THE FISCAL YEAR 2020 HHS BUDGET

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

MARCH 12, 2019

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C O N T E N T S

THE FISCAL YEAR 2020 HHS BUDGET

TUESDAY, MARCH 12, 2019

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 12:01 p.m., in the John D. Dingell Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo (chairwoman of the subcommittee) presiding.

Members present: Representatives Eshoo, Engel, Butterfield, Matsui, Castor, Sarbanes, Luján, Schrader, Kennedy, Cárdenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Rush, Pallone (ex officio), Burgess (subcommittee ranking member), Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Also present: Representatives DeGette, Schakowsky, and Tonko.

Staff present: Kevin Barstow, Chief Oversight Counsel; Jacquelyn Bolen, Health Counsel; Jeffrey C. Carroll, Staff Director; Luis Dominguez, Health Fellow; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Megan Howard, FDA Detailee; Zach Kahan, Outreach and Member Service Coordinator; Saha Khaterzai, Professional Staff Member; Chris Knauer, Oversight Staff Director; Una Lee, Senior Health Counsel; Kevin McAloon, Professional Staff Member; Joe Orlando, Staff Assistant; Kaitlyn Peel, Digital Director; Alivia Roberts, Press Assistant; Tim Robinson, Chief Counsel; Samantha Satchell, Professional Staff Member; Andrew Souvall, Director of Communications, Outreach and Member Services; Kimberlee Trzeciak, Senior Health Policy Advisor; Rick Van Buren, Health Counsel; C.J. Young, Press Secretary; Jennifer Barblan, Minority Chief Counsel, Oversight and Investigations; Mike Bloomquist, Minority Staff Director; Adam Buckalew, Minority Director of Coalitions and Deputy Chief Counsel, Health; Jordan Davis, Minority Senior Advisor; Margaret Tucker Fogarty, Minority Staff Assistant; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; James Paluskiewicz, Minority Chief Counsel, Health; Brannon Rains, Minority Staff Assistant; Kristen Shatynski, Minority Professional Staff Member, Health; and Danielle Steele, Minority Counsel, Health.

Ms. ESHOO. The Subcommittee on Health will now come to order.

The Chair now recognizes herself for 5 minutes. Actually, I will only use 2, so that we can move things along today.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

We welcome the Secretary of Health and Human Services, Alex Azar, to testify on the President's fiscal year 2020 budget.

Good morning, Mr. Secretary.

This is the first time that Secretary Azar is testifying before the Energy and Commerce Committee in the new Congress, and his first stop on the Hill to testify on the President's budget is here. So thank you for starting with us.

The President's budget certainly reflects the priorities of the administration, but I believe that our national budget should be a statement of our nation's national values, and I don't believe that the budget does that. The Trump administration has taken a hatchet to every part of the healthcare system, undermining the Affordable Care Act, proposing a fundamentally-restructured Medicaid, and slashing Medicare. This budget proposes to continue that sabotage.

In November, the American people rejected the sabotage of healthcare that took place, and it is the reason that I am sitting in this chair and that the ratios of this committee and the Congress have changed.

Our subcommittee has worked hard over the past two months to examine ways to undo the sabotage of the Affordable Care Act and advance legislation that will bring down healthcare costs for the American people, and we will continue that work.

I hope, Secretary Azar, that you will be willing to be a partner in our work to lower healthcare costs for the American people, and we welcome your testimony and your presence here today.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Today we welcome the Secretary of Health and Human Services Secretary Alex Azar to testify on the President's Fiscal Year 2020 Budget.

This is the first time Secretary Azar has testified before the Energy and Commerce Committee in the new Congress.

The Health Subcommittee is also Secretary Azar's first stop during his visit to Capitol Hill to testify on the President's Budget which was released yesterday. We're pleased you started with us.

The President's Budget reflects the priorities of an Administration, and I believe the priorities of this Administration are misdirected.

It's clear this Administration has very different aspirations for our country and what our healthcare system should look like.

The Trump Administration has taken a hatchet to every part of our healthcare system, undermining the Affordable Care Act, proposing to fundamentally restructure Medicaid and slashing Medicare. This budget proposes to continue that sabotage,

In November, the American people rejected the vision for our country that this budget represents.

This Subcommittee has worked very hard over the past two months to examine ways to undo the sabotage of the Affordable Care Act and advance legislation that will bring down healthcare costs for the American people. And we will continue that work.

Secretary Azar, I hope that you'll be a partner in our work to lower healthcare costs for the American people and we welcome your testimony.

Ms. ESHOO. The Chair now recognizes Dr. Burgess, the ranking member of the subcommittee, for 5 minutes for his opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Chairwoman.

And, Mr. Secretary, good afternoon. Welcome to our humble, little subcommittee. It is a pleasure to have you testifying before us today to hear your views about the fiscal year 2020 budget proposal.

The President's budget provides Congress with an important blueprint for our appropriations process and with the policies that this President and his administration would like to see in the coming fiscal year. As we know, under the Constitution, no money may be spent from the Treasury unless it is appropriated by Congress, and in a perfect world no money would be appropriated unless the expenditure has previously been authorized.

The Energy and Commerce Committee is a principal authorizing committee of the United States House of Representatives. I believe this is a critical task and it is important to get input from the Department of Health and Human Services when we are authorizing or re-authorizing or reforming programs that are under your control.

While we do hear from the boots on the ground in our districts, it is the agency that both oversees the implementation of these programs and provides funding to ensure that the organizations can carry out the initiatives' goals.

Secretary Azar, thus far, in your tenure as the Secretary of the Department of Health and Human Services, you have proven to be immensely helpful to this committee and its work. You and your team have been responsive to our requests for information and for input, and you have made yourself available to Members, so that we can hear about your priorities and your intention to work with Congress on a number of initiatives.

I will say this: of all the Secretaries of Health and Human Services over the years that I have been in Congress, I have found you to be the most transparent and accessible. And I look can forward to continuing to partner with you on your efforts to improve access and quality of healthcare for Americans.

One issue that I have raised in each hearing in this Congress, and one that I hear consistently from constituents back home, is the cost and complexity of the healthcare system. North Texans frequently tell me that they can barely afford their insurance premiums, let alone the cost they must pay to seek the care they need, especially those with high-deductible plans.

Secretary Azar, I know that addressing the cost of healthcare, and specifically drug prices, has been a priority for the Department under your leadership. I hope this committee, being the one with the primary jurisdiction over these issues, will work with you as we consider ways to solve these issues.

Additionally, as the Energy and Commerce Committee primarily drafted landmark laws, including the 21st Century Cures and last year's opiate effort, the SUPPORT for Communities Act, we should

conduct responsible oversight to ensure that the Department of Health and Human Services is implementing these laws in alignment with congressional intent.

It is encouraging to see that the President's budget request seeks to expand treatment and recovery support for individuals suffering from substance use disorders, in addition to enhancing prevention of addiction in the first place. While it is important to stem the tide of addiction, we cannot ignore those who have a legitimate need for pain treatment, including cancer patients, patients with sickle cell anemia, and others. To that effect, the budget requests $500 million to use for the National Institute of Health to partner with private industry to work towards the development of non-addictive pain therapies, in addition to addiction treatments and overdose reversal technologies.

Additionally, I am encouraged to see that the budget proposes a significant sum of money for childhood cancer therapies and significant money to defeat the HIV/AIDS epidemic. Both efforts are worthy of congressional support.

Another important agency within Health and Human Services, the Office of Refugee Resettlement, is required to provide care for unaccompanied alien children, a task for which your agency was unprepared when this crisis began in 2012, when president Obama signed an Executive Order enacting the Deferred Action for Childhood Arrivals. While conditions and quality of care have improved, the number of illegal border crossings continues to increase. And let me be clear, the Office of Refugee Resettlement does not enforce immigration law. They receive children as a result of other agencies' enforcement activities.

President Trump's budget includes $3.7 billion in fiscal year 2020 for the Unaccompanied Alien Children Program. Congress charged the Office of Refugee Resettlement with the care of unaccompanied alien children. And I hope this committee will support those dedicated HHS and ORR employees as they continue to work with integrity in the face of baseless allegations. If Congress does not want you to undertake that task, Congress should change the law. It is up to you; it is up to us.

Ms. ESHOO. The gentleman's time has expired.

Mr. BURGESS. I yield back. Thank you.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Thank you, Chairwoman Eshoo, and welcome to Secretary Azar. It is a pleasure to have you testifying before the Health Subcommittee this afternoon about the fiscal year 2020 budget proposal. The President's budget provides Congress with an important blueprint for our appropriations process and with policies that the President and his administration would like to see in the coming fiscal year.

Under our Constitution, no money may be spent from the Treasury unless appropriated by Congress and, in a perfect world, no money would be appropriated unless the expenditure is previously authorized. The Energy and Commerce Committee is a principal authorizing committee of the U.S. House of Representatives. I believe this is a critical task and that it is important to get input from the Department of Health and Human Services when we are reauthorizing and reforming programs under its control. While we do hear from the boots on the ground in our districts, it the agency that both oversees the implementation of these programs and provides funding to ensure that organizations can carry out the initiatives' goals.

Secretary Azar, thus far in your tenure as the Secretary of the Department of Health and Human Services, you have proven to be immensely helpful to this Com-

mittee and its work. You and your team have been responsive to our requests for information and input, and you have made yourself available to Members so that we can hear about your priorities and your intention to work with Congress on various initiatives. Of all the Secretaries of Health and Human Services over my years in Congress, I have found you to be the most transparent and accessible, and I look forward to continuing to partner with you on your efforts to improve access and quality of healthcare for Americans.

One issue that I have raised in each hearing this Congress and one that I hear consistently from constituents is the cost and complexity of the healthcare system. North Texans frequently tell me that they can barely afford their insurance premiums, let alone the cost they must pay to seek the care they need, especially of those with high deductible plans. Secretary Azar, I know that addressing the cost of healthcare, and specifically drug prices, has been a priority for the Department under your leadership. I hope that this Committee, being the one with primary jurisdiction over these issues, will work with you as we consider ways to solve these issues.

Additionally, as the Energy and Commerce Committee primarily drafted landmark laws, including 21st Century Cures and last year's opioid effort—the SUPPORT for and Communities Act, we should conduct responsible oversight to ensure that the Department of Health and Human Services is implementing these laws in alignment with Congressional intent. It is encouraging to see that the President's budget request seeks to expand treatment and recovery support services for individuals suffering from substance use disorders, in addition to enhancing prevention of addiction in the first place.

While it is important to stem the tide of addiction, we cannot ignore those who have a legitimate need for pain treatment, including cancer patients, sickle cell anemia patients, and others. To that effect, the budget requests $500 million to use for the National Institutes of Health to partner with private industry to work towards the development of non-addictive pain therapies, in addition to addiction treatments and overdose-reversal technologies. Additionally, I am encouraged to see that the budget proposes $500 million for childhood cancer therapies, and $291 million to defeat the HIV/AIDS epidemic. Both efforts are worthy of Congressional support.

Another important agency within HHS, the Office of Refugee Resettlement, is required to provide care for unaccompanied alien children, a task for which it was woefully unprepared when this crisis began in 2012 when President Obama signed an executive order enacting the Deferred Action for Childhood Arrivals program. While conditions and quality of care have improved, the number of illegal border crossings continues to increase. Let me be clear, the Office of Refugee Resettlement does not enforce immigration law; they receive children as a result of ICE and CBP enforcement.

President Trump's budget includes up to $3.7 billion in FY 2020 for the Unaccompanied Alien Children program. Congress charged the Office of Refugee Resettlement with the care of unaccompanied alien children, and I hope this committee will support these dedicated HHS and ORR employees as they continue to work with integrity in the face of baseless allegations.

Again, thank you to Secretary Azar for your willingness to testify and for taking the time out of your busy schedule to answer our questions.

Ms. ESHOO. Thank you.

I now would like to recognize the chairman of the full committee, Mr. Pallone, for his opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Madam Chair.

Last year, President Trump and Congressional Republicans passed a deficit-busting $2 trillion tax cut for the wealthy and corporations. At that time, we all knew who would take the hit when it came time for the administration to produce a budget. And now, President Trump proposes a sham of a budget that sticks it to average working Americans across the board.

A budget is a reflection of priorities, and this budget makes clear that ensuring all Americans have access to quality healthcare is

not a priority for this administration. The proposed budget for HHS cuts $1.4 trillion in essential healthcare programs that are critical to working families and to seniors across the nation. Under President Trump's leadership, HHS has played a major role in policies to sabotage the Affordable Care Act, slash funding for Medicaid, restrict access to women's contraception, and separate families at the border. This is a devastating record for an agency whose mission is to advance the health and well-being of all Americans.

The fiscal year 2020 budget continues to sabotage by reviving the failed Graham-Cassidy ACA repeal proposal, which would lead to tens of millions of Americans losing their health insurance and would undermine protections for people with preexisting conditions.

The President's budget also continues the administration's assault on the millions of hard-working families that rely on Medicaid for health insurance, proposing $1.5 trillion in cuts to Medicaid. It also continues the administration's illegal efforts to kick vulnerable Americans off Medicaid through work requirements, lockouts, and red tape. This misguided budget also includes over $500 billion in cuts to Medicare, putting healthcare for our seniors at risk. These are severe and extreme healthcare cuts for hard-working middle-class families, seniors, and our most vulnerable. This is a sham of a budget that has absolutely no chance of ever becoming a reality, but it shows the Trump administration's values, and not the values of everyday Americans.

In addition to explaining the cruel cuts made by this budget, Secretary Azar will need to account for HHS's role in implementing the Trump administration's cruel policy of family separation. This policy has caused so much pain and trauma for thousands of children, and it is clear that children are still wrongly being separated from their parents.

And finally, Secretary Azar will also have to answer for HHS's lack of cooperation with this committee's oversight requests. And I stress this, Mr. Secretary over the last two months, this committee has attempted to work with HHS in good faith in asking for information on a variety of topics from the Affordable Care Act to the administration's family separation policy. We are requesting important information that is critical to our ability to conduct oversight of the Trump administration.

But HHS has been largely unresponsive to our requests, and our patience is wearing thin. If Secretary Azar can't commit to providing us all of the information we have requested, we are prepared to take additional steps to make sure that we get the information that we need to conduct this necessary and long-overdue oversight. And I will get back to that when we get to our questions, Mr. Secretary.

But I do want to thank the Chair for having this important budget hearing and thank the Secretary for appearing here today.

Unless someone else would like some of my time, I am going to yield back. All right, I yield back, Madam Chair.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE JR.

Last year President Trump and Congressional Republicans passed a deficit busting $2 trillion tax cut for the wealthy and corporations. At that time, we all knew

who would take the hit when it came time for the administration to produce a budget. And now, President Trump proposes a sham of a budget that sticks it to average working Americans across the board.

A budget is a reflection of priorities, and this budget makes clear that ensuring all Americans have access to quality healthcare is not a priority for this administration. The proposed budget for HHS cuts $1.4 trillion dollars in essential healthcare programs that are critical to working families and to seniors across the nation. Under President Trump's leadership, HHS has played a major role in policies to sabotage the Affordable Care Act, slash funding for Medicaid, restrict access to women's contraception, and separate families at the border. This is a devastating record for an agency whose mission is to advance the health and well-being of all Americans.

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This misguided budget also includes over $500 billion in cuts to Medicare, putting healthcare for our seniors at risk.

These are severe and extreme healthcare cuts for hard-working middle-class families, seniors and our most vulnerable. This is a sham of a budget that has absolutely no chance at ever becoming a reality, but it shows this administration's values are not the values of everyday Americans.

In addition to explaining the cruel cuts made by this budget, Secretary Azar will need to account for HHS' role in implementing the Trump administration's disgraceful and cruel policy of family separation. This policy has caused so much pain and trauma for thousands of children and it's clear that children are still wrongly being separated from their parents.

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Thank you, I yield back.

Ms. ESHOO. We thank the chairman of the full committee.

I now would like to recognize Mr. Walden, the ranking member of the full committee, for his opening statement. Is he here? He is on his way? He is running?

I think that we will recognize——

Mr. BUCSHON. I will claim the time on behalf of the chairman at this point.

Ms. ESHOO. Are you going to——

Mr. BUCSHON. Yes, the ranking member is on the way. So I will start out, if that is OK with the chairwoman.

Ms. ESHOO. Are you making his opening statement? Otherwise, we can just go——

Mr. BUCSHON. I am going to make my statement, and then, probably yield some of my time to the ranking member, yes.

Ms. ESHOO. You can proceed.

Mr. BUCSHON. Thank you, Secretary Azar, for being here to discuss the President's budget. I think every member of this committee appreciates what you are doing, and I echo the ranking member of the subcommittee's comments that you have been open

and accessible to Members of Congress, which is greatly appreciated.

We will look forward to some of the questioning as we go along. I do think that we will have some concerns related to certain areas of the budget, including the National Institutes of Health budget as it relates to healthcare. As you know, I was a healthcare provider before.

And I think we will have a good and solid discussion about our issues at our southern border. By the way, I have been there, and I believe that the Department of Health and Human Services is doing tremendous work with the situation they have been relegated to address. Hopefully, you will continue to do great work on behalf of all these people in the area of the humanitarian crisis that is the southern border.

And with that, I yield to Mr. Walden, the ranking member of the full committee.

OPENING STATEMENT OF HON. GREG WALDEN A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Well, thank you, Doctor. Appreciate it.

To our witness, Mr. Secretary, thanks for being here.

Madam Chair, thanks for having this hearing.

We want to welcome Secretary Azar back to the committee. Thank you.

On a bipartisan basis, this committee has led the way in delivering meaningful healthcare reforms and policies for the American people. Last year, we worked together to pass into law the SUPPORT for Patients and Communities Act. That was the most comprehensive legislation to address a single drug crisis in our nation's history. That bill gave your agency unprecedented resources and tools to stem the tide of the addiction crisis that is still devastating our communities.

CDC data tell us there are more than 70,000 overdose deaths in 2017, and overdoses take the lives of more Oregonians than traffic accidents. Whenever we pass a major piece of legislation, I really think it is important to dive back in and do oversight to find out what is working, what projects are still ongoing, and what we need to do to do better. So I would love to hear from you today, Mr. Secretary, on the Department's work to combat addiction and how we can continue to be partners in getting help to those in need.

We also extended and funded a number of important public health programs, including the longest extension of the Children's Health Insurance Program in the history of the program, 10 full years, with record funding for Community Health Centers, which are both important for my Oregon district and elsewhere across the country. I just met with the Community Health Center over the weekend in Klamath Falls. There are 12 Community Health Centers, 63 sites, serving 240,000 Oregonians. It is really, really important work.

We also need to continue our work on the cost of healthcare. I know the administration is looking at the cost of pharmaceutical drugs. From one end of the supply chain to the other, we need to continue that work, so I appreciate your personal interest in mov-

ing aggressively to bring down the cost of prescription drugs for patients.

Last year, the FDA approved a record number of generic drugs, I would say, in part, because of the bipartisan legislation we passed here. It brings more competition to the market. It drives down prices at the pharmacy counter for consumers. But we have more work to do, and I look forward to continuing this committee's partnership with HHS to rein-in excessive costs for healthcare.

I was also encouraged to see a focus in the President's budget on moving toward value-based care. As a country, we must move into a healthcare system that pays for value and quality of care, but those changes will require major shifts in policy and reimbursement. We must work together on those changes to get them right.

The budget also provides new funding dedicated to the President's goal of ending the HIV epidemic. That is certainly a goal I think everyone on this committee can share.

So in closing, Mr. Secretary, I appreciate your commitment to appear before our committee today, and I look forward to engaging in a thoughtful and meaningful discussion.

If there is anybody else on our side that would like the final minute, I would be happy to yield. Otherwise, Madam Chair, I will yield back to you.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Secretary Azar, welcome back to the Energy and Commerce Committee. Thank you for being so generous with your time here today, and for your leadership at the Department of Health and Human Services.

On a bipartisan basis, this committee has led the way in delivering meaningful healthcare reforms and policies for the American people. Last year we passed into law the SUPPORT for Patients and Communities Act, the most comprehensive bill to address a single drug crisis in our nation's history. That bill gave HHS unprecedented resources and tools to stem the tide of the addiction crisis that is still devastating our communities. CDC data tells us there were over 70,000 overdose deaths in 2017, and overdoses take the lives of more Oregonians than traffic accidents. Whenever we pass a major piece of legislation, I think it's important to dive back in and do oversight to find out what's working, what projects are still ongoing, and what we need to do better. I would love to hear from you today on the department's work to combat addiction and how we can continue to be partners in getting help to those in need.

We also extended and funded a number of important public health programs, including the longest extension of the Children's Health Insurance Program (CHIP)-10 years—in history and record funding for community health centers, which are both important for my Oregon district. I just met with the community health center over the weekend in Klamath Falls, Oregon, and there are 12 community health centers with 63 sites that serve more than 240,000 Oregonians in my district. We also extended funding for teaching health centers and the special diabetes programs in the last Congress. Some of those are whose funding expires at the end of this fiscal year, and I look forward to working with my colleagues across the aisle to ensure these programs are extended and responsibly paid for.

We also need to continue our work on the cost of healthcare, from one end of the supply chain to the other. I appreciate your personal interest in moving aggressively to bring down the costs of prescription drugs down for patients. Last year the FDA approved a record number of generic drugs, bringing more competition into the market and driving down prices at the pharmacy counter. We have more work to do, and I look forward to continuing this committee's partnership with HHS to reign in excessive costs for healthcare.

I was also encouraged to see a focus in the President's budget on moving towards value-based care. As a country, we must move into a healthcare system that pays for value and quality of care, but those changes will require major shifts in policy and reimbursement. We must work together on those changes to get them right.

The budget also provides new funding dedicated to the President's goal of ending the HIV epidemic—a goal I think all of us on this committee share.

In closing, Mr. Secretary, I appreciate your commitment to appear before our committee today. I look forward to engaging in a thoughtful and meaningful discussion.

Ms. ESHOO. We thank the gentleman.

I would like to remind all the Members that, pursuant to committee rules, all Members' written opening statements shall be made part of the record.

So now, welcome again, Mr. Secretary, and you have 5 minutes to address our not-so-small subcommittee, but very powerful one. Welcome, and you have your 5 minutes to impart your testimony to us.

STATEMENT OF ALEX AZAR, SECETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr.AZAR. Thank you very much. Chairman Pallone, Chairwoman Eshoo, Ranking Members Walden and Burgess, thank you for inviting me here to discuss the President's budget for fiscal year 2020.

It is an honor to have spent the year since I last appeared before this committee leading the Department of Health and Human Services. The men and women of HHS have delivered remarkable results since then, including record new and generic drug approvals, new affordable health insurance options, and signs that the trend in drug overdose deaths is beginning to flatten and decline.

The budget proposes $87.1 billion in FY 2020 discretionary spending for HHS, while moving towards our vision for a healthcare system that puts American patients first. It is important to note that HHS had the largest discretionary budget of any non-Defense Department in 2018, which means that staying within the caps set by Congress has required difficult choices that I am sure many will find quite hard to countenance.

Today, I want to highlight how the President's budget supports a number of important goals for HHS. First, the budget proposes reforms to help deliver Americans truly patient-centered, affordable healthcare. The budget would empower States to create personalized healthcare options that put you, as the American patient, in control and ensure you are treated like a human being, not a number. Flexibilities in the budget would make this possible while promoting fiscal responsibility and maintaining protections for people with preexisting conditions.

Second, the budget strengthens Medicare to help secure our promise to America's seniors. The budget extends the solvency of the Medicare Trust Fund for eight years, while the program's budget will still grow at a 6.9 percent annual rate.

In three major ways, the budget lowers costs for seniors and tackles special interests that are currently taking advantage of the Medicare program. First, we propose changes to discourage hospitals from acquiring smaller practices just to charge Medicare more. Second, we address overpayments to post-acute providers. Third, we will take on drug companies that are profiting off of seniors and Medicare. Through a historic modernization of Medicare Part D, we will lower seniors' out-of-pocket costs and create incentives for lower list prices. We also protect seniors by transferring funding for graduate medical education and uncompensated care

from Medicare to the General Treasury Fund, so all taxpayers, not just our seniors, share these costs.

I also want to acknowledge the work of this committee on lowering out-of-pocket drug costs. Thanks to legislation on pharmacy gag clauses that this committee sent to President Trump's desk, America's pharmacists can now always work with patients to get them the best deal on their medicines. I believe there are many more areas of common ground on drug pricing where we can work together to pass bipartisan legislation to help the American people.

Finally, the budget fully supports HHS's five-point strategy for the opioid epidemic: better access to prevention, treatment, and recovery services; better targeting the availability of overdose-reversing drugs; better data on the epidemic; better research on pain and addiction, and better pain management practices. The budget provides $4.8 billion towards these efforts, including the $1 billion State Opioid Response Program in which we focused on access to medication-assisted treatment, behavioral support, and recovery services.

The budget also invests in other public health priorities, including fighting infectious disease at home and abroad. It proposes $291 million in funding for the first year of President Trump's plan to use the effective treatment and prevention tools we have today to end the HIV epidemic in America by 2030.

Finally, I want to highlight an announcement from HHS today. As we commence a process to identify a new Commissioner of Food and Drugs as quickly as possible, I am pleased to announce that the current Director of the National Cancer Institute, Dr. Ned Sharpless, will serve as Acting Commissioner for Food and Drugs following the conclusion of Commissioner Gottlieb's incredibly successful tenure at some point in early April. NCI's Deputy Director, Dr. Douglas Lowy, will serve as Acting Director of the Institute while Dr. Sharpless is the Acting Commissioner.

This year's budget will advance American healthcare. It will help deliver on promises we have made to the American people. I look forward to working with this committee on our shared priorities in the year ahead, and I look forward to your questions today.

Thank you, Madam Chairwoman.

[The prepared statement of Mr. Azar follows:]

PREPARED STATEMENT OF MR. ALEX AZAR

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. This work is organized into five strategic goals, and is unified by a vision of our healthcare, human services, and public health systems working better for the Americans we serve. By undertaking these efforts in partnerships with States, territories, tribal governments, local communities, and the private sector, we will succeed at putting Americans' health first.

Since I testified before this committee in 2018, the HHS team has delivered impressive results. This past year saw HHS, the Department of Labor, and the Department of Treasury open up new affordable health coverage options, at the same time the Affordable Care Act (ACA) exchanges were stabilized, with the national average benchmark premium on Healthcare.gov dropping for the first time ever. According to a report by the Council of Economic Advisers, actions taken by the administration, along with the elimination of the individual mandate penalty, are estimated to provide a net benefit to Americans of $453 billion over the next decade.

Congress worked with the administration to deliver new resources for fighting the opioid crisis, allowing HHS to make more than $2 billion in opioid-related grants to States, territories, tribes, and local communities in 2018. Prescriptions for medication-assisted treatment options and naloxone are up, while legal opioid prescribing is down. HHS also worked to bring down prescription drug prices, including by setting another record for most generic drug approvals by FDA in a fiscal year and working with Congress to ensure pharmacists can inform Americans about the lowest-cost prescription drug options.

The President's Fiscal Year (FY) 2020 Budget supports HHS's continued work on these important goals by prioritizing key investments that help advance the administration's commitments to improve American healthcare, address the opioid crisis, lower the cost of drugs, and streamline Federal programs, while reforming the Department's programs to better serve the American people.

The Budget proposes $87.1 billion in discretionary budget authority and $1.2 trillion in mandatory funding for HHS. It reflects HHS's commitment to making the Federal Government more efficient and effective by focusing spending in areas with the highest impact.

HHS's Fiscal Year 2020 Budget reflects decisions not just to be prudent with taxpayer dollars, but also to stay within the budget caps Congress created in the Budget Control Act. With the largest non-defense discretionary appropriation of any cabinet agency in 2019, HHS must make large reductions in spending in order to stay within Congress's caps, set a prudent fiscal course, and provide for other national priorities. This budget demonstrates that HHS can prioritize its important work within these constraints, and proposes measures to reform HHS programs while putting Americans' health first.

REFORM, STRENGTHEN, AND MODERNIZE THE NATION'S HEALTHCARE SYSTEM

Reforming the Individual Market for Insurance

The Budget proposes bold reforms to empower States and consumers to improve American healthcare. These reforms return the management of healthcare to the States, which are more capable of tailoring programs to their unique markets, increasing options for patients and providers, and promoting financial stability and responsibility, while protecting people with preexisting conditions and high healthcare costs.

The Budget includes proposals to make it easier to open and use Health Savings Accounts and reform the medical liability system to allow providers to focus on patients instead of lawsuits.

Lowering the Cost of Prescription Drugs

Putting America's health first includes improving access to safe, effective, and affordable prescription drugs. The Budget proposes to expand the administration's work to lower prescription drug prices and reduce beneficiary out-of-pocket costs. The administration has proposed and, in many cases, made significant strides to implement bold regulatory reforms to increase competition, improve negotiation, create incentives to lower list prices, reduce out-of-pocket costs, improve transparency, and address foreign free-riding. Congress has already taken bipartisan action to end pharmacy gag clauses, so patients can work with pharmacists to lower their out-of-pocket costs. The Budget proposes to:

Stop regulatory tactics used by brand manufacturers to impede generic competition;

- Ensure Federal and State programs get their fair share of rebates, and enact penalties to prevent the growth of prescription drug prices beyond inflation;
- Improve the Medicare Part D program to lower seniors' out-of-pocket costs, create an out-of-pocket cap for the first time, and end the incentives that reward list price increases;
- Improve transparency and accuracy of payments under Medicare Part B, including imposing payment penalties to discourage pay-for-delay agreements; and
- Build on America's successful generic market with a robust biosimilars agenda, by improving the efficient approval of safe

and effective biosimilars, ending anticompetitive practices that delay or restrict biosimilars market entry, and harnessing payment and cost-sharing incentives to increase biosimilar adoption.

Reforming Medicare and Medicaid

Medicare and Medicaid represent important promises made to older and vulnerable Americans, promises that President Trump and his administration take seriously. The Budget supports reforms to make these programs work better for the people they serve and deliver better value for the investments we make. This includes a plan to modernize Medicare Part D to lower drug costs for the Medicare program and for Medicare beneficiaries, as well as proposals to drive Medicare toward a value-based payment system that puts patients in control. The Budget also provides additional flexibility to States for their Medicaid program, putting Medicaid on a path to fiscal stability by restructuring its financing, reducing waste, and focusing the program on the low-income populations Medicaid was originally intended to serve: the elderly, people with disabilities, children, and pregnant women.

Paying for Value

The administration is focused on ensuring Federal health programs produce better care at the lowest possible cost for the American people. We believe that consumers, working with providers, are in the best position to determine value. The Budget supports an expansion of value-based payments in Medicare with this strategy in mind. That expansion, along with implementation of a package of other reforms, will improve quality, promote competition, reduce the Federal burden on providers and patients, and focus payments on value instead of volume or site of service. Two of these reforms are: (1) A value-based purchasing program for hospital outpatient departments and ambulatory surgical centers; and (2) a consolidated hospital quality program in Medicare to reduce duplicative requirements and create a focus on driving improvements in patients' health outcomes. Advancing value in Medicare along with the other reforms in the Budget will extend the life of the Medicare Trust Fund by eight years, while also helping to drive value and innovation throughout America's entire health system. Furthermore, in December the administration released a report entitled Reforming America's Healthcare System Through Choice and Competition, which contains a series of recommendations to improve the healthcare system by better engaging consumers and unleashing competition acrossproviders.

PROTECT THE HEALTH OF AMERICANS WHERE THEY LIVE, LEARN, WORK, AND PLAY

Combating the Opioid Crisis

The administration has made historic investments to address opioid misuse, abuse, and overdose, but significant work must still be done to fully turn the tide of this public health crisis.

The Budget supports HHS's five-part strategy to:

- Improve access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments;
- Better target the availability of overdose-reversing drugs;
- Strengthen our understanding of the crisis through better public health data and reporting;
- Provide support for cutting edge research on pain and addiction; and
- Improve pain management practices.

The Budget provides $4.8 billion to combat the opioid overdose epidemic. The Substance Abuse and Mental Health Services Administration (SAMHSA) will continue all opioid activities at the same funding level as FY 2019, including the successful State Opioid Response Program and grants, which had a special focus on increasing access to medication-assisted treatment-the gold standard for treating opioid addiction. At this level, the Budget also provides new funding for grants to accredited medical schools and teaching hospitals to develop substance use disorder treatment curricula.

In FY 2020, the Health Resources and Services Administration (HRSA) will continue to make investments to address substance use disorder, including opioid use

disorder, through the Rural Communities Opioid Response Program, the National Health Service Corps, behavioral health workforce programs, and the Health Centers Program.

Medicare and Medicaid policies and funding will also play a critical role in combating the opioid crisis. The Budget proposes allowing States to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder. The Budget also proposes to set minimum standards for Drug Utilization Review programs, allowing for better oversight of opioid dispensing in Medicaid. Additionally, it proposes a collaboration between the Centers for Medicare & Medicaid Services and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

The Ending HIV Epidemic Initiative

Recent advances in HIV prevention and treatment create the opportunity to not only control the spread of HIV, but to end this epidemic in America. By accelerating proven public health strategies, HHS will aim to reduce new infections by 90 percent within 10 years, ending the epidemic in America. The Budget invests $291 million in FY 2020 for the first phase of this initiative, which will target areas with the highest infection rates with the goal of reducing the number of new diagnoses by 75 percent in five years.

This effort focuses on investing in existing, proven activities and strategies and putting new public health resources on the ground. The initiative includes a new $140 million investment in the Centers for Disease Control and Prevention (CDC) to test and diagnose new cases, rapidly link newly infected individuals to treatment, connect at-risk individuals to Pre-exposure prophylaxis (PrEP), expand HIV surveillance, and directly support States and localities in the fight against HIV.

Clients receiving medical care through the Ryan White HIV/AIDS Program (RWHAP) were virally suppressed at a record level of 85.9 percent in 2017. The Budget includes $70 million in new funds for RWHAP within HRSA to increase direct healthcare and support services, further increasing viral suppression among patients in the target areas. The Budget includes $50 million in HRSA for expanded PrEP services, outreach, and care coordination in community health centers. Additionally, the Budget also prioritizes the reauthorization of RWHAP to ensure Federal funds are allocated to address the changing landscape of HIV across the United States.

For the Indian Health Service (IHS), the Budget includes $25 million in new funds to screen for HIV and prevent and treat Hepatitis C, a significant burden among persons living with HIV/AIDS. The Budget also includes $6 million for the National Institutes of Health's regional Centers for AIDS Research to refine implementation strategies to assure effectiveness of prevention and treatment interventions.

In addition to this effort, the Budget funds other activities that address HIV/AIDS including $54 million for the Minority HIV/AIDS Fund within the Office of the Secretary and $116 million for the Minority AIDS program in SAMHSA. These funds allow HHS to target funding to minority communities and individuals disproportionately impacted by HIV infection.

Prioritizing Biodefense and Preparedness

The Administration prioritizes the nation's safety, including its ability to respond to acts of bioterrorism, natural disasters, and emerging infectious diseases. HHS is at the forefront of the nation's defense against public health threats. The Budget provides approximately $2.7 billion to the Public Health and Social Services Emergency Fund within the Office of the Secretary to strengthen HHS's biodefense and emergency preparedness capacity. The Budget also proposes a new transfer authority that will allow HHS to enhance its ability to respond more quickly to public health threats. Additionally, the Budget supports the government-wide implementation of the President's National Biodefense Strategy.

The Budget supports advanced research and development of medical countermeasures against chemical, biological, radiological, nuclear, and infectious disease threats, including pandemic influenza. The Budget also funds late-stage development and procurement of medical countermeasures for the Strategic National Stockpile and emergency public health and medical assistance to State and local Governments, protecting America against threats such as: anthrax, botulism, Ebola, chemical, radiological, and nuclear agents.

STRENGTHEN THE ECONOMIC AND SOCIAL WELL–BEING OF AMERICANS ACROSS THE LIFESPAN

Promoting Upward Mobility

The Budget promotes independence and personal responsibility, supporting the proven notion that work empowers parents and lifts families out of poverty. To ensure Temporary Assistance for Needy Families (TANF) enables participants to work, the Budget includes a proposal to ensure States will invest in creating opportunities for low-income families, and to simplify and improve the work participation rate States must meet under TANF. The Budget also proposes to create Opportunity and Economic Mobility Demonstrations, allowing States to streamline certain welfare programs and tailor them to meet the specific needs of their populations.

The Budget supports Medicaid reforms to empower individuals to reach self-sufficiency and financial independence, including a proposal to permit States to include asset tests in identifying an individual's economic need, allowing more targeted determinations than are possible with the use of a Modified Adjusted Gross Income standard alone.

Improving Outcomes in Child Welfare

The Budget supports implementation of the Family First Prevention Services Act of 2018 and includes policies to further improve child welfare outcomes and prevent child maltreatment. The Budget also expands the Regional Partnership Grants program, which addresses the considerable impact of substance use, including opioids use, on child welfare.

Strengthening the Indian Health Service

Reflecting HHS's commitment to the health and well-being of American Indians and Alaska Natives, the Budget provides $5.9 billion for IHS, which is an additional $392 million above the FY 2019 Continuing Resolution. The increase supports direct healthcare services across Indian Country, including hospitals and health clinics, Purchased/Referred Care, dental health, mental health and alcohol and substance abuse services. The Budget invests in new programs to improve patient care, quality, and oversight. The Budget fully funds staffing for new and replacement facilities, new tribes, and Contract Support Costs, ensuring tribes have the necessary resources to successfully manage self-governance programs.

FOSTER SOUND, SUSTAINED ADVANCES IN THE SCIENCES

Promoting Research and Prevention

NIH is the leading biomedical research agency in the world, and its funding supports scientific breakthroughs that save lives. The Budget supports strategic investments in biomedical research and activities with significant national impact.

NIH launched the Helping to End Addiction Long-term (HEAL) initiative in April 2018 to advance research on pain and addiction. Toward this goal, NIH announced funding opportunities for the historic HEALing Communities Study, which will select several communities to measure the impact of investing in the integration of evidence-based prevention, treatment, and recovery across multiple health and justice settings. The Budget provides $500 million to continue the HEAL initiative in FY 2020.

The Budget supports a targeted investment in the National Cancer Institute to accelerate pediatric cancer research. Cancer is the leading cause of death from disease among children in the United States. Approximately 16,000 children are diagnosed with cancer in the United States each year. While progress in treating some childhood cancers has been made, the science and treatment of childhood cancers remains challenging. Through this initiative, NIH will enhance drug discovery, better understand the biology of all pediatric cancers, and create a national data resource for pediatric cancer research. This initiative will develop safer and more effective treatments, and provide a path for changing the course of cancer in children.

The new National Institute for Research on Safety and Quality (NIRSQ) proposed in the Budget will continue key research activities currently led by the Agency for Healthcare Research and Quality. These activities will support researchers by developing the knowledge, tools, and data needed to improve the healthcare system.

Addressing Emerging Public Health Challenges

CDC is the nation's leading public health agency, and the Budget supports its work putting science into action.

Approximately 700 women die each year in the United States as a result of pregnancy or delivery complications or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Findings from Maternal Mortality Review Committees indicate that more than half of these deaths are preventable. The Budget supports data analysis on maternal deaths and efforts to identify prevention opportunities.

The United States must address emerging public health threats, both at home and abroad, to protect the health of its citizens. The Budget invests $10 million to support CDC's response to Acute Flaccid Myelitis (AFM), a rare but serious condition that affects the nervous system and weakens muscles and reflexes. With this funding, CDC will work closely with national experts, healthcare providers, and State and local health departments to thoroughly investigate AFM.

The Budget also provides $100 million for CDC's global health security activities. Moving forward, CDC will implement a regional hub office model and primarily focus their global health security capacity building activities on areas where they have seen the most success: lab and diagnostic capacity, surveillance systems, training of disease detectives, and establishing strong emergency operation centers. In addition, CDC will continue on-going efforts to identify health emergencies, track dangerous diseases, and rapidly respond to outbreaks and other public health threats around the world, including continuing work on Ebola response.

The Budget also strengthens the health security of our nation by continuing CDC's support to State and local Government partners in implementing programs, establishing guidelines, and conducting research to tackle public health challenges and build preparedness.

Innovations in the Food and Drug Administration

FDA plays a major role in protecting public health by assuring the safety of the nation's food supply and regulating medical products and tobacco. The Budget provides $6.1 billion for FDA, which is an additional $643 million above the FY 2019 Continuing Resolution. The Budget includes resources to promote competition and foster innovation, such as modernizing generic drug review and creating a new medical data enterprise. The Budget advances digital health technology to reduce the time and cost of market entry, supports FDA opioid activities at international mail facilities to increase inspections of suspicious packages, strengthens the outsourcing facility sector to ensure quality compounded drugs, and pilots a pathogen inactivation technology to ensure the blood supply continues to be safe. FDA will continue to modernize the food safety system in FY 2020.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

Almost one quarter of total Federal outlays are made by HHS. The Department employs more than 78,000 permanent and temporary employees and administers more grant dollars than all other Federal agencies combined. Efficiencies in HHS management have a tremendous impact on Federal spending as a whole.

Advancing Fiscal Stewardship

HHS recognizes its immense responsibility to manage taxpayer dollars wisely. HHS ensures the integrity of all its financial transactions by leveraging financial management expertise, implementing strong business processes, and effectively managing risk.

In an effort to operate Medicare and Medicaid efficiently and effectively, both to rein in wasteful spending and to better serve beneficiaries, HHS is implementing actions such as enhanced provider screening, prior authorization, and sophisticated predictive analytics technology, to reduce improper payments in Medicare and Medicaid without increasing burden on providers or delaying Americans' access to care or to critical medications. HHS continues to work with law enforcement partners to target fraud and abuse in healthcare, and the Budget increases investment in healthcare fraud and abuse activities. The Budget includes a series of proposals to strengthen Medicare and Medicaid oversight, including increasing prior authorization, enhancing Part D plans' ability to address fraud, and strengthening the Department's ability to recoup overpayments made to States on behalf of ineligible Medicaid beneficiaries.

Implementing ReImagine HHS

HHS eagerly took up the call in the Administration's government-wide Reform Plan to more efficiently and effectively serve the American people. HHS developed a plan —"ReImagine HHS"—organized around a number of initiatives.

ReImagine HHS is identifying a variety of ways to reduce Federal spending and improve the functioning of HHS's programs through more efficient operations. For example, the Buy Smarter initiative streamlines HHS's procurement process by using new and emerging technologies.

Conclusion

Americans deserve healthcare, human services, and public health programs that work for them and make good use of taxpayer dollars. The men and women of HHS are committed, innovative, hardworking public servants who work each day to improve the lives of all Americans. President Trump's FY 2020 Budget will help advance us toward that goal, accomplish the Department's vital mission, and put Americans' health first.

Ms. ESHOO. Thank you, Mr. Secretary.

We will now move to Member questions. Each Member, of course, will have 5 minutes to question the Secretary. And I will start by recognizing myself for 5 minutes.

Mr. Secretary, the budget proposes to cut funding for premium tax credits which help Americans pay for comprehensive health insurance, but your agency's 1332 waiver guidance supports using Federal subsidies to pay for junk insurance plans that don't cover patients when they get sick. The budget also once again revives the failed Graham-Cassidy ACA repeal bill, and the Trump administration has refused to defend, obviously, the ACA in the *Texas* v. *U.S.* litigation, urging the court to invalidate the entirety of the ACA's major protections for people with preexisting conditions.

Now, really, I call these items out because they scare the hell out of the American people. These policies have consequences. These words walk into people's lives.

So where in your budget are those with preexisting conditions protected as well or better than they are protected under the ACA?

Mr. AZAR. Well, thank you, Chairwoman, for that question.

Ms. ESHOO. Not really "thank you," but——

[Laughter.]

Mr. AZAR. No, that is a good question to have. It is a good question to have.

Ms. ESHOO. You are a gentleman.

Mr. AZAR. And we need to have a debate about this because the position of many is that the Affordable Care Act solved all issues for people with preexisting conditions, and that is simply not the case, as 29 million Americans were priced out of the market with unaffordable care, and those who have access to that care, it may be under-insurance or a card that doesn't really provide for them.

Ms. ESHOO. So will you work with us to strengthen that?

Mr. AZAR. Well, we want to work—actually, that is our proposal. It is a starting point.

Ms. ESHOO. On preexisting conditions?

Mr. AZAR. It is the $1.2 trillion grant program.

Ms. ESHOO. We will hold you to that.

Now, on the actual numbers, $1.4 trillion over 10 years for Medicaid, close to $460 billion from Medicare. How do you reassure the American people that what they count on, what is really necessary in their lives, Medicare beneficiaries, Medicaid beneficiaries, that these numbers, what these numbers are going to do to them? These are massive cuts.

Mr. AZAR. So on Medicare, we are actually putting it on a sounder footing for the future, and these are provider cuts. Providers

aren't going to be happy. Hospitals are not happy. The post-acute providers are not happy, and the drug companies are not happy.

Ms. ESHOO. Well, how does that affect the beneficiaries?

Mr. AZAR. It actually reduces their cost-sharing because they actually pay a percent often of what we reimburse these providers. So as we end that abuse or minimize that abuse, their sharing goes down and we save taxpayers money.

Ms. ESHOO. But why wouldn't providers lessen their coverage to the people that are enrolled with them, if you are going to take almost $460 billion out of it?

