health and Human Services
 U.S. Department of Health and Human Services
 200 Independence Avenue, SW
 Washington, DC 20201

Re: Idaho Department of Insurance Bulletin 18-01 (January 24, 2018)

Dear Secretary Azar:

The 15 undersigned organizations represent millions of patients facing serious, acute, and chronic health conditions across the country. We collectively stand ready

to ensure that these patients have access to affordable, adequate health insurance in order to treat and manage their conditions. We write regarding the recent action by the State of Idaho to authorize the issuance of health insurance plans that violate numerous requirements of the Affordable Care Act (ACA) that provide essential protections to individuals and families. We urge you to address this issue in a timely manner, and provide clarification by the Department of Health and Human Services that Idaho's Department of Insurance Bulletin 18-01 is legally invalid.

Idaho's insurance bulletin would allow insurers to sell individual market plans that do not comply with federal law.¹ Because the Idaho Bulletin purports to authorize the issuance of insurance coverage that is prohibited by federal law, it is legally invalid. Under the Affordable Care Act, a "health insurance issuer" is prohibited from offering "health insurance coverage" in the individual or small group market that violates the statute's consumer protection standards.²

Idaho's insurance bulletin would allow the sale of products that could:

- Deny coverage of pre-existing conditions for those with a break in coverage;³
- Charge older Americans up to five times as much as younger Americans;⁴
- Impose higher premiums on people with pre-existing conditions;⁵
- Put a dollar limit on insurance benefits;⁶
- Increase consumers' annual out-of-pocket costs;⁷ and
- Exclude key health benefits such as maternity care, newborn care, habilitative services, and pediatric vision and dental services—and potentially others such as contraceptive services, tobacco cessation and cancer screening.⁸

Idaho's action—if it is permitted to stand—would seriously injure Idaho patients and consumers and significantly destabilize Idaho's entire health insurance market. Individuals and families who purchase these plans may not have insurance coverage for essential health services and would likely pay more out of pocket for the services that are covered—while older Americans and individuals with pre-existing conditions, because of premium surcharges, would likely pay more for less coverage. Further, older Americans could be charged up to five times the premiums for younger Americans—much more than the three-to-one limit in federal law. People with pre-existing conditions could be charged up to 50 percent on top of what they otherwise would pay. And a person who is both older and has a pre-existing condition could be charged premiums up to 15 times more than a young, healthy American.⁹

Health-care providers that care for patients with these substandard plans may find the plans won't cover the bills, resulting in medical debt for patients or uncompensated care for providers. While the Bulletin would require issuers who offer skinny plans to provide a disclosure "on the face of the policy that: The Policy is not fully

¹The Supremacy Clause of the United States Constitution (Article V, Section 2) provides that federal laws "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." States therefore cannot authorize companies to violate federal law.

²See 42 U.S.C. §§ 300gg and 300gg-4.

³Federal law bars insurers from imposing pre-existing condition exclusions (42 U.S.C. § 300gg-3) or continuous coverage requirements (42 U.S.C. § 300gg-1), but the Idaho bulletin (¶3) permits such exclusions for individuals who lack coverage in the prior 63 days.

⁴Federal law prohibits insurers from setting premium rates that vary by more than a 3:1 age ratio and that vary by more than 50% for tobacco use (42 U.S.C. § 300gg and 300gg-4), but the Idaho bulletin (¶5) allows plans to vary their rates by a 5:1 age ratio.

⁵Federal law prohibits insurers from setting premium rates based on health status (42 U.S.C. §§ 300gg), but the Idaho bulletin (¶5) allows plans to vary their rates based on a risk factor.

⁶Federal law prohibits insurers from setting an annual limit on the amount the insurer will pay (42 U.S.C. § 300gg-11), but the Idaho bulletin (¶6) permits an annual limit of no less than \$1 million per person.

⁷Federal law prohibits health insurance coverage that violates the maximum out-of-pocket cost limit established by Federal law (42 U.S.C. § 18002(c)), but the Idaho bulletin (¶7) applies the out-of-pocket cost ceiling to the bulletin's more restrictive list of essential health benefits (and therefore permits higher out-of-pocket costs than does Federal law) and in addition permits separate maximums for different types of services (*e.g.*, one for prescription drugs and another for other services), which is also contrary to Federal law.

⁸Federal law prohibits individual market coverage that fails to cover specified essential health benefits (42 U.S.C. §§ 300gg-6 and 300gg-13), but the Idaho bulletin (¶4) permits plans that do not cover a number of the essential health benefits specified under Federal law: maternity care; newborn care; pediatric vision and dental care; habilitative services; and the full set of preventive services, such as contraceptive services, recommended cancer screening, and gestational diabetes screening.