Mr. AZAR. Well, some of these are——

Ms. ESHOO. Are we going to depend on the goodness of their hearts?

Mr. AZAR. Well, a lot of them need to be in Medicare. Your hospital is not going to be in existence long if it is not a Medicare provider. What is happening is, for instance, hospitals are gobbling up doctors' practices——

Ms. ESHOO. Well, what about the patients——

Mr. AZAR [continuing]. And jacking up the rates.

Ms.ESHOO [continuing]. The coverage for Medicare enrollees?

Mr. AZAR. I do not believe any of those three which are the major areas of reduction will impact in any way patient access to services there. I think these areas, like MedPAC——

Ms. ESHOO. So you are stating that almost $460 billion, reducing that out of Medicare is not going to affect any beneficiary?

Mr. AZAR. I don't believe it should affect. I think it should reduce their out-of-pocket through their cost-sharing. These are abuses that MedPAC and others——

Ms. ESHOO. I want to go back to the junk plans. They are receiving Federal subsidies, and they are required to disclose to an individual that the plan will not cover their medical bills when they get sick. How does this strengthen coverage for people across the country?

Mr. AZAR. So short-term, limited-duration plans are meant for people in a transition period. They are not right for everybody. And we actually enhanced the consumer disclosures from what the Obama administration had on them.

Mr. AZAR. So we are going to enhance disclosure? I am all for that. In fact, I offered legislation that would state to people on the cover of the policy, "Be advised you are not covered for the following." So I think it needs a "beware" stamp on it.

But my time has expired, and I will now recognize—who am I recognizing now?—the ranking member of the subcommittee, Dr. Burgess, for 5 minutes.

Mr. BURGESS. Thank you for the recognition.

Mr. Secretary, again, thank you for being here today.

Sometimes I feel like I am trapped in a Charles Dickens novel. It is the best of times; it is the worst of times.

So just briefly, can you kind of give us a sense of what it has meant for 2.5 to 5 million people to have been brought back into the workforce, and now, perhaps have the availability of employer-sponsored insurance?

Mr. AZAR. With the booming economy and with the historic low unemployment rates, we have got individuals who now are not only

having the pride and the long-term sustainability of job but have access to healthcare through their employers. But, of course, we have our safety nets. We have our programs like Medicaid. We have, as long as it is on the books, we have the Affordable Care Act and the subsidy program there. But what we are trying to do is expand the reach of available options and affordable insurance and coverage and access to care for the people who were shut out from that marketplace.

Mr. BURGESS. And I appreciate what you are trying to do. I actually have a question I will do for the record on just that issue.

This past Sunday night, "60 Minutes," a television program that I don't normally watch, aired a special on the research that the National Institute of Health has conducted on sickle cell disease. I worked with patients with sickle cell disease back in my residency at Parkland Hospital. I know what a devastating and painful illness that it is.

We heard in this committee two Congresses ago how there had not been a new FDA-approved treatment for sickle cell in almost 40 years. In the last Congress, we approved, and got signed into law, the first major sickle cell legislation, Danny Davis' bill from Illinois, and the President signed it into law.

Can you talk just a little bit about what the American people saw on Sunday night as far as the potential treatment for sickle cell?

Mr. AZAR. What an incredible story that was. And I have talked to Francis Collins, our incredible Director of the NIH. I think we all believe we could be within five years of an actual cure for sickle cell anemia, an actual cure. And it is using the modern techniques we have of both identifying the defective genes that cause the disease, but then different vectors, whether it is CRISPR or, in the case of the sickle cell treatment you saw on "60 Minutes," using a viral vector to actually just change the body's wiring. I mean, to see that young girl and the impact it has had on her life, it is a miracle and we are all so excited about that. We want to keep doing that across the work of NIH.

Mr. BURGESS. Well, again, for somebody who has taken care of sickle patients in crisis, we haven't had much to offer, and this is, indeed, groundbreaking research. You and your team are to be commended, and the administration, for putting their efforts behind this.

So as you know, I have, since the passage of a bill that got rid of the sustainable growth rate formula—we used to fight about that every December; now we don't. And I believe this committee is still committed to the development of alternative payment models.

The physician-led technical advisory panel of PTAC—I think they had a meeting this week—they have recommended over a dozen models, and physicians are just clamoring to join. I understand there is concern over the scalability of some of these models, but can we agree that this is a sign, a good sign, that APM providers want to participate and want to take place?

Mr. AZAR. Absolutely. And, in fact, I know there have been some rough spots in the interactions with the PTAC and HHS. We have met with leadership and the whole committee. We have shared, ac-

tually, the alignment of our philosophies around where we want to go on value-based transformation. I think we are going to see that the projects that they review will help align there. We have emphasized how important it is that these projects be scalable across the program. So I am actually quite optimistic about our work with PTAC. It is an incredible group of people on that committee, and we want to make sure we are getting the full advantage of their work and insight.

Mr. BURGESS. And would you agree that that was particularly visionary legislation that was passed by this Congress?

Mr. AZAR. Absolutely.

Mr. BURGESS. Thank you. I knew I could count on you.

Well, thanks for your comments about Dr. Gottlieb. Again, what a leader he has been. And I appreciate your sharing with us that the agency is going to remain under capable hands. It is just so critically important. The generic throughput that has occurred under Dr. Gottlieb's leadership is going to make a big difference for patients and their pocketbooks. And your commitment is to continue that?

Mr. AZAR. Oh, absolutely, we are going to be carrying forward Commissioner Gottlieb's vision without him. His agenda is my agenda; my agenda is his agenda.

Mr. BURGESS. Very good. Again, we appreciate you being here today. Thank you.

Ms. ESHOO. I thank the gentleman. I now would like to recognize the chairman of the full committee, Mr. Pallone, for 5 minutes of questioning.

Mr. PALLONE. Thank you, Madam Chair.

Mr. Secretary, on June 7th of last year, the administration declined to defend the ACA's protections for preexisting conditions. In this extraordinary decision, the Department of Justice sided with a group of Republican attorneys generals seeking to strike down the ACA and declined to defend the constitutionality of the guaranteed issue and community rating provisions of the ACA. And let me be crystal clear. In declining to defend these protections in the *Texas* v. *U.S.* lawsuit, the Trump administration is seeking to, once again, subject tens of millions of Americans with preexisting conditions to the discrimination they faced before the ACA, and I think it is appalling and indefensible.

Now my questions are about documents. So I just want you to answer these questions yes or no about documents. That is what I am asking, not about policy here.

On June 13, 2018, I sent you a letter regarding the Department of Health and Human Services' involvement in the DOJ's decision and requesting documents, communications, and responses to a series of questions. I was trying to find out whether the Department had conducted any analysis on the effects of eliminating these protections on costs and access to coverage, particularly for individuals with preexisting conditions. And I asked about the Department's contingency planning if the Trump administration prevails in this Texas lawsuit. And yes or no, did you receive this letter I am referring to?

Mr. AZAR. I am sure we did. I don't recall the letter, but I am sure we did.

Mr. PALLONE. Thank you.

On December 7, 2018, a few months later, I sent you and Administrator Verma a follow-up letter reiterating my request. I requested a complete response to my letter, to my previous letter. Again, yes or no, did you receive this letter, to your knowledge?

Mr. AZAR. Again, I am certain that we did.

Mr. PALLONE. OK. So Secretary, my staff subsequently reached out to your staff on December 21st, January 2nd, January 11th, January 3rd, February 24th, February 26th, February 28th, March 3rd, March 7th, March 8th, up to now, and yesterday, to check on the status of the Department's document production. On each of those occasions, my staff has made clear that this inquiry regarding the Department's involvement in the Texas lawsuit is the No. 1 investigative priority for our committee, for our oversight. And it has been over nine months, and I still haven't received a response to my letter or a single document. So my question is, has the Department even begun a search of your records, and the records of others on your staff, in response to these letters, which, again, is how you responded to whether the DOJ is moving forward?

Mr. AZAR. So I apologize for the delay. I do want you to know that I met with our team, I think it was, in fact, just yesterday, and discussed our compliance with your requests there. And I hope they have communicated to Chairwoman DeGette's team. I believe they did yesterday or this morning. We are going to try to get as much of that material over as quickly as possible as we can around contingency planning and analysis.

Mr. PALLONE. Well, would you commit to providing those documents to this committee by the end of the week?

Mr. AZAR. I don't know about the date on it, but we have already met with, we have talked to the staff, I was told, and I was told the staff were happy with the discussion and will be producing that on a rolling basis of reviewing the material.

Mr. PALLONE. Well, look, let me——

Mr. AZAR. I have told them I want to give you as much as we can on that.

Mr. PALLONE. Let me explain. I am not asking about the CMS records, although those can be sent as well. I am asking about your own records. Will you commit to making your records available to search and ensure that the Department turns such records responsive over to the committee? I am not talking about CMS, but correspondence between—your own records, if you will, relative to this Texas——

Mr. AZAR. Well, obviously, materials that would involve potential executive privilege would have to be reviewed by interagency and the White House for review of that. But I have told my team I want to get whatever we can that doesn't implicate those types of concerns that we would have to work together on respective and reasonable accommodations; I want to get you materials that we can as quickly as possible.

Mr. PALLONE. I just want a commitment to make your records available to ensure that the Department turns these documents over to the committee as soon as possible.

Mr. AZAR. We will commit to be as responsive as we can, but I, obviously, can't waive various privileges of the President, if they are implicated.

Mr. PALLONE. OK. Now I just have one more question, Madam Chair.

I am just concerned—again, I have explained. Nine months, no documents, no response. I just hope that this level of non-cooperation doesn't continue moving forward with this Congress on these committees' informational requests. Because if not, we have to see what additional steps to ensure that the committee actually has legitimate oversight. So I mean, do you want to just respond? This level of cooperation is really not acceptable. Is this going to continue where we don't get anything or any response for nine months?

Mr. AZAR. I want you to know, I respect your role and this committee's role, and we have beefed up our oversight staffing. We have tried to build the teams, and we will hope to have a better relationship in the future going forward on any oversight issues.

Mr. PALLONE. All right.

Mr. AZAR. We want to have a good, constructive, productive relationship with you and this committee.

Mr. PALLONE. Well, I appreciate that, and I hope so. And we will continue to monitor it.

Thank you, Madam Chair.

Ms. ESHOO. Thank you, Mr. Chairman.

And we will just count on you getting the information to us.

And now, I would like to recognize the ranking member of the full committee, my friend, Mr. Walden, for 5 minutes.

Mr. WALDEN. Thank you, Madam Chair. And again, thanks for holding this important hearing.

Secretary Azar, I understand that 2018 marked the highest number of combined generic drug approvals and tentative approvals in the history of the Food and Drug Administration's Generic Drug Program. Can you just briefly speak to the savings that created for the American people?

Mr. AZAR. Well, this is thanks to the historic work of Commissioner Gottlieb and the team at FDA. It has just been incredible. They have shattered monthly and yearly generic drug approval records since 2017, approving generics that CEA has estimated have saved Americans since January of 2017 $26 billion.

Mr. WALDEN. Twenty-six billion dollars?

Mr. AZAR. And I believe that is only through June of 2018 on that analysis. So that is on a rolling—that is going to keep on adding savings to the American people.

Mr. WALDEN. That is really impressive. And I think part of that is the new tools that this committee and this Congress, in a bipartisan way, gave to your agency and certainly the FDA.

By the way, I would just say I am really saddened that Dr. Gottlieb is leaving. I wish him godspeed and good health and every success in the world. He has been a fantastic FDA Director, and, frankly, Madam Chair, very cooperative, I think on both sides of aisle. I think he was up here four days in a row once testifying and participating. Sorry, but it was really helpful to our cause.

Mr. Secretary, CMS has proposed a rule to change the formularies for patients in Part D protected classes. What assurances can you provide my constituents and those patients that they will still be able to get access to the medications they need?

Mr. AZAR. Yes, thank you for that question, because there is a lot of misunderstanding there.

Of course, with the protected classes, what is happening is, we have, as a government, disabled these middlemen, the pharmacy benefit managers, from being able to negotiate against the drug companies to get discounts. So for the very drugs that in the commercial space may be yielding 30 percent average discounts, we are getting zero to six percent.

So what we are proposing—and it is a proposal, and we are getting very important feedback from disease groups in, and we will look at that.

Mr. WALDEN. Right.

Secretary AZAR. It is to allow some of the basic formulary management tools used in the commercial space for regular commercial employees. For instance, step therapy, try this drug before that drug.

Mr. WALDEN. Right.

Mr. AZAR. Or prior authorization, make sure that this drug is actually being used for the right indication, with our speedy appeals and exceptions processes, and with the choice that is embedded into Part D, where you can pick a plan; if it is not meeting your needs, you can choose a different one.

But we are hearing the feedback, and we have heard very vigorously back.

Mr. WALDEN. Yes.

Mr. AZAR. We want to protect our beneficiaries, of course.

Mr. WALDEN. Because I have heard from some patients today, before this becomes a rule, on step therapy, that they have a drug that works. They change plans or something. Something happens, and they are told they have to go back through all these drugs they know don't work to get to the one that does. And no patient wants to go through that. And so it is something we have got to pay attention to.

Mr. AZAR. I have heard that feedback, and obviously, we will take that very seriously.

Mr. WALDEN. Yes, I think that is really, really important.

Mr. Secretary, currently, over one-third of beneficiaries are choosing a Medicare Advantage Plan. And I know how important that is to Medicare beneficiaries, especially my colleague here to the left who has become one now. Can you detail why seniors are increasingly choosing private insurance options for their Medicare coverage?

Mr. AZAR. Well, you know, the Medicare Advantage Plans have become so popular. I think it is because so many of us as we age into Medicare—forgive me——

Mr. WALDEN. Right.

Mr. AZAR [continuing]. We are used to having an integrated benefit package. We are used to having medical and drug benefits all together rather than those being managed separately. And so, it is a very convenient form, and it allows us, also, with Medicare Ad-

vantage, we can add supplemental benefits. The plans, we have actually authorized new supplemental benefits that these MA plans can offer people.

Mr. WALDEN. And what would those look like, just quickly?

Mr. AZAR. Oh, that could be lower cost-sharing. I mean, you have Medicare Advantage Plans, for instance, that have zero-dollar generic drug coverage in them. I mean, some of them are just incredible, the opportunities they offer people.

Mr. WALDEN. So under H.R. 1384, known as Medicare for All, my understanding is private health insurance would be eliminated. So the 158 million Americans who get their health insurance through employer or union would lose those policies, but also—and something that has not been written much about—my understanding is the Medicare for All Democrats' plan would also eliminate Medicare Advantage Plans. What would happen to those 20 million seniors?

Mr. AZAR. I believe that is the case under at least that plan. They would lose their Medicare Advantage Plan, and they would have to go to what is called Medicare Fee-for-Service, which has very high deductibles, very high cost-sharing. Now, for the wealthier people, you can buy a very expensive Medigap policy to cover some of that. I do not recall if that particular Medicare for All plan outlaws those Medigap plans or not. Being private insurance, it might. I am not sure.

Mr. WALDEN. So seniors would lose their Medicare Advantage Plans under that legislation?

Mr. AZAR. I believe that to be the case. They are private plans.

Mr. WALDEN. All right. Thank you, Madam Chair. My time has expired. I yield back.

Ms. ESHOO. I thank the gentleman. I now would like to recognize a real gentleman, Mr. Butterfield, for 5 minutes.

Mr. BUTTERFIELD. Thank you. I was about to say, Madam Chairman, Mr. Engel has stepped out for a few minutes. But thank you for——

Ms. ESHOO. To your advantage.

Mr. BUTTERFIELD. Thank you for the compliment.

And thank you, Mr. Secretary, for your testimony here today.

I started reading the President's budget very early this morning. It is not a very thick budget as compared to other Presidential budgets. But I started reading it this morning, and this is the first section that I went to. It appears to me that the President's budget would rip some $1.4–1.5 trillion out of Medicaid by turning it into a block grant or a per-capita program.

And, Madam Chair, if that weren't bad enough, the news organizations this morning are reporting that the administration has plans to bypass Congress entirely and issue guidance that will allow States to block grant or cap Medicaid. Now if you think the emergency declaration Executive Order that the President announced a few weeks ago to bypass Congress has created a firestorm, you just wait for the firestorm that this will create.

One in five Americans, low-income Americans, depend on Medicaid. The President's budget doesn't represent the values of the American people. And so, this Medicaid play was one of the main features of the Republicans' failed attempt to repeal the ACA.

Block-granting and capping Medicaid would endanger access to care for some of the most vulnerable people in the program, including children, children with complex medical needs, and our seniors, and individuals with disabilities.

In September 2017, Avalere Health, a well-known consulting firm, found that the Republican block grant proposal would cut Federal spending on Medicaid by $4 trillion over the new two decades.

Mr. Secretary, Congress has already rejected attempts to block grant Medicaid. So it is deeply troubling to see this administration double down. I will remind you, sir, that under Federal law, you only have the authority to allow demonstration projects. You know it and I know it. You only have the authority to allow demonstration projects that are likely to assist in promoting the objectives of the Medicaid program.

And so, I am asking you, sir, on the record today, do you believe, does the administration believe that you have the authority to block grant Medicaid on your own without the participation of Congress?

Mr. AZAR. So States are able to propose waivers or demonstration projects, as you have described them, to reorient their benefits. And any State could come in requesting, for instance, an approach that might be what you describe as a block grant or capitated amount or different payment structures. If we get that kind of proposal, we have to assess that with our legal counsel and with OMB to——

Mr. BUTTERFIELD. It appears you are going to be aggressive with this, aggressive with block-granting Medicaid and rolling it out.

Mr. AZAR. Absent statute, we can't force a State to do anything like that in Medicaid. That would have to be a governor and legislature coming to us, asking us if that is something that——

Mr. BUTTERFIELD. Let me put it to you this way: can you guarantee this committee that capping Medicaid spending through a block grant will not cause any individuals to lose their health coverage or lose their benefits, or lose access to their doctors or jeopardize their care? Can you make that commitment to us?

Mr. AZAR. Well, you couldn't make that commitment about any type of waiver or demonstration in Medicaid because that is precisely the types of changes that are made——

Mr. BUTTERFIELD. So it is conceivable? If a State came and asked for a waiver, it is conceivable that some of the beneficiaries could experience less care?

Mr. AZAR. That would be, that could be the case with any waiver that is already out there. We operate, my goodness, it must be hundreds of waivers already. And each of those has an impact that is redistributive among this beneficiary or that, or this class. It is ways of States prioritizing and focusing the benefits and the money that they have——

Mr. BUTTERFIELD. I see the direction that you are going with this, and I don't like it. But you answer to the President, and the President has a notion of taking Medicaid in the wrong direction.

The cap of Medicaid that the administration is proposing will only grow at the rate of inflation. That is what I am being told. Do

you believe that the rate of inflation will keep pace with the rising cost of healthcare? Are they going to go up equally, do you believe?

Mr. AZAR. I think that is in the legislative proposal, which, of course, Congress would have to agree to. You would have to agree to that. And if that were the case, no, that would be regular CPI I believe is in the budget. I don't believe it is a CPI medical expense. And that is part of the savings that come from the ongoing—I think it is $300-and-some billion that would be part of the ongoing savings from those types of changes to per-capital or block grant options in this case.

Mr. BUTTERFIELD. Thank you, Mr. Secretary. I only have 14 seconds remaining. And I will say, as I close, that if this administration is serious about block-granting or otherwise readjusting and redefining Medicaid as we know it, we are going to be in for a real serious firestorm, not just from the Congress, but from the American people. So many people, low-income folk, depend on Medicaid.

Thank you, Madam Chair. I yield back.

Ms. ESHOO. I thank the gentleman. I now would like to recognize the former chairman of the full committee, Mr. Upton of Michigan.

Mr. UPTON. Well, thank you, Madam Chair.

And welcome, Mr. Secretary, back. We are pleased that you are here.

And I wonder, as you know and you watch very carefully, every member of this committee supported 21st Century Cures a couple of years ago. Could you briefly give us an update as to how you think things are going three years now since President Obama signed it into law? Because I have a number of questions.

Mr. AZAR. Let me just be short about it. I believe it is directly attributable, and credit to you and this committee for the Cures Act, that we have had the record number of new drug approvals and the record number of generic drug approvals in our system that are leading to such significant savings for the system, for the American people, and frankly, leading to the type of cures like what I hope we are going to see on sickle cell, that the ranking member mentioned before.

Mr. UPTON. That is good. And I missed that show on "60 Minutes," but I am well aware of the progress that we are making on that and other fronts as well.

Somewhat good news and bad news, it is my understanding that the childhood cancer funds in NCI, you have a nice increase for that in the proposal. But I must say that I was alarmed to read a Politico story just in the last couple of days that said, under the plan, the budget plan, the White House proposes an $897 million cut to the NCI, plus more than a billion dollars to institutes that do medical research. Is that story accurate?

Mr. AZAR. Well, it is. That is in the budget as the across-the-board reduction to NIH. We are one of the biggest, if not the biggest, non-Defense discretionary budgets. We take a 12 percent cut in the President's budget. At HHS, that is $12 billion. It is a proportionate cut at NIH that is proposed. I understand the pain. I understand the concern there. And the NCI cut would be proportionate to the NIH one. I believe it is a 12 percent there also.

Mr. UPTON. One of the things that we did in Cures was that, when we saw increases, particularly in the NIH budget and FDA

budget, we actually came up with offsets to make sure that those increases would come about. Are those offsets still in place? I mean, are these reductions——

Mr. AZAR. So we tried to prioritize certain funding within NIH around the opioid funding; of course, the Pediatric Cancer Initiative of the $500-million-over-10 package. And so, yes, there are certain priority areas that we have tried to wall off within that, but, overall, the budget does take that kind of proportional charge because, otherwise, there is just not enough money at HHS to go around to make that kind of a target.

Mr. UPTON. Now a number of us from the House and the Senate this last week participated in a pretty big opioid conference. What is the level of funding, as we try to help the States deal with this crisis that is impacting virtually every community and so many families that we personally know?

Mr. AZAR. The President keeps the opioid funding that this Congress has prioritized last year and that we worked together on. We are going to continue to strengthen our access to treatment and recovery. So that is $2.9 billion. That is an increase of 68 above what our FY19 allotment was across the Department. That is your State Opioid Response Grants, for instance, of $1.5 billion.

Mr. UPTON. We started that in Cures.

Mr. AZAR. And the STR, and that expanded with the State opioid responses in last year's appropriation. Fifty-eight million dollars for infectious disease and opioids, a critical part, also, in our HIV and Hep C work, the spread of those diseases caused through the opioid crisis; prioritizing surveillance activities. So really, a continuation of the great bipartisan work of Congress and the administration on the opioid crisis from last year is what is presented in the budget this year. I could give you details offline, if that is helpful.

Mr. UPTON. So the last question I have is, last week, a letter was sent up to reprogram monies for the Office of Refugee Resettlement. They found offsets for that increase. And I am interested to know, what is the fiscal year '20 budget request compared to the fiscal year '19 request? And is there a chance, then, that you will ask for additional monies to be reprogrammed again, following what happened last week for fiscal year '19?

Mr. AZAR. Thank you for that.

So in FY19, I believe the budget request was $1 billion plus a $200 million contingency fund. And then, the appropriators also put some money into the regular non-UAC refugee program, knowing that usually doesn't spend that much money.

For this budget request, what we have requested is actually $1.3 billion as an appropriation, and then, to create a $2 billion mandatory fund that is a contingency fund with an assumption of $700-or-so million used in this year, plus transfer authority of up to 20 percent, which would be $361 million. So we have requested quite a lot, but at the rate that we are going with the kids coming across the border, it is just an incredible burden financially.

Mr. UPTON. Thank you. My time has expired. Thank you, Mr. Secretary.

Ms. ESHOO. We thank the gentleman. Now I have the pleasure of recognizing the gentlewoman from California, Ms. Matsui, for 5 minutes.

Ms. MATSUI. Thank you, Madam Chair.

And thank you, Mr. Secretary, for appearing before us today.

I have to say I am extremely concerned by the priorities reflected in the President's budget, because this proposal directly and negatively impacts hardworking families who depend on crucial services. It guts Medicaid by over a trillion dollars. These cuts mean working single mothers in between jobs, families with a family member who suffers from addiction, and grandparents in long-term care facilities will have less access to care.

I am disappointed that HHS, which has a mission to enhance and protect the health and well-being of all Americans, has presented a budget that targets the most vulnerable in our communities—women, children, people with disabilities and mental illness, and the LGBT community. I certainly hope that in our conversation today we can address the failings in HHS's budget vision and how the agency should, in fact, be working to protect all Americans.

Now, Mr. Azar, you previously stated that one of your top goals as Secretary is to address the opioids crisis, and this committee shares that goal. Passing H.R. 6, the SUPPORT for Patients and Communities Act, was a highlight of last Congress. And I was pleased to see members of this committee and your administration begin to take meaningful steps toward tackling the opioid epidemic.

Yet, I am concerned that your proposed budget, while it does include funding and investments for the Community Mental Health Services Block Grant and for Certified Community Behavioral Health Centers, it is accompanied by massive cuts to Medicaid, which is a vital source of coverage for mental health and substance use disorder treatment.

The President's 2020 budget proposes to cut Medicaid by $1.5 trillion over 10 years and turning the vital program into a block grant to the States. Yet, shoring up Medicaid and strengthening that program is perhaps the single best thing we can do to expand access to mental health and substance use treatment services.

As I am sure you know, Medicaid is the single most important financing source of mental health services in this country. Medicaid covers approximately a quarter of all adults with serious mental illness. The Medicaid program covers many inpatient and outpatient mental health services, such as psychiatric treatment, counseling, and prescription medications. And Medicaid coverage of mental health services is often more comprehensive than private insurance coverage. Medicaid also covers 4 in 10 non-elderly adults with opioid addiction, and those with Medicaid coverage are twice as likely as those with private insurance or no insurance to receive substance use treatment.

Your rhetoric on mental health and addiction is not matched by your actions. Cutting the very insurance coverage that treats these people for ideological reasons, the coverage that provides critical mental health services and substance use treatment, will not help us address these critical issues.

Secretary Azar, do you agree that Medicaid is a critical tool in helping individuals with mental health conditions or substance use disorders? I just want a yes or no.

Mr. AZAR. Yes, we do believe Medicaid is important for those individuals.

Ms. MATSUI. OK. Secretary Azar, will you commit to not taking any further action in this administration, as your predecessor and CMS Administrator already have, that would negatively impact the coverage that people with mental health or substance use disorders rely upon?

Mr. AZAR. Well, we actually, with our budget, are proposing changes that I think refocuses on the key core populations of Medicaid as opposed to just providing insurance to able-bodied potentially-working adults. So I actually think the budget lets us focus on these people with substance use disorder and mental illness, the disabled, those that really need it, instead the perverse incentives that we have got right now.

Ms. MATSUI. Well, I don't agree with you there. I also believe, too, that it is very difficult to get mental health services, and the population that needs them are certainly ones that don't game the system. They really are people who really need the services. And mental health and substance use services are so critical, and Medicaid is the means by which most of the population receives these services.

Mr. AZAR. If I could just point you to one thing in the budget that I hope you will support. It is we propose extending Medicaid for postpartum pregnant women for up to one year who have suffered from substance use disorder. So I do hope we could advance that.

Ms. MATSUI. That is really wonderful, but I am still talking about the vast population that needs the Medicaid services for mental health services.

And let me just say this: that I want to reiterate the concerns of Ranking Member Walden regarding the protected classes. I have gotten many of my constituents coming forward and saying that they are really very concerned regarding the step therapy. They have medication that they already know works, and to think that they have to go back again and go through the steps, that would really bring them back to a place they don't want to be.

And I have run out of time already. So I just want to make that point. Thank you.

Ms. ESHOO. You yield back. I thank the gentlewoman.

I think the issue that Ms. Matsui just mentioned, and Mr. Walden, and I think both sides hold the same view. So we need to move forward and correct that situation.

I now would like to recognize my friend from Illinois, the gentleman from Illinois, Mr. Shimkus, for 5 minutes.

Mr. SHIMKUS. Thank you, Chairman Eshoo.

Secretary Azar, thanks for being here.

Chairman Eshoo and I cosponsored a bill last Congress called the REVAMP Act. We have worked to address antibiotic drug resistance for over a decade with colleagues on both sides of the aisle. We have secured some wins, not the least of which is the GAIN Act.

Mr. Secretary, can you tell me what your administration is doing to address this concern?

Mr. AZAR. Yes. So we actually announced what we called the AMR Challenge in September of last year at the United Nations General Assembly, which is a CDC Foundation initiative where we received commitments from, I think, over a hundred NGOs and private sector entities to commit around appropriate utilization.

I am focused right now around AMR on what I view as a potential market failure issue there on antimicrobial resistance developing next-generation antibiotics, because here is the problem we have: we want new antibiotics, but, for AMR purposes, we need them not to be used. So that it almost presents a project bioshield-like scenario where we, as the Government, need to actually think about our role there as a purchaser to get developed and park antibiotics that are needed. That is the issue.

Mr. SHIMKUS. I appreciate the way you finished up that, because what we always hear quite a bit is: how do you incentivize the private sector to produce a product that you hope they don't use? And that is kind of what we have been trying to deal with here.

I wasn't here for Dr. Burgess' questioning, but he talked about alternative payment methods. I am a big fan of Medicare Advantage Plans. I understand the move and some discussions in some areas about Medicare for All. But how can using alternative payment methods affect quality and cost in the Medicare Advantage world?

Mr. AZAR. So I actually think we have been often thinking about things the wrong way when we think about, for instance, the Centers for Medicare and Medicaid innovation and our demonstration authorities. We tend to think of Fee-for-Service, the traditional Medicare, as where we need to innovate, and then, Medicare Advantage would just follow. Well, the competitive structures with Medicare Advantage and their customer responsiveness, and frankly, their ability to run plans—these are insurance companies; it is what they do. They know how to run insurance and integrated benefits and deliver outcomes that are quality outcomes.

I have been trying to change our mentality to think about MA as more of the leading edge of innovation, and perhaps Fee-for-Service is a fast follower there.

Mr. SHIMKUS. Yes, let me follow up with that. What about waivers to the Stark and Anti-Kickback Statutes? Do you see that addressing it in that space might be helpful?

Mr. AZAR. Yes. So we actually have—it is called the Regulatory Sprint, which is an effort that our Deputy Secretary has been leading, looking at how the Anti-Kickback Statute interpretations and Stark laws could be barriers to integration, collaboration, and coordination. Because to get the kind of outcomes we want to pay for value, we have to stop paying just each individual provider in a procedure-based rifle shot and pay together, and have them work together, but we have the laws that say don't work together.

So we have to look at it. We have to protect against fraud. We have to protect against abuse. But we have got to open up and make sure we allow that collaboration outside of common ownership structures.

Mr. SHIMKUS. Thank you.

When we knew about the hearing, we opened up to our social media for people to maybe direct a question or two to you. And

Melody Tucker from Charleston, she actually submitted a whole bunch, like 30 of them. So I am not going to go through them all; we don't have time to do that. But one of the questions she had was—I am just going to read it the way she sent it—"Will salaries of healthcare providers, including physicians and professional/para-professional staff, be determined by the Government?" And she is in the reference to the Medicare for All debate. Would you see that as—and she goes on with saying, "If so, how is Medicare for All not socialized medicine?"

Mr. AZAR. Well, I think there is a real risk with Medicare for All that it become, depending on the plan, that it become a single-payer system. And if it is a single-payer system, one eventually may want to move maybe to actually own the providers that are under that, as we see with other countries' socialist systems around healthcare. And so, yes, that would end up with a system where we would, Congress or HHS would set salaries for providers. I hope we don't ever get to that point, but I do think that is a risk of single-payer systems. We have seen it in other countries.

Mr. SHIMKUS. I appreciate that.

Madam Chairman, my time has expired. I will just yield back.

Ms. ESHOO. I thank the gentleman. I now have the pleasure of recognizing the gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Thank you, Madam Chair.

And thank you, Secretary Azar, for appearing before us today on the Trump budget.

After reviewing the Trump budget, I know my neighbors back home in Florida would want me to ask you, why does the administration continue to undermine the law that protects them from discrimination by insurance companies for preexisting conditions? And they would want me to ask you, why does the administration continue to saddle families with higher healthcare costs, copayments, and premiums? And let's get into the specifics here.

Your Department finalized a rule to expand short-term, limitation-duration health plans. These junk plans are not required to comply with the comprehensive consumer protections of the Affordable Care Act. Junk plans undermine protections for people with preexisting conditions. They increase costs. They leave American families with fewer financial protections and expose them to fraud.

So yes or no, are you aware, and did you consider in rulemaking, that these junk plans discriminate against Americans with preexisting conditions?

Mr. AZAR. The short-term, limited-duration plans do not have to comply with the Affordable Care Act's full requirements, and we need to be sure people understand that.

Ms. CASTOR. I will take that as, yes, you were aware?

Mr. AZAR. Some plans may and I believe are covering preexisting conditions; some are not. And that needs to be fully disclosed.

Ms. CASTOR. Did you know, are you aware that—so, you are aware that these plans can exclude coverage for preexisting conditions or decline to offer coverage to individuals with preexisting conditions? Yes or no?

Mr. AZAR. That is correct.

Ms. CASTOR. Yes.

Mr. AZAR. That is correct. And that is why people need to be fully aware of that, if they go into buying them.

Ms. CASTOR. No, I think what should happen is that we should adhere to the law of the land, that we do allow discrimination against our neighbors with preexisting health conditions. That is what the law says.

Mr. AZAR. If that was the law of the land, then President Obama violated during his entire Presidency.

Ms. CASTOR. Secretary Azar, yes or no, are you aware, and did you consider in rulemaking, that these junk plans exclude coverage for basic healthcare services, such as hospitalization, treatment for substance use disorders, or prescription drugs? Yes or no?

Mr. AZAR. Short-term, limited-duration plans may exclude coverage.

Ms. CASTOR. So yes?

Mr. AZAR. That is exactly why they can be more affordable options for some people.

Ms. CASTOR. So the Department also concluded that expanding junk plans will, and I quote, "increase premiums and cause an increase in the number of individuals who are uninsured. Other nonpartisan estimates, including the CBO, have also projected that expanding junk plans will increase premiums." So yes or no, are you aware, and did you consider in rulemaking, that expanding junk plans will lead to higher premiums in the individual market?

Mr. AZAR. Did consider that. The CMS actuary had some analysis around that. But, given that we now pay for the insurance for everybody in the individual market—we are subsidizing, I think, over 87 percent of people's premium acquisition—nobody should be leaving subsidized insurance to buy one of these plans. If we are buying you a full insurance package, I don't know why you would leave and buy a short-term, limited-duration plan out of your own pocket.

Ms. CASTOR. Well——

Mr. AZAR. It doesn't make any sense to me, but——

Ms. CASTOR. Let me say, the CBO was very clear on this. They projected premiums will increase by at least three percent due to your junk plan rule. And other studies, including one of out of the Urban Institute, they have projected higher premium increases across the board as well.

Mr. AZAR. Well, the rule——

Ms. CASTOR. You are going in the wrong direction.

Mr. AZAR. Well——

Ms. CASTOR. Families need relief. And what is happening is you have sabotaged—allowing these junk plans is hurting everybody. And we had expert testimony last week from folks that are implementing in many States that said as much.

Your Department also finalized a proposal in the final rule that would allow junk plans to be renewed for up to 36 months. This was not presented in the proposed rule, and stakeholders did not have an opportunity to provide input in rulemaking. Why did HHS sidestep the rulemaking process and finalize a major policy change that was not presented in the proposed rule?

Mr. AZAR. I don't believe we did, and my memory is that we asked the question whether there was legal authority for renew-

ability, but I am not confident of that. But I thought we had asked that question, but I am not aware of any legal infirmity in the administrative processes there.

Ms. CASTOR. So you are saying the Department's general counsel provided a legal opinion on the renewability provision?

Mr. AZAR. No, I am saying that I thought we had asked for comment in the Notice of Proposed Rulemaking around the question of renewability. I may be mistaken. My memory is——

Ms. CASTOR. Would you please share those documents with the committee?

Mr. AZAR. No, I am saying we asked the question to the public as to whether—and asked for comment. You were asking about whether something was fairly included in the Notice of Proposed Rulemaking.

Ms. CASTOR. Yes. Could you provide those documents that you said you provided to the public and any of the legal opinions or questions——

Mr. AZAR. It would be in The Federal Register because it would be—what I am saying is I think in the Notice of Proposed Rulemaking we asked that question. I may be mistaken.

Ms. CASTOR. So you are saying you would not provide those documents if——

Mr. AZAR. I don't think you are listening to what I am saying, which is that it is in the Notice—I believe in the Notice of Proposed Rulemaking we asked the question, and——

Ms. CASTOR. But your Department's general counsel's legal opinion would not be in The Federal Register. Would you please provide those documents to the committee?

Mr. AZAR. We would have to review that under a request for privilege and decide, and determine whether that is appropriate to share.

Ms. CASTOR. I don't believe that you did.

Ms. ESHOO. The gentlewoman's time has expired. I now would like to recognize the gentleman from Kentucky, Mr. Guthrie.

Mr. GUTHRIE. Thank you.

Thank you, Mr. Secretary. Just a couple of things before I get to my questions.

I believe short-term duration plans were legal under the previous administration?

Mr. AZAR. That is correct. For the entirety of the Obama administration, they existed for 12 months, up until just the waning hours of the Obama administration, when they cut them back only to three months to try to drive people into the exchange market.

Mr. GUTHRIE. All right. Thanks.

Also, we are talking about per-capita caps, and I worked on this in the previous Congress. And I remember having a letter—and it was entered in the record when we had a hearing—that each member, Democrat member of the Senate who had been serving at the time, who was still serving, who were serving in the 1990s—I think it was '96—signed a letter for per-capita allotments through Medicaid and Medicare—Medicaid. I'm sorry.

And former committee chairman Henry Waxman, in a 1996 congressional hearing, said that, "the Federal Government would maintain its commitment to sharing the costs of providing basic

healthcare and long-term coverage to vulnerable Americans." And he correctly pointed out that "States would have both incentives and the tools to manage Medicaid more efficiently." He did say that, obviously, the Federal assistance would have to change if there was increases beyond the control of States—hurricanes, floods, outbreaks of contagious diseases. But that was something that, in the '90s at least, was more bipartisan.

Let me just get to—I had a lady who came into my office the other day. A lot of us have people that come regularly with different groups with diseases, and she has ovarian cancer, and it touched my heart. But her biggest struggle, when I was talking to her, was about her daughter—she had her grandchildren because her daughter had an opioid addiction. With everything she was going through, that was really on her heart and mind, and we talked about the opioid bill that we passed. I know that it is supported in this budget.

And I particularly had an area called Comprehensive Opioid Recovery Centers Act, which would give comprehensive coverage. It became Section 7121 of H.R. 6. And could you talk about that specific section, if you have that information, and implementation of it moving forward, or just the overall implementation of H.R. 6 as well?

Mr. AZAR. I would be happy to get back to you. I am afraid I don't have details on that particular aspect of the implementation. We are, obviously, thankful to you and this committee and Congress for the SUPPORT Act and the tools that it provided us on the opioid epidemic.

Nearly every part of HHS is involved in implementing the SUPPORT Act. It is such a comprehensive piece of legislation. We are driving forward under the direction of our Assistant Secretary for Health, Admiral Brett Giroir, and trying to make sure we meet all deadlines in implementing all the various provisions of the Act.

Mr. GUTHRIE. Thank you very much.

And also, I wanted to just kind of ask you this: The House Republicans strongly believe that it is important that we ensure protections for individuals with preexisting conditions. And this is a commitment by you and President Trump, correct?

Mr. AZAR. That is correct. The President has made clear he will sign no legislation that would change the Affordable Care Act that does not protect preexisting conditions. His budget mandates that, that if Congress were to pass it, the $1.2 trillion American Healthcare Grant to States would have to have effective risk-pooling mechanisms or other genuine protections for preexisting conditions, which we have actually worked with States to do. I have granted, I believe, seven waivers to States under the Affordable Care Act to create reinsurance pools that have actually brought premiums down from 9 to 30 percent as a result of these preexisting conditions pooling mechanisms.

Mr. GUTHRIE. Thank you.

And also, under the Obama administration, premiums in the individual market increased every year. But President Trump has enacted several deregulatory reforms, and premiums have decreased. Is this true?

Mr. AZAR. That is absolutely true. Premiums, for the first time in the history of the Affordable Care Act, actually went down almost two percent from 2018 to 2019, and we saw the first increase in the number of plans since 2015. These are directly attributable to steps that we have taken to try to stabilize the marketplace, including the first thing that we did on it was a marketplace stabilization rule that were the things the insurance industry said we need to be able to run a predictable, actuarially, non-gamed system.

Mr. GUTHRIE. Thank you.

Mr. AZAR. So we think we have a way to try to protect, to make the premiums lower and choices better.

Mr. GUTHRIE. OK. Thank you.

There have been proposals for Medicare for All, a single-payer, government-run Medicare for All bill. A 158 million Americans receive their insurance through their employer or their unions. What would happen to these 158 million employees if we passed Medicare for All, from the proposals you have seen?

Mr. AZAR. So CMS's data is actually 174 million Americans have their insurance through their employers. And under the plans, at least some that I have seen, your employer insurance would immediately go away because it would be outlawed; you would have to go on Medicare. Even plans that don't mandate that immediately would eventually cause the private sector plans to go away because you would create such a financial advantage for the Medicare plans, which I think pay 40 percent less to providers by law. They end up paying 40 percent less than commercial plans. It would effectively drive all private plans out of business. So one way or the other, the different iterations would lead to 174 million Americans not having the insurance they have today.

Mr. GUTHRIE. Thank you.

My time has expired. I yield back. Thank you.

Ms. ESHOO. I thank the gentleman. I now have the pleasure of recognizing the gentleman from New York, Mr. Engel.

Mr. ENGEL. Thank you, Madam Chair.

And thank you, Mr. Secretary, for being here today.

Fifteen months ago, the Republican tax scam bill passed and was signed into law. And I said at the time, and it is even more true today, the impact of that legislation has led to exploding deficits, and therefore, also has led to the President's budget calling for a 12 percent decrease in the HHS budget. This budget continues to promote the long-sought goal of dismantling the Affordable Care Act by another failed attempt at so-called repeal and replace the law and weakens protections for people with preexisting conditions. This would leave millions of Americans without meaningful health insurance.

Over 10 years, this budget calls for a $1.5 trillion cut in Medicaid and a $500 billion cut in Medicare, partially offset by inadequate investments in health plans which bypass consumer protections. The cut in Medicaid is approximately $1 in $4 spent today, resulting in millions of Americans losing their coverage.

The budget does provide a very modest $291 million towards what the President call halting the spread of HIV. As chairman of the House Foreign Affair Committee, I am particularly opposed to

cuts in funding for global AIDS programs. There is a 22 percent cut in PEPFAR, used to treat millions internationally, mostly in Africa, a program started by President George W. Bush. There is also a proposal to water down the U.S. contribution in the global fund to fight AIDS, TB, and malaria from $1.35 to $1.1 billion.

Inexplicitly, we also see budget slashes to the CDC of nearly 10 percent. Funding for the NIH takes a 12 percent cut of $4.5 billion, with the National Cancer Institute absorbing most of that hit. Can you imagine that?

Now, Mr. Secretary, this HHS budget is completely unacceptable and is a direct threat to the health and well-being of all Americans. I have a couple of questions.

I would like to ask you, Mr. Secretary, yes or no, can you guarantee that cutting almost $26 billion from hospitals that serve low-income and uninsured individuals will not result in a reduction in services, endanger access to vulnerable populations, or contribute to hospital closures?

Mr. AZAR. I am not sure which particular cut to hospitals you are referring to in $26 billion. If it is the Medicare changes on hospitals gaming the system by jacking up private practice rates when they buy a physician practice——

Mr. ENGEL DSH payments is what I am referring to. Under this formula, some of the largest DSH cuts will be on States like mine that chose to expand Medicaid, while States that rejected Medicaid expansion will get much smaller cuts. So will the additional DSH cuts you are proposing continue this policy of punishing states that expanded Medicaid with steeper hospital costs?

Mr. AZAR. Correct me if I am wrong, but I thought the point of the Medicaid expansion, actually, was tied to DSH payments going down. That was part of the funding mechanism in it. I may be mistaken, but I think that is actually part of the original—what President Obama and the Congress enacted, and we are sort of carrying through on that, I believe.

Mr. ENGEL. Well, yes, how do the cuts in the CDC and NIH budgets promote lifesaving research for those Americans desperate for a cure?

Mr. AZAR. The cuts at CDC and NIH were a challenge and it is a starting point. With a tough budget environment, these are difficult choices. We have tried to prioritize, and I understand you or others will disagree with those choices. And we are happy to engage in an ongoing discussion. It is a starting point for that.

Mr. ENGEL. Well, the choice I am really against is the choice that gives tax breaks to very wealthy people in exchange for what we are seeing right now in this budget, hurting the poor and the middle-class and their ability to have adequate healthcare.

You have hospitals in my district and all the surrounding districts that serve a high number of Medicaid patients, and the uninsured are a critical part of our healthcare infrastructure. They ensure that our most vulnerable citizens have access to the care they need when they need it most. And these hospitals rely on funding. I know you know this. For the Medicaid Disproportionate Share Hospital, a DSH will help keep their doors open and their lights on. And Medicaid DSH payments help support hospitals across the country in all types of communities, urban and rural. And at the

end of this year, hospitals will face substantial cuts to their DSH funds if Congress doesn't act.

So the President's budget, the way I look at it, doesn't propose to reduce or delay these cuts. Instead, it doubles down and proposes increasing the size of these cuts over a longer period of time. And by your own objections, this would result in $25.9 billion in cuts to Medicaid DSH on top of a $44 billion in DSH allotment reductions under current law. I don't see how hospitals will be able to sustain cuts of that size. Could you please explain to me how that would be possible?

Mr. AZAR. Again, I believe that is inherent in the Affordable Care Act's structure. And in terms of uncompensated care, I thought that the Medicaid expansion and the Affordable Care Act were supposed to get rid of the uncompensated care. I mean, we can't keep the old system and have the new system on top of it and keep paying the same amount of money. That is at least our perspective in the budget.

Mr. ENGEL. But let me just say, Madam Chair, and then, I will end, to me, it doesn't matter as long as we are not pulling away help that people need now. It seems to me that, from these cuts, there is no way that you can call it any other thing, but we are taking money away and many, many more people will be left uninsured and will have no help. And to me, that is not the way we should be going, providing tax cuts for the wealthy in exchange for everybody else getting screwed.

Ms. ESHOO. I thank the gentleman. I now have the pleasure of recognizing the gentleman from Virginia, Mr. Griffith, 5 minutes for questioning.

Mr. GRIFFITH. Mr. Secretary, in trying to answer some of the questions just a minute or two ago, you were talking about the DSH payments and some of the bigger hospitals buying up small satellites in order to be able to get DSH payments they wouldn't otherwise be qualified for. Did you want to expand on that?

Mr. AZAR. I am afraid on the DSH payment issues I have to get back to you on that. If you have a question on that, on detail, I would be very happy to get back to you there.

Mr. GRIFFITH. That is fine.

In regard to having socialized medicine and have it the same parameters as the current Medicare system, where you referenced that the medical folks are paid 40 percent less under Medicare, have you all done any studies on how many healthcare providers would leave the field?

And let me tell you why I ask that question. My mother is 88 years old, and obviously, she has been on Medicare for a while. Recently, her primary care physician retired. She started making phone calls and made a couple of calls and found that the doctors that she called were not taking any new Medicare patients because of the reduced payments that they were going to get. And she just decided she would work with her older doctors who were the specialists that dealt with the areas of concern, instead of having a primary care physician. So she is actually getting less care now than she got before.

And it made me think that perhaps, at a 40 percent reduction, a fair number of healthcare providers, particularly those who might

have other means of supporting themselves, might just go do something else. Have you all done any studies on that?

Mr. AZAR. I am not aware of any studies that have been conducted yet. I think that is a fruitful area for inquiry. We ought to look at that.

We certainly see that with European socialist systems, though, that you get the better providers or hospitals who will often opt out of the socialist system because of underpayment. And what you get is a two-tier system. You will have basically an essential medicine, essential services systems, and then, you have others who can buy up in a private sector system, alternative providers and hospitals in there. That is not to say that these are bad healthcare systems, but it is a two-tier system.

Mr. GRIFFITH. And with our current system where a lot of people get it through their employer, it doesn't matter whether you are the CEO or the guy working the line or the lady working the line; you get the same system. And now we are headed toward a system that might actually have two tiers, where the people with the money can get that specialist, but the people who are working on the factory floor may not be able to get that specialist. Is that correct, yes or no?

Mr. AZAR. I am extremely concerned about a two-tier system like that.

Mr. GRIFFITH. And so, that is a yes?

Mr. AZAR. Yes, that is a yes. And let's protect everybody.

Mr. GRIFFITH. My time is slipping away from me. Just let me say this as you all look at things. We have got to figure out a way to do reimbursements for telemedicine across the board because telemedicine can save us money in the long term and provide better care in rural districts like mine. And I am a big proponent. And any way I can help you with that, I would greatly appreciate it.

Also, you all have been looking at the DIR fees, the direct and indirect payments to pharmacists. It seems to me it is an inequitable situation that we have now, where, months later, a pharmacist who has sold a drug—and I have lots of these across my rural district, community pharmacies. They are not big companies. They are little, small, mom-and-pop operations. And they get notice that they owe tens of thousands of dollars six months after they have already filled the prescription. You can't go back to the patient and say, "Oh, by the way, I told you it was a $20 drug. It turns out it was a $30 drug." You just can't do that, and the pharmacists are having to eat that. You all are working on that, and I appreciate that.

You all, last year, in a Senate hearing, you stated that you were going to direct your agency's Office of Inspector General to conduct a study on these DIR fees and how these fees specifically impact community pharmacists. Has that study been completed and, if so, when do you expect to release the results?

Mr. AZAR. I believe it well underway and I hope it will come out quite soon.

Mr. GRIFFITH. All right. I appreciate that.

I also want to talk about durable medical equipment, prosthetics, orthotics, and supplies, et cetera. Competitive bidding programs have been put on hold. I appreciate that. One of the concerns in

a rural area is that you may only have one or two suppliers, and while the equipment might be available to somebody if they drive down the mountain in 45 minutes to an hour, but sometimes these folks aren't capable of doing that. And we are squeezing out the folks who would actually take the equipment to them.

In that regard, the agency now has plans to include non-invasive ventilators in the durable medical equipment program. Those, obviously, assist people that can't breathe on their own. Can you explain the rationale and clinical criteria used in the decision to include non-invasive ventilators in the next round of bidding?

Mr. AZAR. Sure. The Social Security Act gives us authority to phase in items that begin with the highest-cost and the highest-volume items or services and those items that we determine have the largest savings potential. And so, all of the items that we have selected for competitive bidding are high-cost, high-volume items with a very large savings potential.

We have got a comprehensive monitoring program, and it has shown that beneficiary access and health status outcomes have been preserved under the program. We have been very concerned about the impact in rural. That is why we made the modifications that we did, I believe, midyear last year, and then, carrying forward, to attempt to ensure fair reimbursement and fair competition for rural areas especially.

Mr. GRIFFITH. I appreciate it, and yield back, Madam Chair.

Ms. ESHOO. I thank the gentleman. I now have the pleasure of recognizing the gentleman from Maryland, Mr. Sarbanes, for 5 minutes of questioning.

Mr. SARBANES. Thank you, Madam Chair.

And thank you, Secretary Azar, for being here.

I just wanted to make sure the record was clear on a couple of things. In response to Congresswoman Castor's questions with regard to the junk plans, I just want to point out that, while with respect to the renewability question of these plans it does look like the Department went through the normal course in terms of the NPR and allowing public comment there with respect to the extension of these plans to 36 months, that did not come until the final rule was proposed. And in that sense, it sidestepped the kind of transparency that I think we have a right to expect. So that is the first thing.

The second thing I wanted to note is you have been asked a number of times about the cuts to NIH, and you really don't have a good answer for that, because I think it is indefensible and there is going to be a lot of continued inquiry in that regard. Because we want to stay on the cutting edge in terms of researching and finding cures to these life-threatening diseases that afflict so many Americans across the country.

But I wanted to talk specifically about the opioid crisis and address the impact of the pharmaceutical manufacturer marketing efforts with respect to the crisis. On February 26th, a Washington Post article titled, "Inside the House of OxyContin," detailed the actions of Purdue Pharmaceuticals and their owners, the Sackler family, in marketing opioids as safe and effective to the medical community. It highlighted, the article did, that Purdue pioneered direct-to-physician marketing and used this approach to lead a

marketing strategy to persuade providers that opioids were both safe and effective for long-term use, despite a lot of scientific evidence to the contrary.

One member of the Sackler family was quoted from an email in 1996 saying, quote, "This strategy has outperformed our expectations, market research, and fondest dreams." End quote. Twenty years later, we are dealing with the consequences of this marketing strategy. And I don't need to remind my colleagues that opioid deaths hit a record high in 2017 with 70,000 recorded opioid deaths that year.

So how is HHS going to hold pharmaceutical manufacturers accountable for drug-marketing strategies that are boosting profits while harming our communities? Could you speak to that, please?

Mr. AZAR. Congressman, thank you for raising it. It is really important because, you are right, that is a big part of how we got into this opioid crisis, were the practices in getting legal opioids out there and getting them out in primary care and getting them extensively overprescribed. Is it five times, I think, the European average in terms of legal opioids?

We have been aggressively working on that. We have actually gotten opioid, legal opioid prescribing down 22 percent, and on a morphine molecular equivalent, down 27 percent so far since January of 2017.

The President has directed, and the Justice Department has been working. We will support fully the Justice Department in going after any manufacturers who engaged in illegal or unethical conduct. DOJ joined in the litigation by the States against these manufacturers, and that process is ongoing. But, certainly, we will take any cases anywhere the evidence goes. I share your concern. We are deeply disturbed, and we see the foundation of this crisis in the legal opioid use that started, I think, back in the '90s.

Mr. SARBANES. Well, I do think we need to step back and systematically look at what these marketing strategies are and decide whether we are going to lean against them going forward.

What is the standard of scientific evidence at HHS and FDA in terms of what is required from pharmaceutical manufacturers when approving drug applications, especially in the case of opioids?

Mr. AZAR. New drug applications, I want to defer to my colleagues at FDA. So I would say my current belief, but, please, I will ask my colleagues, and we will correct it if I get it wrong.

Usually, for an on-label indication, you would require two double-blind controlled studies, randomized clinical trials, to support a labeled indication. And then, for other information that you would provide about the drug, I believe it is a substantial evidence test, but I——

Mr. SARBANES. I am worried that whatever the standards are that are being applied are not achieving the goals that the public would want to see in terms of kind of rigorous decisions about what is safe and what is not safe. And you may have heard that the former FDA Commissioner, David Kessler, is concerned that opioids are being used in a way that was never proven to be safe or effective, particularly the decision on FDA's part to expand the label use of opioids to allow long-term use, which is something that probably should not have happened.

So as I close, I just want to say that I think HHS and FDA have to put a plan in place for retroactively reviewing the safety and efficacy of existing opioid projects. Let's go look at what is happening right now because it could be continuing to fuel this opioid crisis. So it is not just retrospective here. This is about making decisions going forward that can help us get out of this crisis.

With that, I yield back my time.

Ms. ESHOO. I thank the gentleman. I now would like to recognize the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you, Madam Chair. I appreciate it so very much.

And welcome, Mr. Secretary. Appreciate it.

I want to talk about Medicare Part D. When Congress created Medicare Part D, it did so with the belief that private sector organizations which are already administering employer-sponsored drug benefits could be used to administer a Medicare drug benefit. We now have Medicare Part D, where drug plans compete against each other to provide the lowest price to beneficiaries. It is probably the only Federal program that consistently comes in under budget with premiums that have remained largely unchanged. And I know this has been going on for years. It is a very successful program.

In my district, we have 191,000 seniors, and about 80 percent of them are on either Medicare Part D or they participate in a Medicare Advantage program with a drug benefit. Some people have talked about changing Part D and having the Government negotiate drug prices. Do you think the Government can negotiate a better deal than what the plans have been able to negotiate over the past 15 years? Again, we want what is best for our constituents. We want low drug prices, and I know you do, too, and the President as well. So that is the question. Again, do you think the Government can negotiate a better deal than what the plans have been able to negotiate over the past 15 years?

Mr. AZAR. I do not believe that we could do a better job negotiating than these pharmacy benefit managers do, absent creating a highly-restrictive, uniform formulary for every senior citizen in America. And that is what Peter Orszag, the head of the Congressional Budget Office and President Obama's OBM Director, concluded also. These PBMs have significant market power. They negotiate discounts, where we let them, that are comparable to European OECD levels of discounting, is my understanding and experience.

But we would have to create a single formulary. We would have to say that, every senior, you may have this drug; you may not have this drug. We have heard the bipartisan concern even today on step therapy and utilization management within protected classes. Imagine the outcry if we were to say to all seniors, "You may have"—and I will just pick a drug—"You may have HUMIRA; you may not have Enbrel." That is the only way I could get better savings than the PBMs are able to negotiate.

And I think a lot of the concerns would be here. I am not sure a lot of folks who ask us for that negotiation understand the implications from a beneficiary choice and access perspective. I am happy to have that discussion with both sides of the aisle on this,

because we want to solve the drug pricing crisis. We want to solve that, but we want to solve it in the right way, with patients at the center.

Mr. BILIRAKIS. All right. Thank you very much, Mr. Secretary.

Again, yes, you are right. I mean, your heart is in the right place. The President's heart is in the right place. Everyone, we want lower drug prices, but, again, also choice and accessibility are so very important for our seniors.

I assume that you have reviewed the Medicare for All proposal?

Mr. AZAR. I have seen and heard about different iterations of it, sir.

Mr. BILIRAKIS. Yes, yes. So how would the Medicare for All proposal affect the successful Medicare Part D program, in your opinion?

Mr. AZAR. It would take it away because Medicare Part D is a private-plan-administered program with private insurance, is my understanding, at least of some of the versions of that.

Mr. BILIRAKIS. Yes, and, in my opinion, it is not perfect, and we are going to close the donut hole. But it has been a very successful program. I hear from my seniors all the time.

Medicare Advantage is very popular in my district. Fifty-three percent of our seniors are on Medicare Advantage. They really love the program. How would Medicare for All affect the Medicare Advantage Program?

Mr. AZAR. I believe Medicare for All, under at least some versions of the Medicare for All program, that Medicare Advantage would disappear because it is a private insurance program administered by the Government. But I believe it would go away and all would go onto a Medicare Fee-for-Service, the old-style 1960s Medicare that people are increasingly not choosing because they want the more private sector, flexible, choice-full benefit package of Medicare Advantage.

Mr. BILIRAKIS. Well, thank you very much. It would be a real shame if we lost that.

Mr. AZAR. Thank you.

Mr. BILIRAKIS. Thank you very much. I yield back.

Ms. ESHOO. I thank the gentleman. I now would like to recognize the gentleman from Oregon, a wonderful member of this committee, Mr. Schrader.

Mr. SCHRADER. Thank you very much. I appreciate this.

Thank you for being here today, Mr. Secretary. I appreciate it very much.

I am not particularly a big fan of the budget that is rolled out for HHS, to be honest. We are a big fan of the ACA. This would repeal it, and the Medicaid program gets cut, cuts to research, those types of things.

But I try to look at the silver linings here, and the prescription drug costs suggestions merit, I think, some good look-sees. In particular, generics are saving us $250 billion a year. It is a big area. I prefer, like my good colleague from Florida, market-based solutions in terms of how we encourage competition, as probably the best way to go about that.

And in the generic space, we currently give manufacturers 180 days exclusivity when they file for a new generic drug, but there

have been some problems with that, with that exclusivity. Sometimes they don't just get around to marketing the drug in a timely manner, and that exclusivity drags out well beyond 180 days, basically, blocking others from getting into the marketplace and further reducing costs for the consumer.

So a couple of questions, if I may. One is, how often does a first filer block competition from subsequent generic manufacturers, and how long does that parking actually seem to last? Any examples recently?

Mr. AZAR. So my understanding is that, on average, we see about five of those instances a year where you will have that first-to-file, essentially, squat on their 180-day exclusivity. And on average, that leads to about a 12-month delay in generics coming to market. So it is a very significant access and financial issue.

Mr. SCHRADER. All right. Any recent examples of that?

Mr. AZAR. I don't have a particular company or product in mind. We could try to get that to you. But those are the average numbers there.

Mr. SCHRADER. All right. Well, it would be great to get that information, some real-life examples.

And what is the motivation, basically, what is the advantage for these manufacturers to park their exclusivity, which seems sort of obvious, but what you seen?

Mr. AZAR. Well, there could be instances where they simply can't make the drug. There are often manufacturing problems. So somebody gets approved, but they are not able to bring it across the finish line and manufacture. But there may also be instances where there is a deal, where there is a deal between the generic company and the branded manufacture to forestall the starting of that 180-day clock, so that the branded company can keep selling the branded drugs.

Mr. SCHRADER. I see. I see.

Mr. AZAR. It is a likely potential source of great abuse on access to generic medicines for our people.

Mr. SCHRADER. Yes, and I think the goal would be, hopefully, to provide opportunity for folks to get into the market as soon as possible. Maybe some changes can be made, so that a second generic that comes to market in a timely manner would start triggering a clock.

Mr. AZAR. And the President's budget has that proposal in there. And I appreciate your leadership and Congressman Carter's leadership supporting reform here that would fix this real abuse of our generic system.

Mr. SCHRADER. Last question is, some people argue that the forfeiture of that exclusivity that is currently in statute provides enough protections against the parking issue that we are talking about here. I understand there have been some problems, frankly, enforcing that forfeiture portion.

Mr. AZAR. Yes. I think the evidence would be to the contrary, that, in fact, we are seeing this as a real problem. And getting rid of that abuse by having the clock start as soon as the drug is available from an approval perspective, and if they don't launch as soon as there is a second drug available to come on, that clock should start or other different solutions. So the forfeiture provisions that

are there are, obviously, not quite sufficient. We need to fix this 180-day clock issue.

Mr. SCHRADER. Very good. Very good. Well, I appreciate your interest in that issue, and hopefully, it is one of many areas we can work together on.

Mr. AZAR. I hope so.

Mr. SCHRADER. Thank you very much, and I yield back, Madam Chair.

Ms. ESHOO. I thank the gentleman. And we are going to have a legislative hearing tomorrow on the very issue that you just raised with the Secretary. I hope that we have good bipartisan support on addressing that abuse.

I now would like to recognize the gentleman from Indiana, Dr. Bucshon.

Mr. BUCSHON. Thank you.

And welcome, Secretary Azar, to our subcommittee.

I do agree with one of my colleagues on the other side that my constituents do need relief, but it is from the high deductibles and premiums created the ACA and the following years after that.

Secretary Azar, I was pleased to see the administration's focus on the 340(b) program again this year in the budget, specifically, a call to require transparency regarding the use of program savings by 340(b) entities. This goes hand in hand with the important work done by this committee, the Energy and Commerce Committee, last Congress in the Oversight Subcommittee in highlighting the need for 340(b) reform, and also, in exploring specific legislative proposals aimed at strengthening the program.

I was proud to sponsor a bill last Congress that would introduce common-sense data collection for 340(b) entities previously facing no oversight. It is very concerning to me that a significant number of hospitals in the 340(b) program may be providing low levels of charity care, despite the rapid growth in the program, recently, mostly through the acquisition of child sites, and face no requirements to report on their use of 340(b) savings.

The first question I would have, would you support including a charity care requirement as a condition of eligibility for the program?

Mr. AZAR. I would have to look at that and see what the administration position would be there. In our budget, of course, we do propose that, to get the benefit of savings from our reimbursement change——

Mr. BUCSHON. Correct.

Mr. AZAR [continuing]. That you would have to provide, I believe, at least one percent charity care.

Mr. BUCSHON. One percent.

Mr. AZAR. So to be a beneficiary of the budget neutrality from the outpatient changes, you would have to do that. So we are at least partway there already.

Mr. BUCSHON. OK. Do you think that we should have a minimum charity care level met across all hospital networks at the main hospital, but also within their network?

Mr. AZAR. Well, it's certainly——

Mr. BUCSHON. It is a complicated question.

Mr. AZAR. The rationale on 340(b) is that you are providing that type of care. And so, it is something we need to be looking at. I am happy to work with you on that.

Mr. BUCSHON. I appreciate that.

And based on your budget, would you agree that HRSA needs more authority to create clear and enforceful standards for the 340(b) program?

Mr. AZAR. Absolutely. We need regulatory authority. We need oversight authority. We need transparency in 340(b). And we need a user fee program, so that those benefitting from 340(b) pay for the oversight that we need to provide over their use of the program.

Mr. BUCSHON. Thank you for that answer. And could you also agree that we need to require all 340(b) covered entities to report savings achieved from the 340(b) program and their uses?

Mr. AZAR. I think that type of transparency could be very useful. That is not, obviously, a formal statement of administration position, but we are generally in favor of that type of transparency.

Mr. BUCSHON. I understand. Thank you again for addressing 340(b) in your budget.

And I yield back.

Mr. BURGESS. Will the gentleman yield?

Mr. BUCSHON. The gentleman will yield to the ranking member, yes, I will.

Mr. BURGESS. I thank the gentleman for yielding.

This is such an important topic. Of course, this committee, the Subcommittee on Oversight and Investigations did do a significant amount of body work and produced a report last Congress that I encourage people to look at.

But, Mr. Secretary, there was something that occurred along the way in the 340(b) genesis that got us to this point. And that was the ability of a contract pharmacy to participate in the 340(b) program. Do you have any thoughts as to whether or not that is adding to our difficulties?

Mr. AZAR. It is adding to the difficulties and the issues around integrity of the program and just original purpose. And I do think it would be great if this committee could look into this question. It was a well-meaning idea at the start, which was, if a hospital doesn't want to run its own pharmacy for low-income patients when they come in, let somebody else run it. OK, that made perfect sense. But, then, it became, well, what if they need something a little closer to home? So extend the contract pharmacy out to pharmacies maybe in the neighborhood of the patients of that hospital. It has now become an industry. It has begun an industry of contract pharmacy, of basically shared profit between the pharmacies and these hospitals. It is worth looking at it to see the extent to which it is fulfilling the original purpose and what Congress really intends 340(b) to be about. I leave that to you all. But I do think it is worthy of being on your agenda.

Mr. BURGESS. Yes, and I completely agree, and to the extent that mergers and acquisitions might evolve out of those 340(b) contract pharmacies, it is worthy of our discussion.

So I thank the gentleman for yielding. I will yield back to you.

Mr. BUCSHON. I yield back.

Ms. ESHOO. I thank the gentleman. I now have the pleasure of recognizing the gentleman from New Mexico, Mr. Luján.

Mr. LUJÁN. Thank you very much, Madam Chair.

Secretary Azar, yes or no, were you given advance warning of the Department of Justice's decision to not defend the law?

Mr. AZAR. I am sorry, you are speaking, I assume, about the Texas litigation? I just want to be sure I—you said "the law". I just want to make sure the law we are talking about——

Mr. LUJÁN. Yes, Mr. Secretary.

Mr. AZAR [continuing]. Is the Affordable Care Act?

Mr. LUJÁN. Yes, Mr. Secretary.

Mr. AZAR. Yes, I knew the filing that was going to happen on behalf of the United States.

Mr. LUJÁN. How were you notified of the Department of Justice decision? Did you receive a phone call, an email, or a written letter?

Mr. AZAR. Our Department is involved in consultations regarding the filing of litigation in which the Department has interest or is a party. And so, we have communications with the Justice Department.

Mr. LUJÁN. You had a phone call or was it an in-person meeting? Was it a letter? Was it a——

Mr. AZAR. The nature of the discussions that I have regarding deliberations on filing of the position of the United States in litigation in this case are not ones that I can have full discussion about.

Mr. LUJÁN. You can't say? I understand that you have already refused to share those documents, but you can't say if it was a phone conversation or an in-person meeting?

Mr. AZAR. Our Department has discussions with the Justice Department and other officials regarding the position in highly significant cases of litigation on the position of the United States. And, yes, I had a——

Mr. LUJÁN. Mr. Secretary, did you personally have those conversations?

Mr. AZAR. I did, indeed.

Mr. LUJÁN. Look, it is simple. If the District Court ruling stays, millions of Americans would lose their health coverage, healthcare costs would skyrocket, and lifesaving healthcare would become unaffordable for American families. Secretary Azar, yes or no, did your Department conduct an analysis to evaluate the effects of the Department of Justice's position on consumer cost and coverage?

Mr. AZAR. I don't know if we did at the time, and as I spoke with Chairman Pallone earlier, we are working to gather up, if we do have analytics around impacts of the court decision in the case, we are working to provide those to the committee.

Mr. LUJÁN. Can you commit to providing that, then, to the committee? That is something you will do?

Mr. AZAR. I asked my team to find any materials like that and provide those to the committee, that type of analytics, and to provide those to the committee. Absent some problem—and I think they have communicated with committee staff to that regard—absent something I am not aware of, I want to make sure you get that information.

Mr. LUJÁN. So, Mr. Secretary, surrounding the initial questions that I asked as well, why is it that there is a reluctance to share that information with the committee?

Mr. AZAR. To share the analytics? I have——

Mr. LUJÁN. Not the analytics, Mr. Secretary. Why is it that there is a reluctance from you to share the information, pursuant to the conversation surrounding the Department of Justice's decision to not defend the law in the Texas case?

Mr. AZAR. Well, obviously, discussions of individual Cabinet members at a certain level regarding positions of the United States in litigation are historically over the course of the history of this country highly-privileged, sensitive discussions, especially with pending litigation.

Mr. LUJÁN. Well, Mr. Secretary, I think that there is a decision that was clearly made associated with positions of the administration. The question that I have, and why I am asking the questions that I am, is in your Senate confirmation hearings you repeatedly stated that you were committed to enforcing and upholding the Affordable Care Act. Is that correct?

Mr. AZAR. I absolutely am. As long as it is the law of the land, I will in my administrative authorities work to make it work for the American people, in my judgment, as best I can.

Mr. LUJÁN. Well, Mr. Secretary——

Mr. AZAR. But that is not a statement of whether something is constitutional or not.

Mr. LUJÁN. Mr. Secretary, if I may, the administration has made an unprecedented decision to throw away the responsibility to defend the Affordable Care Act and law.

Mr. AZAR. So I want to be very clear. Our policy position, as an administration and mine, is to protect preexisting conditions. You are speaking about a legal piece of litigation the Justice Department leads on. We want preexisting conditions protected. Our budget actually has a concept about how we can do that with a replacement of the Affordable Care Act. I am happy to work with this Congress on alternative ways and approaches. The President has made it very clear he will never sign any new legislation replacing the ACA that he does not believe does protect people who have preexisting conditions.

Mr. LUJÁN. Well, Mr. Secretary, I am glad that you brought attention to the fact of the policy related to people with preexisting conditions because you and I very well know that the Trump administration has specifically disavowed ACA provisions that guarantee coverage and protect people with preexisting conditions. I think that that is ignoring what has occurred. Your testimony today seems to be ignoring positions that have been taken by this administration, that you, yourself, said you would uphold in court.

Mr. AZAR. I think you are probably referring to short-term, limitation-duration——

Mr. LUJÁN. No, no, no. I know what I am referring to, Mr. Secretary.

Mr. AZAR. It is totally transparent——

Mr. LUJÁN. And I think that it is critically important that we understand what is occurring here today and what is not occurring.

And I certainly hope that you will reverse your refusal to share documents with this committee.

And with that, Madam Chair, I yield back.

Ms. ESHOO. I thank the gentleman.

We have three votes on the floor. So the subcommittee will stand in recess until immediately after votes.

We still have several members that are in line to question. I have 14 members. There are three that waved on, but that is still a large group.

So, Mr. Secretary, it is a chance for you to take a stretch, relax for a few minutes, figure out how you might answer the questions that are to come.

And we will return as soon as votes are completed.

Thank you.

[Recess.]

Ms. ESHOO. I call the subcommittee back to order.

Thank you, Mr. Secretary, for your patience.

And we will move on with questions. It is a huge pleasure because she has been such a wonderful partner in so many things—the gentlewoman from Indiana, Mrs. Brooks, for 5 minutes of questions.

Mrs. BROOKS. Thank you, Madam Chairwoman.

And, Secretary Azar, we have talked about this in the past, the Pandemic and All-Hazards Preparedness Act, a program that, while we have reauthorized it once again in this Congress—and I really want to thank the chairwoman, Congresswoman Eshoo, who worked with me both last Congress and this Congress to get this across the finish line here in the House once again—it has not yet been reauthorized. We have not yet been able to get it through the Senate.

It is supported by a host of public health groups, the Alliance for Biosecurity. And when we kicked off the Congressional Biodefense Caucus together, you participated and spoke at that Biodefense Caucus. And I thank you for speaking about the importance of PAHPA. During your remarks, you mentioned that you were involved in the writing in 2002 of the Bioterrorism Act. And I want to commend you because it appears that in the Public Health Services Emergency Fund there is, for the most part, either level funding or some increased funding relative to Pandemic and All-Hazards Preparedness.

But can you share with us the negative impact of PAHPA not being authorized? And if we cannot get this through the Senate—there are several programs that actually expired in 2018; I won't go into those—but what does this do for our private partners in the very critical public-private partnership in the Medical Countermeasures Enterprise?

Mr. AZAR. Well, thank you, Congresswoman Brooks, for your support of PAHPA and for your advocacy of the bioterrorism front.

We are committed to reauthorization of PAHPA. We are committed to protecting Americans, and reauthorization of PAHPA is an important part of that.

There are several expired provisions that HHS does need to be able to continue the important work in this area. There is a FOIA exemption. There is an antitrust exemption. There is a National

Advisory Committee on Children and Disasters. And there is a provision for temporary reassignment of Federally-funded personnel.

And the expiration of these provisions does endanger our security and the broader Medical Countermeasures Development Enterprise that we have. These medical countermeasures are dependent upon a very unique and fragile U.S. Government-industry partnership in this cradle-to-grave enterprise. Specifically, if a pandemic were to occur, BARDA, which is our research and development agency, would currently be unable to negotiate and bring together certain critical medical countermeasures manufacturers due to a lack of antitrust exemptions. That is just one example of how we are at risk right now.

Mrs. BROOKS. And I think because it is not commonly understood, that is because BARDA does sit with different manufacturers of vaccines to have a discussion. Is that correct?

Mr. AZAR. Exactly. We can convene competitors under the antitrust exemption, and they can speak freely in ways that they otherwise wouldn't be able to.

Mrs. BROOKS. And that provision has expired?

Mr. AZAR. That has expired.

Mrs. BROOKS. OK. So right now, they cannot convene that type of meeting if we were to have an unusual or a pandemic and have those discussions?

Mr. AZAR. If we had a pandemic and needed to scale-up production immediately for a pandemic flu vaccine, right now we would not be able to engage in those collaborative private-public partnership discussions across industry.

Mrs. BROOKS. Right. Thank you.

With respect to the funding, I certainly see that the National Disaster Medical System has actually been plused-up from $57 million in FY19 to $77 million. If I am not mistaken, that is bringing in medical providers from around the country to help us in cases of disaster, of which we have seen quite a bit. Is there anything you would like to say about that? And then, we also went down, though, a bit on the Hospital Preparedness Program by $7 million.

Mr. AZAR. Right. So the National Disaster Medical System is a bedrock of our preparedness and response program. So these are individuals who have day jobs, doctors, emergency medical technicians, veterinarians even, who work with us and allow us to surge in. For instance, you will see these people when you are at various events. Like the State of the Union, a lot of the medical professionals that are here are actually NDMS members here to protect you and me when we are here for national security events like that. And so, it is a vital, important program, and I am very glad that we have a proposal to continue the investment with them.

Mrs. BROOKS. Can you talk very briefly about the other provision that expired and the National Advisory Committee on Children and Disasters?

Mr. AZAR. So this is, of course, just getting advice from the best advisors out there on how we can focus on children in disasters. There are very unique needs and threats for children in the disaster situation, trauma, mental health, and we do want to get the best advice possible. PAHPA enables that.

Mrs. BROOKS. Well, thank you. We look forward to working with you to help us get that over the finish line in the Senate.

Mr. AZAR. Thank you.

Mrs. BROOKS. Thank you. I yield back.

Ms. ESHOO. I thank the gentlewoman. It is a pleasure to recognize the gentleman from Massachusetts, Mr. Kennedy, for 5 minutes of questioning.

Mr. KENNEDY. Thank you, Madam Chair.

Mr. Secretary, thanks for being here. Thanks for your patience as we went over to vote.

Last fall, Mr. Secretary, it was reported that your agency was considering establishing a legal definition of sex under Title IX. According to The New York Times, the memo would narrowly define gender as a biological condition determined at birth, and any dispute about one's sex would have to be clarified using genetic testing.

Mr. Secretary, is that memo real?

Mr. AZAR. So there was litigation, I think it was at the end of the Obama administration, and a Federal court actually enjoined enforcement of—I think this is the Section 1557. Is that the provision that you are talking about?

Mr. KENNEDY. Yes, but does the memo exists? The New York Times said this memo exists.

Mr. AZAR. I am not going to comment on whether some preliminary memo exists. We are working on complying with the court's order to come up just how do we—the court said that the Obama administration's regulation was invalid. And we will just work to faithfully implement that across relevant agencies.

Mr. KENNEDY. Can you give us a copy of that memo? Can you give us a copy of that memo then?

Mr. AZAR. We will certainly look at that. I don't know. If it is an internal memo like that, if it is appropriate to disclose——

Mr. KENNEDY. It is potentially going to impact millions of Americans in not disclosing that, or at least hundreds of thousands——

Mr. AZAR. I wouldn't necessarily assume that is operative continued thinking, that whatever was in any previous document——

Mr. KENNEDY. Thank you.

So moving on, sir, do you believe that healthcare is a right for all Americans in this country?

Mr. AZAR. I believe that we have an important duty, all of us, this committee and this administration, to make healthcare as affordable as possible for all Americans.

Mr. KENNEDY. So in a less than a year, nearly 20,000 low-income people in Arkansas, sir, have lost their healthcare because of a work requirement that your agency approved. At the same time, the unemployment rate in Arkansas has barely budged. Is that a successful policy implementation?

Mr. AZAR. So at the request of the Arkansas Government, we did approve a community engagement waiver program with them. The individuals who have fallen off that program, we do not yet have data as to why they fell off the program.

Mr. KENNEDY. Have we asked them? Have you asked them?

Mr. AZAR. Yes. We are working with them. That is part of the data gathering. That is part of the learning process.

Mr. KENNEDY. And when do you expect to have that data back?

Mr. AZAR. I don't know if it is timely for that. It is quite new. It is quite new in its implementation. So tracing the data out to see that individuals, as you said, who advance into work with an employer insurance, and hence, do not qualify for Medicaid anymore, need Medicaid anymore, we just don't know at this point.

Mr. KENNEDY. Mr. Secretary, so in your agency's budget you propose implementing mandatory work requirements for Medicaid beneficiaries, not knowing what the impact will be across every single State. And according to some estimates, upwards of 4 million Americans can lose access to healthcare, 83 percent of whom would only lose coverage because of onerous reporting requirements. You just said you are not sure why people are losing it. Yet, you have now said that you want to extend that to every single State. What is the logic in that?

Mr. AZAR. The logic behind that is we believe that it is a fundamental aspect for able-bodied adults, if you are receiving free healthcare from the taxpayer, it is not too much to ask that you engage in some form of community activity engagement, work training. That is consistent with TANF and the important welfare reforms that were bipartisan. The administration's budget proposal would actually harmonize these across all public welfare programs.

Mr. KENNEDY. Mr. Secretary, your mission is to try to make sure that everybody gets access to healthcare in this country. Can you point me to one study that says that work requirements make people healthier? One?

Mr. AZAR. We believe that individuals who have employment have healthier outcomes. I don't have the data to cite. We have used that in litigation, though.

Mr. KENNEDY. Sir, you run an agency responsible for healthcare for millions of Americans. Healthier people working does not mean that work requirements make people healthier. I assume you understand that?

Mr. AZAR. Well, we are dealing with—because of the Obama——

Mr. KENNEDY. Is that true, yes or no?

Mr. AZAR. Could you repeat the question?

Mr. KENNEDY. Healthier people working is not the same thing as work making people healthier? Is there any single study you can point to, yes or no, that shows that work requirements make people healthier?

Mr. AZAR. I would have to provide that in writing to you, if we have that.

Mr. KENNEDY. I look forward to the answer. Thank you.

You are aware of studies in Ohio and Michigan that show that Medicaid expansion actually helped beneficiaries obtain jobs or remain employed? Are you aware of that, the studies?

Mr. AZAR. Medicaid can be a hand-up for individuals to help them with transitioning into work. The goal of all these programs should be to help people become independent, and that is all of our goal.

Mr. KENNEDY. Except the data that you are looking at seems to indicate that there are tens of thousands of people that are losing healthcare in a policy that you want to extend across the country without answering why.

Mr. AZAR. Well, we don't know if they lost their—if they fell out and stopped complying with the work or community engagement requirements because they are actually secured jobs and, they just didn't need to keep applying.

Mr. KENNEDY. And does cutting Medicare and Medicaid by $1.5 trillion actually make this program easier to extend healthcare to more people?

Mr. AZAR. So what we want to do is we want to remove the Medicaid expansion for able-bodied adults——

Mr. KENNEDY. The budget indicates, Mr. Secretary——

Mr. AZAR [continuing]. And focus the program on the aged, blind, disabled——

Mr. KENNEDY. Yes or no, you are cutting these programs by $1.5 trillion?

Mr. AZAR. Our proposal does have a $1.4 trillion, I believe, cut over 10 years to Medicaid, yes.

Mr. KENNEDY. And so, I would imagine that cutting a program by $1.4 trillion doesn't actually make the program, strengthen the integrity of the program or make it easier for people to gain access to insurance.

I would like to finally conclude with the basis for my comments on this, which is it is the perspective of at least this Member of Congress, and I think other colleagues of mine, that Medicaid work requirements are against the Social Security—the very statute that incorporates Medicaid, Section 115 of the Social Security Act, and are illegal.

I yield back.

Ms. ESHOO. I thank the gentleman. Now I would like to recognize the gentleman from Oklahoma, Mr. Mullin, 5 minutes of questioning.

Mr. MULLIN. Thank you so much.

Let me go back to the work requirements for just a little bit. Social Security is something that people paid into because they work and it is deducted out of their paycheck, and it is something they have earned. It is not an entitlement. It is something that they were required to pay into. And so, it is supposed to be there.

If I am not mistaken, the work requirement, it only targets individuals that are abled individuals—able-bodied individuals means there is no disability; there is not a reason why they can't work. It is able-bodied individuals that are single with no dependents. Isn't that correct?

Mr. AZAR. Able-bodied individuals. I don't know about the single. They would need to be able-bodied and you wouldn't have pregnant women, and I believe with all of our waivers they have ensured that there is an exclusion of, for instance, women who have young children.

Mr. MULLIN. Right, with no dependents, right.

Mr. AZAR. Trying to be very simple about it.

Mr. MULLIN. And the proposal that I looked at was able-bodied individuals with no dependencies.

Mr. AZAR. I would need to check if that is in the budget. That is certainly the theme of what we approved with waivers, has been ensuring that it is very common sense—individuals who there is no issue why they couldn't go do volunteer work or job training.

Mr. MULLIN. Right. And one of the things you were saying is you don't have the data because a lot of these able-bodied individuals, they were able to go get jobs and we have employer healthcare that could be covering them? There is no statistics out there to say one or the next. But if they dropped off, they probably went and got a job. Just like my employees, since I have had my very first employee back in '97, I provided healthcare for them. There is no need for them to be on there at that point, is that correct?

Mr. AZAR. Right. If the program has enabled—if the booming economy, the historic low unemployment rate, and this program has enabled individuals to secure jobs where they get employer insurance——

Mr. MULLIN. Right.

Mr. AZAR [continuing]. They don't need to be on Medicaid anymore. That seems to be a win for taxpayers and a win for them, a win all around.

Mr. MULLIN. Sure. I mean, listen, we have got 7.3 million-plus job openings right now. We are all competing, all employers like myself, we are competing for that employee, and benefits sometimes is what puts it over the top.

So I commend you for giving Arkansas and other States the ability to run their State as they see fit. Because we have got to put more people in the workforce. Otherwise, we are just going to be holding our economy back. So thank you so much for doing that and explaining it.

Let me turn my attention right now to 42 CFR Part 2. Are you familiar with that, sir?

Mr. AZAR. I am, yes.

Mr. MULLIN. As you know, last year, we worked pretty tirelessly here in the House, had hearings on it. We were able to get it out of this committee to the floor. It passed overwhelmingly with bipartisan support, 357–to–57. And unfortunately, it goes to the Senate and dies, which so many great things do. And so, we are now faced with the real possibility that we are costing people's lives at this point. We have doctors that aren't able to really see the full patient's history. And we understand that HHS may be working on some rules that could help soften this a little bit. Is that correct?

Mr. AZAR. So we have been very public about the fact that we have heard the concerns from you, from patients, from family members about——

Mr. MULLIN. Physicians?

Mr. AZAR. Physicians, law enforcement, just around the care for people with serious mental illness and substance use disorder, and are they getting what they need or are our regulations artificially standing in the way, while still trying to protect their privacy needs? So yes, we are working on proposals where we might try reform there, and also, of course, we appreciate the work of Congress in looking to reconcile Part 2 with HIPAA's requirements. And thank you for your leadership and work on this issue.

Mr. MULLIN. It is vitally important. I think it has hit home to most people around the country right now, especially with the drug abuse that is taking place and the amount of opioids that are out there on the streets. So I appreciate it. Is there anything that we

can help you with that HHS might be considering with 42 CFR Part 2?

Mr. AZAR. I would say certainly continuing Congress' efforts to look at reconciling Part 2 to HIPAA, to make sure that we have uniform standards. There is just so much confusion out there. And that is one of the things that I hear a lot, is with these privacy provisions, they are important privacy provisions, but you get a lot over-lawyering at hospitals and schools——

Mr. MULLIN. Right.

Mr. AZAR [continuing]. And otherwise, that basically tell people, no, you can't do this; no, you can't do that.

Mr. MULLIN. So true. Over-lawyering, I like that word.

Mr. AZAR. We try to correct it with FAQs. But, as you said, people's lives are actually at risk. If parents don't know their kid is suffering from an opioid addiction, that is a problem. If a patient goes back into the hospital and the providers don't know they are a recovering opioid addict, and they give them opioids and put them back on it in a procedure, that is a problem.

Mr. MULLIN. Right. I couldn't agree with you more.

I don't have time to get to my IHS questions, but I do want to work with you in getting some of the recommendations that have been recommended for IHS. It is in disarray, especially with what just came to the light with the physician, the pediatrician who has been abusing the patients for over 25 years, and there was a lot of missteps and opportunities to get him out. So we would love to work with you, and then, maybe see if we can implement just some standard SOPs through IHS and help modernize that system.

Mr. AZAR. I look forward to that. Thank you.

Mr. MULLIN. Thank you so much for your time.

I yield back.

Ms. ESHOO. I thank the gentleman. I would now like to recognize with pleasure the gentleman from California, Mr. Cárdenas, 5 minutes for questions.

Mr. CÁRDENAS. Thank you, Secretary Azar. Welcome to the People's House, and thank you for coming today, for the opportunity to ask questions, and more importantly, to finally receive some of the answers in full view of the American public.

There are certainly many topics to select today, but I want to spend some time focusing on an administrative policy that shocked the nation in the not-so-distant past, the policy of separating children from their families. Just recently, Secretary Nielsen testified before Congress on this same policy. But I am particularly interested to hear from you, Secretary Azar, considering your position leading the agency whose mission statement, as you said in your opening statement today, is: "to enhance and protect the health and well-being of all Americans by providing for effective health and human services by fostering sound, sustained advances in sciences underlying medicine, public health, and social services."

That being the case, I am interested to hear what, if anything, was done to protect these children and what is being done to address these ill effects on the children and their physical and mental condition. So my first question is, in cases where a parent is separated from a child because of criminal conduct or safety-related concerns, what evidentiary standard is required to justify the sepa-

ration? And what written guidance or policy, if any, is provided to your Department by DHS personnel making these determinations when it comes to the child's welfare and expertise that comes out of your Department?

Mr. AZAR. So we do not separate children.

Mr. CÁRDENAS. Correct, but, then, after that——

Mr. AZAR. Right, the decision to separate would be made over generally at DHS, and it would usually be CBP, sometimes ICE, over there.

I do know there are standards in the TVPRA, the Trafficking Victims Protection Act, that certain felonies—where a felony conviction is required there, but I would have to defer to DHS on what the contours are. We don't actually have a say in what the standards are necessarily that they would use.

We get children, and hopefully, we get as much information as possible why they are coming to us, either across the border or coming from a family unit.

Mr. CÁRDENAS. Thank you. Reclaiming my time, what I am trying to get at here is HHS is better qualified with expertise to deal with children, especially when they are separated from their family. DHS doesn't do that as well as you do. They turn them over to you, is that correct?

Mr. AZAR. That is correct, yes.

Mr. CÁRDENAS. OK. So the root of my question is this: that having been the case, and thousands and thousands of children having been turned over to HHS from DHS, is HHS engaged in advising DHS, so that they can make better decisions in the interest of the physical and mental health and well-being of that child?

Mr. CÁRDENAS. So I think that is a very fair question. I don't think we are fully engaged in the sense that they have their agents who have to make judgment calls on individual cases. They have their standards internally. I don't have those. I would, obviously, welcome the opportunity for HHS's child welfare professionals to provide advice and assistance to DHS in making those calls and setting standards for their SOPs. We may have done so. I apologize, if it is happening, I don't want to slight the process. But we would be very happy always to be engaged in that.

Mr. CÁRDENAS. And also, if HHS has been engaged in dialoging with DHS on these matters, if you could forward any of that to us, so we can understand the collaboration that is going on. So that, hopefully, should these separations ever continue—and it is my understanding that some children are still separated from their parents—that we would at least expect that in the United States of America, with all the resources and expertise we have, they would be minimizing the effects on these children's physical and mental well-being, adverse effects on their well-being. So if there is any information showing that that dialog is going on, to me, that is good. We would love to know what that is.