⁹Tim Jost, "Idaho's Proposal for State-Based Plans Violates the Affordable Care Act," The Commonwealth Fund, February 8, 2018, available at <http://www.commonwealthfund.org/publications/blog/2018/feb/idaho-state-based-plan>.

compliant with federal health insurance requirements,”¹⁰ we are concerned that this disclosure is insufficient education to consumers to warn them of the limitations of the plan’s coverage.

The cap on insurers’ payments and increased out-of-pocket limits for families could impose serious financial burdens on Idaho families. For instance, a person who has an accident and requires an expensive medication after being hospitalized may pay twice the federal limit on out-of-pocket spending of \$7,350: once for medical care and a second time for the prescriptions.

Individuals and families who continue to purchase plans that comply with Federal law will likely pay more for it, because healthier individuals are more likely to be siphoned off, which will unbalance the risk pool for lawful plans.¹¹ Insurers that do not offer these plans will incur losses as their risk pools are left with sicker, costlier patients.

The Federal Government must uphold the requirements of Federal law that protect patients, their families, and the health system against these consequences. On behalf of our patients, and all Americans, we urge you to make clear that Idaho cannot authorize the issuance of health insurance coverage that violates federal law, and that any insurer that issues such plans risks enforcement action and serious penalties.

Sincerely,

American Cancer Society Cancer Action Network
 American Diabetes Association
 American Heart Association
 American Liver Foundation
 American Lung Association
 Cystic Fibrosis Foundation
 Epilepsy Foundation
 Hemophilia Federation of America
 Leukemia and Lymphoma Society
 Lutheran Services in America
 March of Dimes
 Mended Little Hearts
 Muscular Dystrophy Association
 National MS Society
 National Organization for Rare Disorders

EXCERPT FROM THE HEARING TO CONSIDER THE
 GRAHAM-CASSIDY-HELLER-JOHNSON PROPOSAL

September 25, 2017

Senator WYDEN. Mr. Chairman, one of our past great chairmen, Pat Moynihan, said everybody is entitled to his own opinion, but not his own facts. So let us hear from the American Cancer Society with respect to the real facts. They have a lot of members who understand the hurt that comes from being discriminated against for having a pre-existing condition. Mr. Woodruff, what do you think with respect to this bill and what it is going to do to people with a cancer fight on their hands?

Mr. WOODRUFF. Well, it does not protect them, Senator. It basically makes the patient protections that were enacted into law in the Affordable Care Act discretionary on the part of each State. And each State can decide to keep those patient protections or not. But what is important about what the Act achieved is, it created a definition, a national standard for what is adequate insurance and what is affordable. And so with the essential health benefits, we actually have an assurance that

¹⁰Idaho Bulletin at ¶8.

¹¹Policy experts surmise that the skimpy plans will be attractive to younger and healthier consumers, while older and sicker individuals will gravitate to ACA-compliant plans “rendering coverage unaffordable for many Idahoans who don’t qualify for the ACA’s premium tax subsidies and aren’t young or healthy enough to afford the State-based plans.” This will result in higher Federal subsidies needed to pay for the more expensive plans offered on the exchanges. See Sabrina Corlette, “Idaho Goes Rogue: State Authorizes Sale of Health Plans That Violate the Affordable Care Act,” Georgetown University Health Policy Institute Center for Children and Families, February 1, 2018, available at <https://ccf.georgetown.edu/2018/02/01/idaho-goes-rogue-state-authorizes-sale-of-health-plans-that-violate-the-affordable-care-act/>.

when you buy insurance, it is going to cover the services that you need when you are sick, whether you have cancer or any other disease. The essential health benefits are there to protect you.

Senator WYDEN. Thank you.

Mr. WOODRUFF. Sure.

Senator WYDEN. And I want the American people to understand the consequence of that statement. The Cancer Society knows something about what it means for patients to get clobbered by an extraordinary illness, and what they have said is, this opens up the door to charging those people more.

COMMUNICATION

CENTER FOR FISCAL EQUITY

Statement of Michael G. Bindner

Chairman Hatch and Ranking Member Wyden, thank you for the opportunity to submit these comments for the record to the Committee on Finance on the HHS FY 2019 Budget Request.

Most of our proposals are about tax and entitlement policy and the process of estimating discretionary spending, rather than specific recommendations for departmental budgets. We are wondering, however, why this hearing, which mainly presents discretionary budget request data for the subject fiscal year, is still being held when on Friday last an Omnibus Appropriation for the period in question was passed and signed into law. For the record, we fully support the increases to the NIH budget, which was horribly underfunded of late. Regardless, our comments still apply so we will preface them with our comprehensive four-part approach, which will provide context.

- 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 to fund net interest payments, debt retirement, and overseas and strategic military spending and other international spending, with graduated rates between 5% and 25%.
- 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 short-

ly 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.

Congress just adopted a Chained CPI, but 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 \$1,000 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. It was not, but it will soon with the end of mandates. Rates will soon start going up as 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.

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.