Mr. AZAR. Yes. Thank you. I mean, it is very important question and concern.

Mr. CÁRDENAS. Thank you.

Mr. AZAR. I appreciate your doing that.

Mr. CÁRDENAS. OK. And also, has HHS already instituted policies, protocols, and procedures to limit harm to children and their

families during these separations? In other words, since these separations have become so public and the numbers have grown most recently, has HHS changed or instituted new policies? Because we are in a paradigm shift right now with the numbers being higher than they have probably ever been before in American history.

Mr. AZAR. So we have dramatically improved the information-sharing practices, the IT systems between the Departments, so that we can track and make sure that we always have it very easy to keep the kids connected to the parent. We want to make sure they are in touch all the time. OK?

All of our children who are separated, in one form or another, they all are under mental health evaluation. Within 24 hours, they all get mental health evaluations. And I think we continue to learn how to deal with the particular traumas and mental health issues associated with being away from one's parents, whether back in Guatemala or in ICE custody. And so, I think we continue to try to be a learning organization and improve the quality of care for these kids while we are entrusted with them.

Mr. CÁRDENAS. My time has expired. Thank you, Madam Chair.

Ms. ESHOO. I thank the gentleman. Now it is a pleasure to recognize the gentleman from North Carolina, Mr. Hudson.

Mr. HUDSON. I thank the Chair.

Mr. Secretary, thank you for being here today what is almost three and a half hours now because of our vote. But I really appreciate you making yourself available for so much time.

Your leadership at HHS has been exemplary. And in general, I really appreciate the efforts you are making on behalf of the American people to make healthcare more accessible and more affordable. I want to put that on the record in case my questions today make it appear that I only have concerns.

But the first being that, on February 15th, I sent a letter with 22 of my colleagues, three of which are here today, to Commissioner Gottlieb in regard to recent proposal by the FDA on menthol cigarettes and e-cigarette sales in convenience stores. It was reported on March 1st that Commissioner Gottlieb presented his plan to the White House. Yet, the FDA has still not responded to serious concerns raised by colleagues and me about this proposal. Will you commit to getting FDA's response back to our letter before HHS moves forward with this proposal?

Mr. AZAR. We have different elements in what was publicly discussed by the Commissioner regarding both e-cigarettes, and then, there was a separate issue of menthol additives. And I am sorry you haven't had a response yet from Commissioner Gottlieb on that. I don't want to delay any process that may be underway, though, to take action, especially on this issue of the e-cigarette epidemic that we have. This is a real public health crisis with the access and the attractiveness to our teenagers and even middle school kids. And so, I don't want to do anything that might delay that process. It really is we are very, very concerned about this e-cigarette issue and what is happening to our kids.

Mr. HUDSON. Well, sure. And even if you share the goal of wanting to keep these out of the hands of kids, I think it is still important for us to understand the process and what kind of rules you are proposing. So we would appreciate a response.

Mr. AZAR. Anything that we do in this space would be subject, of course, whether it is rulemaking or good guidance practices, would be a public process with comment and feedback to make sure we are striking the right measure. We have to make sure with e-cigarettes—they can be a very important public health tool for getting adults who are addicted to combustible tobacco off of that. It is better to be on an alternative nicotine-delivery product than to be on combustible tobacco. But, at the same time, we can't allow it to become an on ramp to nicotine addiction or eventually combustible tobacco use by our middle school kids and teenagers, and just the utilization is soaring through the roof of those products there. So that balance, we will get feedback on that, and we will get input on that, on how to strike that right balance because it needs a balance.

Mr. HUDSON. I agree with that, and I think the industry, for the most part, except for some bad actors out there, and also, a concern about shipments from China of illegal product and counterfeit product, I think those are all things we need to work on, and I think we can agree to work on together.

But I think the data shows this is a safe alternative. And so, the process is flowing one way where we are seeing people come off combustible tobacco to the vapor-type products, and we are not seeing the reverse as the case. And so, I do think it is a public health improvement and would appreciate being in the loop as much as we can, as you move forward and look at that.

The second issue, I saw in the budget proposal HHS is proposing that FDA begin collecting user fees from the e-cigarette industry to support regulation of the products. In general, I think FDA has demonstrated how beneficial user fees can be, especially in the drug and device space, to provide much-needed resources that an agency responsible for regulating one-fifth of every dollar spent by Americans. In the tobacco space, however, FDA has not had the same relationship. The Tobacco Control Act has been the law for a decade. Yet, FDA has approved zero products through the Modified Risk Tobacco Product pathway. Is it your intention that these new resources, through a user fee, would begin a new period of approval at FDA?

Mr. AZAR. Yes, that is the purpose of extending the user fees to the e-cigarettes as alternative tobacco products, would be to provide us the resources to enable us to build out the regulatory architecture and approval processes for these products, which we have executed regulatory forbearance on to date.

Mr. HUDSON. Right. I appreciate that.

The last issue, changing course a little bit, the President has pledged in the State of the Union to eliminate new HIV infections by 2030, as a far-reaching and important goal for U.S. public health. The financial resources proposed in yesterday's budget release speaks to the President's commitment to improving diagnosis, testing, and linkage to care for HIV. I commend the President for taking such a monumental effort and hope to do what I can to support his plan.

Given this goal, though, I must ask about a problem a number of my constituents that are HIV patients have raised with me. Medicare Part D provides for protected classes where Medicare

must generally cover all drugs within that class. With HIV drugs being one of the current six classes—I am running out of time here—but my basic question is, how does HHS intend on balancing the goal of introducing cost-control measures such as prior authorization and step therapy with elimination of new HIV infections by maintaining patient adherence to working drug regimens in the HIV space?

Mr. AZAR. I am happy to get back to you in writing on that, for the chairwoman, if that is OK.

Mr. HUDSON. Sorry about that. An important issue, but I would appreciate the response.

Mr. AZAR. It is. It is a very important issue. Thank you.

Mr. HUDSON. Thanks.

Ms. ESHOO. I was expecting a long answer from the Secretary. He is able to get back to you.

I thank the gentleman for his questions. And now, I have the pleasure of recognizing the gentleman from Vermont, a high-value member of this committee, Mr. Welch.

Mr. WELCH. Thank you very much.

Secretary Azar, thank you so much for being here.

You know, there are two things about healthcare. One is access related to cost, and the other is cost. There are two ways to bring down the overall cost of healthcare, restrict access or lower cost. And I am opposed to cutting access, but I am determined to work with you on your efforts to lower costs.

And I want to say something. I believe that President Trump on prescription drug prices is intent on bringing down the cost. I believe you are. I thank you for your meeting. I believe you are committed to doing that. I know Chairwoman Eshoo is, and I believe Ranking Member Burgess and our ranking member, the entire committee who is here, Mr. Upton is. So we have got a chance.

A couple of things. You have got some good things in the budget. It calls a statutory demonstration authority for up to five State Medicaid programs to test the closed formulary. And we can address that later.

It proposes to authorize you to leverage Medicare Part D plans in negotiating power for certain drugs covered under Part B. So I support those.

And the proposals you have made in the budget, they are in the budget, yes, about opposing delay tactics, where I think some of my colleagues like Mr. Carter, who has got a lot of experience in this, are totally supportive. My goal is for us to do those things, ideally do them together, because I think that will increase our prospects of success in the Senate, and a bipartisan approach on that would really be helpful.

So I do have a couple of questions, just to see your position on a few other things. You do support, as I understand it, ending pay for delay. Is that the case?

Mr. AZAR. We do. In fact, our budget has a unique pay-for-delay provision in it, in that if you do a pay-for-delay agreement, you would actually be penalized in the Medicare Part B system, yes.

Mr. WELCH. Right, and that is really good. And you want to curb the REMS abuses?

Secretary AZAR. Absolutely do. So the CREATES Act, I am working with you on that.

Mr. WELCH. Right. And the product hopping that has been occurring is another way. Are you opposed to that as well?

Mr. AZAR. I want to make sure I am understanding the product——

Mr. WELCH. It is the abuse of citizens—it is product hopping, the citizen petitions——

Mr. AZAR. Oh, the citizen issues, yes, we want to crack—yes.

Mr. WELCH [continuing]. And other forms of evergreening.

Mr. AZAR. Yes, we want to crack——

Mr. WELCH. I mean, that is just manipulating the market.

Mr. AZAR. We want to crack down on any forms of manipulation or evergreening of patents and exclusivity beyond what the original deals were, absolutely.

Mr. WELCH. All right. And the President also indicated that he wants to require the drug companies to disclose the price of the products they are advertising——

Mr. AZAR. Yes.

Mr. WELCH [continuing]. Something Jan Schakowsky and our committee is championing.

Mr. AZAR. Right.

Mr. WELCH. Now, on this question of negotiation, you raised earlier what is the dilemma. If you want to get real savings, you need a strict formulary, and that restricts patient choice. But if you have no formulary, the cost is so highs it restricts patient access.

And the way we approached this in Vermont is we did have a formulary created by physicians and pharmacists like Mr. Carter, but there was a failsafe. So that if the doctor said, "Peter, you just need the other drug," that would get me outside of the formulary.

Are you open to exploring some ways to try to address I think the shared concern about not having a formulary restrict appropriate access, but to get the benefits of lower costs that would spread out across the system for all of us?

Mr. AZAR. So I agree with you that the simple fact is, if you don't have a formulary and the ability for someone, the middleman, the pharmacy benefit manager, to control and move share, they can't jam pharmaceutical companies for discounts and rebates. They need power.

Mr. WELCH. Right.

Mr. AZAR. They have got to be able to move. That is what our proposals in Part D and Medicare Advantage have been about, is how do we create power against the pharma companies to get discounts. But with the competition of D and MA, you can still choose. If the patient doesn't like the approach that one plan is making, they can choose a different——

Mr. WELCH. Right, but there has got to be that balance.

Mr. AZAR. Yes, these are difficult calls, absolutely.

Mr. WELCH. Right, but what I am trying to say here is that we share the desire for the patient to get what the doctor thinks——

Mr. AZAR. Yes.

Mr. WELCH [continuing]. The patient needs. But we want to get overall cost savings. So let's work together to try——

Mr. AZAR. Absolutely.

Mr. WELCH [continuing]. To address that concern.

The other thing is high-cost specialty drugs don't have any competition, and the PBMs don't have any leverage, what you were just talking about, to use competition to lower net prices. Would you be open to negotiation to lower drug prices in these cases where competition simply doesn't work?

Mr. AZAR. So I am happy to work with you on ideas that keep the patient at the center. We propose foreign reference pricing in Part B——

Mr. WELCH. Right.

Mr. AZAR [continuing]. Where we don't have a competitive mechanism for pricing. And we are happy to look at different approaches that create proxies for effective pricing there.

Mr. WELCH. OK. I yield back.

But thank you very much, Secretary Azar.

And I hope, Madam Chair, that we are able to make some concrete progress with our Republican colleagues on this.

Ms. ESHOO. I agree with you.

Now I would like to recognize the gentleman from Georgia, the patient Mr. Carter, for 5 minutes of questioning.

Mr. CARTER. Thank you, Madam Chair.

And, Mr. Secretary, thank you for being here.

Mr. Secretary, as you know, for the past four years, I have been the only pharmacist currently serving in Congress, and I currently remain the only pharmacist.

Prescription drug prices have been something that is extremely important to me and something that I have concentrated on. And I want to thank you for your work, and thank you, and your staff, in particular, particularly John O'Brien, who has done an outstanding job in helping us.

This is something you are familiar with. You are familiar, having been a CEO of a pharmaceutical manufacturer, and that certainly gives you a unique insight. But I have dealt with it in over 30 years of practicing pharmacy and seeing the evolution of the middleman, of the pharmacy benefit managers, the PBMs, and the abuses that I feel like that they have had over the years.

And now, the administration is finally addressing that. I can't tell you how much that means. And, Mr. Secretary, I feel like this will be your legacy, and I think it is an honorable legacy. And I want to thank you for that, and this administration as well, as was mentioned. This administration has made this a top priority, and I think it will be one of their legacies. There could not be a more honorable legacy, in my opinion, after having practiced pharmacy for 30 years and seeing the impact that high prescription prices has on people.

I have seen it at the front counter. I have witnessed it. I have seen senior citizens have to make a decision between buying medicine and buying groceries. I have seen mothers in tears because they couldn't afford medications for their children. This is very serious and something that is bipartisan.

Representative Schrader mentioned earlier a bill that we are working on in a bipartisan fashion, the BLOCKING Act, that will be brought up next week. That is something that is very important.

We have to do away with the abuse of the generic manufacturers to delay this system like this.

Two things have been proposed by HHS. One has to do with DIR fees. DIR fees are atrocious. Two weeks ago, I got a text from a pharmacist who showed me where they had been charged, his pharmacy has been charged over $300,000 in DIR fees for the year. Only this morning, I got another text from a pharmacist who owns seven drugstores, $500,000 in DIR fees. Mr. Secretary, you can't stay in business in that kind of business model. It is just not feasible.

Moving the discounts to the point of sale, I have always said that the most immediate and most significant impact we can have on prescription drug pricing is to have transparency. This will help bring about transparency. Only this morning, United Healthcare announced that they are going to move this into the private sector as well. This is exactly what we need. This is exactly what we have been fighting for. That is why I want to thank you for this.

I find it interesting that, in the rebate rule, that HHS and OIG, they have asked for three different scores. That is a little bit unusual, isn't it? Can you explain what has come about with that?

Mr. AZAR. Yes, absolutely. So the reason there are multiple scores in the proposed rule—and we wanted to be transparent about it, so we published them—is our actuary from CMS came out with a score. And you are trying to predict the behavior of private market actors, and I am sorry, actuaries are well-meaning, but they don't predict how businesses and private actors will behaviorally change. You all see that with CBO and so-called lack of dynamic scoring around legislation. We have the same issue on regulations.

And so, we wanted to get these different perspectives of what might happen in the marketplace. I firmly believe that, if we can work together to get this rebate rule out, we will bring $29 billion of savings to seniors at the point of sale at pharmacies, starting January 1st. And I believe that we will keep premiums stable in Part D because it is a highly-sensitive marketplace to premium, and I believe the Part D plans will manage that effectively. I think it will get list prices down. It is, I think, the best tool we can have to completely change how drugs are priced in this country for the benefit of our citizens.

Mr. CARTER. I couldn't agree with you more, Mr. Secretary. I just thank you for that and thank you for your efforts in this. And I hope you will continue on with this. This is exactly the route we need to be taking and exactly the direction we need to be having.

Moving very quickly to the 340(b) program, look, we don't want to end the 340(b) program. It is a good program, but it needs some guardrails on it, and we understand that. And that is what we are trying to do, is just tighten it up, get some accountability, some transparency, make sure it is going where it was supposed to be going. We are not saying that anybody is cheating. We are just saying that it is not being done in the way that we intended it to be done. Your comments on that?

Mr. AZAR. We would love to be a partner with Congress and this committee on how we can bring that kind of transparency, oversight, and keep 340(b) effective for the purposes it was intended.

Mr. CARTER. Thank you, Mr. Secretary. Again, I want to thank you for your work, thank your staff for their work, the administration for this. This is about the patient. This will bring about lower cost for patients. It will bring about more accessibility, more affordability, and better healthcare in America. Thank you, Mr. Secretary.

Mr. AZAR. Thank you.

Ms. ESHOO. I thank the gentleman. I now am pleased to recognize Mr. Ruiz from California for 5 minutes of questioning.

Mr. RUIZ. Thank you. Thank you, Madam Chair.

Secretary Azar, I am an emergency physician. And from the Coachella Valley farm worker community where I grew up to the hospitals where I worked as an emergency medicine physician, to the alleys and parks where I practiced street medicine, I have seen so many examples of how inadequate access to healthcare has devastated families, communities, and local economies.

Passage of the Affordable Care Act, including Medicaid expansion, has dramatically improved access to care. According to California Healthcare Foundation, Medicaid enrollment in the Inland Empire region of California, where my district resides, increased by 57 percent in less than two years after Medicaid expansion.

Instead of enacting policies that would shore up healthcare coverage, this administration has worked to undermine the ACA. In addition to selling junk health plans, dramatically rolling back enrollment outreach efforts, and refusing to make cost-share reduction payments, this budget continues to try to repeal the ACA, turns Medicaid into a block grant program, and imposes barriers like Medicaid work requirements.

In my district and across the nation, the effects of the budget would result in increased premiums, increased out-of-pocket costs for consumers, and more people without insurance. According to data from Georgetown University, in my district 1 in 4 adults are covered by Medicaid and 58 percent of children are covered by Medicaid or CHIP. Cutting this coverage is unacceptable, and I will stand up for my constituents and the millions of Americans across the country that rely on these programs.

In addition, Secretary Azar, I would like to discuss the administration's final rule on the Title X family planning program issued late February that would make it more difficult to access essential services like birth control, HIV and STD testing, women's and men's healthcare, and pregnancy testing for individuals in underserved areas. This rule would directly hurt four Title-X-funded health centers in my district and thousands of my constituents who are served by them, often in underserved areas.

Let me explain. The final rule prohibits Title X providers, like those in my district, from referring their patients for abortion services, despite being allowed under current law and even if the patient specifically requests it. Never mind that Title X already cannot fund any abortion. But that means doctors won't be able to provide the best medical advice to their patients.

It also requires all Title X grantees to have strict financial and physical separation from any activities that fall outside the program scopes. That means a facility where 97 percent of the services are for prevention, cancer screenings, oral contraceptives, STD

screenings, would not be able to receive Title X funds. They would have to, in order to receive these funds, build an entirely different facility, which is costly, cost-prohibitive, and they wouldn't be able to do that. What most likely will happen, if this is allowed to go forward, is these clinics will shut down, making breast exams, pap smears, and other critical healthcare services unavailable for those who need it.

So I want to get your sense, Secretary Azar. Do you believe that the Title X program has successfully served as a source of critical, preventative care for patients?

Mr. AZAR. The Title X program is very important. It provides important resources, contraceptive and comprehensive family planning for individuals. And that is why we fully funded it.

Mr. RUIZ. Great.

Mr. AZAR. But we also want to ensure the fiscal integrity of the program.

Mr. RUIZ. So let me ask you, then why has the administration chosen to move forward with changes to the program that would drastically alter how the current program operates and how patients can receive care?

Mr. AZAR. By definition, in the example you just gave, Federal taxpayer money is being used to support the provision of abortions. It is subsidizing that. If they wouldn't be able to run that business independently, absent our Title X money, it means that we are subsidizing that.

Mr. RUIZ. But those monies cannot go towards abortion.

Mr. AZAR. Then they should be able to separate——

Mr. RUIZ. Those monies help for breast exams, pap smears, and other preventative services. That is what they use those monies for. It is illegal for them to use that money for abortions.

Can you explain why you believe that withholding necessary information from patients, from doctors, even when specifically requested, even if a patient specifically requests, "What are your referrals? Where can I go if I am considering an abortion?", et cetera, is appropriate under medical ethics?

Mr. AZAR. So under the final rule, we allow, as the statute allows, non-directive counseling, including related to abortion, and the provider is allowed to provide a list of service providers, including those that do provide abortions, but they are not allowed to just pick up the phone and actually directly refer them over.

Mr. RUIZ. OK. Do you believe this rule will increase access to care for patients served by Title X?

Mr. AZAR. I think we actually may see an influx of additional providers willing to come in and be part of Title X. And these are fiscal integrity provisions——

Mr. RUIZ. So in terms of access, in terms of a young woman's ability to get their pap smears going to an underserved area where the only providers are those receiving Title X funds, 98 percent of the services are for oral contraception, family planning, counseling, and breast exams, as well as pap smears, et cetera, for cancer prevention, you think by defunding them or making it hard for them to function in their clinic, when they are the only clinic in that community, is going to increase healthcare access for women?

Mr. AZAR. Not allowing them, through the Title X program affiliate, to support abortions——

Mr. RUIZ. I would take that as a——

Mr. AZAR [continuing]. Shouldn't be a problem. It shouldn't impact their operations.

Mr. RUIZ. But it will. That is the whole point of this conversation, is that it will. It creates barriers for those individuals who provide 98 percent of their services for basic primary care to deliver on those services.

Ms. ESHOO. The gentleman's time has expired. It is an important conversation. Thank you, Mr. Ruiz.

I would like to now recognize the gentleman from Montana, Mr. Gianforte.

Mr. GIANFORTE. Thank you, Madam Chair.

Secretary Azar, thank you for coming before the committee today.

I want to note for the record that, after hours of testimony, you look fresh and energetic. I appreciate your endurance.

I have four topics I want to touch on quickly, if I could. Many in Montana, especially our rural communities, struggle with meth and opioid abuse. The rural nature of Montana makes it challenging to ensure these individuals have access to treatment. The President's budget request $120 million for the Rural Communities Opioid Response Program, which supports treatment and prevention of all substance use disorders in the highest-risk rural communities. Could you touch briefly on how this program will help focus resources on reducing meth and opioid abuse, particularly in underserved communities?

Mr. AZAR. Absolutely. Thank you.

And we are very concerned about not just the opioid issues, but any type of substance use disorder, especially in our rural areas. So that is why the program, Congress, on a bipartisan basis, enacted with the Rural Communities Opioid Response Program last year is so important. In '95, one year, our core planning awards were made to support rural communities to identify opioid use disorders in their communities and develop plans to resolve these issues. And we are going to introduce additional awards in FY 2019 that we hope will yield large-scale organizational and infrastructure improvements at the rural and State level. And we also were going to develop a program just for rural and critical access hospitals, as well as Medicaid-certified rural health clinics, in an effort to expand MAT in rural communities.

Mr. GIANFORTE. Yes. OK. Thank you. And our office stands ready to help——

Mr. AZAR. Thank you.

Mr. GIANFORTE [continuing]. Particularly with rural.

I want to switch topics. Suicide is among one of the leading causes of death in the United States, exceeding the rate of death for car accidents. Unfortunately, Montana has the highest rate of suicide per capita in the country. What is the administration doing to help us reduce the deaths from suicide?

Mr. AZAR. Yes. So on serious mental illness and mental healthcare, we have invested, I believe it is over a billion dollars in the budget that is dedicated towards serious mental illness. Sui-

cide, as you know, is the 10th leading cause of death for adults, the second leading cause of death for our youth. As SAMHSA, our largest mental health program, the Community Mental Health Services Block Grant, actually provides formula funding to enable States for serious mental illness and emotional disturbance. The Community Mental Health Services Block Grant is funded at $722 million. Our total mental health budget is actually $1.506 billion just in SAMHSA. And our suicide prevention program is $74 million. And another very interesting program is the Assertive Community Treatment for Adults with Serious Mental Illness. That is actually increased to $15 million, allows a much more interactive approach to individuals who are facing risk of mental illness and suicide.

Mr. GIANFORTE. OK. I appreciate your attention there. It is critically important to us back in Montana.

Switching topics again, 18 percent of Montanans are over the age of 65. Your budget would allow these seniors to expand their ability to have health and medical savings accounts. These are options that are widely supported and encourage people to save for their healthcare needs. Can you just briefly detail how this works and why it is a good idea?

Mr. AZAR. So what we want to do is expand the ability of individuals to use tax-free savings to assist them in building the healthcare that they want. So for instance, in our health savings account proposal, we want to allow you to save more money. We want to allow the health savings account to be used not just for high-deductible plans, but really any plan that achieves a 70 percent actuarial evaluation. It is a technical insurance term. But it basically would allow HSAs to be used more frequently, expanding the use of, I think the old Archer, the Medicare Savings Accounts, to expand. It has been a fairly small program. We want to just create more options, especially in rural areas, and to take the money and be able to seek out alternatives that meet your needs.

Mr. GIANFORTE. My last question, and you will be happy to hear it is a yes/no question, an easy one. Montana farmers grow a diverse range of crops. Last Congress I signed onto a bill that would allow industrial hemp farming. And the bill was signed into law as part of the farm bill. Now that hemp is legal, I am glad that the FDA has begun thinking about how to regulate CBD. Dr. Gottlieb had stated that the FDA planned to hold a public meeting on CBD regulation in April. Is the FDA still planning on having this hearing now that we have had a change in leadership?

Mr. AZAR. Yes.

Mr. GIANFORTE. OK.

Mr. AZAR. Yes.

Mr. GIANFORTE. So that is still going to occur?

Mr. AZAR. It is. It is an important issue. We have got to figure out how we deal with CBD oil and the constituent element issues around marijuana. So absolutely, yes.

Mr. GIANFORTE. Great. Well, I want to thank you once again for your hard work. We have to work together across the aisle to get healthcare costs down and maintain access, and I appreciate your leadership.

And with that, I yield back.

Ms. ESHOO. I thank the gentleman. Now it is a pleasure to recognize the gentlewoman from New Hampshire, a new member of Energy and Commerce and the Health Subcommittee, Ms. Kuster.

Ms. KUSTER. Thank you very much, Madam Chair.

And thank you, Secretary Azar, for your patience with us. This has been a long day for all of us.

The ACA helped millions of Americans enroll in affordable comprehensive coverage. The law, Section 1332, provides States with the flexibility to experiment with health reforms, but the law makes clear that States seeking 1332 waivers must provide comprehensive affordable coverage to a comparable number of residences under the ACA.

I have a few yes-or-no questions on 1332 waiver guidance. Simply yes or no, are you aware that the guidance could substantially raise costs for Americans with preexisting conditions?

Mr. AZAR. The guidance is guidance. We would have to see an individual request from a State. Nothing in the guidance changes the ACA. It just says that to States, please come in with plans if you want to enroll.

Ms. KUSTER. Well, these would be preexisting conditions. If they did not have coverage, would you agree that it would be more expensive?

Mr. AZAR. We are not able to approve any plans that waive preexisting conditions coverage under 1332. I think that is rock solid, is my understanding.

Ms. KUSTER. Are you aware that the guidance could substantially increase consumers' out-of-pocket costs and monthly premiums?

Mr. AZAR. The guidance cannot do that. A State plan would have to come in with a request, and that would certainly be something that we would evaluate as part of that process. The guidance is simply saying to States, you can come in with plans; we will look at them. There is no commitment to approve——

Ms. KUSTER. Well, would you acknowledge that insurance companies could substantially reduce the benefits that the product would cover?

Mr. AZAR. I don't know that, under 1332, we are able to waive the essential benefits coverage. I would have to check on that to get back to you on that.

Ms. KUSTER. Do you think it is appropriate to spend taxpayer dollars on junk insurance plans rather than comprehensive coverage for Americans?

Mr. AZAR. So one Washingtonian's view of junk could be to somebody in rural New Hampshire their lifeline of some form of insurance that they couldn't afford. Twenty-nine million Americans still are lacking insurance, and we are trying to make other options available for people. Short-term, limited-duration is one, expansions to HRAs. No one has talked about this, which could actually add 10 million people into the ACA exchanges through the HRA regulation that we have proposed. So we are just trying to make more and more options available, so people can choose——

Ms. KUSTER. Well, can you explain why HHS has sidestepped the full rulemaking process in promulgating its guidance?

Mr. AZAR. Yes. The 1332 guidance was promulgated actually using, I believe, the identical processes that the Obama administration used in putting out their 1332 guidance.

Ms. KUSTER. Did your Department's general counsel provide a legal opinion on the guidance, including on the statutory guardrails and whether the guidance should be subject to the APA?

Mr. AZAR. I don't know, but I presume so, because any action coming out would normally be subjected to legal review. But it was put out exactly the same as Obama put out.

Ms. KUSTER. Will you commit to sharing this analysis with the committee? I am focused on your administration. Would you commit to sharing this analysis with the committee?

Mr. AZAR. We will look at it and determine if it is appropriate to share in terms of privilege.

Ms. KUSTER. And you will get back to the committee on that?

Mr. AZAR. Absolutely.

Ms. KUSTER. And the statutory text is clear that a State waiver must meet these four guardrails specified in the law. Do you agree that any State waiver has to meet the guardrails specified in statute in order to be approved by your Department?

Mr. AZAR. Well, of course. We have to act consistent with the statute, and we will do so.

Ms. KUSTER. And if a State submitted a waiver application that would provide less comprehensive or less affordable coverage to its State residents, would your Department approve it?

Mr. AZAR. I think we laid out in the guidance an alternative way of looking at the comprehensiveness aspects. What we found was that the previous administration had so interpreted the comprehensiveness aspects that no States were actually, whether red, blue, whatever, were willing to come in with requests because it was so confining and lacking in flexibility, and we thought violated the 1332——

Ms. KUSTER. Well, will you commit to upholding the law and only approving 1332 waivers that meet the guardrails specified in the statute?

Mr. AZAR. We certainly will only do so to meet the guardrails in the statute. We may in candor, though, you and I, our administrations may differ on what it means in terms of, what it may mean in terms of the comprehensiveness.

I just want to correct something, if I could. Essential health benefits are actually waivable in the guidance. I misstated that. I misrecollected. So I do want to clarify. I have been informed that essential health benefits would be waivable, and that is why it opened the door to short-term, limited-duration plans.

Ms. KUSTER. OK. I am going to switch gears now, if I could reclaim my time.

Mr. AZAR. Sorry. Sorry for the error there.

Ms. KUSTER. Is it true that your request in the budget cuts $52 million from the SAMHSA mental health programs?

Mr. AZAR. There may be a part of it that does, that does cut a part of the program that we find less effective.

Ms. KUSTER. And $31 million from substance abuse treatment programs?

Mr. AZAR. Well, I mean, we can play these games. There is $1.5 billion of serious mental illness and mental health programs within SAMHSA that we are requesting funding in the budget.

Ms. KUSTER. But, for example, the ONDCP has been cut completely? Or that is funded?

Mr. AZAR. First, ONDCP is not part of SAMHSA. What happened is, the one program which SAMHSA already administered, I believe the funding for that was actually moved over to SAMHSA to regularize how that is administered. I believe that was——

Ms. KUSTER. I am sorry, my time is over. I am just trying to follow this bouncing ball, because I think SAMHSA actually is losing over $160 million for this program, with this trick of moving the ONDCP funding.

But I yield back.

Ms. ESHOO. I thank the gentlewoman. I am now pleased to recognize the gentleman from Missouri, Mr. Long, 5 minutes for questioning——

Mr. LONG. Thank you, Madam Chairwoman. Thank you.

Ms. ESHOO [continuing]. And a few seconds of something lighthearted.

Mr. LONG. I'm sorry?

Ms. ESHOO. And a few seconds of something lighthearted.

[Laughter.]

Mr. LONG. I will tell you, it has been a long day. I will tell you that. I don't know how much of that I have got in me right now.

But I had another subcommittee hearing most of the day, why I was late getting in here, and I hope I don't repeat anything that was said earlier.

But, Secretary Azar, I want to thank you for being here today. And I understand you have been here some four hours now. I want to commend you for all your hard work from all of us that you do.

And I also want to recognize President Trump for proposing a fiscally-responsible budget which reflects the reality of the Budget Control Act. Can you detail what your priorities are and how you worked to restrain spending, in light of the current law?

Mr. AZAR. Thank you very much, Congressman.

As you know, we are trying to submit a budget that complies with the cap's agreements. We have submitted a budget that tries to comply with the caps, the budget caps, that the Congress and President Obama actually put into statute. And so, to do that, it requires tough choices.

So the prioritization that we used in looking at our budget, working with OMB and the White House, has been, first, fiscal discipline. So make sure that we are contributing across the board to the overall functioning of the budget. The second is ensuring responsible stewardship of taxpayer dollars. We actually eliminate 90 programs that we find to be ineffective or less effective than others, supporting and prioritizing direct service delivery. So where are we actually providing healthcare or human services to people as opposed to capacity-building, and providing flexible funding to States and others, rather than just categorical programs. So those would be some of the ways.

Obviously, there are some other areas like opioid funding that we have prioritized, ending the HIV epidemic that we have really prioritized funding, and bioterrorism preparedness, of course.

Mr. LONG. Yes, I always say that, of the 435 congressional districts, there is 435 of us that will swear that our district has the worst opioid epidemic in the country. So it is a huge problem.

As you are well aware, the Community Health Center Fund expires on September 30, 2019, and the budget proposes to continue funding them at $4 billion in mandatory resources for each of the fiscal years 2020 and 2021. How do Community Health Centers serve as a gateway to integrated care for individuals for mental illnesses and substance disorders?

Mr. AZAR. The Community Health Center Program is absolutely vital to our efforts around substance use disorder, mental health, primary care provision. So, as you mentioned, the budget that we have on the Health Center Program, in that budget, in the FY 2020 proposal, we continue the $544 million of ongoing annual investment and expanded mental health and substance use disorder services related to the treatment, prevention, and awareness of opioid abuse, which were initially awarded in FYs 2016 through 2019.

Mr. LONG. OK. Community Health Centers are increasingly using telehealth, which is very important to rural districts like mine, to better meet patients' needs, especially in those rural areas where residents face long distances between home and healthcare providers, and sometimes it is just not worth it. The elderly don't want to drive 70 miles to get services, or 100 miles, or whatever the case may be. Do you see the value in allowing more use of telehealth in health centers?

Mr. AZAR. I am passionate believer in telehealth, especially as part of how we need to bring services to rural areas and other underserved areas. The HRSA Telehealth Network Grant Program is part of that, which provides funding. But we want to keep working with Congress to find other ways to help address the rural healthcare crisis in the country and the underserved crisis. Telehealth has to be a part of that.

Mr. LONG. HHS developed the reimagine HHS plan to increase the efficiency of the Department. Could you talk a little more about this plan and how it can improve the functioning of HHS's programs?

Mr. AZAR. Thank you very much. So with Reimagine HHS, what we did is, it is essentially taking the President's management agenda and looking at this $1.3 trillion agency with 80,000 people, and we talk to our career people. I have got just tremendous respect over the two decades that I have been around HHS and the career officials we have at our Department. And we did a bottom-up process asking them, if you could run HHS differently, what would you do differently?

And so, first, we want to make HHS the best place to work. We want high employee engagement. We want people to feel very fulfilled in the important mission of our work.

We want to improve NIH's operations. So part of Reimagine HHS is to create, essentially, regional hubs within NIH where we can optimize several platform services there, not a single service pro-

vider for all of NIH, but create some collaborative hubs that will save money and, hopefully, improve efficiency and improve quality.

We want to reform our acquisition processes, so that we can buy smarter.

Just a couple of examples of good common-sense ways to run a massive department better using the genius of our own career people.

Mr. LONG. OK. I am going to have to stop you there. I don't have any time left, but if I did, I would yield it back.

Ms. ESHOO. That was generous.

[Laughter.]

He is known for his generosity.

The patient gentlewoman from Illinois, Ms. Kelly——

Ms. KELLY. Thank you, Madam Chair.

Ms. ESHOO [continuing]. Robin Kelly.

Ms. KELLY. Thank you.

I think we can all agree that, regardless of political affiliation, we should all want to ensure that children have access to healthcare. After years of decline, recently, the number of uninsured children in this country has been significantly increasing. In 2017, the first year of the Trump administration, according to the American Community Survey conducted by the Census Bureau, the number of uninsured children increased by 276,000. And according to HHS's data, in 2018, the number of children enrolled in Medicaid and CHIP declined by nearly 600,000. There is no data showing that the number of children enrolled in private health insurance coverage increased by 600,000 over the same period. So it is pretty clear that hundreds of thousands more children will be uninsured.

Since all of this is happening on your watch, I have a couple of questions. Your CMS Administrator, Seema Verma, likes to say that Medicaid will always be around for those who truly need it. But, according to these numbers, there are a significant number of children who are losing health coverage under Medicaid and CHIP, and many children going uninsured.

Secretary, just yes or no, are low-income children included in your definition of those how truly need Medicaid?

Mr. AZAR. Absolutely. They are one of the core populations of Medicaid, of course, as well as our SCHIP program. Absolutely, the low-income children are a core of that, of the traditional—I mean, that is part of what we want to do, is really make sure we are not losing our focus on some of the core populations Medicaid was built for, and low-income children, absolutely.

Ms. KELLY. What does the President's budget propose to stem the increase and return uninsurance rates among children to the historically low rate that the President inherited in 2016?

Mr. AZAR. So we haven't, to my knowledge—and if we have, I would like to know; if there is something that we have done in regulation, or otherwise, in Medicaid that is impacting that and access to Medicaid for low-income children, please let's talk about that.

Ms. KELLY. OK.

Mr. AZAR. I would like to know that.

Ms. KELLY. OK.

Mr. AZAR. And then, we can build interventions around that. So I would like to solve the problem. I am glad you are highlighting this for my attention, and I am happy to work with you on that.

Ms. KELLY. OK. We would love to.

In some States, you have approved waivers to take away health coverage from parents who failed to work a certain number of hours each month. We know from research that, when parents have health insurance, their children are more likely to be covered. Another yes-or-no question. Can you guarantee that no children will be affected by their parents' coverage loss in those States?

Mr. AZAR. Children should not be impacted by any of the work requirement or community engagement programs that I am aware of in terms of the waivers that we have granted. Even if the parent were to come off, they would have been qualified as able-bodied under Medicaid expansion populations. I want to double-check on that, though, if I could get back to you there. I would be very surprised if that would impact child coverage, but I just want to make sure that I am being accurate with you. If I could get back to you on that, to be sure——

Ms. KELLY. I would appreciate it.

Mr. AZAR [continuing]. If you don't mind?

Ms. KELLY. And just changing a little bit, I was asked by some young people to ask this. Menthol cigarettes have had a particularly devastating impact on young African-Americans. Seven out of ten African-American youths smoke menthol cigarettes. You prohibit tobacco companies from using cherry, strawberry, and other flavors to attract kids. It has been four years since the FDA announced that it would issue a proposed rulemaking on menthol. Can you assure me the FDA will soon issue a proposed rule to prohibit menthol cigarettes?

Mr. AZAR. So I share your concern about menthol as an additive in tobacco. I share the public health concern about attractiveness, especially in the African-American community, and some of the data that we've seen around possible fostering of addiction or attractiveness there. We want to make sure we are gathering all the public health information on this. And so, I do anticipate that we continue to run processes to learn here. I don't know that the first step would be a regulatory action as opposed to initiating a process to make sure we get—we have to build the public health base very solid with evidence on rulemakings in that space.

But I know your concern. I share your concern. Commissioner Gottlieb shares that concern. He addressed that in some public comments he made recently. And so, we want to keep moving on that. But I don't know the exact mechanism that the next one would be.

Ms. KELLY. I will report your answer back.

Mr. AZAR. Thank you.

Ms. KELLY. I yield back the rest of my time.

Ms. ESHOO. OK, let's see. Now I would like to recognize the gentlewoman from California, a new member of the full committee and this subcommittee, Ms. Barragán.

Ms. BARRAGÁN. Thank you, Madam Chairwoman.

Mr. Azar, thank you for being here today.

Have you had a chance to visit the Homestead detention facility in Florida?

Mr. AZAR. I have, yes.

Ms. BARRAGÁN. When was that?

Mr. AZAR. It would have been about a month or a month and a half ago that I visited.

Ms. BARRAGÁN. Do you remember when you visited the facility, roughly, how many children were being housed there?

Mr. AZAR. Actually, I may have that information. It should have been relatively stable. I don't have the actual census in front of me now. I don't want to speculate on a number.

Ms. Barragán OK.

Mr. AZAR. I just don't have that in front of me at the moment.

Ms. BARRAGÁN. And the Homestead facility, it is a temporary shelter, is that correct?

Mr. AZAR. It is what we call a temporary influx shelter. What we do, because the inflow of unaccompanied alien children across the border is so unpredictable, we build permanent shelters.

Ms. BARRAGÁN. Right, but this is a temporary one?

Mr. AZAR. And we have temporary influx to give us flux capacity, but we keep working to try to add permanent capacity, because we would much prefer permanent capacity to temporary influx, absolutely.

Ms. BARRAGÁN. OK. So when it is temporary, there is no requirement to get a license from the State of Florida, is that correct?

Mr. AZAR. So the temporary influx shelters are not subject to State licensure, but they are subject to all of ORR's regulatory requirements, yes.

Ms. BARRAGÁN. Well, the permanent facilities have different requirements, is that right?

Mr. AZAR. A permanent facility actually does have to be licensed by the State——

Ms. BARRAGÁN. OK.

Mr. AZAR [continuing]. As a temporary influx to be——

Ms. BARRAGÁN. I just want to make sure we are clear. The permanent facilities actually do have regulations that are followed. The temporary ones don't have to follow those same regulations as the permanent ones?

Mr. AZAR. They do not have to be State licensed. They still have to follow all of the ORR's regulatory and practice requirements for——

Ms. BARRAGÁN. Right, and they are different. I just want to note for the record——

Mr. AZAR. And they are subject to Florida's regulatory——

Ms. BARRAGAN [continuing]. That they are different, and a temporary has different requirements than a permanent one?

Mr. AZAR. That is correct.

Ms. BARRAGÁN. OK. Why are we running emergency unlicensed facilities when there has been no unexpected surge of unaccompanied minor arrivals?

Mr. AZAR. No unexpected surge? We have had 120 percent unaccompanied alien children coming into this country in February over last year. I am sorry, we are in a crisis. We——

Ms. BARRAGÁN. There is no surge, though, sir. If you take a look at your own numbers, in February 26, 2019, I was told there were 1600, per your own—actually, it is your own release that I have here. Sixteen hundred unaccompanied minors were housed there. There have been many, many more in the past, and there has been no surge to really need a temporary facility in which children really are being treated differently.

Let me ask you, Mr. Secretary, about your visit when you were there. When you visited there, did you get to see the rooms that are really cold, where immigrants are being packed like sardines there? Did you see that when you were there?

Mr. AZAR. I saw dormitory rooms that had, I think there were 10 beds in the rooms, that had air conditioning. You are in southern Florida. They had air conditioning.

Ms. BARRAGÁN. So did you not see——

Mr. AZAR. Sometimes the kids do complain that we keep the temperature a little cold.

Ms. BARRAGÁN. Sir, I am asking you a very specific question. In your assessment when you went to go see there, did you see children being packed into these cold rooms?

Mr. AZAR. Of course not.

Ms. BARRAGÁN. So you did not see what other people are seeing? You did not see 70, up to 250, kids in these rooms?

Mr. AZAR. Oh, so if what you are referring to is not the dormitory, the age 17 part of the facility on, I think it is the north campus, does have congregate living for the 17-year-olds, I believe it is. And they are in a large, open area. And interestingly, I asked about exactly the thing you are asking. And what I was told—it may be incorrect—was that the kids actually prefer, that 17-year-olds actually prefer that more open, congregate setting, social setting.

Ms. BARRAGÁN. Do we let the kids decide if they want to—how they want to sleep? My understanding is that, beforehand, most kids would sleep in rooms of 12. Now you have children in these large rooms that sleep up to 70 to 250 kids. From my reports that I have seen, it is inhumane, the way kids are being treated there. It is inhumane that they are being situated there. They are certainly not a family setting. Would you say it is a family setting there?

Mr. AZAR. I would just dispute inhumane. I met with the student council representatives and——

Ms. BARRAGÁN. Do you feel like it is a family setting there? Everything I have heard is that it is like a prison. And the kids, they form lines and——

Mr. AZAR. I have got to tell you, you know, these—I hope I——

Ms. BARRAGÁN. Do you think that is an inaccurate assessment?

Mr. AZAR. It disgusts me when people refer to the grand——

Ms. BARRAGÁN. Mr. Secretary, I am just asking you a very simple question.

Mr. AZAR. We are talking there——

Ms. BARRAGÁN. Do you think it is like a prison setting or do you disagree?

Mr. AZAR. No, I do not. No, I do not.

Ms. BARRAGÁN. You do not think it is like a prison setting?

Mr. AZAR. No, I do not.

Ms. BARRAGÁN. OK. I want to ask you really quickly, sir, because I know my time is expiring here, do you agree that anytime that a child is abused in the care of ORR, that is one too many children?

Mr. AZAR. Any child abused is one too many children abused, absolutely.

Ms. BARRAGÁN. OK. There have been reports of thousands of children who have had sexual abuse incidences in ORR custody. Do you know of any where there have been against staff?

Mr. AZAR. I am sorry, where what? Any where?

Ms. BARRAGÁN. Any complaints where they have been against staff?

Mr. AZAR. Against staff?

Ms. BARRAGÁN. Yes.

Mr. AZAR. Against ORR staff?

Ms. BARRAGÁN. Yes.

Mr. AZAR. Absolutely not. ORR doesn't——

Ms. BARRAGÁN. You don't know of one incident?

Mr. AZAR. ORR itself does not take care of the children. We have nonprofit grantees who take care of children.

Ms. BARRAGÁN. But they are under your——

Mr. AZAR. No, but you asked about ORR staff. The grantees, we have received in the past four years over 4,000 complaints, including in the Obama administration, about a thousand sexual misconducts. Of those, 178 over four years involved allegations of children regarding staff members, adult-minor sexual abuse, all of which are reported to authorities and investigated. We will actually be putting a report out soon showing a very high rate of those being unsubstantiated, but we take each one deadly seriously, absolutely,

Ms. BARRAGÁN. Well, they are under your jurisdiction, sir.

Ms. ESHOO. The time has expired. I thank the gentlewoman. And now, I would like to recognize the gentlewoman from Delaware, Ms. Blunt Rochester, for 5 minutes of questioning.

Ms. BLUNT ROCHESTER. Thank you, Madam Chairman.

And thank you, Secretary, for being before our subcommittee today.

Mr. Secretary, I get a lot of visits in my office. Even as recent as today, I had folks come in from the American College of Obstetrics and Gynecology. I had women from the sorority Delta Sigma Theta. There is a lot of concern, No. 1, about the budget proposals, everything from NIH funding to Medicare and Medicaid cuts.

But one of the big things that people focused on was the real rollbacks to the Affordable Care Act and what people have witnessed as, from day one, actions that the administration and your Department have taken that have made it much harder for Americans to access and afford the vital health insurance coverage that they rely on.

The administration has undermined the health insurance market by cutting off cost-sharing reductions, gutting ACA marketplace enrollment periods and outreach, reducing funding for the Navigator program, while promoting the sale of short-term, limited plans, also known as junk plans, which don't comply with the ACA consumer

protections, don't provide adequate healthcare coverage or financial protections for families.

And so, my question, the first question is, Mr. Secretary, your Department recently proposed a rule that would change the formula for the ACA subsidies. Your Department's own analysis acknowledges that the proposed policy would increase premiums for 7 million individuals and cause hundreds of thousands to lose coverage. Mr. Secretary, in deciding to propose this policy, did you consider the fact that it would increase premiums and out-of-pocket costs for millions of Americans? And that is just a yes-or-no question.

Mr. AZAR. I want to make sure I am understanding what you are asking about. I think you might be talking about the notice with the premium indexing? Is that what you are referring to? Because, with the notice on premium indexing, it had been indexed just to employer increases in premiums. We proposed, actually, index the premium contribution based on a metric that would include employer as well as the individual market premiums, as the basis for what the individual maximum required contribution towards insurance coverage is. So I think that is what you are referring to.

Ms. BLUNT ROCHESTER. But is it correct that it would increase premiums for 7 million individuals?

Mr. AZAR. The indexing, by increasing the index, it would increase for some individuals.

Ms. BLUNT ROCHESTER. So yes? So the answer is——

Mr. AZAR. I don't know the 7 million, but it would increase, yes, the indexing increases to account for that.

Ms. BLUNT ROCHESTER. OK. So 7 million people.

Mr. Secretary, your Department also requested comment on a policy that would end the practice of automatically re-enrolling consumers in the marketplace. The Department acknowledges that 2 million Americans rely on automatic re-enrollment. Approximately 2 million individuals could lose coverage if the Department terminates this policy. So you are basically getting rid of one of the easiest pathways for Americans to get health coverage.

The Department has also made a concerted effort to make it more difficult for people to obtain coverage in the exchanges by drastically reducing funding for outreach and education activities, as we mentioned, gutting the Navigator program and limiting the time of enrollment, ultimately, giving consumers less opportunities and less time to make informed choices.

Secretary Azar, can you commit to ensuring that Americans wishing to enroll in coverage are well-informed about the opportunities to enroll?

Mr. AZAR. I think they are, and we see those results, I believe, through the enrollment numbers, which show actually a fairly consistent pathway on enrollment numbers year over year. And we saw, I think, historic levels of 90 percent satisfaction with call center interactions. We didn't even have to use the waiting room in the call center, I think for the second year in a row. I think we are——

Ms. BLUNT ROCHESTER. Well, I am just going to jump in for a quick minute because I don't have that much time. But I know that it has been a challenge for folks to do the outreach. And I know

that the budget in the past was cut by 90 percent for marketing and outreach. And so, if you could share with us specifically, with that kind of cut, what do you propose to reach out to folks?

Mr. AZAR. So we have had that, consistent with last year and this year, we have had more limited Federal spending around outreach. And what we have done is relied on the private plans, who have every incentive to get people enrolled in their plans to do so. And we have seen very efficient and effective enrollment seasons where I believe they have stayed relatively consistent, certainly in light of economic indicators. And so, I think it is actually working. They are bearing the burden, as they should——

Ms. BLUNT ROCHESTER. You mentioned, also, something about enhanced disclosure. I am sorry, I only have 10 seconds. For the so-called junk plans, can you talk about what does an enhanced disclosure actually mean?

Mr. AZAR. We have required that they very clearly disclose that this is not compliant with the Affordable Care Act EHB provisions.

Ms. BLUNT ROCHESTER. It is just inconsistent to cut off the marketing and outreach, but at the same time you are acknowledging that you need enhanced disclosure and more information to people. So my goal is that we would really make it more available to people, easier for them to get automatic enrollments, and more time for people to make informed choices.

And thank you for your patience as well, for being here.

Ms. ESHOO. I thank the gentlewoman for her excellent questions. Now I would like to recognize the gentleman from Illinois, Mr. Rush, for 5 minutes of discussion. And then, we will be moving to the second round of questions, and there are designated members that will participate in that.

Mr. Rush, 5 minutes.

Mr. RUSH. I want to thank you, Madam Chairman.

Secretary Azar, studies have found that short-term, limited-duration health plans, often referred to as junk plans, engage in deceptive marketing tactics and insurance brokers who are selling these plans fail to provide consumers with detailed plan information.

I would like to share a story that a patient, Sam Bochar, a 29-year-old patient from Chicago wrote in a testimony submitted to this subcommittee earlier year at a hearing entitled, "Strengthening our Healthcare Systems: Legislation to Reverse ACA Sabotage and Ensure Preexisting Conditions Protection".

Sam enrolled in a junk insurance policy after an insurance broker misled him about the benefits covered under the plan. Sam had been experiencing back pain. After enrolling in a junk insurance plan, Sam was diagnosed with cancer. His insurer refused to pay for his treatment, claiming that the cancer was a preexisting condition that was not covered because, Sam should have known that cancer was the cause of his back pain. He was left with almost a million dollars in medical bills.

Mr. Secretary, your Department acknowledged that consumers who purchase junk plans and, then, get sick or, quote,"develop chronic conditions could face financial hardship as a result". End quote.

Mr. Secretary, yes or no, do you think that it takes this country in the right direction to go back to the days when a policy could

be rescinded if you get sick or you get declined for preexisting conditions? Yes or no?

Mr. AZAR. We don't believe that. We believe people should have the option to have their preexisting conditions covered. The short-term, limited-duration plans, though, are helpful for the 29 million Americans who got shut out of the Affordable Care Act market.

Mr. RUSH. Thank you, Mr. Secretary. All right.

A study by the Georgetown University Health Policy Institute found that many consumers enrolling in these deceptive plans are led to believe they are purchasing comprehensive policies, what, in fact, they are not. Plain and simple, these plans are nothing but garbage. The same study found that brokers often fail to disclose to consumers the junk plans are not comprehensive coverage and would deliberately steer consumers toward junk plans. For example, brokers selling junk plans over the phone pressure consumers to quickly purchase these plans without providing written information, including information on the benefits covered.

Mr. Secretary, are you aware and did you consider in rulemaking that these plans often engage in aggressive marketing, and that means people do not understand what they are buying? Yes or no?

Mr. AZAR. So yes, we enhanced the protections compared to what the Obama administration had around the short-term duration plans that they had in their rulemaking.

Mr. RUSH. Mr. Secretary, are you aware that insurers of these junk plans currently engage in the practice post-claims underwriting, as the insurance Commissioner of Pennsylvania testified before this subcommittee?

Mr. AZAR. These plans are subject to State law and regulation. So that would be that insurance Commissioner's issue on how to regulate these plans.

Mr. RUSH. Secretary Azar, someone with insurance should not have to worry about filing for bankruptcy or not having access to lifesaving treatment. These junk plans are not about consumer choice and freedom. These products are a risk to people's health and to their economic security.

Thank you, and I yield back the balance of my time.

Ms. ESHOO. As previously discussed with the minority, we will now move to a second round of questions, which the Secretary has agreed to, from three Democratic members and three Republican members.

I now would like to recognize Ms. DeGette of Colorado. Let's see, how much time? Five minutes? I recognize her for 5 minutes in this round.

Ms. DEGETTE. Thank you very much, Madam Chair, for recognizing me.

Mr. Secretary, as you know, I am the Chair of the Oversight and Investigations Subcommittee, and we had hoped to have you here for our hearing that we had on the border separations, but we are glad to have you now.

I wanted to just ask you a couple of questions about the zero tolerance policy, instituted on April 6th, 2018, under which nearly 3,000 children were separated from their parents. Secretary Azar, were you consulted prior to the issuance of this policy or informed it was under consideration?

Mr. AZAR. I was not aware that that policy was under consideration before the Attorney General announced it on April—was it April 6th, or so?

Ms. DEGETTE. Now wouldn't you normally be, since HHS has the Office of Refugee Resettlement which would be taking these children, wouldn't it be normal to consult HHS before instituting a policy like this?

Mr. AZAR. I would have hoped so.

Ms. DEGETTE. But they didn't talk to you beforehand?

Mr. AZAR. Not to me, no.

Ms. DEGETTE. If you had been consulted, what would your recommendation have been?

Mr. AZAR. I think it is very hard now, looking back with all that we have been through, to do 20/20 backwards. You know, it is easy to Monday morning quarterback.

Ms. DEGETTE. Do you think you may have said it was a good idea?

Mr. AZAR. I hope that I would have raised the significant child welfare issues, the significant issues around program and reputational——

Ms. DEGETTE. But you are not sure if you would have?

Mr. AZAR. I just want to be fair to my colleagues and everyone else. It is very easy in retrospect to say——

Ms. DEGETTE. But wait, let me ask you this: when did you learn about this? When did you learn about this policy?

Mr. AZAR. So this policy, let's be clear, the Attorney General, on April 6th, announced zero tolerance.

Ms. DEGETTE. That is right.

Mr. AZAR. And then, I believe it was March 7th, announced the implementation of the zero tolerance and 100 percent referral.

Ms. DEGETTE. Well, March 7th is before April.

Mr. AZAR. May, I am sorry, May 7th. May 7th, zero tolerance and——

Ms. DEGETTE. But when did they start taking the kids from the parents?

Mr. AZAR. I don't know when they first started. I learned about the fact of the zero tolerance, of course, when it would have been in the press April 6th.

Ms. DEGETTE. But when did you, as the head of HHS, learn that the children were starting to be taken from their parents and put into the custody of your agency?

Mr. AZAR. If you wouldn't mind, I will be happy to tell you. So April 6th, I would have seen it in the media or learned about it.I very quickly fell ill and was in the hospital for several weeks of hospital-at-home care in the month of April. Around when the Attorney General made his announcement of implementation May 7th, I would have known about the fact that that was coming out. But I want to be clear. I did not connect the dots that zero tolerance and 100 percent referral meant implications for our program, nor was there any indication from discussions with me.

Ms. DEGETTE. Well, when did you learn of that?

Mr. AZAR. It would have been in the days and weeks following the announcement on May 7th.

Ms. DEGETTE. May 7th?

Mr. AZAR. Yes. As we started seeing kids and seeing media stories around that.

Ms. DEGETTE. Did you talk to the Attorney General, or anybody else, about that?

Mr. AZAR. I did not speak to the Attorney General himself about that, but there were various meetings——

Ms. DEGETTE. Who did you talk to about it?

Mr. AZAR. We would have talked to the Department of Homeland Security.

Ms. DEGETTE. Who did you, Secretary Azar, talk to?

Mr. AZAR. Talked to when and about what?

Ms. DEGETTE. In the weeks after May 7th about this policy.

Mr. AZAR. In the weeks after May 7th, our immediate concern was taking care of these kids.

Ms. DEGETTE. So no, no, no. Who did you talk to in the weeks after May 7th about this policy?

Mr. AZAR. I would have talked to, I would have spoken with the Secretary of Homeland Security routinely, the White House, the interagency policy process around immigration policy.

Ms. DEGETTE. And what did you tell them at that time your agency's view was towards this policy?

Mr. AZAR. So our focus was on how do we take these kids in and deal with the issues——

Ms. DEGETTE. So you didn't register an objection to it at that time?

Mr. AZAR. I did not.

Ms. DEGETTE. OK. Now Commander White came before the Oversight and Investigations Subcommittee. He told us he raised concerns with HHS leadership about the family separation policy. Did you know of Commander White's concerns?

Mr. AZAR. I did not. In fact, I, unfortunately, did not know Commander White until I brought him in to help with this problem in June.

Ms. DEGETTE. OK. And you don't recall him ever telling you or you never learned that he was expressing concerns throughout the agency?

Mr. AZAR. No, and——

Ms. DEGETTE. OK. Can I just say, this is the frustration for us because he was there; you are here. We have asked for documents. Mr. Pallone is going to talk to you about it. But I would appreciate it if we could get those email communications to find out what the agency knew. You can work with us on that.

Mr. AZAR. We are certainly working on it. I believe we produced several thousands already, and we will keep working with you on a rolling basis on producing materials.

Ms. DEGETTE. Thank you.

One last thing. There was an article in The New York Times on the 9th of March, and it said that the separations are still happening; there are 245 children that have been removed since the policy was reversed. And it also says that staff members have raised questions with Border Control agents about what appear to be little or no justification. Do you have any knowledge of that?

Mr. AZAR. Yes, I do. And if I could answer?

Ms. DEGETTE. If you can please answer?

Mr. AZAR. So separations have always happened, and they continue to happen under the TVPRA as well as just child welfare principles. So DHS will send us children where there is a felony conviction. Under the TVPRA, there are certain ones, especially violent crimes, where there is a concern about child welfare, where an individual claim to be a parent but isn't a parent. So we get those.

In addition, my understanding is we get a small number of children at this point still where local officials use their discretion to prosecute the parent for a felony violation of immigration laws, only felony. We may have received some where it appears it was based only on a misdemeanor offense and prosecution. That is not the policy, is my understanding. I think our people, sometimes we don't always get full information why they were separated and sent to us. And so, I think, in fairness, some of our people have expressed concern about some cases saying, "Why is this child being sent to us? I don't quite know and understand why you separated them. And does it"——

Ms. ESHOO. I think your time has expired.

Mr. AZAR. All of that. All right.

Ms. DEGETTE. Thank you. Madam Chair, I would just ask unanimous consent to place this New York Times article in the record. And also, we will be sending follow up questions. I would appreciate if the Secretary could answer them.

Ms. ESHOO. So ordered.

Ms. ESHOO. Now I would like to recognize the gentleman from Kentucky, Mr. Guthrie, for 5 minutes.

Mr. GUTHRIE. Thank you, Madam Chair. I appreciate it very much.

And just to reiterate what was said, because I was going to point this out, the decision to separate parents from their children, the immigration enforcement decisions are made by the Department of Justice and carried out by DHS. My understanding is HHS hasn't separated a single child. And while I do support strong enforcement of our borders by DHS and the Justice Department, I do not support separating families from their children. I don't know of anyone here that supports separating families from children. We want to keep children together.

In a previous hearing, there were some allegations brought up about HHS, ORR, so within your Department. So I just want to bring these up.

And so, recent reports have detailed allegations of abuse, including sexual abuse, of minors in ORR facilities over the past four years. This was an issue that this committee examined in 2014, upon learning of abuse detailed and reports published by the Houston Chronicle. I believe Dr. Burgess led that. And we remain concerned about recent reports.

What is ORR's process for reporting and investigating sexual abuse allegations? And does this process differ, depending on if the allegations are between two unaccompanied minors or versus an unaccompanied child and an adult staff member?

Mr. AZAR. Yes, thank you. And obviously, any allegation of abuse or neglect against a child has to be taken very seriously, and especially sexual misconduct or abuses, absolutely unacceptable. And

we want to work with you and make sure our processes and procedures protect against that.

We received three types of sexual misconduct that fit into that group of about 1,000 a year of reports that we have gotten over the last four years, including in the previous administration. There is inappropriate sexual behavior. That can be as little as a child saying something inappropriate to another child, inappropriate touching. It can be sexual harassment. It could be child on child or, most seriously, sexual abuse.

We received over the last four years, when we have had about 180–289 thousand children in that period, 178 allegations of sexual abuse of adult-on-child, staff member issues. Those sexual misconduct allegations must be reported to ORR within four hours. Sexual abuse cases must be reported to Federal, State, Local law enforcement officials, child safety welfare individuals, for investigation.

ORR received these investigations. We have put in place a full-time prevention of sexual abuse coordinator in this administration. We have put together a committee to review allegations and ensure proper oversight. We receive reports on any developments in the case within 24 hours. So we try to aggressively pursue that. If we can improve our procedures, we are welcome to be a learning organization and get better and better at this. We do not want any of these cases ever to happen.

Mr. GUTHRIE. To clarify, it was in another committee and with a different Secretary. And I know you have answered some questions in other departments. So they were asked about what is going on in your Department. So I just wanted to clarify.

Recently, there has been some incorrect information regarding who the allegations are made against. When we say "staff," allegations against staff, does that mean HHS staff or ORR staff or an appointee or a contractee's staff?

Mr. AZAR. Thank you for asking for that clarification. These are allegations, where it involves staff, it would be staff of grantees. These are the nonprofit entities that run the approximately 100 facilities that we have to care for children. Obviously, still, we have oversight. We want a safe environment. We have to investigate. So it is not to diminish in any way responsibility that we have to ensure a safe environment. But, to my knowledge, I am not aware of any allegations against an actual HHS employee or ORR employee with regard to these children.

Mr. GUTHRIE. When you see this—so, walk me through the process of—I know it may not get to your level, but what happens? I mean, what happens? So we understand how these children are being protected. I know that you want, we all want the children to be protected, and obviously, you do as well. So how do you react when your cabinet—well, I won't say "cabinets," what we call them in Kentucky—your Department react when you have an allegation?

Mr. AZAR. So the process, especially when we get a sexual abuse allegation, is that the grantee is required to alert immediately child protective services and State officials for potential prosecution and investigation for child welfare. We are alerted within four hours. That goes to this national sexual abuse prevention coordinator.

We have in each of our grantee facilities actually a hotline. It is like a telephone booth. If you visit our facilities, you should see that, where a child may make a claim of sexual misconduct through that reporting hotline to make sure we learn of it immediately. Then, we conduct, of course, the regular oversight, and we take, I hope we take swift, appropriate, remedial action anytime there is a finding of inappropriate conduct.

Mr. GUTHRIE. I believe there are three contractors—I am probably out of time—but three contractors that the most allegations have been against. Has anything happened with those three contractors?

Mr. AZAR. I would say most of the allegations you have heard about involve a contractor in the Arizona area. In that instance, we shut down before anything was public. There was a pulling-hair incident that you might have seen a video of. Before that was ever public, we actually shut that facility down. We pulled our children out of it. We shut another facility down, I believe, pulled children out of it. We stopped placement of children in the other six facilities of that grantee, revoked their licensure.

And for any facilities to come back online, they would have to go through the State licensing procedure recertification, as well as ORR being satisfied that the leadership, policies, practices, everything had changed sufficiently for that, because we really have to ensure the safety of our children.

Mr. GUTHRIE. OK. I thank the Chair for her indulgence.

And thank you for your answers. I appreciate that. Thank you.

Ms. ESHOO. I thank the gentleman for his important questions. Now the ever-patient, ever-present Ms. Schakowsky from Illinois is recognized for 5 minutes.

Ms. SCHAKOWSKY. I thank the Chair for allowing me to wave on. This is such an important issue.

According to the Government Accountability Office, months before the Attorney General's April 2018 zero tolerance policy memo was issued, the Office of Refugee Resettlement saw a tenfold increase in the number of children who were separated from their parents. Furthermore, ORR officials told GAO that, a few months prior to the April 2018 zero tolerance memo, they considered planning for a continued increase in the separated children, but HHS leaders advised them not to engage in such planning.

So, Secretary Azar, were you aware that ORR officials were seeing a tenfold increase in the number of children who were separated from their parents?

Mr. AZAR. I was not. I wasn't actually aware of an issue of separating children at the time really until we got into that May timeframe.

Ms. SCHAKOWSKY. I heard what you said, but, according to Commander White's testimony in front of this very committee, the Oversight and Investigations Subcommittee, though, the HHS leaders who told him not to plan for continued increase in separated children were Scott Lloyd, the head of ORR, and Maggie Wynne, your counsel for human services policy.

So, Secretary Azar, before the issuance of the zero tolerance policy, did Mr. Lloyd or Ms. Wynne ever discuss family separation with you?

Mr. AZAR. Not to my knowledge. And I am disappointed that I didn't know that. I am disappointed they did not tell me if they were engaged in——

Ms. SCHAKOWSKY. And has there been any consequence for them for not telling you something like separating children?

Mr. AZAR. So the issue is what would we have done differently, of course. I am concerned——

Ms. SCHAKOWSKY. Stop separating children is one idea.

Mr. AZAR. First, we don't separate children. But the other is——

Ms. SCHAKOWSKY. Whoa. Go back to that.

Mr. AZAR. We don't at HHS separate children.

Ms. SCHAKOWSKY. I see.

Mr. AZAR. We have never—we at HHS do not separate children.

Ms. SCHAKOWSKY. I know.

Mr. AZAR. We receive children sent to us.

Ms. SCHAKOWSKY. Yes.

Mr. AZAR. And we just try to care for them the best we can.

Ms. SCHAKOWSKY. Stop the policy though?

Mr. AZAR. I'm sorry?

Ms. SCHAKOWSKY. You could have stopped the policy in some way, made a stink about it?

Mr. AZAR. Correct. If I had been alerted to it, I could have raised objections and concerns, absolutely. And I wish we had had more knowledge flow, and I wish more people had been engaged in these issues, absolutely. Of course.

Ms. SCHAKOWSKY. So once you found out about all this, have you done anything at all in terms of raising this issue?

Mr. AZAR. So once we found out about it in May, we scrambled immediately towards dealing with the issues that we were dealing with. What I told our team, I convened our team, and I said, because I was seeing the same press stories you were seeing, and I was very disturbed by it, I said, "I want every child to know where their parent is. I want every parent to know where their child is. I want every parent and child in regular communication, telephone or Skype. And I want us to begin an immediate reunification process to get them outplaced with sponsorship."

Now we use reunification differently than the later Judge Sabraw order. Reunification means placing, often with a level 1 or level 2 sponsor, in the homeland. And so, I pulled in our Assistant Secretary for Preparedness and Response to add logistics capabilities on top of our normal——

Ms. SCHAKOWSKY. Reclaiming my time, so tell me, Secretary Azar, as this nation's top health official, after separation began taking place, did you ever attempt to just put your foot down and stand up for the children, and tell DOJ, DHS, or the White House, that separation should be stopped?

Mr. AZAR. All of that was preempted. The President, on January 22nd, issued his Executive Order stopping separations. And at that point, we moved immediately towards compliance with the June 26th court order and reunifications. All of our efforts were focused on that.

Ms. SCHAKOWSKY. Well, you say that, but did you read The New York Times on Sunday?

Mr. AZAR. As I mentioned to Congresswoman DeGette, the separations that are currently occurring, to my knowledge—again, I don't separate children—are the types of separations that are normally happening for child welfare. They are from felony violations for child welfare, lack of parentage. There can be some felony prosecutions. I believe those are fairly rare.

Ms. SCHAKOWSKY. OK. Well, let me quote. Let me tell you what some of your staff said. Staff members have in some cases raised questions with Border Patrol agents about separations with what appears to be little or no justification.

Mr. AZAR. And I am glad they are doing so, and I encourage them to do so. We don't always get—sometimes there is law enforcement sensitive information——

Ms. SCHAKOWSKY. So what are you doing? People, American people are horrified by this. They see this, I see this as State-sponsored child abuse, I would say even State-sponsored kidnapping, children being taken away from their parents, hundreds, maybe thousands of children. And it's continuing. I want to know what you are doing, a sense of urgency to come from you about what you are doing about stopping this.

Mr. AZAR. I will not stop or advocate DHS to stop separating children from individuals who present a harm for child welfare. And if that is what is occurring, and that is what should be occurring——

Ms. SCHAKOWSKY. OK, but you are the child welfare agency.

Mr. AZAR. That is what I will stand up for.

Ms. SCHAKOWSKY. And you need to find out if these are legitimate child—because——

Mr. AZAR. And that is what I——

Ms. SCHAKOWSKY [continuing]. It is also said that some of your staff found that the border agents said, "No, we're not doing anything about this. We are going to separate the children." That is in that article. Read it.

Ms. ESHOO. The gentlelady's time has expired. The gentleman, the ranking member of the full committee, Mr. Walden.

Mr. WALDEN. From Oregon. Thank you, Madam Chair. I appreciate it.

Mr. Secretary, thanks for being here and taking on these tough questions. We appreciate it.

And I want to go back to part of this again to make clear that your professionals do not separate children?

Mr. AZAR. That is correct. We do not separate children.

Mr. WALDEN. And tell me, how many children show up at these ORR facilities on a given day? I mean, you probably get some count. And you don't control that flow, right?

Mr. AZAR. We have no control over the flow of children to us. We currently have 11,668 children in our care. We received the other day, the last report we received, 229 children. We have seen rates up——

Mr. WALDEN. In a given 24-hour period?

Mr. AZAR. In a day. In a day. We are seeing rates—it is surging—we are seeing rates upwards of 300 children coming over a day now. It is 120 percent increase in unaccompanied alien chil-

dren crossing the border and being sent to us from a year ago February. We are in a crisis situation.

Mr. WALDEN. And these children that are coming across, you say unaccompanied?

Mr. AZAR. Unaccompanied. This is a 12-year-old girl walking across the border or a coyote shoving her across the border by herself.

Mr. WALDEN. So they have been separated from their parents——

Mr. AZAR. Their parents separating them by sending them here or they ran away on their own up to here. They are coming here by themselves. They are unaccompanied. And then, our job is to take care of them and try to find them some relative that, hopefully, is here in the States that we can vet and place them with that person who is responsible——

Mr. WALDEN. And in the prior administration, didn't we learn that there were times where children, unaccompanied, were put with the wrong people?

Mr. AZAR. Yes. Yes. Unfortunately, we try to do as good a job as we can vetting individuals, the family members and others that we place as sponsors. But, yes, in the prior administration, there was one instance that became quite a cause celebre. The permanent Subcommittee on Investigations in the Senate held inquiries around children that Senator Portman was very focused on, children sent to sponsors in Ohio, who ended up actually with traffickers and working as, essentially, trafficked labor at an egg processing plant, if I remember correctly.

Mr. WALDEN. So is that because they were pushed out of the ORR system into the wrong hands too fast?

Mr. AZAR. Obviously, the screening process and vetting process on sponsors failed.

Mr. WALDEN. And have you changed anything to make sure that is not happening on your watch?

Mr. AZAR. So we try to ensure enhanced vetting of any individual that we put children with. We have case managers that work with us and with the grantees that take on these children's cases. And we vet the individuals. We fingerprint them. We fingerprint others as necessary, for instance, other household members. We send them for FBI background checks. We do common public record checks. I think we can check the child abuse files on them. We learn immigration status on them because that can be a relevant factor. For instance, placing a child with someone who is in the middle of a removal proceeding, that wouldn't be a stable environment. So we are constantly trying to improve the quality of our vetting process to place the children in a safe environment.

Mr. WALDEN. And during that whole process, do these kids have the opportunity to talk to their families back in their home countries?

Mr. AZAR. Oh, yes. Yes. In fact——

Mr. WALDEN. How often?

Mr. AZAR. I believe they are required to speak, to have the opportunity to speak at least twice a week. And we try to——

Mr. WALDEN. They have to pay for those calls?

Mr. AZAR. No. No, no. We pay for that. And they have limited access to their attorneys, and they——

Mr. WALDEN. Do they get access to any kind of healthcare?

Mr. AZAR. They get free healthcare, free mental healthcare, free vision.

Mr. WALDEN. How often do they get mental health services?

Mr. AZAR. They are assessed for their mental health needs within 24 hours of arriving at an ORR intake facility.

Mr. WALDEN. Within 24 hours, they see a mental health counselor?

Mr. AZAR. Yes.

Mr. WALDEN. And how often do they get access to health services?

Mr. AZAR. They also receive that care immediately. I believe within 48 hours they are vaccinated and receive the suite of CDC vaccinations if they do not have documentation of prior vaccination. And then, we provide ongoing healthcare, including emergency services.

Mr. WALDEN. What about educational services?

Mr. AZAR. We provide them with education services in all of our facilities, and—yes.

Mr. WALDEN. Have you ever gone down to one of these facilities and met with these kids?

Mr. AZAR. I have, indeed. I meet with the children when I am there. I met with the student council when I was down at the Homestead facility.

Mr. WALDEN. Wait a minute. They have student councils?

Mr. AZAR. They have an elected student council who——

Mr. WALDEN. And what are the student councils? Are they free to tell you the good, bad, ugly?

Mr. AZAR. I beg them, I beg them, tell me any complaints and concerns that you have.

Mr. WALDEN. What are their complaints?

Mr. AZAR. Well, there were three themes. The first thing they said was, "We miss our parents who sent us here." The second thing they said was, "We are grateful to America. We are safe and secure for the first times in our lives." It is actually heartwarming to see the gratitude on these beautiful children's faces. It was just such gratitude. And even any complaint they had, one girl wanted better sneakers. She felt so guilty saying it because she feels such gratitude to this country.

Mr. WALDEN. What about food?

Mr. AZAR. They want pizza night. They want pizza night more often. That's the most common thing they say. They don't like our breakfast because they have to comply with the Federal nutrition standards. And so, they do complain about the breakfast.

Mr. WALDEN. They are like other teenagers then?

Mr. AZAR. Yes.

Mr. WALDEN. Yes.

Mr. AZAR. Yes, yes.

Mr. WALDEN. All right. My time has expired, Madam Chairman. Thank you.

And, Mr. Secretary, thank you for being here.

Ms.ESHOO [presiding]. Thank you. Thank you very much, Mr. Walden.

The Chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Madam Chair.

I just wanted to explore, Mr. Secretary, the lessons learned from the family separation policy to see if we can figure out what went wrong.

But, first, let me mention an issue of documentation. You know, I am very frustrated with the lack of documentation on this and other issues, as you know from my previous questions. The committee sent you a letter nearly two months ago requesting documents relating to family separations. What few documents we have received, sir, have been largely unresponsive. And in these cases, in these productions that we have received from you, we have received little substance, including very few communications from key HHS leaders.

One weekly production, in other words, documents, included almost 800 pages, but only 14 of those pages was responsive to our request. Another time, the weekly production consisted of only seven pages of documents. And I think it is now fair to ask, what is HHS hiding? Mr. Secretary, we have been working with HHS in good faith, but our patience has really run out. So what explains this slow production? Are there certain documents you don't want us to see? I know, previously, you mentioned executive privilege. Would you commit today to fully cooperate with this investigation and produce all of our requested documents related to family separations?

Mr. AZAR. We are certainly working to do so. I believe we have produced over 2800 pages of materials. We are doing it on a rolling basis.

Mr. PALLONE. But very little of it responds to our questions, you know, on family separation.

Mr. AZAR. I am not personally sitting and reviewing each document that is going over. So I can't comment on that. I want to be cooperative. I want you to get the materials you need to do your job. There may be limited areas where we can provide materials to you or have to have an accommodation, an appropriate accommodation discussion. But your oversight is appropriate. We want——

Mr. PALLONE. Just please——

Mr. AZAR. I assure you I want to do the lessons learned on this. I want to learn how we can do better always.

Mr. PALLONE. Well, just please get back to us with the requested documents about family separation and responsive to our request.

At our hearing last month on this topic, we heard from child welfare experts about the decades of research showing that family separations lead to toxic stress. There are often long-term traumatic consequences. Countless other organizations have spoken out about this harm.

Mr. Secretary, why was this misguided policy allowed to engulf HHS and harm both children and their families and the reputation of this critical program, if you would?

Mr. AZAR. I share the concerns about child welfare, and I especially share the concerns that Commander White, who spoke to

your committee—I have just the absolute highest respect and regard for Commander White and the advice——

Mr. PALLONE. Well, what is the reason why this was allowed to continue without—I mean, you agree that it wasn't good.

Mr. AZAR. The President's Executive Order on June 22nd was able to short circuit that right as we were in the throes of this. I focused immediately my energy on those three priorities I talked about, which is just ameliorating harm as quickly as possible, which was kids know where parents are; parents know where kids are. Get them in contact and get them placed, reunified or placed with sponsors as quickly as possible. And then, the Executive Order came along, and all of our energies switched over—that stopped—and switched over towards Judge Sabraw's order and compliance, which was a full-court press to do that. So I think the timing didn't really facilitate that, but the concerns are absolutely valid around child welfare. I share them. I said at the time nobody wants children separated from their parents.

Mr. PALLONE. No, I know, and I can't help, you know, there is that quote on the wall at your headquarters from Hubert Humphrey where he said, "the moral test of a government is how that government treats those are in the dawn of life, the children; the twilight of life, the elderly; and the shadows of life, the sick, the needy and the handicapped."

I mean, you don't believe that this policy past the moral test that Vice President Humphrey spoke of? I mean, you would agree, right?

Mr. AZAR. I absolutely share the concern about child welfare, of separating children. I can't speak to the questions of enforcing. There are significant issues, though, about exempting someone. As long as Congress has the law on the books making it crime to cross our border, there are significant questions that this Congress has to focus on about exempting somebody from those laws simply because they have a child with them. That is a real concern.

Mr. PALLONE. I understand, but——

Mr. AZAR. As a lawyer, it is a concern I have.

Mr. PALLONE. All I really want is an assurance today. Because I don't know if I am the last person; I think I might be. But can you assure us today that wholesale family separations will never happen again under your watch?

Mr. AZAR. I will certainly advocate for the child welfare. There are three major concerns I have. One is child welfare. The second is the operational concerns that you raised about our program. The third is the reputational harm——

Mr. PALLONE. I just want an assurance that this kind of wholesale family separation is never going to happen again under your watch. Can you just say, answer that?

Mr. AZAR. Of course, I am not the President. I do not get the final judgment.

Mr. PALLONE. No, just you.

Mr. AZAR. I can tell you my perspective is I will always advocate for the child welfare concerns, the reputational concerns, and the operational concerns of our program.

Mr. PALLONE. No, I don't think that answers the question, but whatever.

Thank you, Madam Chair.

Ms. ESHOO. I would just take a moment to remind the witness that, if someone is coming across the border as a refugee, that is a legal entry.

All right. The Chair would now recognize Dr. Burgess for 5 minutes.

Mr. BURGESS. Thank you.

And thank you, Mr. Secretary, for spending the day with us.

I am going to mostly do the talking at this point. Feel free to interject whatever you may wish.

First off, Madam Chairwoman, I am going to ask unanimous consent to place into the record a newspaper article from February 19th, 2019. The title of the article is, "Texan Republican Rejects Democrats' Criticism of the Homestead Facility for Migrant Kids." I visited the facility, along with four of your colleagues, in February.

You know, this was odd because they had a press conference after the visit but wouldn't let me participate in the press conference. So I actually called one of the reporters and provided a different perspective from what was reported.

But I would like to place this article in the record.

Ms. ESHOO. Without objection, the article is admitted.

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. I went to the Central American countries that are primarily involved with most of the children that are coming over. And just so people understand what is going on here, a family will decide to send their child north because perhaps they have other family members who have already made the trip and they want their child to go north.

I actually asked Democrats to go with me on that CODEL. I couldn't get anyone to accompany me.

One of the things that I learned that really concerns me is that it costs $6 to $10 thousand for a child to make that journey. That is no small sum of money in a country that is relatively poor. And I asked the question, "Where do they get the money to make this journey?" I was told that they borrow it from the bank. They borrow it from the bank, putting their home or their farm up as collateral. I don't know, this doesn't sound like a good system to me.

Now part of that Homestead visit, I also went to the Bryan Walsh Children's Village that the Democrats did not go. That is a permanent facility that is down in Florida. One of the things that struck me about the Bryan Walsh Children's Village is they have got a big mural that they have drawn on the outside of one of the buildings. It is a mural of a train with children sitting on top of it. It is not like a ride at an amusement park. This is "la Bestia." This is how those children get from Central America. They are brought by traffickers on the top of a train through the deserts of Central Mexico and deposited at our border.

They are, then, brought across the river in the case of Texas. They are brought across the river by a coyote who leaves them in a small lot of people, and then, hopes that Customs and Border Patrol will find them before they dehydrate or burn under the Texas sun.

It is not a good system that is being set up. And I cannot imagine why people wouldn't want that system to not exist anymore. Why would we continue to provide the magnet for people to want to make that dangerous journey or, worse yet, send their child on that dangerous journey?

Now, Secretary Azar, during a House Judiciary Committee hearing on February 26th, there was, unfortunately, a gross mischaracterization of the work being done at HHS to care for unaccompanied alien children. And a member on the other side of the dias on the Judiciary Committee stated that, "ORR created an environment of systemic sexual assaults by HHS staff on unaccompanied alien children." Close quote.

So that accusation is false and it was made without this member, to the best of my knowledge, having ever visited an ORR facility. His comments discredit the efforts by ORR employees to deal with problems, and these problems date back to a previous administration. They weren't created when Donald Trump took his hand off the Bible.

So Madam Chair, I have a letter that was written by Jonathan Hayes to this member of the Judiciary Committee, characterizing the remarks that were made and asking for an apology. And I ask unanimous consent to insert this letter into the record. And I would, further, ask that this committee ask Representative Deutch to issue an apology to the men and women at ORR and HHS who work every day to see that these children are well taken care of.

And I will yield back my time.

But I do ask unanimous consent——

Ms. ESHOO [presiding]. That unanimous consent is not approved.

Mr. BURGESS. Is not approved?

Ms. ESHOO. Is not approved.

Mr. BURGESS. You are not going to put this letter into the record?

Ms. ESHOO. Is approved. I am sorry.

Yes, it is a letter condemning another member, and I am not going to pursue taking the words down, but I am going to draw a line and not accept it for the record.

Mr. BURGESS. Madam Chair, could I appeal the ruling of the Chair?

Ms. ESHOO. Let it remain—well, if you want to do that, you may, but I am not going to put those words in the record. I don't think they are fit for the record. And you have been in this chair, Mr. Burgess, and I think that, were you to hear me making that request, that you would do the same thing.

Mr. BURGESS. If it is any consolation for you, they are already in the record of the Rules Committee from yesterday.

Ms. ESHOO. All right. Well, are you finished with your questioning?AZAR. Madam Chairwoman? Madam Chairwoman?

Ms. ESHOO. Who is asking for——

Mr. AZAR. Me, upfront.

[Laughter.]

Ms. ESHOO. Oh, I am sorry. I am sorry.

Mr. AZAR. I am terribly sorry to interrupt.

If I could, I just wanted to clarify, I think in response to Chairman Pallone, when we were speaking, I made reference to approxi-

mately 2800 documents. My staff informs me I was incorrect. It is approximately 2,080 pages. I just wanted to be clear that they have corrected me. I made a mistake in my statement there, and I wanted to be sure to get that on the record. I am sorry about that. I apologize.

Ms. ESHOO. You have got good staff behind you——

Mr. AZAR. I have got a good team.

Ms. ESHOO [continuing]. Giving you the notes to make the correction.

Mr. AZAR. Thank you.

Ms. ESHOO. So noted and appreciated.

Hardly anyone is left, but I still want to put out the reminder that Members have 10 business days to submit their additional questions for the record.

And, Mr. Secretary, there were many requests and you made several offers to provide the information that was requested. Please do that, and also respond promptly to the questions that are going to be submitted to you by Members.

I just want to close this hearing. It has been a long one. We thank you, Mr. Secretary.

It is the budget of our nation, and the budget of our nation is a statement of our national values. And there have been those that have supported some of the things that are in the budget. You have also heard those that have spoken out where they believe it doesn't meet our national values.

I would just ask you to do the following: and that is, to go online and tap in President Ronald Reagan's last speech as President of the United States. It is one of the most magnificent set of remarks I have ever heard. It is a love letter to immigrants. Call me after you have watched that, and I want to have a discussion with you about it.

With that, the committee has concluded its business for today and the end of the hearing.

Thank you.

[Whereupon, at 5:03 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Texas Republican rejects Dems' criticism of Homestead facility for migrant kids | Fort Worth Star-Telegram

star-telegram.com/latest-news/article226529385.html

Young girls rest after playing soccer at the Homestead Temporary Shelter for Unaccompanied Children, Tuesday, Feb. 19, 2019, in Homestead, Florida. Wilfredo Lee AP

Texas Republican Rep. Michael Burgess on Wednesday said the conditions he witnessed at a Homestead, Florida holding facility for migrant children were nothing like the "prison-like" experience his Democratic colleagues have described.

"I don't speak a lot of Spanish but I speak enough to ask, 'How are you feeling?' And universally, I was told by the kids, who were all smiles and thumbs-up, 'Bueno,'" Burgess told the Star-Telegram

Burgess, an ally of President Donald Trump, said he was asked by the Health and Human Services Department to attend the tour of the facility with Texas Rep. Joaquin Castro and Florida Reps. Debbie Mucarsel-Powell and Donna Shalala — all Democrats.

Democrats have grown increasingly critical of the holding facilities after Trump instituted a "zero-tolerance" policy requiring that children be separated from their families as they tried to enter the United States for asylum in April 2018. That policy was later reversed amid criticism.

"It's like we had been on different planets," Burgess said of the Democrats' accounts of the facility. "They're down there saying these facilities are terrible they ought to be closed... and that's just not true."

Burgess said he was disinvited from that press conference, after originally being asked to attend. A Democratic staffer in charge of planning the event confirmed that Burgess was asked to not join.

Duration: 2:00

Government releases video of Texas detention facility for immigrant children

At a detention facility in Tornillo, TX, immigrant children are seen eating, coloring and playing soccer in this video from the U.S. Department of Health and Human Services released on June 21, 2018. (Video contains no audio)

By U.S. Department of Health and Human Services

Burgess is a senior member of the House panel that oversees the Office of Refugee Resettlement, and has spent years working to improve their facilities.

That subcommittee held hearings on ORR during the height of the child migrant crisis in 2014, during which Burgess, a doctor before he ran for Congress, pushed for better medical treatment at the holding facilities.

He said Democrats on the visit were naive about how much better the conditions in Homestead were compared to facilities at that time, when children didn't see doctors and were released into the public with little-to-no screening for disease.

"I've been to a number of ORR facilities in the last five years... Things are so much better than they were in 2014," said Burgess.

The Trump Administration removed young migrants from a holding facility in Tornillo, Texas, last month after watchdogs flagged concerns about the safety of the minors who are fleeing violence in their home countries in Central America.

Critics of the facilities are now looking at Homestead, which is holding 1,600 young people.

Burgess has proposed cutting foreign aid to Central American countries for each of their children that shows up at the U.S. border, as a way to get the countries to help stop them from coming.

He argues that the facilities are keeping the young people safe while officials screen the people they'll be sent to live with.

"These are shelters, and they are providing much more than shelter for these youngsters," said Burgess, who added that all the lawmakers on the trip spoke with children at the facility.

"The time that they're staying in the facilities is longer than it was in 2014; some people point to that as a criticism of the Trump Administration," said Burgess. "But I would reference my trips in 2014 and 2015... I was horrified that there kids were being sent off to families and no one had done even a cursory background check to find out if the people they were sending the kids to were really who they said they were."

U.S. Continues to Separate Migrant Families Despite Rollback of Policy

Silvia Maribel Ramos arrived in the United States last month to learn that her husband had been deported to Guatemala and her 3-year-old daughter had been taken. Credit...Jim Wilson/The New York Times

By Miriam Jordan and Caitlin Dickerson

March 9, 2019

OAKLAND, Calif. — Nearly nine months after the Trump administration officially rescinded its policy of separating migrant families who have illegally crossed the border, more than 200 migrant children have been taken from parents and other relatives and placed in institutional care, with some spending months in shelters and foster homes thousands of miles away from their parents.

The latest data reported to the federal judge monitoring one of the most controversial of President Trump's immigration policies shows that 245 children have been removed from their families since the court ordered the government to halt routine separations under last spring's "zero tolerance" border enforcement policy. Some of the new separations

are being undertaken with no clear documentation to help track the children's whereabouts.

Images of crying mothers and children at the border last year prompted an intense backlash across party lines, with all four living former first ladies and Melania Trump expressing horror at the policy. But despite President Trump's June 20 executive order rescinding it, the practice was never completely suspended.

Under the original policy, most children were removed because parents who illegally crossed the border were subject to criminal prosecution. The recent separations have occurred largely because parents have been flagged for fraud, a communicable disease or past criminal history — in some cases relatively minor violations, years in the past, that ordinarily would not lead to the loss of parental custody.

[*Read the latest edition of Crossing the Border, a limited-run newsletter about life where the United States and Mexico meet. Sign up here to receive the next issue in your inbox.*]

The new separations are taking place amid an unprecedented influx of migrant families from across the southern border that has highlighted the failure of the Trump administration's hard-line policies to deter them. The Border Patrol detained 76,103 migrants in February, an 11-year high for that month. Among those intercepted were about 40,000 members of families, two-thirds more than in January.

In Congress last week, Democrats grilled Kirstjen Nielsen, the Homeland Security secretary, over the separation policy, citing research that has found that separations from parents can inflict long-term psychological harm on children.

Family separations also sometimes occurred under the Obama administration, but only rarely and in extreme cases in which a child's safety appeared to be at risk.

Customs and Border Protection officials say the separations are legal under the parameters set by the court and are intended to protect children, who they say may be threatened by human trafficking or by adults pretending to be a parent to capitalize on the advantage that gives them under American immigration laws.

"C.B.P. does not declare that a parent poses danger to a child arbitrarily or without merit," the agency said in a statement. It said agents "will maintain family unity to the greatest extent operationally feasible," separating children only in the presence of "a legal requirement" set out in written policy or "an articulable safety or security concern that requires separation."

But opposition to the new separations has been growing from both outside and inside the federal government. At the Health and Human Services Department's Office of Refugee Resettlement, which oversees the care of separated children until they can be

reunited with their families, some officials have tried to resist receiving children referred to the agency by the Border Patrol.

According to an official who was not authorized to discuss government business and spoke on the condition of anonymity, staff members have in some cases raised questions with Border Patrol agents about separations with what appear to be little or no justification. In some of those cases, border agents have refused to provide additional information, the official said, or if additional documents were provided, they were sometimes redacted to the point of illegibility.

The official, along with another staff member at the Department of Homeland Security, the Border Patrol's parent agency, said that some separations were occurring with no formal notification to the refugee resettlement office. Both officials said they had been made aware of concerns about an apparent inconsistency in standards applied by border agents when determining whether a family should be separated.

The failure to keep accurate records suggests that more children could have been separated than the 245 accounted for by Feb. 20 in official records.

The New York Times reviewed several cases of children who have been separated since the policy was officially ended, and learned of many others through the lawyers who handled them. Some of the new separations, the review showed, occurred in families with a parent who had a drunken-driving conviction in the past, or a 20-year-old nonviolent robbery conviction. In one case, a parent had been convicted of possession of a small amount of marijuana.

Donna Abbott, vice president for refugee and immigrant services at Bethany Christian Services, a contractor that accommodates migrant children in temporary foster homes until they can be reunited with family members, said most cases of family separations do not list detailed reasons, making it difficult to evaluate whether they were appropriate.

For example, some files state only that the parent was suspected of having gang affiliations or a criminal history, without additional information. "Is it trespassing or is it murder?" Ms. Abbott said.

In December, a mother traveling from El Salvador with her three children was arrested and put on a bus to an immigration detention facility in Arizona while her children, ages 5, 8 and 15, were sent to foster care in New York.

The woman, Deisy Ramirez, 38, said it was nearly six weeks before she talked to her children.

They were "devastated," said Ms. Ramirez's sister, Silvia Ramirez, who was trying to persuade the government to allow her to take the children to live with her in Seattle

while her sister was in custody. "They couldn't understand why they were separated," she said.

On March 1, Ms. Ramirez's eldest daughter was transferred to a hospital after threatening to take her own life, Silvia Ramirez said, and she remained there even after her mother's release from detention last week.

"I never imagined this could happen," Deisy Ramirez said on Friday, her voice breaking. "All I want is to hold my children and to be with them."

Her lawyer, Ricardo de Anda, said he had received no response to his formal request for a reason for the separation. He suspects it may be connected to the fact that Ms. Ramirez had been deported from the United States more than a decade ago. He sent government lawyers a series of emails, ultimately securing her release.

On Saturday, the day after her release from the Arizona detention facility, Ms. Ramirez was preparing to fly to New York to reunite with her children.

Border agents removed 3-year-old Ashley Ramos from her father after they were detained last month in Arizona. He was swiftly deported to Guatemala and the girl was sent to a shelter.

The child's mother, Silvia Maribel Ramos, who had been separated from the pair during their journey from Guatemala when Mexican police pulled her and other migrants off their bus for questioning, arrived in Arizona a few days later, only to learn from authorities that her child was gone.

"They told me they had no idea where she was, that I would find out after being released," said Ms. Ramos, who is staying with relatives in Oakland, Calif.

The child was located nearly two weeks later, she said, after her husband contacted Guatemalan authorities back home. Now Ms. Ramos is struggling with the paperwork required to recover Ashley. "My daughter can't understand. She just weeps and begs to be with us," she said.

In late January, Victor Antonio Marin was separated from his 4-year-old son, whose mother is deceased, after they were detained near Calexico, Calif. According to his lawyer, Bob Boyce, Mr. Marin had a 20-year-old nonviolent robbery conviction in the United States that did not involve the use of a weapon. He served time and was deported back to El Salvador.

Now Mr. Marin remains locked up in an immigration detention center while his child is in a shelter in Texas.

Ruben Garcia, who runs a network of migrant shelters in El Paso, said that immigration authorities this month dropped off a distraught 18-year-old woman from Guatemala.

The woman said she had given birth less than a week earlier and had been separated from her baby. Child welfare authorities had come to the hospital to take the child, who was a United States citizen; immigration agents took the mother back to a detention cell where she waited for several days. The baby's first two weeks were spent away from the mother, who finally regained custody after interventions from multiple legal-aid groups, Mr. Garcia said.

Since Mr. Trump ended the family separations under "zero tolerance" on June 20, about 2,700 children have been reunited with their parents. Still, thousands more children who were separated before the policy officially went into effect have not been accounted for, according to the Office of the Inspector General of the Department of Health and Human Services. The investigators cited the lack of an efficient tracking system.

The American Civil Liberties Union requested that the government locate the families, and on Friday, Judge Dana M. Sabraw ruled that they should be included in the pending litigation over protecting and reuniting separated families.

"The hallmark of a civilized society is measured by how it treats its people and those within its borders," the judge wrote in his opinion.

Some families affected by the earlier zero-tolerance separations continue to face repercussions.

A 9-year-old Guatemalan boy named Byron Xol has been shuffled among four shelters since he was dragged away from his father at the border nine months ago, while the policy was still in place.

After his father was deported to Guatemala, the boy's parents decided that the child should remain in the United States for safety reasons. With the help of a lawyer, they designated an American family in Buda, Tex., to care for him.

But authorities have refused to allow Byron to join the family, citing an anti-trafficking policy that bars a child from being released to a nonrelative sponsor unless the sponsor has a verifiable relationship with the child going back at least a year.

Detentions and deportation proceedings have also resulted in family separations far from the border.

Christy Swatzell, an immigration lawyer in Memphis, said that two of her clients who crossed the border without authorization and were released to await the outcome of their cases were told by Immigration and Customs Enforcement to leave their children at

home ahead of their monthly check-in with the agency. When they showed up at the I.C.E. office, they were detained and transferred to an immigration facility in Louisiana.

One of the clients, Francisca Yanes, 33, is the mother of a 6-year-old girl who is physically disabled. "I was in tears, telling them about my daughter. But it didn't matter," said Ms. Yanes, whose child, Paola, remained in the care of family members for the entire 45 days she was in detention.

The Guatemalan migrant was released on a $7,500 bond set by the court after her lawyer filed a motion on her behalf. "What we are seeing is that families are being effectively separated," said Ms. Swatzell. "Just not at the border anymore."

Energy & Commerce Subcommittee on Health QFRs
Hearing on
"The Fiscal Year 2020 HHS Budget"
Hearing Date: March 12, 2019

Drug Pricing

The Honorable Frank Pallone, Jr. (D-NJ)

Prescription Drug Rebate Rule

On January 31st, the Department of Health and Human Services (HHS) and the HHS Office of Inspector General (HHS OIG) issued a proposed rule to exclude from safe harbor regulations certain prescription drug discounts currently protected from liability under Federal anti-kickback statute. If finalized, this rule would ban the use of certain rebates in the Medicare Part D and Medicaid managed care programs and dramatically alter the payment structure for prescription drugs in these programs.

The Centers for Medicare & Medicaid Services (CMS) Office of the Actuary (OACT) estimated that Federal spending would increase by $196 billion over 10 years as a result of this rule, and that premiums would increase by $50 billion for Part D enrollees. This is a significant price tag for a proposed rule, especially when the goal of the rule is to lower costs for consumers.

1. In addition to the Office of the Actuary's analysis, the proposed rule also included two additional independent analyses that were commissioned by HHS. Why did HHS include these additional analyses in the proposed rule?

   Response: The proposed rule addressing the removal of safe harbor protections for rebates involving prescription pharmaceuticals included the perspectives of the CMS Office of the Actuary and two external actuarial firms, Milliman and Wakely, who were chosen by ASPE based on their commercial experience assisting plan sponsors with their plan bids.

2. Why were Milliman and Wakely Consulting Group selected to perform these independent analyses? Did HHS provide Milliman and Wakely Consulting Group with any directions or assumptions to factor into their analyses?

   Response: Milliman and Wakely are independent actuarial firms experienced with helping Part D plans and other insurers file their annual plan bids. As such, they were engaged to help the department anticipate strategic behavioral responses to future rulemaking and, ultimately, have a more informed regulatory impact analysis. Specifically:

   - HHS/ASPE studied actuarial models related to Part D rebates as part of its work evaluating a proposed rule published by CMS in November 2017.

   - The CMS Office of the Actuary conducted the analyses contained in that

proposed rule.

- During a literature review conducted by ASPE in 2017, Milliman was identified as a consulting actuary with experience providing actuarial estimates for both manufacturers and PBMs. As such, they were chosen because of their insights into the strategic behavior used on either side of the negotiating table.

- Wakely was similarly engaged because they were already under contract with ASPE for a different project, and had expertise related to commercial health plans outside of the Part D program.

- As a result, the Department's rulemaking was informed by actuarial estimates assuming a variety of industry responses, included manufacturers keeping a portion of their rebate and Part D plans negotiating larger price concessions from manufacturers.

3. Going forward, does HHS plan to include additional commissioned analyses in all proposed rules, or just in the rules in which HHS disagrees with its own actuary?

   Response: HHS believes it is important for taxpayers to understand the potential real-world impact of economically significant rules and will commission future outside analyses where appropriate.

4. Which actuarial analysis should be considered the official estimate for the purposes of considering this rule?

   Response: All three estimates are included in the proposed rule for public consideration.

5. The Office of the Actuary determined that the majority of beneficiaries in Medicare Part D would see an increase in their total out of pocket costs, as well as their premiums. Does HHS have concerns regarding the beneficiary impact of this rule?

   Response: If there is a change in the safe harbor rules effective in 2020, CMS will conduct a demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program. The demonstration would consist of a modification to the Part D risk corridors for plans. For Calendar Year 2020, under the demonstration, the government would bear or retain 95 percent of the deviation between the target amount, as defined in section 1860D-15(e)(3)(B) of the Social Security Act (the Act) and the actual incurred costs, as defined in section 1860D-15(e)(1) of the Act, beyond the first 0.5 percent. Participation in the two-year demonstration would be voluntary and plans choosing to participate would do so for both years. Further guidance regarding the application process for the demonstration will be provided at a later date.

6. In the rule, HHS acknowledges that it is difficult to predict how manufacturers and insurers might respond to this rule. Does HHS agree that there is significant uncertainty around the implications for this policy?

Response: HHS wants to be certain that the rule is beneficial for American patients and taxpayers. That is why we commissioned additional studies and issued further guidance to Part D plans to help industry and the public understand the changes proposed and to ensure as smooth a transition as possible.

7. Is there anything in the proposed rule that would directly require drug manufacturers to reduce the list prices for their drugs?

8. Is it fair to say this proposal relies on the assumption that pharmaceutical companies will voluntarily reduce their prices?

9. I understand that the Administration believes that beneficiaries may see deeper discounts at the pharmacy counter, but is there anything in this rule that would affirmatively require this?

10. Does HHS disagree with the Office of the Actuary's analysis that manufacturers may use this rule as an opportunity to recoup lost revenue?

Response to 7-10: The current rebate system rewards list price increases, which benefit everybody but patients and taxpayers. If the proposed rule were to be finalized, plan sponsors would have an incentive to select lower-cost drugs over high-cost drugs with higher rebates and manufacturers would have an incentive to lower list prices or provide additional price concessions. Nothing in the proposed rule reduces the ability of PBM or plan sponsors to negotiate, nor relies on voluntary discounts by drug companies. Rather, the competitive nature of the Part D market would reward plan sponsors able to negotiate lower drug prices, reduce gross drug costs, and continue to offer affordable premiums.

Medicare Part D Protected Classes

On November 26th, CMS issued a proposed rule that would make changes to Medicare Part D's six protected classes. These six protected classes ensure that Medicare beneficiaries with serious conditions, such as HIV/AIDS, mental health conditions, cancer, and epilepsy have access to the medications they need. By ensuring that all Part D plans cover all or substantially all drugs within the six classes of drugs, beneficiaries with these conditions can know that their drugs will be covered when they need them the most.

Beneficiaries with these conditions are especially vulnerable to significant health consequences if there are interruptions in their drug therapies and often their medications are not easily substituted with other medications.

1. Does HHS believe the Administration has sufficiently considered the impacts this proposal could have on patients with conditions within the six protected classes?

2. Does HHS have concerns that changes to the protected classes could increase costs elsewhere if patients have lapses in their drug therapies, such as through increased hospital costs or emergency room visits?

3. Does HHS believe the savings from this rule outweigh the impact it could have on beneficiaries?

Response to 1-3: Under the current protected class policy, Part D sponsors are permitted to utilize step therapy (ST) and prior authorization (PA) on new starts (that is, enrollees initiating the therapy), with respect to five out of the six protected classes (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, and immunosuppressants for the treatment of transplant rejection but not antiretrovirals). Further, CMS conducts reviews of ST and PA criteria as part of the annual formulary review and approval process, and will only approve PA and ST criteria that are clinically supported. As such, under the current policy, a Part D sponsor is not permitted to interrupt a patient's course of treatment to require the patient to meet step therapy requirements.

In CMS' Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses Proposed Rule, issued in November 2018, CMS proposed broadening the use of prior authorization and step therapy. CMS' goal was to provide additional flexibility so that Part D sponsors could better manage the benefit from a clinical as well as a cost savings perspective. CMS believes that the existing beneficiary protections, including our extensive clinical formulary review and approval process, would adequately protect enrollees from the inappropriate application of PA and ST requirements. Moreover, CMS would effectively limit most ST criteria to new starts as best practice, except when a change in therapy is clinically supported by the recognized compendia or widely accepted treatment guidelines. When step therapy is applied, CMS would expect to approve PA or ST requirements with initial treatment that is comparably supported by recognized compendia or widely accepted treatment guidelines.

In the Final Rule issued on May 16, 2019, CMS concluded, based on comments received during the rulemaking process, that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to PA or ST requirements outweighs the potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility. Therefore, in the Final Rule, CMS finalized a codification of existing policy that allows Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except for antiretroviral medications, only for new starts, to determine if a drug's intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications.

Exclusivity Forfeiture

1. In the FY2020 budget request, HHS proposes triggering an initial generic drug applicant's

180-day exclusivity when a subsequent application is tentatively approved, subject to specific conditions. Some have noted that federal law already forces a forfeiture of exclusivity when an initial generic drug applicant fails to market a drug. Why are forfeiture events already specified in law not sufficient to ensure first filers have the incentive to bring their drug to market in a reasonable time frame? Are further changes needed to FDA's current forfeiture authority to ensure timely entry of generics?

Response: Further statutory changes are needed because, currently, some generic drug applicants who file first limit competition by intentionally delaying seeking final approval in order to not trigger their 180-day exclusivity, thereby blocking subsequent generic competitors. The proposal, if enacted, would ensure that first-to-file generic applicants awarded a 180-day exclusivity period would not be able to unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period.

National Institutes of Health

1. In the FY2020 budget request, HHS proposes cutting funding at the National Institutes of Health (NIH) by more than $4.5 billion. Americans rely on the NIH for groundbreaking research in healthcare therapies, treatments, and cures. Although the HHS budget suggests that the requested funding level would preserve "research in the highest priority areas," the Administration has proposed cutting nearly every account at NIH by millions of dollars, including a $897 million cut from that National Cancer Institute, a $769 million at the National Institute of Allergy and Infectious Diseases, and a $486 million cut at the National Heart, Lung, and Blood Institute. Invariably, some high-priority research will not be funded. Can HHS provide context and detail on what specific programs and research initiatives the Administration is proposing to cut across the NIH?

   Response: NIH estimates that the number of new and competing Research Project Grants (RPGs) awarded would decrease from about 11,675 in FY 2019 to 7,894 in FY 2020. In addition, funding for noncompeting RPGs would be reduced; the size of the reduction to specific awards would depend on the Institute involved. Similar reductions to other types of research grants would also be expected. In general, NIH seeks to avoid reductions of a magnitude that would end programs or close labs, so that existing research activities can continue on a smaller scale or slower timeline.

Healthy People 2030

1. The Healthy People 2030 objectives for immunization and infectious disease are a cornerstone to federal, state, and local efforts to monitor our progress as a nation in protecting against vaccine-preventable conditions across the lifespan. I understand the draft Healthy People 2030 objectives includes very few immunization objectives (eight total). At a time when we are seeing increased outbreaks of diseases that were virtually eliminated in this country, can HHS explain the rationale behind the reduction in immunization objectives in the draft Healthy People 2030 framework and what the process looks like moving forward?

   Response: Ensuring that the United States' population is protected from infectious

diseases is an important national public health priority. While the number of immunization objectives proposed to be included in Healthy People 2030 has been reduced, the overarching strategic goal remains to increase vaccination across the lifespan for all Advisory Committee on Immunization Practices (ACIP) recommended vaccines. HHS and its agencies will continue to focus on monitoring, assessing, and responding to, any threats from infectious diseases.

As part of the process to develop Healthy People 2030, HHS issued a charge to the members of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (the Committee) to assist "in reducing the number of objectives while ensuring that the selection criteria identify the most critical public health issues that are high-impact priorities supported by current, national data sets." With guidance from this Committee, input from Healthy People's Federal Interagency Workgroup (a group of more than 30 Federal departments, agencies, and offices, who provide ongoing guidance to the initiative), and with leadership and support from the HHS Office of Disease Prevention and Health Promotion and the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics, criteria were developed to select objectives for Healthy People 2030. These criteria include: having current and regularly available, nationally representative data; addressing health concerns of national importance; having evidence-based approaches for improvement; and having an impact on reducing health disparities and achieving health equity. Federal subject matter experts were asked to prioritize the objectives that were the most crucial to the field and to improving the health and well-being of the Nation.

Experts from CDC spearheaded the efforts to prioritize the immunization and infectious disease objectives for Healthy People 2030. Using the criteria provided, they strategically chose the proposed priority areas to provide proxy measures for vaccination coverage across the lifespan. The broad national goal that HHS and its agencies are working towards in this area remains to increase and support vaccination coverage across the lifespan, and progress toward this goal will be monitored carefully.

While this set of objectives is being proposed for the launch of Healthy People 2030, there will be opportunities throughout the decade to review these objectives. If necessary, new or revised objectives can be proposed to help ensure that the health of the public across the lifespan is protected from infectious diseases by immunizations.

Nursing Workforce

1. For more than 50 years, nursing workforce development programs have helped us ensure that we have adequately trained nursing professionals. Nurses provide high quality care across the country and are vital for ensuring the long-term health of all Americans. I was dismayed when I saw that once again the Trump Administration has proposed cutting HRSA's nursing workforce programs, this time by 67 percent. Despite the success of these programs and the fact that demands are only increasing for nurses, the Trump budget proposes eliminating all but one Title VIII nursing workforce program. Can HHS explain how the Trump Administration believes cutting the Title VIII nursing programs will help ensure that we have the nursing workforce needed to meet the increasing health

needs of the U.S. population? Please detail the steps the Administration is taking to ensure that nursing workforce needs are met now and in the future.

Response: The Fiscal Year (FY) 2020 President's Budget includes funding for the Nurse Corps Scholarship and Loan Repayment Programs, both of which seek to ensure that we have the nursing workforce needed to meet the increasing health needs of the U.S. population. The Nurse Corps Scholarship Program provides scholarships to nursing students in exchange for a minimum two-year full-time service commitment (or part-time equivalent), at an eligible health care facility with a critical shortage of nurses. The Nurse Corps Loan Repayment Program provides loan repayment assistance to professional registered nurses (RNs), including advanced practice nurses (APRNs), in return for a minimum two-year full-time service commitment to work at eligible health care facilities with a critical shortage of nurses or serve as nurse faculty in eligible schools of nursing.

Title VII Workforce Programs

1. Title VII workforce development programs help ensure that we have a robust and diverse workforce of healthcare professionals who provide quality care. The programs promote ethnic and cultural diversity in the healthcare workforce and help ensure that the needs of all Americans, including those in rural and underserved areas, are met. As we continue to see an aging population and greater needs across many already underserved communities, the Trump budget once again slashes these critical workforce programs, including eliminating the Primary Care Training and Enhancement program, Health Professions Training for Diversity, Area Health Education Centers, and Geriatric Programs. Can HHS explain how the Trump Administration believes eliminating these workforce programs will help ensure that we have a diverse and sufficient workforce to care for the aging population and those in rural and underserved areas?

   Response: The FY 2020 President's Budget prioritizes funding for health workforce activities that provide scholarships and loan repayment to clinicians in exchange for their service in areas of the United States where there is a shortage of health professionals. While funding for the cited programs has been eliminated in the FY 2020 President's Budget, the budget continues to request funding for the National Health Service Corps (NHSC), which supports clinicians who demonstrate a commitment to serve our Nation's medically underserved populations at NHSC-approved sites located in Health Professional Shortage Areas.

   Moreover, the Budget requests $83.1 million for the Nurse Corps Scholarship and Loan Repayment Programs. The Nurse Corps Scholarship Program provides scholarships to nursing students in exchange for a minimum two-year full-time service commitment (or part-time equivalent), at an eligible health care facility with a critical shortage of nurses. The Nurse Corps Loan Repayment Program provides loan repayment assistance to professional registered nurses (RNs), including advanced practice registered nurses (APRNs), in return for a minimum two-year full-time service commitment to work at eligible health care facilities with a critical shortage of nurses or serve as nurse faculty in eligible schools of nursing.

In addition, the President's Budget includes funding for the Teaching Health Center Graduate Medical Education (THCGME) program. The THCGME program increases healthcare access in underserved communities by supporting primary care medical and dental residency programs in community-based ambulatory patient care settings. The President's Budget includes $126.5 million in funding for the THCGME program in each of FY 2020 and FY 2021, for a total of $253 million over two years.

Tobacco

In July 2017, the FDA announced a new Comprehensive Plan for Tobacco and Nicotine Regulation. It is critical that the agency follows through on these efforts to improve public health and reduce the hundreds of thousands of premature deaths per year linked to the use of tobacco products.

1. Commissioner Gottlieb outlined a broad tobacco prevention plan during his time at FDA that, if implemented, would have a significant impact on tobacco use in the United States. Following Commissioner Gottlieb's recent departure from FDA, will HHS commit to continuing to move his agenda forward to prohibit the sale of flavored cigars and menthol cigarettes as well as reduce nicotine levels in cigarettes to non-addictive levels?

   By what dates does HHS intend to have notices of proposed rulemaking and final rules issued for each of these regulations? Specifically, what is the Department's timeline for promulgating regulations pertaining to the ANPRM released on March 16, 2018, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes" and the ANPRM released on March 21, 2018, "Regulation of Flavors in Tobacco Products"?

   Response: HHS is fully supportive of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, including the Youth Tobacco Prevention Plan. Protecting our nation's youth from the dangers of tobacco products is a priority for the Department. Specifically, the epidemic use of e-cigarettes among children is one of our biggest public health challenges. This disturbing and accelerating trajectory of use in youth, and the resulting path to addiction, must end. While we are unable to provide specific timelines for issuing any regulations, HHS continues to take these issues very seriously and we will keep you updated on our work related to the comprehensive plan.

2. The most recent National Youth Tobacco Survey data from FDA and CDC reflects a worsening public health crisis. What additional steps is HHS taking to curb youth usage and access to tobacco products?

   Response: The 2018 National Youth Tobacco Survey (NYTS) data highlights a troubling epidemic of e-cigarette use among youth. Protecting our nation's youth from the dangers of tobacco products is among HHS's most important responsibilities, and FDA will continue to take aggressive steps to make sure tobacco products are not being marketed or sold to kids. These efforts are a cornerstone of FDA's comprehensive plan for the regulation of nicotine and tobacco, and are also the focus of the multi-pronged Youth Tobacco Prevention Plan. FDA's Youth Tobacco Prevention Plan demonstrates the

Agency's commitment to using its authorities to protect our children. These authorities include enforcement, product standards, premarket review, sales and promotion restrictions, and public education.

One of the ways FDA is addressing the sharp increase in youth use of e-cigarettes is to revisit the compliance policy for premarket review of these products.

Additionally, FDA continues to take aggressive enforcement action to address youth access to these products. These include the largest coordinated enforcement effort in Agency history that resulted in more than 1,300 warning letters and civil money penalty complaints (fines) to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores last summer and actions to address products that were misleadingly labeled and/or advertised, including e-liquids resembling kid-friendly food products such as candy and cookies. FDA has also taken action against e-cigarette and e-liquid products that are adulterated under section 902(6)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 387b(6)(A)) for not having a required FDA marketing authorization order in effect and/or being misbranded under section 903(a)(6) of the FD&C Act (21 U.S.C. § 387c(a)(6)) because a required notice or other information respecting the products was not provided. FDA has issued warning letters to companies, and sent letters to more than 60 companies seeking information about whether more than 90 tobacco products, including e-cigarette and e-liquid products, may be currently on the market without requisite premarket authorization and outside of the Agency's compliance policy.

HHS continues to educate both youth and parents about the public health concern of youth e-cigarette use. For example, FDA expanded its public education efforts to prevent youth use of e-cigarettes. Last year, FDA launched "The Real Cost" Youth E-Cigarette Prevention Campaign to educate teens about the dangers of nicotine on the developing brain and other health consequences associated with e-cigarette use. This new effort targets nearly 10.7 million youth, aged 12-17, who have used e-cigarettes or are open to trying them. The campaign features advertising on digital and social media sites popular with teens, as well as posters with e-cigarette prevention messages in more than 37,000 high schools nationwide. Additional materials have been provided to over 700,000 teachers and school administrators across the country. The Centers for Disease Control and Prevention (CDC) has also published fact sheets on the risks of e-cigarettes for youth and young adults.

Currently, the Tobacco Control Act does not provide a means for FDA calculation of user fees for Electronic Nicotine Delivery Systems (ENDS) products and certain other deemed products. These products represent an increasing share of the tobacco marketplace as well as FDA's tobacco regulatory activities. The FY 2020 Budget requests an additional $100 million in tobacco fees and requests authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. To ensure that resources keep up with new tobacco products, the proposal would also index future collections to inflation.

3. Flavored cigars are widely popular among youth; nearly two-thirds of those 12 to 17 years of age who have ever smoked cigars report using a flavored cigar as their first product. Some flavored cigars are grandfathered onto the market and are not subject to product review. In May 2016, FDA announced that it intended to issue a proposed rule that would eliminate characterizing flavors in grandfathered cigars. Commissioner Gottlieb reiterated FDA's intention to ban flavored cigars in November 2018. When can we expect to see the agency finally issue this proposed rule to prevent more youth from becoming addicted to these flavored tobacco products?

   Response: As you know, FDA announced the Agency's intention to advance an NPRM that would ban characterizing flavors in cigars. A product standard can only be done through the rulemaking process, and we remain committed to issuing an NPRM. At this time, we are unable to provide a timeline, however, we will continue to keep you informed of our progress.

4. The Draft Guidance that FDA released last month restricts the sale of some flavored e-cigarettes to age-restricted locations but allows mint and menthol e-cigarettes to avoid even these modest age restrictions. Mint and menthol e-cigarettes are widely popular among youth; more than half of high school students who currently use e-cigarettes use menthol or mint products according to the 2018 National Youth Tobacco Survey. Why did the FDA choose to allow mint and menthol e-cigarettes to stay on the market when these products are so popular with young people?

   Response: FDA is revisiting its compliance policy as it applies to flavored ENDS products other than tobacco, mint, and menthol flavored ENDS products. The change in policy reflects a careful balancing of public health considerations.

   Data indicate that mint- and menthol-flavored electronic nicotine delivery systems (ENDS) products are preferred more by adults than minors, and that some adult smokers may be using mint- and menthol-flavored ENDS products with the goal of ceasing combusted tobacco use, seeking potential health benefits at the individual level, and may be at risk of migrating back to cigarettes. Recent evidence also indicates that mint- and menthol-flavored ENDS products are preferred more by adults over other flavors, but that other flavors are preferred by minors over mint and menthol flavors. Wave 4 of the PATH Study found that, in a combined response option, mint- and menthol-flavored e-cigarettes ranked fourth among youth (age 12 to 17 years), third among young adults (age 18-24 years) and second among adults (age 25 years and older).

   FDA will continue to monitor the rates and use patterns among youth and adults for menthol, mint, and other flavored ENDS products, and the Agency will reconsider its policies with respect to these products, if appropriate. In addition, the Agency continues to take a comprehensive approach to prevent youth from using all tobacco products, including ENDS products. This approach includes aggressive compliance and enforcement actions and a new public education campaign focused on preventing youth use of ENDS products.

5. Use of e-cigarettes and other Electronic Nicotine Delivery Systems (ENDS) skyrocketed from 2017 to 2018. How does the Department plan to build on efforts such as FDA's The Real Cost Campaign to educate minors on the harms of e-cigarettes?

   Response: To address the rising rates of youth e-cigarette use, the FDA's Center for Tobacco Products has invested significant resources in a media prevention campaign. In September 2018, the FDA launched a campaign to prevent youth vaping by expanding its successful youth tobacco prevention brand, "The Real Cost," to reach the more than 10 million youth ages 12-17 who have used e-cigarettes or are open to trying them. The campaign urges these teens to "know the real cost of vaping," with advertising designed to snap youth out of their "cost-free" mentality by educating them about the potential risks of using e-cigarettes.

   "The Real Cost" Youth E-cigarette Prevention Campaign reaches teens where they spend most of their time: in school and online. In addition to a suite of digital content on "The Real Cost" campaign website and social media channels, ads run on digital platforms where age is verified, including Hulu, Facebook, Spotify, and YouTube. As teens are increasingly faced with peer pressure to use e-cigarettes when they are in the school environment, the campaign places e-cigarette prevention materials in high schools across the nation, both in school bathrooms and on educational digital platforms accessed by students during the school day. The campaign also sent educational materials to every high school in the United States—over 37,000 schools—through the Scholastics network and with Students Against Destructive Decisions (SADD).

   In the coming months, FDA plans to expand its education efforts by:
   - Launching new "The Real Cost" youth e-cigarette prevention advertising;
   - Extending paid media to include broadcast television channels such as Teen Nick, MTV, Adult Swim, and Hulu; and
   - Developing a toolkit for stakeholders to educate at-risk youth audiences.

   As of May 2019, FDA's e-cigarette prevention messages were seen by teens nearly 500 million times and have higher than average online engagement rates. FDA is evaluating this comprehensive effort with a longitudinal, nationally representative study that measures teen tobacco-related knowledge, attitudes, beliefs, and behaviors.

6. Commissioner Gottlieb previously stated that if the 2019 National Tobacco Youth survey reveals an additional increase in youth e-cigarette use, market withdrawal of pod and cartridge-based e-cigarettes may be necessary. Does HHS agree?

   Response: HHS has made clear that absent a reversal in the trends of youth e-cigarette use, we envision a world where the FDA will continue to narrow the off-ramp for adults seeking a less harmful alternative to combustible cigarettes, in order to close the on-ramp that has resulted in the widespread and increasingly frequent use of e-cigarettes by teens. It is premature to make any decisions or prejudge the results of the 2019 National Youth Tobacco Survey (NYTS). Once we have the benefit of the updated data, we will review our efforts to reduce youth use of e-cigarettes. We are taking a comprehensive approach

to addressing the youth use of e-cigarettes and will take further action, as appropriate.

7. Last fall, the FDA sent warning letters to 21 companies that it suspected of introducing new tobacco products to the market without the required review from the agency. Has the FDA received any response from these companies or taken any action to remove these products from the market? How does FDA currently monitor the market for the illegal introduction of new products? With the delay in product review for newly deemed tobacco products, how does FDA determine whether a deemed product entered the market after August 8, 2016?

   Response: As part of its comprehensive enforcement effort to address the illegal sale of tobacco products, FDA investigates and pursues companies that it believes are selling or distributing deemed new tobacco products, including ENDS products, that first entered the market after August 8, 2016, and have not been authorized for marketing by FDA. The marketing and distribution of these products without FDA review and authorization is outside the Agency's compliance policy (the compliance policy only applies to deemed new tobacco products that were on the market as of August 8, 2016), and the products are adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act. However, after an investigation, FDA may find that a deemed new tobacco product was on the market as of August 8, 2016. For example, in some instances, FDA has found that companies who had marketed their products as of August 8, 2016, have changed their products' labels, including the product name, after August 8, 2016. Pursuant to an August 2016 court decision, FDA explained in the December 2016 guidance for industry, https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM436468.pdf that a change to an existing tobacco product's label, standing alone, does not result in a separate new tobacco product. Alternatively, the FDA may find evidence of a reported violation or other potential violations that require additional surveillance, monitoring, or inspections. FDA's investigation is essential to determining whether a particular product was on the market as of August 8, 2016, the critical date for the Agency's compliance policy.

   As of April 2019, FDA has sent letters to more than 60 companies seeking information on over 90 brands of tobacco products to determine if those products are being illegally marketed outside the FDA's compliance policy. These letters indicate that regulated industry may be promoting a tobacco product in a manner that potentially violates the Federal Food, Drug, and Cosmetic Act and its implementing regulations, and are not intended to communicate that FDA is considering enforcement action. After completing investigations, FDA may take advisory or enforcement actions in instances when it has determined that products are unlawfully marketed and sold outside the FDA compliance policy. FDA will continue to investigate potential violations of the FD&C Act and regulations, and will take action when appropriate.

   FDA's activities, including inspecting physical retail establishments, monitoring and reviewing tobacco sales and advertising in publications and online, including other sales and promotional activities, inspecting manufacturing establishments, investigating qualified adult-only facilities that distribute free samples of smokeless tobacco, and

reviewing complaints, as well as other FDA observations, may lead to an advisory or enforcement action, if appropriate.

Within the last year, FDA has taken action in multiple instances when the Agency has determined that products are unlawfully marketed and sold outside the FDA compliance policy. FDA has issued warning letters to a number of ENDS product manufacturers, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm626249.htm, as a result of inspection findings that revealed they were, among other things, selling new e-liquids that were not on the market as of August 8, 2016 without the required premarket authorization, and illegally selling e-liquids with labeling and/or advertising that cause the product to imitate kid-friendly food products.

Oversight of Medicaid

HHS has not always provided the necessary oversight of state Medicaid managed care to ensure that vulnerable people have the care they need and are entitled to. For example, the Dallas Morning News reported last year that managed care plans in Texas systematically denied access to needed services for extremely frail people with disabilities.

One such example is the case of D'ashon Morris, a foster care child with special healthcare needs who needed a breathing tube. Unfortunately, because of the reductions in D'ashon's in-home nursing care, when D'ashon dislodged his breathing tube, he choked and went without oxygen for 40 minutes.

Another tragic example is Heather Powell, who is completely paralyzed from the neck down, and had to fight Superior HealthPlan, the managed care plan she was enrolled in, for a special mattress that her doctors prescribed to relieve pain and prevent sores that can kill immobilized people.

In spite of these and other shocking examples, HHS recently proposed to further weaken beneficiary access standards and quality measurement, and did nothing to strengthen beneficiary protections.

1. Does HHS believe that it is acceptable for managed care plans to deny necessary services to individuals with disabilities to the extent that it causes irreversible, sometimes life-threatening, harm?

2. Can HHS point to the budget proposals intended to prevent tragedies such as this from ever happening again?

3. Does HHS believe that weakening access standards and quality standards, as the Department has proposed, is likely to improve care for vulnerable children who rely on Medicaid managed care plans to keep them alive?

Response to 1-3: Please be assured that HHS remains steadfast in its commitment to providing access to high quality healthcare to all beneficiaries, including those enrolled in Medicaid managed care plans. The Medicaid program was designed to

serve our most vulnerable populations including children and persons with disabilities. Indeed, the President's FY 2020 Budget includes a number of proposals to improve federal health programs so they work better for the people they serve and to ensure that Medicaid can adequately serve the most vulnerable populations.

ACA Navigator Program

On August 31, 2017, the Trump Administration reduced funding for the Navigator program from $63 million to $36.8 million, a 40 percent cut from the previous year. The Administration further reduced funding for 2019 to $10 million. A report by the Government Accountability Office (GAO) found that the Administration's decision to cut Navigator funding was based on "incomplete and problematic data." The report also found that CMS described the enrollment goals in an "unclear manner" and "failed to provide Navigators guidance on the performance measure." The GAO report concluded that the decision to distribute funding based on inaccurate data likely meant that certain Navigators did not receive the appropriate level of funding.

1. What actions will HHS take to address the issues identified in the GAO report?

2. Going forward, what metrics will HHS use to evaluate Navigators' performance and what process will be used to review applications?

Response to 1-2: HHS appreciates the ongoing work of the GAO to study critical aspects of our health care system, including outreach and enrollment for the Federally-facilitated Exchange. In the report,[1] the GAO provided a number of recommendations. CMS concurred with GAO's recommendation to ensure that the approach and data we use for determining Navigator award amounts accurately and appropriately reflect Navigator performance. CMS has provided guidance to Navigators that their grant funding will be explicitly tied to their self-identified goals and their ability to meet those goals. CMS also concurred with the GAO's recommendation to assess other aspects of the consumer experience to ensure we has quality information to achieve our goals. CMS has assessed the consumer experience through the availability of the two largest customer channels supporting exchange operations—the call center and HealthCare.gov—as well as customer satisfaction surveys. CMS believes these metrics represent a comprehensive assessment of the consumer experience. CMS is always looking for ways to improve the consumer experience and will consider focusing on other aspects of the consumer experience as needed. The GAO also recommended that CMS establish numeric enrollment targets for HealthCare.gov to monitor its performance. CMS did not concur with this recommendation because there are numerous external factors that can affect a consumer's decision to enroll that are outside our control, such as the state of the economy, issuer rates, employment rates, and the number of people who effectuate their coverage. These are factors that are wholly unrelated to the performance of HealthCare.gov. The Department believes that a more informative performance metric is whether everyone who utilized HealthCare.gov, who qualified for coverage, and who desired to purchase coverage, was able to make a plan selection. HHS does

[1] *"Health Insurance Exchanges: HHS Should Enhance Its Management of Open Enrollment Performance"* (GAO-18-565), July 2018.

not believe that numeric enrollment targets are relevant to assess the performance of objectives related to a successful open enrollment period for the Exchange.

The Administration's decision to reduce funding has compromised Navigators' ability to perform the full range of duties specified in statute. Navigator entities reported conducting 68 percent fewer outreach events during the 2018 Open Enrollment period as compared to the 2017 period. Eight Navigator organizations have withdrawn from the program, and 81 of the 98 organizations have experienced a loss of funding.

3. How does HHS expect Navigator entities to fulfill the wide breath of responsibilities legally required of Navigators at the $10 million funding level?

4. What steps will HHS take to ensure that Americans wishing to enroll in Marketplace coverage are well informed about opportunities to enroll?

Response to 3-4: Data from the 2019 Open Enrollment Period shows steady plan selections through the Federal platform (i.e., HealthCare.gov), with more than 8.4 million consumers selecting a plan as of the end of open enrollment, December 15, 2018. As was the case last year, CMS remained committed to our primary goal of providing a seamless enrollment experience for HealthCare.gov consumers, and data show that CMS achieved this goal. Consistent with last year, the consumer satisfaction rate at the call center remained at an all-time high—averaging 90 percent—throughout the entire Open Enrollment Period and, for the second year in a row, CMS did not need to deploy an online waiting room during the final days of Open Enrollment. As a result, HealthCare.gov consumers were able to shop and pick a plan with minimal interruption throughout the entire enrollment period.

When Exchanges were in their infancy, and public awareness and understanding of coverage options was low, HHS encouraged Navigators to cast a wide net and to provide intensive face-to-face assistance to consumers. Since that time, public awareness and education on options for private coverage available through the Exchanges has increased. Certified application counselors, direct enrollment partners, and Exchange-registered agents and brokers serve as additional resources for education on options and outreach to consumers. Enrollment data from previous years show that Navigators failed to enroll a meaningful number of people through the Federally Facilitated Exchanges (FFE)s, comprising less than 1 percent of enrollment in both plan year 2017 and plan year 2018—not nearly enough to justify the millions of federal dollars spent on the program. By contrast, agents and brokers assisted with 42 percent of FFE enrollment for plan year 2018, which cost the FFE only $2.40 per enrollee to provide training and technical assistance. It was appropriate to scale down the Navigator program and other outreach activities to reflect the enhanced public awareness of health coverage options through the Exchanges. Additionally, in the Funding Opportunity Announcement (FOA) for the FFE Navigator Program for plan year 2019, Navigator applicants were encouraged to leverage volunteers as well as strategic partnerships with public and private organizations to target consumers who would benefit from Exchange coverage and

more efficiently meet their enrollment goals. These changes are based on the success of private sector-focused programs like those within Medicare Advantage.

Navigators differ from agents and brokers in that they are required to provide unbiased information to consumers. The Committee has heard stories from consumers who have been misled about the nature of their coverage by agents and brokers who had their own financial interest in mind rather than the consumer's interest. Commissioner Jessica Altman of the Pennsylvania Insurance Department testified in front of the Committee at a legislative hearing that her Department has suspended the licenses of at least eight insurance brokers and agents who misled consumers about the nature of the coverage they were selling.

5. What steps will HHS take to ensure that consumers are protected from bad actors, such as unscrupulous agents and brokers, moving forward in the Marketplaces?

Response: CMS Marketplace Program Integrity is an increasing concern in the Health Insurance Exchanges – both in the Federally-facilitated Exchanges and the State-based Exchanges. CMS has conducted a fraud risk assessment of the Health Insurance Exchange consistent with best practices developed by the Government Accountability Office. In FY 2017, CMS's Exchange integrity team performed investigations to identify areas of fraud and abuse in the Exchanges to include pilots to test the value of consumer complaints and identify leads that could result in administrative action, test the value of monitoring the license status of insurance agents once they register with CMS, and identify areas that appear to have a higher risk of fraud and abuse. CMS will continue these activities, including implementing an Exchange Program Integrity Contractor (EPIC) to facilitate analysis and investigations.

Office of Civil Rights

In October 2018, the New York Times reported on a leaked memo from the Department of Health and Human Services that called on other Departments—including the Departments of Justice, Labor, and Education—to adopt a uniform definition of sex. The proposed definition would narrowly define sex as a "biological, immutable condition determined by genitalia at birth". Such a definition would effectively erase protections for transgender people under federal civil rights laws.

1. Was HHS consulted about this reported memo or is the Department aware of its contents?

2. What is HHS trying to achieve with this definition of sex?

3. Does HHS agree with this proposed definition of sex—which would limit the application of federal civil rights laws only to people who fully conform with gender stereotypes?

4. Will HHS commit to not pursuing this change?

Response to 1-4: HHS does not comment on alleged leaked documents. HHS believes every person should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. On May 24, 2019, HHS

issued a proposed rule to revise regulations implementing and enforcing Section 1557 of the Affordable Care Act (ACA) (published in the Federal Register on June 14, 2019 at 84 Fed. Reg. 27846). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. The proposed rule would maintain vigorous civil rights enforcement of existing laws and regulations prohibiting discrimination on the basis of race, color, national origin, disability, age, and sex, while, consistent with the position the Department of Justice has taken in briefs filed with the Supreme Court on behalf of the United States on a similarly worded civil rights statute, revising certain provisions of the current Section 1557 regulation that a federal court has said are likely unlawful.

HHS is in the process of revising a 2016 ACA rule related to nondiscrimination in health programs, specifically the Department has stated its intent to revise the rule's sex discrimination protections, including its protections related to transgender status. This reversal of Administration position comes even though the overwhelming majority of federal courts have found that sex discrimination laws—including the ACA—protect transgender people.

5. In an absence of any meaningful change in case law, what prompted HHS to reverse its position that transgender people are included in the ACA's nondiscrimination protections?

6. What outside groups did HHS consult in arriving at this position?

7. When does HHS anticipate releasing a revised version of the rule?

8. What is HHS doing to uphold the right of transgender people to access health care free from discrimination?

9. How many complaints of discrimination on the basis of gender identity has HHS received since January 2017? What is HHS doing with these complaints?

Response to 5-9: HHS believes every person should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. On May 24, 2019, HHS issued a proposed rule to revise regulations implementing and enforcing Section 1557 of the Affordable Care Act (ACA) (published in the Federal Register on June 14, 2019 at 84 Fed. Reg. 27846). Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities. The proposed rule would maintain vigorous civil rights enforcement of existing laws and regulations prohibiting discrimination on the basis of race, color, national origin, disability, age, and sex, while, consistent with the position the Department of Justice has taken in briefs filed with the Supreme Court on behalf of the United States on a similarly worded civil rights statute, revising certain provisions of the current Section 1557 regulation that a federal court has said are likely unlawful.

Although Congress prohibited discrimination on the basis of sex in 1972 (Title IX), and

Section 1557 applied that law to healthcare and the Exchanges established under the ACA, HHS's 2016 Section 1557 regulation redefined discrimination "on the basis of sex" to include gender identity and termination of pregnancy, and defined gender identity as one's internal sense of being "male, female, neither, or a combination of male and female." As a result, several states and healthcare entities filed federal lawsuits against HHS. On December 31, 2016, the U.S. District Court for the Northern District of Texas issued an opinion in Franciscan Alliance, Inc. et al. v. Burwell, preliminarily enjoining HHS's attempt to prohibit discrimination on the basis of gender identity and termination of pregnancy as sex discrimination in the Section 1557 regulation. This federal court concluded the provisions are likely contrary to applicable civil rights law, the Religious Freedom Restoration Act, and the Administrative Procedure Act. The preliminary injunction applies on a nationwide basis. A separate federal court in North Dakota agreed with the reasoning of the Franciscan Alliance decision, and stayed the rule's effect on the plaintiffs before it. Consequently, HHS does not have legal authority to implement the provisions on gender identity and termination of pregnancy in light of the court's injunction which remains in full force and effect today.

The Honorable Eliot Engel (D-NY)

1. Secretary Azar, last year over 40 bipartisan members of Congress, including the original authors of the legislation, wrote to HHS and CMS stating that CMS was not following Congressional intent in the implementation of the new home infusion transitional benefit. However, CMS still chose to implement a short-sighted, misguided policy that will actually push more patients back into a costlier nursing home setting.

   As you know, home infusion therapy allows patients with heart disease, pulmonary hypertension, immune deficiencies, certain cancers, and other conditions to access intravenous, infused drugs in the safety and comfort of their own homes.

   The Agency's decision to reimburse services only on a day when a professional is present in the patient's home, ignoring the fact that lifesaving and life-improving treatment is occurring, is inexplicable. It is not what we intended when we passed the law, it is not how private payers reimburse for these services, and it is incompatible with efforts in increase access to cost-effective home-based care.

   - Can you commit to me that officials at CMS will fix this issue and insure patients will have access to home infusion therapy? If not, I think this Committee is going to have to consider legislation to instruct CMS to do this all over again.

   Response: Section 50401 of the Bipartisan Budget Act of 2018 establishes a temporary transitional home infusion therapy services payment for eligible home infusion suppliers for two years (CYs 2019 and 2020) for the provision of home infusion therapy services pending full implementation of the home infusion therapy benefit in 2021 required by section 5012 of the 21st Century

Cures Act. This home infusion therapy services payment is a single payment that covers the cost of the professional services, including nursing services, training and education (not otherwise paid under the durable medical benefit), and monitoring and remote monitoring services furnished in accordance with the plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished. This home infusion therapy services payment is required to be made on an infusion drug administration calendar day.

In the Calendar Year 2019 final rule, CMS defined infusion drug administration calendar day as the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. CMS recognizes the concerns from stakeholders and members of Congress on its interpretation of "infusion drug administration calendar day", including with respect to professional services that may be provided outside of the home and, as applicable, payment amounts for such services. CMS stated in the final rule that it is our intention to ensure access to home infusion therapy services in accordance with the Bipartisan Budget Act of 2018. Therefore, CMS plans to monitor the effects of finalizing this definition on access to care in a patient's chosen setting and, if warranted and within the limits of its statutory authority, engage in additional rulemaking or guidance regarding this definition.

2. Mr. Secretary, home infusion wouldn't be possible without the professional expertise and services of a pharmacist, who is responsible for a range of activities, including sterile drug compounding, care planning and implementation, care coordination, and other services that are typically furnished by a pharmacist. Congress enacted the 21st Century Cures Act and the Bipartisan Budget to assure that beneficiaries have access to home infusion therapy. The law called on CMS to reimburse for each day that a patient receives a drug infusion. For many patients, that's every day.

   Unfortunately, CMS interpreted the law in a way that home infusion providers only get reimbursed on a day when a nurse is present in the patient's house, which might only be once a week for those patients receiving daily infusions, despite the costs that are incurred every day a patient is treated. So home infusion providers went from getting paid every day under the law, to only once a week.

   To compound this situation, in a recently issued "Frequently Asked Question" document for home infusion therapy providers, CMS determined that home infusion providers cannot bill for home infusion therapy services for patients that are under a home health episode of care. So for homebound patients, home infusion providers who originally thought they were going paid every day, and then thought they were going to get paid only one day a week, are now learning that, for about one-third of their patients, they won't get paid at all.

   - Mr. Secretary, do you think we can reasonably expect health care providers to keep delivering care when they don't get paid? I don't think the current policy is what Congress intended, and needs to be fixed by you immediately.

Response: The Bipartisan Budget Act and the 21st Century Cures Act requires the payment for home infusion therapy services to be a single payment that covers the cost of the professional services, including nursing services, training and education (not otherwise paid under the durable medical benefit), and monitoring and remote monitoring services furnished in accordance with the plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished.

CMS plans to monitor the effects of the home infusion therapy services payment on access to care in a patient's chosen setting and, if warranted and within the limits of its statutory authority, engage in additional rulemaking or guidance on the implementation of this new benefit.

3. Mr. Secretary, do you think we can reasonably expect health care providers to keep delivering care when they don't get paid? I don't think the current policy is what Congress intended, and needs to be fixed by you immediately.

Response: The Bipartisan Budget Act and the 21st Century Cures Act requires the payment for home infusion therapy services to be a single payment that covers the cost of the professional services, including nursing services, training and education (not otherwise paid under the durable medical benefit), and monitoring and remote monitoring services furnished in accordance with the plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished.

CMS plans to monitor the effects of the home infusion therapy services payment on access to care in a patient's chosen setting and, if warranted and within the limits of its statutory authority, engage in additional rulemaking or guidance on the implementation of this new benefit.

The Honorable G. K. Butterfield (D-NC)

Medicaid is a critical source of financial support for hospitals and other health care providers that serve communities and middle-class families across the country. The Government Accountability Office found that states that expanded Medicaid had fewer rural hospitals close than states that chose not to expand. In my state of North Carolina, which has not yet expanded Medicaid, five rural hospitals have closed since 2010. Currently, Washington County Hospital in Plymouth North Carolina and in North Carolina's First Congressional District is in danger of closing. Capping Medicaid through a block grant will make that problem worse, not better. In fact, hospitals have previously said that capping Medicaid "would have serious negative consequences for communities across America."

1. Has the Administration considered the effects of the Medicaid cuts in this budget on rural hospitals?

2. Can you promise that block granting Medicaid will not result in hospital closures that put entire communities, not just Medicaid beneficiaries, at risk?

Response to 1-2: The Trump Administration has placed an unprecedented priority on improving the health of Americans living in rural areas. CMS furthered this commitment by introducing the first ever Rural Health Strategy as part of its Rethinking Rural Health Initiative to focus on ways CMS can strengthen the rural healthcare system and avoid unintended consequences of CMS policy and program implementation. The Rural Health Strategy focuses on applying a rural lens to the vision and work of CMS, improving access to care through provider engagement and support, advancing telehealth, empowering patients in rural areas about making decisions on their healthcare and leveraging partnerships to improve rural health. CMS's goal is to develop programs and policies that ensure rural Americans have access to high quality care, support rural providers and not disadvantage them, address the unique economics of providing healthcare in rural America, and reduce unnecessary burdens in a stretched system to advance the Administration's commitment to improving health outcomes for Americans living in rural areas.

States play a critical role in fostering innovation in program design and financing, and CMS is committed to giving them the flexibility they need to meet the needs of their residents, including their residents in rural areas. The FY 2020 President's Budget proposal to allow states to choose block grant or per capita cap proposals would restore significant flexibility to the states, enable them to manage their programs more efficiently and hold them accountable for producing positive outcomes within a defined budget.

3. The budget proposes to take away Medicaid from jobless and underemployed Americans. Does the budget prevent laid-off workers, people who are going to school, and those taking care of family members from qualifying for Medicaid?

4. Arkansas is currently the only state that takes away coverage from individuals that do not meet a work requirement. In the first seven months of that effort, one in five people who were previously eligible for coverage lost it. Should work requirements be implemented nationally, how many individuals does the Administration estimate will lose coverage?

Response to 3-4: Millions of adults became eligible for Medicaid through the Medicaid expansion provisions in the Patient Protection and Affordable Care Act (PPACA). While medical coverage is important, public assistance programs trap many individuals in dependency. In addition to ensuring access to health care for Americans, the Trump Administration also prioritizes personal responsibility and helping individuals obtain economic self-sufficiency. That's why the President's FY 2020 Budget includes a proposal that would improve consistency between work requirements in federally funded public assistance programs, including Medicaid and Temporary Assistance for Needy Families (TANF), by requiring that certain individuals find employment, train for work, or volunteer (community service) in order to receive welfare benefits. This would enhance service coordination for program participants, improve the health and financial well-being of those receiving assistance, and conserve funding for public assistance

programs to help ensure that they are available for the most vulnerable populations. This proposal is estimated to save $8.3 billion in FY 2020, $55.6 billion over 5 years, and $130.4 billion over 10 years.

In January 2018, the Administration announced its intention to break the cycle of poverty and dependence through approval of Section 1115 community engagement demonstrations. Since then, CMS approved community engagement demonstrations in nine states. The demonstrations promote community engagement activities (e.g., volunteering, caregiving, educational activities, job training or employment) for certain adults to promote improved health and well-being. States may also choose to consider caregivers as an exempted population, in alignment with TANF work-related requirements.

CMS remains committed to supporting states in their efforts to develop new and innovative solutions to improve their Medicaid programs and to provide individuals on Medicaid with better health, the ability to experience the dignity of a job and personal responsibility, and move individuals forward on the path to independence and greater well-being.

5. Secretary Azar, while your budget provides $4.5 billion for combatting the opioid epidemic, it decimates the ACA and slashes Medicaid by $1.5 trillion. Those numbers pale in comparison. How many millions of Americans utilize Medicaid and the ACA to receive opioid treatment?

6. Can the Administration guarantee that slashing the ACA and Medicaid will not exacerbate the nation's opioid crisis?

7. Secretary Azar, by eliminating the ACA's Medicaid expansion, 12 million low-income adults will lose coverage, including many with substance use disorders. Can you guarantee those 12 million individuals will still have access to substance use treatment if they no longer are eligible for Medicaid?

Response to 5-7: Combatting the opioid epidemic is a top priority of this Administration, and promoting access to prevention, treatment, and recovery services for substance use disorder is a critical part of HHS's strategy. HHS continues to pursue a five-point strategy to combat the opioid epidemic by (1) improving access to prevention, treatment, and recovery support services;(2) collecting opioid epidemic data; (3) updating guidance for pain management; (4) targeting of overdose-reversing drugs; and (5) increasing support for research on pain and addiction.

This Administration has made historic investments to address opioid misuse, abuse, and overdose, and the President's FY 2020 Budget provides $4.9 billion in discretionary funding to combat the opioid overdose epidemic. In addition, Medicare and Medicaid policies and funding will play a critical role in combating the opioid crisis. The President's FY 2020 Budget proposes to make it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use

disorder. The Budget also proposes to set minimum standards for Medicaid Drug Utilization Review programs, allowing for better oversight of opioid dispensing in Medicaid. Additionally, it proposes a collaboration between CMS and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

The President signed the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which includes Medicaid provisions to address the opioids crisis. This bold, bipartisan legislation addresses the opioid crisis by expanding access to substance abuse treatment, cracking down on shipments of illicit drugs, and providing more grant funding for prevention, treatment, and recovery. For instance, the SUPPORT for Patients and Communities Act includes a $55 million Medicaid demonstration project over 4.5 years. CMS will oversee efforts to increase substance use provider capacity, by providing an enhanced Medicaid match rate for select states. CMS may select at least 10 states to receive planning grants to assess their behavioral treatment and provider needs to improve provider networks treating substance use disorders. CMS may choose up to five (provided they meet specified criteria) of the 10 states to award planning grants to receive the enhanced federal match rate and implement the activities under this demonstration:

- Supporting ongoing analysis of state behavioral health treatment needs;
- Supporting recruitment training and providing technical assistance for providers offering substance use disorder treatment or recovery services;
- Improving reimbursement for and expanding the amount or treatment capacity of participating providers through the provision of education, training and technical assistance authorized to dispense Food and Drug Administration-approved drugs; and
- Improving reimbursement for and expanding the amount or treatment capacity of providers through the provision of education, training and technical assistance to address the treatment needs for certain populations enrolled under the State plan or waiver.

In addition, on November 1, 2017, CMS offered states the to pursue demonstration projects under section 1115 of the Social Security Act for states to receive the authority to pay for short-term residential-treatment services in an institution for mental disease for individuals diagnosed with substance use disorders (SUDs), including opioid use disorder. Since January 2019, CMS has approved SUD waivers for 22 states to expand access to inpatient options for patients with a SUD diagnosis. We believe that these waivers will strengthen the treatment s options available to individuals with substance use disorders and we encourage additional states to consider this option as well.

The Honorable Debbie Dingell (D-MI)

1. Secretary Azar, as you may know, the EPA recently released its PFAS Action Plan. Did HHS play any role in advising, assisting, or contributing to the proposed action plan? And does HHS have anything in the works currently to propose its own action plan to address PFAS in consumer products, like food substance containers, dental floss, and cosmetics?

Response: As part of an intergovernmental review process, HHS agencies reviewed the PFAS Action Plan during development. In addition, HHS agencies participated in EPA-lead meetings to discuss PFAS including regional summits and consultations.

More specifically, FDA recently established a working group to consider whether further action is needed to address potential health risks arising from the presence of PFAS in food and food contact substances. The work group will also address issues associated with the potential contamination of FDA-regulated foods from an environmental source. At present, FDA is not aware of any food use of PFAS aside from their limited use in food contact materials. In 2010, FDA identified safety concerns with long-chain PFAS used as "grease-proof" coatings on fast-food wrappers, to-go boxes, and pizza boxes. These PFAS are no longer authorized or are no longer in use.[2] FDA is currently evaluating new scientific literature to determine whether short-chain PFAS present food safety concerns when used in food packaging.

For FDA-regulated products more generally, FDA is committed to taking appropriate actions under its authority to protect public health, consistent with available scientific and safety data. With regard to cosmetics, the information available to FDA is limited because FDA does not have pre-market review authority for cosmetics, and manufacturers are not required to tell FDA what ingredients are used in their cosmetic products. Regarding dental floss, FDA has assessed all currently available information regarding dental floss and PFAS and has determined that, at this time, it does not have sufficient evidence to warrant further action beyond this assessment. FDA will continue to monitor and assess the evidence as new information becomes available, as it does with medical devices generally.

2. Secretary Azar, at what level (in parts per trillion) is PFOA and PFOS considered harmful to human health in adults, according to HHS experts? At what level is PFOA and PFOS considered harmful to human health in children, according to HHS experts?

Response: The science around the relationship between PFAS and human health effects is constantly evolving as more information becomes available. HHS is constantly evaluating new research and identifying gaps. The Agency for Toxic Substances and Disease Registry (ATSDR) has developed draft Minimal Risk Levels (MRLs) for four PFAS, including PFOA and PFOS. MRLs are screening levels that ATSDR uses to identify environmental exposures that might harm people's health. ATSDR sets each MRL well below a value that is likely to cause a health effect. If an exposure is below the MRL, it is not expected to result in adverse health effects. It is important to note that MRLs are a screening tool that help identify exposures that could be potentially hazardous to human health. Exposure above the MRLs does not mean that health problems will occur. Instead, it may act as a signal to health assessors to look more closely at a particular site where exposures may be identified.

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[2] https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm528911.htm

3. Secretary Azar, the CDC and ATSDR are looking to conduct PFAS exposure assessments, community engagement activities, and a number of studies—specifically the Pease Study and the Multi-Site Health Study. Will either of these studies or activities look at or will be conducted in Michigan? My state of Michigan has been hit hard by PFAS contamination.

   Response: CDC and ATSDR are committed to addressing PFAS in communities across the US. Currently, the agency is providing support through health assessments and consultations in over 30 communities. We are aware of the PFAS concerns in Michigan, and have been working in multiple sites in Michigan. In consultation with the Michigan Department of Health and Human Services (MDHHS) and the Kent County Health Department, ATSDR has been providing assistance in the development of study protocols, data management, communications, and overall project coordination. In addition, as a result of the state-wide testing of municipal water systems for PFAS, in July 2018, the City of Parchment (Kalamazoo County) found that their drinking water system had contamination with PFAS. CDC/ATSDR provided assistance to the Kalamazoo County Health Department regarding clinician guidance and communication with healthcare workers. ATSDR's Region V office continues to provide technical assistance and support the MDHHS and the Michigan PFAS Action Response Team regarding PFAS issues.

   In the National Defense Authorization Act, Congress asked CDC/ATSDR to conduct a health study looking at the relationship between PFAS exposure and health outcomes. The goal of the multi-site health study is to learn more about the relationship between PFAS exposure and health outcomes among differing populations. CDC/ATSDR recently announced a competitive funding opportunity, and all states, universities and communities are eligible to apply. The information about the relationship between PFAS exposure and health outcomes can be applied to communities across the nation, including those that are not selected as a site.

4. Secretary Azar, Michigan recently had a Medicaid work requirement approved by this Administration. One study estimated that between 61,000 and 183,000 people in Michigan will lose their health insurance because of this policy. Did your Department consider the potential impact on children's health insurance coverage when approving this policy?

5. Secretary Azar, do you think your Department could have done anything differently to prevent so many children from losing health insurance in the past two years, and is that reflected in this budget?

6. Secretary Azar, it's clear to me, based on this large increase in the number of uninsured children after years of steady progress, that this Administration's policies are not serving children's interests. How large would the increase in uninsured children have to be in order for you to be convinced to change course and revise your policies?

   Response to 4-6: CMS approved Michigan's request to extend its section 1115

demonstration project, the "Healthy Michigan Plan (HMP)" on December 21, 2018. This five year extension with amendment allows Michigan, no sooner than January 1, 2020, to require all demonstration beneficiaries, ages 19 through 62, with certain exemptions, to participate in and report 80 hours per month of community engagement activities, such as employment, education, job skills training, or community service, as a condition of continued Medicaid eligibility.

HMP covers beneficiaries in the new adult group (defined at section 1902(a)(10)(A)(i)(VIII) of the Social Security Act) from age 19 to 64 with incomes up to 133 percent of the federal poverty level (FPL). Children are not included in community engagement requirements under the demonstration.

CMS is aware of the Medicaid and CHIP enrollment declines that states have reported for the past few months. There are a number of possible factors that could contribute to these enrollment declines, and CMS is looking closely at the impact those drivers may be having on enrollment. CMS knows some of the enrollment decline can be attributed to the improved economy and state functionality and operational issues in conducting the eligibility renewal process. We are continuing to look at other factors to ensure that eligible people can continue to be enrolled.

Regarding whether increasing the frequency of eligibility redeterminations is likely to further depress enrollment in Medicaid and CHIP, current regulations prohibit states from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on MAGI financial eligibility. The FY 2020 President's Budget allow states the option to conduct more eligibility redeterminations for MAGI populations to ensure that their Medicaid programs are focused on the individuals that need it most. It will also ensure that individuals who have incomes that exceed the Medicaid income eligibility threshold are not taking advantage of our scarce federal resources by staying on Medicaid when they are no longer eligible.

The Honorable Tony Cárdenas (D-CA)

1. According to the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which coordinates Federal efforts to enhance public health preparedness, there are several medical countermeasures in the Strategic National Stockpile (SNS) that will need to be restocked in the near term. However, the President's budget does not take into account the need to replenish the existing inventory in the SNS. What are the implications for not adequately funding the SNS? What new procurements will ensure we are prepared to meet public health threats could be delayed or cancelled due to lack of funds?

   Response: At the FY 2020 President's Budget level of $620 million, the Strategic National Stockpile (SNS) will replace the highest priority expiring countermeasures identified through an HHS requirements setting process. This includes $61.4 million for two products transitioning to the SNS from Project BioShield funded contracts (a thermal burn bandage and smallpox antiviral drug).

The Honorable Joe Kennedy (D-MA)

Work Requirements
When you testified before the Energy and Commerce Committee on March 12th, you stated, in response to my inquiry into the reason over 18,000 beneficiaries lost Medicaid coverage in Arkansas, "We do not yet have data as to why they fell off the program." Additionally, you said, "We just don't know at this point." However, two days later, when testifying before the Senate Committee on Finance, you stated, "Only 1,452 of those 18,000 people even reapplied for Medicaid...That seems a fairly strong indication that the individuals who left the program were doing so because they got a job..."

1. What information did you receive between March 12th and March 14th that caused you to change your understanding of why Medicaid beneficiaries fell off the program in Arkansas because of the work requirements? Provide a full explanation why your answer changed from when I questioned you at the Energy and Commerce Committee hearing to the point when you provided different information at the Senate Committee on Finance hearing two days later.

2. What evaluations has the Department of Health and Human Services or the Centers on Medicare and Medicaid Services conducted into the reason more than 18,000 Arkansas residents lost coverage due to the work requirements? Provide all studies, evaluations, and data regarding the impact of work requirements in Arkansas and all other states for which you have this information. Provide a list of all the states for which you do not have this data.

3. According to Georgetown University's Center for Children and Families, less than one percent of those subject to the new rules in Arkansas are newly reporting work hours. Of that one percent, how many Arkansas residents have secured health insurance coverage through their new employers? Of the total number of Arkansas residents who lost Medicaid coverage because of the work requirements, how many now have health insurance?

   Response to 1-3: Currently, the State publishes monthly enrollment reports that include the number of individuals who did not comply with the community engagement requirement, and subsequently, how many have been disenrolled from Medicaid due to their noncompliance for three consecutive months. The State has recently issued a report that since the requirement went into effect, 4,384 Arkansas Work Participants found employment. In addition, the State reported that more individuals had their coverage terminated for other reasons than failing to meet the community engagement requirement, including an increase in household income, moving out of the State, and failing to return requested information. This type of "churn" is not uncommon in Medicaid. Pursuant to the last report, which was published in February, nearly 90 percent of the 116,229 beneficiaries subject to the requirement were compliant either due to work, training, or another activity.

Addendum with updated information: On March 5, 2018, CMS approved Arkansas's request for an amendment to this demonstration which allowed the state, no sooner than June 1, 2018, to require all Arkansas Works beneficiaries ages 19 through 49, with exemptions for certain groups, to participate in and timely document and report 80 hours per month of community engagement activities, such as employment, education, job skills training, or community service, as a condition of continued Medicaid eligibility.

On March 27, 2019, the U.S. District Court for the District of Columbia vacated the amendment approved on March 5, 2018. While we have appealed this court decision, the Centers for Medicare & Medicaid issued a letter to the state indicating that the state is required to administer their section 1115 demonstration waiver under the special terms and conditions that were approved as of December 8, 2016.[3]

HHS and CMS believe that it is critical to conduct regular and robust monitoring and rigorous evaluation in order to understand the impacts of Medicaid 1115 demonstrations.

As a condition of approval, CMS requires that, from the onset of the implementation of any community engagement demonstration, states collect, analyze and report meaningful data on a quarterly basis in a way that will assist CMS and states to understand the short-term effects (through monitoring) and longer-term impacts and outcomes (through an independent, research-driven evaluation) of community engagement policies. These monitoring reports do not include the full range of information that will be collected and provided under the state's evaluation plan, which will permit CMS to track the impact of the demonstration on Medicaid enrollees' employment or health status. CMS is working with all participating states to ensure that each has a CMS-approved evaluation design that meets our expectations. Through both monitoring and evaluation, states and CMS will learn whether these Medicaid demonstrations support states' hypotheses and achieve expected outcomes.

CMS has devoted substantial effort to establishing expectations for state evaluation designs that reflect the high standards of evaluation research. For instance, CMS has developed tools for use by states and independent evaluators to guide the development of evaluation designs and to prepare evaluation reports for Medicaid section 1115 demonstrations.[4] CMS has developed resources and best practices in causal inference, selecting comparison groups, and creating evaluations specific to managed long-term services and supports, among other specific demonstration projects.[5]

Last year, the State of Ohio published as assessment of the State's Medicaid program. It found Medicaid enrollment facilitates and enables employment. Almost nine out of ten respondents who are employed and who participated in the survey said having Medicaid make it easier to

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[3] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ar/Health-Care-Independence-Program-Private-Option/ar-works-court-decision-ltr-20190504.pdf

[4] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

[5] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/index.html

continue working. It is no surprise that having health insurance means people can fill prescriptions and go to the doctor in order to get and stay healthy. And being healthy is an important part of being able to get up and go to work every day. However, it's important to note this logic only works in one direction. Health insurance yields healthier people and healthier people are thus more able work. Ensuring access to coverage and benefits is the first step, not the last step, in making Americans healthier and empowering them to find work and to stay in the workforce.

1. Can you provide any and all studies that say taking away someone's health care, or threatening to do so, such as with work requirements, improves health outcomes for current Medicaid beneficiaries? Similarly, can you provide any and all studies that say taking away someone's health care, or threatening to do so, such as with work requirements, improved health outcomes for previous beneficiaries who lost coverage as result of Arkansas' work requirements?

2. Of the 18,000 Arkansas Medicaid beneficiaries who lost coverage because of work requirements, how many of them are healthier now? What studies has the Department of Health and Human Services or the Centers on Medicare and Medicaid Services conducted into the health status of those individuals who lost coverage and what are the results of those evaluations?

3. The Centers of Medicare and Medicaid Services recently approved work requirements for the State of Ohio. How many individuals will lose health insurance as a result of those work requirements? Provide all evaluations your department conducted, prior to approving the Ohio work requirements, indicating the number of Ohioans who will lose coverage.

   Response to 1-3: CMS believes that programs that incentivize community engagement have the potential to further Medicaid objectives by promoting better mental, physical, and emotional health, by helping individuals and families rise out of poverty and attain independence, and by promoting the fiscal sustainability of state Medicaid programs. While high-quality health care is important for an individual's health, there are many other determinants of health. CMS recognizes that a broad range of social and economic factors can have a major impact on an individual's health and wellness, and a growing body of evidence suggests that targeting certain health determinants, including community engagement, can improve health outcomes for the individual. Community engagement programs can also help individuals and families rise out of poverty and preserve the fiscal sustainability of the safety net for those individuals who need it most.

   We understand your concerns regarding the potential impact that community engagement requirements may have on Medicaid beneficiaries. However, CMS carefully reviews each state's request for a section 1115 demonstration on an individual basis and only approves state requests for demonstration projects if, in the Secretary of Health & Human Services's judgment, the demonstration project is likely to help promote the objectives of the Medicaid program.

We agree that it is critical to conduct regular and robust monitoring and rigorous evaluation in order to understand the impacts of Medicaid 1115 demonstrations. As a condition of approval, CMS requires that from the onset of the implementation of any community engagement demonstration, states collect, analyze and report meaningful data on a quarterly basis in a way that will assist CMS and states to understand the short-term effects (through monitoring) and longer-term impacts and outcomes (through an independent, research-driven evaluation) of community engagement policies. These monitoring reports do not include the full range of information that will be collected and provided under the State's evaluation plan, which will permit CMS to track the impact of the demonstration on Medicaid enrollees' employment or health status. CMS is working with all participating states to ensure that each has a CMS-approved evaluation design that meets its expectations. Through both monitoring and evaluation, states and CMS will learn whether these Medicaid demonstrations support states' hypotheses and achieve expected outcomes.

CMS has also devoted substantial effort to establishing expectations for state evaluation designs that reflect the high standards of evaluation research. For instance, CMS has developed tools for use by states and independent evaluators to guide the development of evaluation designs and to prepare evaluation reports for Medicaid section 1115 demonstrations.[6] CMS has developed resources and best practices in causal inference, selecting comparison groups, and creating evaluations specific to managed long-term services and supports, among other specific demonstration projects.[7] CMS has also developed evaluation guidance specific to more recent demonstration project approvals in state Medicaid director letters, including demonstrations designed to expand access to substance use disorder treatment.

As you indicated, CMS recently approved Ohio's section 1115 demonstration project on March 15, 2019. With approval of the demonstration, Ohio will require, as a condition of continued eligibility, that non-exempt beneficiaries in the new adult group at section 1902(a)(10)(A)(i)(VIII) of the Social Security Act, ages 19 through 49, engage in qualifying community engagement activities for at least 80 hours per month. Included in the waiver approval are certain guardrails to ensure that Ohio protects its most vulnerable residents, including beneficiaries who are pregnant or 60 days or less post-partum.

In assessing the coverage impact of proposed demonstration features, the state noted in its application that, of the 710,000 beneficiaries expected to be enrolled in the new adult group, approximately 36,000 would not be considered exempt or currently working and would need to complete qualifying activities to comply with the community engagement requirement. Of the beneficiaries considered not to be exempt, the State estimates that 10 percent of beneficiaries will elect not to comply

[6] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html
[7] https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/index.html

and would thus lose their Medicaid coverage.[8] Actual coverage impact will greatly depend on the choices made by each individual beneficiary, and it is therefore challenging to estimate the impacts of this new program before it even begins. It is important to CMS that, for all community engagement requirements, compliance is achievable for every beneficiary subject to the new requirements, such that every beneficiary enrolled in Medicaid can stay enrolled in Medicaid unless and until they move into other forms of coverage or become ineligible for reasons such as income. In light of the safeguards discussed above, CMS has determined that compliance with Ohio's community engagement requirement should be achievable for every beneficiary. Furthermore, CMS is undertaking vigorous evaluation and monitoring of a variety of metrics, including enrollment metrics.

Mental Health

Medicaid is the largest payer of mental health services in the United States. Its role in providing access to mental health care is critical to the health and wellbeing of millions of Americans; yet, this budget proposes to cut Medicaid by $1.5 trillion over ten years, endangering every single beneficiary with mental illness. Instead of supporting and fixing the mental health system, this budget would worsen the system on every metric, whether through beneficiaries' loss of coverage, weakened network adequacy, inadequate reimbursement levels, or unnecessarily burdensome paperwork requirements for states and beneficiaries.

1. Given this Administration's proposed funding cuts, and the inevitable, wide-spread loss of coverage that would occur, how does the Administration predict Americans will be able to afford and access timely mental health care? When millions of Americans lose Medicaid coverage, what is the anticipated impact on the opioid crisis?

   Response: The Administration has made historic investments to address opioid misuse, abuse, and overdose. Successful partnerships between leadership at HHS and the leaders of every state Medicaid program is vital to delivering on the mission of HHS and the mission of the Medicaid program: improving the health and well-being of the Americans we serve. This Administration is committed to granting states more freedom to design innovative local solutions, including ways to improve access to timely mental health care, and we have followed through on that promise. For example, in November 2017, CMS issued guidance to states announcing a new policy to allow states to design demonstration projects that increase access to treatment for opioid use disorder (OUD) and other substance use disorders (SUD). Through this updated policy, states will be able to pay for a fuller continuum of care to treat SUD, including critical treatment in residential treatment facilities that Medicaid is unable to pay for without a waiver. In addition, in November 2018, CMS published a State Medicaid Director letter discussing strategies under existing authorities for states to implement innovative service delivery system reforms for adults with serious mental illness, and children with serious emotional disturbance. Examples of these innovations include improving availability of behavioral health screenings and mental

[8] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/oh/oh-work-requirement-community-engagement-ca.pdf

health and substance use disorder services in schools, to identify and engage children with serious emotional disturbance sooner. The letter explained a demonstration opportunity for states to receive federal financial support for treating Medicaid beneficiaries with these conditions during short-term acute care stays in psychiatric hospitals or in residential treatment facilities that qualify as an Institution for Mental Diseases.

The President's FY 2020 Budget provides $4.9 billion to combat the opioid overdose epidemic. The Substance Abuse and Mental Health Services Administration (SAMHSA) will continue all current opioid activities at the same funding level as FY 2019, including the State Opioid Response Program and grants, which had a special focus on increasing access to medication-assisted treatment - the gold standard for treating opioid addiction. The Budget also provides new funding for grants to accredited medical schools and teaching hospitals to develop substance abuse treatment curricula. In FY 2020, the Health Resources and Services Administration (HRSA) will continue to make investments to address substance abuse, including opioids abuse, through the Rural Communities Opioid Response Program, the National Health Service Corps, behavioral health workforce programs, and the Health Centers Program. Medicare and Medicaid policies and funding will also play a critical role in combating the opioid crisis. The Budget proposes making it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder. The Budget also proposes to set minimum standards for Drug Utilization Review programs, allowing for better oversight of opioid dispensing in Medicaid programs. Additionally, it proposes a collaboration between the Centers for Medicare & Medicaid Services and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

The President's 2020 budget proposal includes a proposal to make it easier for states to provide full Medicaid benefits, for one year postpartum, to women who have substance use disorders and have given birth. I certainly agree in the value of ensuring long-term, continuous care for individuals who have given birth. There is no substitute for good health when parents bring home a new baby and work hard at raising a family, and this is especially important when it comes to mental health.

2. How does the Administration expect twelve months of continuous coverage to post-partum women will benefit them and their families? Additionally, does the proposal extend a guarantee of coverage for the newborn children and the older children of a postpartum parent?

3. There is well-documented evidence showing the value of mental health care to individuals who have given birth; yet this budget would extend twelve months of care only to women with a substance use disorder. What is the rationale for limiting the benefit to women with substance use disorders only versus expanding the benefit to all postpartum individuals with mental illness? What is the rationale for limiting the benefit to women with substance use disorder versus expanding the benefit to all individuals who have given birth regardless of their mental health status at delivery?

Response to 2-3: HHS is home to a range of agencies whose work touches the health care of pregnant women, mothers, and infants, as protecting maternal and infant health is one of our health care system's most important responsibilities. As the single largest payer for maternity care, Medicaid plays an important role in perinatal and maternal health, and has a significant opportunity to improve maternal and infant health outcomes, including during the postpartum period.

The President's FY 2020 Budget includes a number of proposals aimed at improving maternal mortality and morbidity rates in the U.S., including making it easier for states to extend Medicaid coverage to pregnant women with substance use disorders for a full year postpartum. The postpartum period is often stressful, particularly for infants with neonatal abstinence syndrome (NAS) and their mothers. These infants have numerous needs and are twice as likely as infants without such conditions to be readmitted to the hospital within 30 days of discharge. After these infants leave the hospital, the needs of the infant and the mother require care from multiple providers and programs, including obstetric and addiction treatment for the mother in addition to pediatric care for the infant, as well as the potential involvement of child welfare services. Navigating all of these services requires significant care coordination and case management, access to which frequently ends when mothers with a substance use disorder (SUD) lose their Medicaid coverage. Ending coverage for treatment after 60 days may put the mothers of these infants at increased risk for relapse because relapse is more common during the postpartum period than during the pregnancy and because women with SUDs have a heightened risk of relapse after delivery due to postpartum depression and the stress of parenting, among other factors.

Improving access to treatment and care coordination during the postpartum period should improve the health and wellness of mothers, increase the ability of these mothers to care for their infants born with NAS, and reduce the risk of neglect resulting from the mothers' SUDs. The postpartum period is a time when women with SUDs may be particularly motivated to engage in treatment, and therefore extending coverage is critically important during that window of opportunity. Improved access to treatment among new mothers with SUDs should help reduce the impacts of the opioid crisis on child welfare systems.

In addition, this proposal is intended to improve the ability of women with SUDs, including opioid use disorder (OUD), to care for their infants. The first year of life is a difficult transition time. The Substance Abuse and Mental Health Services Administration's (SAMHSA's) recent clinical guideline on treating pregnant and parenting women with OUD recommends that discontinuation of pharmacotherapy be delayed until, at the very least, after the infant is consistently sleeping through the night, has completed breastfeeding, and mother and baby have multiple indicators of life stability. These milestones are unlikely to be reached earlier than the end of the first year postpartum. Under this proposal, states would also have to ensure the benefits provided to these women include coverage for SUD and mental health

treatment as well as case management and care coordination, since these services may not be included in the state plan Medicaid benefits in all states.

The President's FY 2020 Budget also proposes to use CMS's Center for Medicare and Medicaid Innovation (CMMI) to develop and test innovative health care payment and service delivery models to improve maternal and child health. CMMI is currently working on two recently released opportunities, the Integrated Care for Kids (InCK) and Maternal Opioid Misuse (MOM) payment and service delivery models. These models were designed to expand access to health care services for vulnerable Medicaid and CHIP beneficiaries, in particular those affected by the nation's opioid crisis, and to improve quality of care and reduce expenditures for beneficiaries.

In addition to these current projects, CMS launched previously several initiatives and pilot programs to improve the well-being of women and children. In 2012, CMS, the Health Resources and Services Administration, and the Administration for Children and Families launched the Strong Start for Mothers and Newborns (Strong Start) initiative to reduce preterm births and improve outcomes for pregnant women and newborns. The Strong Start initiative was comprised of two strategies. The first was a public-private partnership and awareness campaign to reduce the rate of early elective deliveries. The second was a four-year initiative testing the effectiveness of three enhanced prenatal care models – Birth Centers, Group Prenatal Care, and Maternity Care Homes – among pregnant Medicaid and CHIP beneficiaries at high risk for preterm births. Strong Start funded 27 awardees and 211 provider sites across 32 states, the District of Columbia, and Puerto Rico. Birth Centers were the most successful of the models, and CMS determined that women who received prenatal care in Strong Start Birth Centers had better outcomes and lower costs compared to similar Medicaid beneficiaries not enrolled in the initiative.

Further, in 2014, CMS launched a three-year Pilot Mobile Health Program to engage pregnant and postpartum women enrolled in Medicaid. The program delivers evidence-based health education messages and links these women to needed community-based resources, using a free text messaging service, Text4baby, as the core intervention. The pilot was implemented with Medicaid agencies in California, Louisiana, Ohio, and Oklahoma. These Medicaid agencies work to integrate Text4baby into their processes to complement their states' current maternal and infant health activities. In the first year, progress included a substantial growth in partnerships to support outreach.

Lastly, section 1115 demonstration projects offer states additional freedom to test and evaluate innovative solutions to improve the quality, accessibility, and health outcomes of pregnant and postpartum women and infants in the Medicaid program.

The Honorable Raul Ruiz (D-CA)

1. Mr. Secretary, as a country we are facing both supply and demand issues in regard to provider access. The patient load for the average clinician has grown considerably, particularly in underserved areas, and by 2030 experts predict a national shortage ranging

between 40,800 to 104,900 physicians. What is the Administration's plan to address this growing shortage?

2. Mr. Secretary, many of our country's medical residents traveled to Washington, D.C. recently to meet with their representatives. They spoke about a variety of policy matters, and especially highlighted problems related to the dearth of residency programs. Given that medical school enrollment is on the rise, but residency positions have not increased at the same pace, what steps is the Department taking to ensure future students don't end up without a residency program to continue their education?

Response to 1-2: The President's Fiscal Year (FY) 2020 Budget requests resources to address physician shortages in underserved areas. The FY 2020 Budget provides $760 million in mandatory and discretionary resources for HRSA health workforce programs. The Budget prioritizes funding for health workforce programs requiring service commitments in underserved areas, training health care professionals to deliver integrated behavioral health services, and the National Center for Health Workforce Analysis. The FY 2020 President's Budget, requested funding for the National Health Service Corps (NHSC), which supports clinicians who demonstrate a commitment to serve our Nation's medically underserved populations at NHSC-approved sites located in Health Professional Shortage Areas. In addition, the President's Budget includes funding for the Teaching Health Center Graduate Medical Education (THCGME) program. The THCGME program increases healthcare access in underserved communities by supporting primary care medical and dental residency programs in community-based ambulatory patient care settings. The President's Budget includes $126.5 million in funding for the THCGME program in each of FY 2020 and FY 2021, for a total of $253 million over two years.

The FY2020 Budget also proposes to reform graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2020 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. 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. The new grant program would be jointly operated by the Administrators of CMS and the Health Resources and Services Administration. This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (e.g., primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health care professional shortages and educational priorities. These changes modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable.

3. Mr. Secretary, last year, Dr. Bucshon and I, along with several other members of this Committee, sent a letter to your Department regarding the Centers for Medicare and Medicaid Services' existing authority to extend flexibility to residency programs when setting Medicare graduate medical education caps. Will you commit to utilizing this authority, granted in 1997, to give new residency programs in medically underserved areas longer to build out their programs before they are capped by Medicare?

   Response: HHS shares your goal of improved support for hospitals' efforts to train more residents in underserved areas. New teaching hospitals have a 5-year cap-building period, which CMS adopted primarily to allow sufficient time for these hospitals to meet accreditation requirements and gain experience in training residents. However, new and existing rural teaching hospitals, unlike urban teaching hospitals, are not limited to a single cap-building period. Rural teaching hospitals receive a 5-year cap-building period each time they participate in training residents in a new residency training program and as such, can receive multiple permanent adjustments to their caps.

   In addition, the President's FY 2020 Budget includes a proposal that would consolidate Federal GME spending from Medicare, Medicaid, and the Children's Hospitals GME program into a single grant program for teaching hospitals. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (e.g., primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health care professional shortages and educational priorities. Patients and providers would be well served by these commonsense reforms and the new grant program would be operated jointly by the Administrators of CMS and the Health Resources and Services Administration.

The Honorable Lisa Blunt Rochester (D-DE)

1. I understand that CMS is currently reconsidering the 2012 National Coverage Decision (NCD) for Transcatheter Aortic Valve Replacement (TAVR), which treats aortic stenosis, a condition affecting more than two million people in the United States. Data shows proposed volume requirements put in place with the existing NCD for this service restricts access for patients to this safer, more preferred technology without necessarily improving quality. Do you agree that CMS should not increase volume requirements for hospitals and instead, focus on quality metrics and prioritize access to TAVR for all patients?

   Response: On March 26, CMS proposed to update its national coverage policy for Transcatheter Aortic Valve Replacement (TAVR), a procedure for a condition known as "aortic stenosis" in which the heart valve that propels blood from the heart to the rest of the body becomes narrowed. The current national coverage determination, effective May 1, 2012, established CMS coverage for TAVR under Coverage with Evidence Development (CED). Since the finalization of the 2012 national coverage determination, TAVR programs have been established in over 500 hospitals across the country.

   Under the coverage proposal, CMS would continue to cover TAVR under CED when

furnished according to an FDA-approved indication. However, CMS is updating the coverage criteria for hospitals and physicians to begin or maintain a TAVR program. The proposed decision provides more flexibility in how providers can meet the requirements for performing TAVR, while continuing to ensure good health outcomes for patients receiving the procedure.

In developing the proposed decision, CMS met with numerous stakeholders including medical professional societies which continue to recommend requirements for providers to perform a certain volume of heart procedures. The proposed decision includes requirements for providers to perform a certain volume of procedures, given the link between heart procedure volume and patient outcomes in the medical literature and the risks from receiving care in low-volume settings. However, the proposed decision provides more flexibility in how providers can meet these requirements to reflect the latest evidence on volume and outcomes. The proposal is generally consistent with the 2018 Consensus Statement from the American College of Cardiology, the American Association for Thoracic Surgery, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons.

In the proposed decision, CMS is also seeking to gather more information about metrics other than volume that could be used to assess quality and safety. CMS is specifically proposing a question regarding the relationship between other metrics and patient health outcomes, which could inform a future change to replace the volume criteria with a different metric.

The proposed decision was made in response to a formal request and is consistent with recommendations from a meeting of the MEDCAC (Medicare Evidence Development & Coverage Advisory Committee) on July 25, 2018. The MEDCAC provides CMS with an external review of medical literature, technology assessments, public testimony, and other data and information on the benefits, harms, and appropriateness of therapies under review.

CMS issued a final decision on June 21, 2019. The decision memo is available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=293&bc=AAAAAAAAACAA&

The Honorable Michael C. Burgess, M.D.

1. Home visiting for pregnant and post-partum mothers, specifically visits conducted by a trained nurse, have been shown to have a demonstrated impact on not only the health of the baby, but also the mother. A 20-year follow-up study of the Nurse-Family Partnership shows that the Partnership is effective at reducing all-cause mortality among mothers and preventable-cause mortality in their first-born children living in highly disadvantaged settings. Can you explain what HHS is doing to invest in and promote smart, evidence-based solutions like Nurse-Family Partnership that improve maternal health outcomes and reduce maternal mortality?

   Response: HHS has a number of agencies and program areas whose missions involve

caring for pregnant women, mothers, and infants. Of particular note is the work done by the Centers for Medicare and Medicaid Services (CMS) and the Health Resources & Services Administration (HRSA).

CMS measures maternal morbidity and mortality through Child and Adult Core Sets, which assess the quality of care women receive at each step in their lifecycle. The collected data is used to improve transparency and accountability in maternal and infant health through the Medicaid Scorecard. It also directs the work of CMS's Maternal and Infant Health Initiative.

The President's FY 2020 Budget proposes using CMS's Center for Medicare and Medicaid Innovation (CMMI) to develop and test innovative health care payment and service delivery models to improve maternal and child health. CMMI is currently working on two recently released opportunities, the Integrated Care for Kids (InCK) and Maternal Opioid Misuse (MOM) payment and service delivery models. These models were designed to improve quality of care, reduce expenditures for beneficiaries, and expand access to health care services for vulnerable Medicaid and Children's Health Insurance Program (CHIP) beneficiaries, especially those affected by the nation's opioid crisis. MOM will run from January 1, 2020 through December 31, 2024. The InCK model is anticipated to begin on January 1, 2020 and run through December 31, 2026.

In 2012, CMS, HRSA, and the Administration for Children and Families launched the Strong Start for Mothers and Newborns (Strong Start) initiative to reduce preterm births and improve outcomes for pregnant women and newborns. Strong Start was comprised of two strategies. The first was a public-private partnership and awareness campaign to reduce the rate of early elective deliveries. The second was a four-year initiative testing the effectiveness of three enhanced prenatal care models – Birth Centers, Group Prenatal Care, and Maternity Care Homes – among pregnant Medicaid and CHIP beneficiaries at high risk for preterm births.

Strong Start has funded 27 awardees and 211 provider sites across 32 states, the District of Columbia, and Puerto Rico. Birth Centers were the most successful of the models and CMS determined that women who received prenatal care in Strong Start Birth Centers had better outcomes and lower costs compared to similar Medicaid beneficiaries not enrolled in the initiative.

HRSA leads the Department in addressing maternal mortality and morbidity through health promotion, risk prevention, and the training of health care professions. More specifically, HRSA supports the Alliance for Innovation on Maternal Health and Safety Initiative which is working with 26 states and more than 1,300 hospitals to implement maternal safety bundles to improve the quality and safety of maternity care. The goal is to prevent 100,000 maternal deaths and severe morbidity by 2018.

Maternal, Infant, and Early Childhood Home Visiting Program, which is funded at $400 million for each Fiscal Year through FY 2022, helps states, territories, and tribal entities fund, develop, and implement evidence-based, voluntary home visiting programs for at-

risk pregnant women and parents with young children up to kindergarten. This builds upon decades of scientific research showing that home visits by a nurse, social worker, early childhood educator, or other trained professional during pregnancy and early childhood improve the lives of pregnant women, mothers, young children and their families.

The FY 2020 Budget provides HRSA $661 million for the Maternal and Child Health Block Grant, which address states' highest maternal child health priorities and serves an estimated 56 million people, including 86 percent of pregnant women, 99 percent of infants, and 55 percent of children nationwide. More information about how HRSA addresses maternal morbidity and mortality can be found at https://www.hrsa.gov/maternal-mortality/index.html.

2. Secretary Azar, I have introduced a bill, H.R. 1510, that would allow states to use the available funds for reinsurance, but also for services such as maternity coverage and newborn care, promoting participation in the markets, and reducing out-of-pocket costs for patients. What are the benefits of coupling reinsurance with other efforts to reduce costs and improve quality of care for patients?

   Response: Reinsurance programs have lowered premiums for consumers, improved market stability, and increased consumer choice. Using flexibility available under section 1332 of the PPACA to provide for State Empowerment and Relief waivers, CMS has worked with States to implement a variety of models to operate their state-based reinsurance programs. To date, seven such state-based programs are currently operating.

3. You noted that the budget "supports a five-part strategy to improve access to prevention, treatment and recovery services, including the full range of medication-assisted treatments." Section 3204 of H.R. 6 was written to assist health care providers who want to prescribe next-generation, injectable or implantable buprenorphine to treat their patients for opioid overuse disorder (OUD). Unfortunately, the Administration has not yet clarified the key provisions of section 3204, including the following:

   a. Dispensing of these next-generation buprenorphine products is now allowable through specialty pharmacies, not only through "buy and bill" with specialty distributors;

   b. Injectable and implantable buprenorphine may now be dispensed to non-waivered health care professionals for injection but only pursuant to a prescription from a DATA-waivered prescriber;

   c. There will be requirements that accompany this distribution method, such as record-keeping safeguards, an inability to stockpile, a 14-day limit on administration, and compliance with state law.

      Response to a-c: HHS is committed to expanding access to evidence-based treatments for opioid use disorder (OUD) including access to medication assisted

treatment (MAT). We agree that it is important to provide patients with OUD with the full range of MAT services in order to best meet an individual patient's treatment needs. HHS continues to work with its federal partners to educate providers and supply them with the information they need to effectively treat OUD. As directed by Section 3204 of the SUPPORT Act, HHS is committed to supporting DEA's efforts to implement key components of this provision.

4. Experts agree that health care providers treating opioid overuse disorder should be empowered to inform their patients about all the potential treatment options to best meet the individual patient's needs. While the language of Section 3204 amends law under the authority of the DEA, nonetheless, the purpose of this language is entirely consistent with the goals you enunciated for improving access to treatment services, including the full-range of MAT services. Will HHS work with DEA on a priority basis to provide health care providers with the information they need about how this provision will be implemented?

   Response: HHS is committed to expanding access to evidence-based treatments for opioid use disorder (OUD) including access to medication assisted treatment (MAT). We agree that it is important to provide patients with OUD with the full range of MAT services in order to best meet an individual patient's treatment needs. HHS continues to work with its federal partners to educate providers and supply them with the information they need to effectively treat OUD. As directed by Section 3204 of the SUPPORT Act, HHS is committed to supporting DEA's efforts to implement key components of this provision.

5. Due to challenges in securing research funding, recent graduates are discouraged from pursuing careers in research. Congress emphasized the importance of support for early career researchers in passing the 21st Century Cures legislation. Can you describe the current efforts at the National Institutes of health (NIH) on this issue, including the Next Generation of Researchers Initiative and how they would be impacted by the administration's proposed budget for the National Institutes of Health (NIH) in FY2020?

   Response: NIH leadership, scientists in the research community, Congress, and the public have grown increasingly concerned about the long-term stability of the biomedical research enterprise. Over time, the number of applications seeking NIH support has increased faster than available funding, which may contribute to early-stage career scientists turning away from careers in research. But they are our future, and we cannot afford to lose them.

   In August 2017, NIH launched the Next Generation Researchers Initiative (NGRI). This initiative – which also responds to provisions in the 21st Century Cures Act – addresses challenges faced by early-stage investigators trying to embark upon and sustain independent research careers. As a key part of the initiative, NIH is prioritizing meritorious applications from early stage investigators seeking their first award, and also for investigators currently supported by NIH who are at risk of losing all research support. Moreover, in their award decisions, NIH Institutes and Centers will consider

factors such as emerging areas of scientific inquiry, the distribution of the scientific portfolio, and the projected needs of the scientific workforce, including enhanced workforce diversity.

The FY 2020 Budget includes a dedicated $100 million in the Office of the Director for NGRI to supplement efforts undertaken by the Institutes and Centers with their own appropriations.

6. The opioid epidemic is driving increased rates of multiple infectious diseases, including HIV, hepatitis B and C, and infections of the heart, skin, soft tissue, bones, and joints among people who inject drugs. For instance, according to the Centers for Disease Control and Prevention (CDC) the number of reported cases of hepatitis C more than tripled from 2010 to 2016 nationwide, with most new infections due to increased injection drug use associated with the opioid epidemic. While there are less available data on many other infections due to insufficient reporting and surveillance, regional and state analyses indicate a significant increase in hospital infections due to endocarditis (an infection of the heart valve) linked to injection drug use. The administration's plan addresses the opioid crisis, in part, by proposing $58 million in new funding for the CDC to explicitly address the infectious diseases impacts and is supported by many infectious disease organizations. How will this additional funding be utilized to ensure that the federal response to the opioid epidemic includes greater emphasis on public health interventions, research, and workforce support to prevent, track, and treat opioid-related infectious diseases?

Response: CDC is committed to protecting the public's health and preventing infectious diseases associated with the opioid epidemic, particularly viral hepatitis, and HIV, bacterial and fungal infections (which can cause heart, skin, soft tissue, bones, and joint infections) and related co-morbidities. CDC works to help prevent and treat infections and reduce overdose deaths through community-based programs that provide comprehensive preventive services and ensure people are linked to care.

The proposed FY 2020 President's Budget level of $58 million for Infectious Disease and the Opioid Epidemic activities would build upon the $5 million received in FY 2019 for Infectious Disease and the Opioid Epidemic. CDC will work to reduce new infections and prevent morbidity and mortality from infectious diseases related to the opioid crisis.

In FY 2020, CDC would target resources to state and local jurisdictions to address identified infectious disease vulnerabilities. CDC's support for state and local jurisdictions would provide increased capacity to test for viral hepatitis and HIV in high-impact settings, link people to treatment for infectious diseases, and, where needed, refer people for substance use disorder treatment, and ensure quality implementation of programs. CDC will also strengthen surveillance and laboratory capacity, providing critical information to guide patient-centered response, including information on co-morbidities. CDC will also work to ensure that evidence-based and comprehensive preventive services are provided for people who use drugs. With these investments, CDC will help reduce new infections, prevent morbidity and mortality of infectious diseases,

and help reduce overdose and overdose deaths.

7. The standard base monthly Part D premium is $33.19 in 2019, an increase of only 3% from 2006 whereas the standard Part B premium has increased 53% in that same time. Can you explain how Part D's design has led to this constraint on premiums? How do we insure in tackling the cost of prescription drugs we maintain the program's ability to control premiums?

Response: Rebates and other price concessions are growing faster than Part D gross drug costs. Plan sponsors may subtract expected rebate amounts from their bids. Because premiums are based on bid amounts, rebate growth has held down premiums – even during period of double-digit increases in Part D gross drug costs. However, rebates are not subtracted from point-of-sale prices paid by Medicare beneficiaries. As a result, beneficiaries pay more out of their own pocket than they would if rebates were paid at the point of sale. These higher pre-rebate prices can also cause faster progress into the catastrophic phase of the benefit, where the Federal Government pays a greater share of drug costs. As a result, the Medicare Trustees have annually documented an increase in drug prices, rebates, and Federal reinsurance spending, while Part D premiums and Federal direct subsidy spending have remained relatively flat.

The Administration has proposed to address these perverse incentives with a proposed rule removing safe harbor protection for manufacturer rebates, and an FY 2020 budget proposal encouraging Part D plans to better manage beneficiary costs by restructuring catastrophic coverage and requiring Part D plans to bear more of the risk.

In addition, under the American Patients First Blueprint, the Administration has been working to strengthen the negotiating power of Part D plans so that they can offer the best value to beneficiaries. With improved negotiation between plans and drug companies, premiums could be held constant and savings could be even greater.

8. The budget asks for reform to the calculation of True out of Pocket calculations to exclude manufacturer discounts. Can you explain why this proposal is important and how the current means of calculating TROOP is not reflecting of what beneficiaries pay out of pocket and shifts costs onto the taxpayer?

Response: Under the current benefit structure, Part D plans are incentivized to encourage beneficiaries to use costly brand drugs in order to accelerate their progression through the coverage gap into the catastrophic phase, where Medicare covers 80 percent of costs. Required discounts paid by brand drug and biosimilar manufacturers in the coverage gap are included in the calculation of a beneficiary's "true out-of-pocket costs (TrOOP)," which are a combination of a beneficiary's actual out–of-pocket costs and these discounts. In contrast, generic drugs are not subject to a manufacturer discount that counts toward TrOOP. Once a beneficiary's out-of-pocket spending reaches the annually updated TrOOP threshold, a beneficiary moves out of the coverage gap and into the catastrophic phase of the benefit. The manufacturer discounts mean that patients using

generic drugs are required to spend more out of their own pockets before reaching this threshold, compared with patients using brand drugs. The Budget proposal restructures the coverage gap discount program to exclude manufacturer discounts from the calculation of true out-of-pocket costs in order to correct this misaligned incentive that encourages plans to promote costly brand drugs.

9. States, most notably Louisiana, have proposed contracting with drug manufacturers of expensive medications to set up a guaranteed payment subscription model. This has the potential to guarantee returns for manufacturers but allow the state to spread out payments making them more likely to try to target as much of the drug at needy populations instead of looking at ways to control costs by restricting access. Can you tell the Committee your thoughts on this proposal and what the Administration can do to explore this option with states?

   Response: Increasing access to quality, affordable medication is a priority for this Administration. HHS worked with the State to provide technical assistance in developing a model that ensured access for the state's Medicaid population and 340B drug discount program.

10. The budget has several proposals regarding site neutral payments. Can you detail what these proposals are and why they are necessary to protect the trust fund but also save beneficiaries money in their coinsurance?

    Response: The Administration is focused on ensuring Federal health programs produce quality outcomes and results at the lowest possible cost for the American people. The President's FY 2020 Budget supports an expansion of value-based payments in Medicare. That expansion, along with implementation of a package of other reforms, would improve quality, promote competition, reduce the federal burden on providers and patients, and focus payments on value instead of volume or site of service.

    The President's FY 2020 Budget includes a proposal to redesign outpatient hospital and ambulatory surgical center payment systems to make risk-adjusted payments. Under current law, Medicare bases payments for services furnished at outpatient hospital and ambulatory surgical centers on the setting of care rather than patient acuity. The proposal would risk-adjust payments to these facilities based on the severity of patients' diagnoses. These adjustments would be made in a budget neutral manner. This proposal would promote site neutrality in payments for similar services and similar patient characteristics at these facilities.

    The President's FY 2020 Budget includes a proposal to pay on-campus hospital outpatient departments at the physician office rate for certain services. Medicare generally pays on-campus hospital outpatient departments substantially more than physician offices for the same services. Effective CY 2020, this proposal would make site neutral payments between on-campus hospital outpatient departments and physician offices for certain services such as clinic visits, eliminating the disparity between what Medicare pays in these settings for the same services. This would result in an estimated

$131.4 billion in savings over 10 years.

The President's FY 2020 Budget includes a proposal to address excessive payment for post-acute care providers by establishing a unified payment system based on patients' clinical needs rather than site of care. Medicare payment for post-acute care service can differ substantially for similar beneficiaries depending on the setting, due to variation in supply and lack of evidence-based criteria regarding patient eligibility, the most appropriate setting, and level of care required. Under this proposal, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities would receive a lower annual Medicare payment update from FY 2020 to FY 2024 and, beginning in FY 2025, a unified post-acute care payment system would span all four post-acute care settings, with payments based on episodes of care and patient characteristics rather than the site of service. Payment rates would be budget neutral in FY 2025, risk adjusted, and set prospectively on an annual basis, with episode grouping and pricing based on the average cost for providing post-acute care services for a diagnosis, similar to the Diagnosis-Related Group methodology under the Inpatient Prospective Payment System. This proposal would reduce costs, increase fairness, and give the Secretary the authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors as deemed appropriate. This would result in an estimated $101.2 billion in savings over 10 years.

The President's FY 2020 Budget includes a proposal to pay site neutral rates to all hospital-owned physician offices located off-campus. Medicare pays most off-campus hospital outpatient departments higher rates than the Physician Fee Schedule for the same services. These facility types include emergency departments, cancer hospitals, and grandfathered off-campus hospital outpatient departments billing under the Outpatient Prospective Payment System or under construction before November 2, 2015. This proposal would require all off-campus hospital outpatient departments to be paid under the Physician Fee Schedule, effective CY 2020. This change would promote site neutrality by aligning payments to hospital outpatient departments with payments to physician offices, regardless of hospital ownership or facility type. This would result in an estimated $28.7 billion in savings over 10 years.

The President's FY 2020 Budget includes a proposal to authorize long-term care hospital site neutral exceptions criteria. Medicare pays a higher prospective payment rate to Long Term Care Hospitals (LTCHs) when admissions follow an acute care hospital stay with three or more days in an intensive care unit, or the LTCH provides at least 96-hours of mechanical ventilation services. Absent meeting these criteria, LTCHs receive a lower Medicare payment rate comparable to acute care hospitals under the Inpatient Prospective Payment System. Effective FY 2020, this proposal would raise the intensive care unit stay threshold from three days to eight days to more accurately identify the chronically ill patients who typically receive the specialized care LTCHs provide. This change would promote site neutrality by basing payment on clinical characteristics and the needs of patients, rather than on location of care. This would result in an estimated savings of $10 billion over 10 years.

11. Can you detail the impending solvency of the Medicare Trust Fund and what will happen to beneficiaries if Medicare is not reformed?

Response: On April 22, the Medicare Board of Trustees released their annual report for Medicare's two separate trust funds – the Hospital Insurance (HI) Trust Fund, which funds Medicare Part A, and the Supplementary Medical Insurance (SMI) Trust Fund, which funds Medicare Part B and D.

The Trustees project that total Medicare costs (including both HI and SMI expenditures) will grow from approximately 3.7 percent of GDP in 2018 to 5.9 percent of GDP by 2038, and then increase gradually thereafter to about 6.5 percent of GDP by 2093. The faster rate of growth in Medicare spending as compared to growth in GDP is attributable to faster Medicare population growth and increases in the volume and intensity of healthcare services.

The report found that the HI Trust Fund will be able to pay full benefits until 2026, the same as last year's report. The SMI Trust Fund, which covers Medicare Part B and D, had $104 billion in assets at the end of 2018. Part B helps pay for physician, outpatient hospital, home health, and other services for the aged and disabled who voluntarily enroll. It is expected to be adequately financed in all years because premium income and general revenue income are reset annually to cover expected costs and ensure a reserve for Part B costs. However, the aging population and rising health care costs are causing SMI projected costs to grow steadily from 2.1 percent of GDP in 2018 to approximately 3.7 percent of GDP in 2038. Part D provides subsidized access to drug insurance coverage on a voluntary basis for all beneficiaries, as well as premium and cost-sharing subsidies for low-income enrollees. Findings revealed that Part D drug spending projections are lower than in last year's report because of slower price growth and a continuing trend of higher manufacturer rebates.

The President's Fiscal Year 2020 Budget, if enacted, would continue to strengthen the fiscal integrity of the Medicare program and extend the solvency of HI Trust Fund by about 8 years. Under President Trump's leadership, CMS has already introduced a number of initiatives to strengthen and protect Medicare and proposed and finalized a number of rules that advance CMS's priority of creating a patient-driven healthcare system through competition. In particular, CMS is strengthening Medicare through increasing choice in Medicare Advantage and adding supplemental benefits to the program; offering more care options for people with diabetes; providing new telehealth services; and lowering prescription drug costs for seniors. CMS is also continuing work to advance policies to increase price transparency and help beneficiaries compare costs across different providers.

12. Mr. Secretary, under the Obama Administration, premiums in the individual market increased every year. But President Trump has enacted several deregulatory reforms, and premiums decreased. Is this true?

13. Democrats like to say the President is sabotaging Obamacare. But under his leadership and as a result of the deregulatory actions he's taken, premiums have dropped for the first time since 2014. Not to mention, the number of counties with only one insurer has dropped from 56% last year to 39% this year. Is lowering health care costs and increasing plan options, "sabotage," in your view?

Response to 12-13: This Administration took action to address the skyrocketing price of health insurance, and we are starting to see the results in the form of lower premiums, more stable markets, and increased choice. Our 2019 Open Enrollment Report confirms another successful open enrollment period coinciding with a stabilization of premiums after years of substantial increases. Specifically, the report showed plan selections in Exchange plans in the 50 states and D.C. remained steady at 11.4 million, representing a minimal decline of around 300,000 plan selections from the same time last year. Also, as outlined in the report, average total premiums for plans selected through HealthCare.gov dropped by 1 percent from the prior year, the first decline since the Exchanges began operations in 2014.

Recognizing individual health insurance premiums are no longer affordable for many Americans, the Trump Administration is committed to expanding more affordable coverage options to this group of people left behind by the PPACA, which spurred recent actions to try to expand access to association health plans and short-term health plans, as well as to extend the "grandmothered" plan non-enforcement policy for another year.

14. House Republicans believe in the importance of ensuring protections for individuals with pre-existing conditions. This is a commitment you and President Trump share, correct?

Response: This Administration is committed to protecting individuals with pre-existing conditions. For example, under the Budget proposal, states will be required to allocate at least 10 percent of their grant funding to ensure protections for high-cost individuals, including those with pre-existing conditions. This demonstrates the importance of ensuring protections for individuals with pre-existing conditions and that all Americans have access to affordable, high value care, including those with pre-existing conditions.

15. The budget proposes reducing the grade period for exchange premiums from 90 days to 30 days. Dr. Burgess has a bill that would make this proposal law. Do you believe this is smart policy?

16. Are individuals gaming the system by taking advantage of the 90 day grace period?

Response to 15-16: The President's FY 2020 Budget includes a proposal to reduce the premium payment grace period for individuals enrolled in Health Benefit Exchange plans and receiving Advanced Payments of the Premium Tax Credit (APTC) from 90 days to 30 days. This proposal closes a loophole that allows for a subsidized enrollee in an Exchange plan to discontinue their premium payments for up to 90 days, deciding to "catch up" only if he or she has sudden medical needs during the 90-day grace period.

Current law dictates that individuals receiving APTC to subsidize their enrollment in Exchange plans are entitled to a 90-day grace period to give additional time to pay monthly health insurance premiums before coverage is terminated for non-payment of premium. The Patient Protection and Affordable Care Act (PPACA) established a uniform timeframe for subsidized enrollees to "true up" any past due payments prior to their health insurance policy being terminated. During the 90-day grace period, issuers must pay claims for the first month and are allowed to set aside claims for the second and third months of coverage until past due premiums are settled. Before the enactment of the PPACA, grace periods were determined by states and varied among them, with the majority of states providing for a 30-day grace period. These state laws continue to apply for consumers not receiving subsidies through an Exchange.

This proposal places more responsibility on individuals that fall behind on premiums, thereby reducing the amount of time payments remain outstanding. It would result in an estimated $78 million in savings to Treasury over 10 years, and may also reduce health insurance premiums on the Exchanges by reducing some of the uncertainty associated with "gaming" that issuers may load into their premiums.

17. Mr. Secretary, ad you may know, eight Democratic members of this subcommittee helped write their party's single-payer, government run Medicare for All bill. Would Medicare for All speed up the insolvency of the Medicare Trust Fund?

Response: Proposals for "Medicare for All" would put the program's funding further into jeopardy. We need to focus on a conversation about the drivers of health care costs in America, where health care spending is on course to eclipse one-fifth of national GDP by 2026. The answer to the skyrocketing cost curve is not greater government intervention leading to the evisceration of the private insurance marketplace, but just the opposite: increase choices, unleash private competition and innovation, and lighten regulations on plans, doctors and providers.

18. To date, 14 states have submitted waivers under section 1332. Eight of these states have active waivers. Mr. Secretary, would you agree that instead of a one-size-fits-all approach under narrow bounds established by the previous Obama administration interpretation of the statute, we should allow states to continue to review and reform their markets based off Trump administration guidance, so they can continue their appropriate role as laboratories of innovation?

Response: Last November, CMS issued guidance[9] related to section 1332 of the PPACA. This guidance intends to expand state flexibility, empowering states to address problems with their insurance markets and increase coverage options for their residents, while at the same time encouraging states to adopt innovative strategies to reduce future overall health care spending. The overarching goal of 1332 waivers is to empower states to develop innovative health coverage options that best fit the states' individual needs. This aligns with the Administration's goal to give all Americans the opportunity to gain quality and affordable health coverage regardless of income, geography, age, sex, or

[9] https://www.federalregister.gov/documents/2018/10/24/2018-23182/state-relief-and-empowerment-waivers

health status. Through section 1332 waivers, CMS aims to assist states with developing health insurance markets that offer more choice, competition, and affordability to Americans.

19. According to CMS, for plan year 2019, the Trump administration "...sent over 700 million reminder emails and text messages to consumers, as well as 3.2 million outreach emails to help Navigators, agents, and brokers assist consumers." Mr. Secretary, do you think this is a more efficient and effective way to reach younger consumers than spending tens of millions of dollars on Navigators?

Response: When Exchanges were in their infancy, and public awareness and understanding of coverage options was low, HHS encouraged Navigators to cast a wide net and to provide intensive face-to-face assistance to consumers. Since that time, public awareness and education on options for private coverage available through the Exchanges has increased. Certified application counselors, direct enrollment partners, and Exchange-registered agents and brokers serve as additional resources for education on options and outreach to consumers. Enrollment data from previous years show that Navigators failed to enroll a meaningful number of people through the Federally Facilitated Exchanges (FFE)s, comprising less than 1 percent of enrollment in both plan year 2017 and plan year 2018—not nearly enough to justify the millions of Federal dollars spent on the program. It was appropriate to scale down the Navigator program and other outreach activities to reflect the enhanced public awareness of health coverage options through the Exchanges. Additionally, in the Funding Opportunity Announcement for the FFE Navigator Program for plan year 2019, Navigator applicants were encouraged to leverage volunteers as well as strategic partnerships with public and private organizations to target consumers who would benefit from Exchange coverage and more efficiently meet their enrollment goals. These changes are based on the success of private sector-focused programs like those within Medicare Advantage.

20. Regulation of combination products has a direct impact on the cost of things insulin, epi-pens, and naloxone auto-injectors. Can you provide an update on the progress that has been made in modernizing regulation of combination products at FDA?

Response: Combination products present significant opportunities for improvement in patient care. Because combination products often combine a drug or biologic with a device, these products can sometimes be more complex to develop and it can be less clear to innovators on how to best engage the regulatory process to advance these innovations. For example, potential differences in the premarket review pathways across medical product centers can impact the regulatory processes and timelines for development.

Just this past February, FDA announced a framework designed to enhance clarity, predictability, efficiency and consistency of premarket review for combination products. This framework will help ensure that the FDA coordinates effectively around the premarket review of these products. Among other steps, FDA clarified what pathways to approval are available, depending on whether a combination product is drug-led, biologic-led, or device-led. FDA will also be publishing additional guidance on specific

premarket considerations for combination products to ensure efficient product development. FDA is focused on implementing an efficient framework to ensure the timely and effective review of combination products to create the most robust pathway to advance these kinds of innovations.

The Honorable John Shimkus

1. I appreciate and share your commitment to improving the standard of care for dialysis patients through the adoption of incentives to promote drug innovation. CMS' proposed expansion of the Transitional Drug Add-on Payment Adjustment is a promising first step. I understand that CMS has broad statutory authority to add devices to this transitional payment adjustment. Can you comment on the need for new technology payment incentives in the Medicare ESRD payment system and commit to engaging with me to find ways to encourage medical device innovation in dialysis care specifically?

   Response: We are committed to supporting Medicare beneficiaries with access to innovative technologies that are necessary and improve beneficiary health outcomes, including in the treatment of kidney disease and ESRD. In the interest of supporting innovation, ensuring appropriate payment for all drugs and biologics, and as a complement to the Transitional Drug Add-on Payment Adjustment (TDAPA) proposals, CMS solicited comments in the CY 2019 ESRD PPS proposed rule on whether we should expand the outlier policy to include composite rate drugs and supplies. With regard to composite rate supplies, an expansion of the outlier policy could support use of new innovative devices or items that would otherwise be considered in the ESRD PPS bundled payment. CMS specifically requested feedback about how such items might work under the existing ESRD PPS outlier framework or whether specific changes to the policy to accommodate such items are needed. CMS received a number of comments from stakeholders on this issue. We will take these comments into account as we consider any changes to the outlier policy and other payment adjustments such as TDAPA for future rulemaking.

   CMS is also doing some work through CMMI to test payment models related to kidney care. The Comprehensive ESRD Care (CEC) Model, which started in 2015 and runs through 2020, is designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with ESRD. Through the CEC Model, CMS is partnering with health care providers and suppliers to test the effectiveness of a new payment and service delivery model in providing beneficiaries with person-centered, high-quality care.

The Honorable Brett Guthrie

1. H.R. 6, the SUPPORT for Patients and Communities Act included language from the Eliminating Opioid-Related Infectious Diseases Act, which expands surveillance and education about infections associated with injection drug use. How does this program complement the Administration's broader plan to end the HIV Epidemic in America?

   Response: CDC is committed to protecting the public's health and preventing infectious

diseases that are associated with the opioid epidemic, particularly viral hepatitis and HIV, by increasing testing in high-impact settings, helping to refer people for substance use disorder treatment, and ensuring high quality implementation of public health programs. The intersection of opioids and infectious diseases puts our progress in HIV prevention at risk. One of the greatest successes in HIV prevention has been the 80 percent decrease in incidence of injection drug use-associated HIV infections over the past two decades. But, since 2011, our progress has stalled and is impacted by injection drug use-associated HIV.

The Administration's initiative to end the HIV epidemic in the U.S. complements and enhances other CDC programs addressing the infectious disease consequences of the opioid crisis through three strategies of the HIV initiative: diagnose, protect and respond.

- **Diagnose all individuals with HIV as early as possible after infection.**
  - Systems to make HIV testing more accessible in non-traditional settings will support efforts to increase knowledge of status and linkage to care for people who use drugs and their partners (i.e., make testing routine in syringe services programs (SSPS), medication-assisted therapy (MAT), STD services, and jails/prisons).
- **Protect the target populations using proven prevention approaches.**
  - Comprehensive SSPs are proven prevention interventions. CDC will support comprehensive SSPs as they provide a suite of care, treatment, and prevention services for people who inject drugs and can serve as an entry point to HIV care and treatment, recovery services, and overdose prevention.
- **Respond rapidly to detect, characterize, contain, and control growing HIV clusters.**
  - Large increases in drug use across the country have resulted in multiple HIV clusters and outbreaks. Currently nationwide, there is limited capacity to detect and respond to growing clusters and outbreaks. Expanding and accelerating the deployment of effective cluster detection and responses systems is critical to quickly identify and respond to every concerning cluster of new HIV infections – and stop the spread of HIV.

The Honorable Gus M. Bilirakis

1. In December 2018 comments to CMS, a group of eight leading clinical respiratory groups and organizations representing patients with severe health challenges expressed concern that putting ventilators under the DMEPOS bidding program would "undoubtable create grave clinical risks" and "result in patient deaths and increased hospital and nursing home costs." These groups included the American Lung Association, the ALS Association, The COPD Foundation, and the National Association for the Direction of Respiratory Care. Do you know what kind of analysis CMS has done to assure that these kind of drastic outcomes won't come to pass for medically vulnerable populations who depend on non-invasive ventilators?

Response: CMS is required by law to phase items into the DMEPOS competitive bidding

program. Items that are to be phased in are those items with high Medicare spending or rapidly increasing Medicare spending. In November 2018, CMS sought comments on phasing in new items, including non-invasive ventilators, for the next round of the DMEPOS competitive bidding program.

Under the DMEPOS competitive bidding program, CMS will be conducting real-time claims analysis to monitor health status of Medicare beneficiaries in competitive bidding areas, including emergency room visits and admissions to skilled nursing facilities. This monitoring is to ensure that there are no negative changes in beneficiary health outcomes or access to DMEPOS items.

2. I would like to first commend the work you and the FDA have and continue to do to address e-cigarettes and other tobacco products that cause public policy health officials youth usage and access concerns. I am aware FDA sought and received public comments from industry and other interested parties for a Cigar ANPRM last year which have been indefinitely shelved for long term consideration. Can you provide an update on the current status of this ANPRM?

   Response: As you know, last year, FDA issued an ANPRM to provide an opportunity for the public to provide new information for the Agency to consider in the regulation of "premium" cigars. FDA sought 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. FDA received over 32,000 comments in response to the ANPRM on the regulation of "premium" cigars and it continues to review these comments.

   In the meantime, all cigars remain subject to regulation based on FDA's previous determination that there was no appropriate public health justification to exempt "premium" cigars.

3. Congress passed legislation to allow Physical Therapists to use locum tenens in rural and underserved areas. Since the passage of the law can you provide us information on the implementation of the program?

   a. How many patients were seen by a locum tenens physical therapist since it became law? Please provide the answer for each year, as well as each quarter.
   b. Was the provision used more in exclusively rural, rural medically underserved areas, or urban medically underserved areas?
   c. What was the average number of consecutive visits where a locum tenens was utilized?
   d. What was the longest duration where a locum tenens physical therapist provided care?
   e. What was the shortest number of visits where care was provided by a locum tenens physical therapist?
   f. What was the average age of the Medicare beneficiary who was seen by a locum tenens physical therapist?

Response to 3a-f: Approximately 60 million people live in rural areas, including millions of Medicare and Medicaid beneficiaries. HHS recognizes the many obstacles that rural Americans face, including living in communities with disproportionally higher poverty rates, having more chronic conditions, being uninsured or underinsured, as well as experiencing a fragmented healthcare delivery system with an overworked and shrinking health workforce, and lacking access to specialty services. That's why CMS developed the Rural Health Strategy (issued in May 2018) to focus on areas where the agency can better serve individuals in rural areas and avoid unintended consequences of policy and program implementation for these communities. The strategy applies a rural lens to new and ongoing activities of the Agency and informs the pathway by which CMS can achieve its rural health vision through intra-agency collaboration, stakeholder engagement, and the elevation of programs and policies that will advance the state of rural health care in America.

HHS appreciates the tools given by Congress in the 21st Century Cures Act to help improve the quality of health care services in rural and underserved areas. Under section 16006 of the 21st Century Cures Act, a Medicare-enrolled physical therapist may use a substitute physical therapist to furnish outpatient physical therapy services in a Health Professional Shortage Area, a Medically Underserved Area, or a rural area under a locum tenens or reciprocal billing arrangement on or after June 13, 2017.

A patient's regular physical therapist may submit the claim, and receive the Part B payment, for covered visit services of a substitute physician or physical therapist, if:

- The regular physical therapist is unavailable to provide the services;
- The Medicare beneficiary has arranged or seeks to receive the services from the regular physical therapist;
- The regular physical therapist pays the substitute for his/her services on a per diem or similar fee-for-time basis;
- The substitute physical therapist does not provide the services to Medicare patients over a continuous period of longer than 60 days subject to the following exception: A physical therapist called to active duty in the Armed Forces may bill for services furnished under a fee-for-time compensation arrangement for longer than the 60-day limit; and
- The physical therapist indicates that the services were provided by a substitute physical therapist under a fee-for-time compensation arrangement meeting the requirements of this section by entering HCPCS code modifier Q6 (service furnished under a fee-for-time compensation arrangement by a substitute physical therapist furnishing outpatient physical therapy services in a health professional shortage area, a medically underserved area, or a rural area) after the procedure code.

While CMS has not analyzed the specific data you referenced, it is always looking for ways to improve its programs, and CMS is committed to making sure

beneficiaries in rural and underserved areas have access to the care they need, including physical therapy services. We welcome the opportunity to work with your office on this and other issues.

4. Over the course of the last several years, there have been significant advancements in the development of gene therapies. In response to those developments, FDA and NIH proposed an update of the federal oversight framework for gene therapies last summer and the FDA released draft guidance to aid the development of gene therapies for rare diseases, retinal disorders, and hemophilia in 2018. In addition, FDA indicated recently that it plans to take a number of steps related to gene therapies in the coming year, including developing a guidance document related to the development of gene therapies for particular neurodegenerative diseases. Given the potential promise of these new therapies, particularly for patients with life threatening or disabling conditions, such as Parkinson's disease or sickle cell disease, and the government's updated regulatory framework and newly introduced guidance documents, does HHS plan to take additional steps to educate patients, health care providers, and other key stakeholders about the evolution of the field of gene therapies and its potential for addressing significant unmet health needs?

   Response: Cell-based and directly administered gene therapies hold tremendous promise for addressing some of the most intractable diseases. But with their novelty comes new uncertainties and some unique potential risks. Our efforts are aimed at helping innovators proactively address these potential risks, while we outline a modern and efficient pathway for the continued development of these innovations. FDA intends to work with stakeholders working in the field, including patient advocacy organizations and other groups, to help provide additional education about the nature of gene therapy, its potential risks, and the potential benefits. Some of the steps that the FDA has taken include the following:

   In early 2019, FDA's Center for Biologics Evaluation and Research (CBER) published its 2019 guidance agenda.[10] This list includes the guidance documents CBER intends to publish during calendar year 2019. Since the beginning of 2019, CBER has issued the following guidances identified on the agenda that are related to cell and gene therapies:

   - Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry (Issued February 2019)
   - Evaluation of Devices used with Regenerative Medicine Advanced Therapies; Guidance for Industry (Issued February 2019)
   - Standards Development and their Use in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Guidance for Industry and Food and Drug Administration Staff (Issued March 2019)

   In addition, as noted on the 2019 guidance agenda, CBER intends to finalize the six draft guidance documents related to gene therapies during calendar year 2019.

[10] The 2019 CBER Guidance Agenda is available at https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/ucm431409.pdf.

- Testing of Retroviral Vector-Based Human Gene Therapy Products for Replication Competent Retrovirus during Product Manufacture and Patient Follow-up; Guidance for Industry
- Long Term Follow-Up After Administration of Human Gene Therapy Products; Guidance for Industry
- Chemistry, Manufacturing, and Control Information for Human Gene Therapy Investigational New Drug Applications; Guidance for Industry
- Human Gene Therapy for Hemophilia; Guidance for Industry
- Human Gene Therapy for Retinal Disorders; Guidance for Industry
- Human Gene Therapy for Rare Diseases; Guidance for Industry

However, CBER is not bound by the list of topics on the guidance agenda, required to issue every guidance on the list, or precluded from developing guidance documents on topics not on the list. CBER intends to be responsive to the needs of stakeholders as it considers what guidance documents are most urgently needed to facilitate the development of products to benefit patients. CBER will update the guidance agenda if it intends to develop guidance on new topics, including for diseases such as neurodegenerative diseases.

Recognizing the promise that such products hold, as part of the 21st Century Cures Act, Congress established the Regenerative Medicine Advanced Therapy Designation (RMAT) designation program, which is intended to help facilitate the development and review of certain regenerative medicine therapies. The benefits of RMAT designation include earlier and more frequent interactions with FDA, similar to those available to Breakthrough Therapy-designated products, potential eligibility for priority review and accelerated approval, and flexibility regarding fulfillment of postmarketing requirements if accelerated approval is granted. CBER has robustly implemented these provisions since the enactment of the 21st Century Cures Act and has interpreted the RMAT designation program to apply to gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues.

Building on the benefits that such early discussions with product developers can have in facilitating advancement of product development, CBER established a new meeting program - INitial Targeted Engagement for Regulatory Advice on CBER producTs (or INTERACT). The INTERACT meeting program was created for potential sponsors to engage with CBER staff and obtain initial, nonbinding advice on a specific topic or issue that is critical to early product development. These discussions can help answer important questions, remove roadblocks, and ultimately help create a clearer route to getting safe and effective products to patients.

FDA remains committed to facilitating access to promising investigational medicines for patients with serious or immediately life-threatening diseases or conditions outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

5. CMS has proposed changes to Part D to shift rebates to the point-of-sale in 2020. From conversations I've had with the Part D plans, there is concern that they will have to submit bids before the OIG finalizes its rule and CMS issues guidance on the new rebate system. How will CMS get the plans to be able to successfully bid and understand the payment requirements in time for January 2020?

   Response: On February 6, 2019, the Department of Health and Human Services, Office of Inspector General (OIG), published a proposed rule that would expressly exclude from safe harbor protection under the Anti-Kickback Statute rebates on prescription drugs paid by manufacturers to Part D plan sponsors, Medicaid managed care organizations, and pharmacy benefit managers under contract with them. The rule also proposed the creation of two new safe harbors.

   In guidance released through a memorandum to Part D Plan Sponsors on April 5, 2019, CMS specified for CY 2020 the following practice and procedure with respect to the submission of bids: plan sponsors will submit bids for CY 2020 in a form and manner that is consistent with the Anti-Kickback Statute law and regulations in effect as of the bid submission deadline, including, for the purposes of bid development, the treatment of manufacturer rebates pursuant to CMS' existing rules and guidance related to Direct and Indirect Remuneration.

   In addition, in the memorandum, CMS stated that if there is a change in the safe harbor rules effective in 2020, CMS will conduct a demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D program. The demonstration would consist of a modification to the Part D risk corridors for plans for which a bid is submitted. Under the demonstration, the government would bear or retain 95 percent of the deviation between a target amount and actual incurred costs beyond the first 0.5 percent. Participation in the two-year demonstration would be voluntary and plans choosing to participate would do so for both years. If the OIG rule is finalized and CMS conducts the demonstration, further guidance regarding the application process will be provided.

6. Approximately 3 million Medicare beneficiaries take the drug Coumadin and rely on regular blood tests to monitor their levels of clotting factor to reduce their risk of stroke or hemorrhage. For many of these patients, home testing has been a patient-friendly option to minimize lab or physician office visits. Patients who self-test have been demonstrated to achieve improved therapeutic management, resulting in fewer hospitalizations, reduced occurrence of stroke, and reduced drug related complications. Despite the importance of regular testing for Coumadin patients, CMS has reduced reimbursement for self-testing by 35% since 2017. The reimbursement reductions occurred because the pricing for testing in the home is being calculated as if it was done in a physician's office which does not account for indirect costs such as those associated with home visits, additional capital equipment to allow for each patient to have a testing device in the home, and continued patient follow-up calls. Do you think that we should be looking for ways to promote home based care options when appropriate, rather than pushing patients into less convenient

clinical settings, especially if that change causes compliance to suffer, resulting in increased medical costs?

Response: In the calendar year (CY) 2018 Medicare Physician Fee Schedule (PFS) final rule, CMS changed the prothrombin time (PT/NR) test home monitoring codes and finalized payment rates for these services based on updated resource assumptions. In response to public comments on our proposed policy, CMS increased the number of included test strips, lancets, and alcohol swab-pads by two each. CMS used paid invoices to update the price of the supply "INR test strip."

With regard to indirect practice expense for particular services paid under the PFS, CMS generally does not conduct a separate indirect practice expense survey for individual specialties or services. Instead, it uses survey data on specialty level indirect practice expense incurred per hour. In this way, CMS has data for all specialties.

In the CY 2019 PFS final rule, CMS repriced many of the items in the direct practice expense category. CMS initiated a market research contract to conduct an in-depth and robust market research study to update the PFS direct practice expense inputs for supply and equipment pricing for approximately 1,300 supplies and 750 equipment items for CY 2019. Among the items it reported on was the INR test strip used in these codes, which had a CY 2018 price of $5.66, and which was updated to a price of $4.71, based on invoice submissions, to be phased in over four years. The current CY 2019 price for the supply is $5.42.

The complete list of updated supply and equipment pricing is available in the final rule and on CMS' website. CMS welcomes the submission of updated pricing information regarding these particular supply items through the submission of valid invoices from commenters and other stakeholders to consider in future rulemaking.

The Honorable Markwayne Mullin

1. As you know, 42 CFR Part 2 creates barriers for providers to treat patients with substance use disorder. My bill, the Overdose Prevention and Safety Act passed the House with wide bipartisan support in the last Congress by a vote of 357-57. Do you believe that modernizing Part 2 is imperative to allow physicians to give the highest quality treatment to patients with substance use disorder?

    a. Through the rulemaking process, what can HHS do to further modernize Part 2?
    b. Is this something that HHS is considering?

    Response to a-b: It is critical that we protect the rights of individuals with substance use disorders while also providing these individuals the safest and most effective treatment possible when they experience medical illnesses. This requires that healthcare providers be able to share information and for care to be provided in a coordinated and integrated manner. The FY2020 Budget proposes changes that would further align Part 2 and its governing statute with HIPAA. Additionally, in

both the 2017 final rule and 2018 supplemental final rule, SAMHSA signaled its intent to continue to monitor implementation of 42 CFR Part 2 and explore potential future rulemaking, in an ongoing effort to better address the complexities of health information technology, patient privacy, and interoperability. HHS has submitted to the Office of Management and Budget, for interagency review under Executive Order 12866, two draft proposed rules that would amend Part 2.

2. As you know, the Indian Health Service is in disarray. Numerous reports and watchdogs over the years that highlighted the failings of the agency. Most recently a Wall Street Journal investigation highlighted the mishandling of a pediatrician who sexually assaulted his patients for over 25 years. IHS needs more than an investigation, it needs a complete overhaul and change in leadership.

   a. How does your agency plan on reforming IHS?

   Response: The Trump Administration established a new leadership team at the Indian Health Service (IHS), led by RADM Michael Weahkee, who is vigorously pursuing and is committed to ensuring a culture of quality, leadership, and accountability across the agency. The IHS mission of providing quality health care requires a safe environment for patients. Patient security and protection is a crucial responsibility, especially when children are involved. We are committed to continuously improving our IHS health care delivery system to uphold this important responsibility.

   In February 2019, I requested the HHS Office of Inspector General to review the effectiveness of IHS actions concerning Dr. Weber. In addition, IHS recently selected an independent contractor to conduct a medical quality assurance review to examine whether laws, policies, and procedures have been followed. The review will also recommend additional improvements IHS can implement to better protect patients.

   Recently, IHS has realized significant improvements to quality care for American Indians and Alaska Natives. These improvements include establishing an Office of Quality; implementing credentialing and privileging software agency-wide for all applicants; and, awarding a new contract for an adverse events reporting and tracking system that replaces an older legacy system.

   Also, after consultation with tribes and tribal organizations, IHS developed and is implementing an IHS Strategic Plan for Fiscal Years 2019-2023. The new Strategic Plan includes ongoing efforts to provide health care for American Indians and Alaska Natives throughout the United States. The plan details how IHS will achieve its mission through three strategic goals, each of which are supported by objectives and strategies.

   IHS's new Office of Quality was formally established in January 2019, with a new Deputy Director for Quality Healthcare. The Office of Quality will oversee, direct,

and evaluate, agency-wide activities to ensure quality health care, and will include four divisions: Enterprise Risk Management (ERM), Quality Assurance, Innovation and Improvement, and Patient Safety and Clinical Risk Management. The Office of Quality supports IHS hospitals and health centers by providing resources and tools for quality assurance and improvement, to attain and maintain compliance with Centers for Medicare & Medicaid Services regulations and accreditation standards. The Office of Quality will collaborate with the IHS Office of Information Technology to ensure that the agency has effective systems in place to promote patient care, encourage data collection and reporting, provide secure credentialing and privileging, and prepare for the reporting and evaluation of adverse events. The Office of Quality will also focus on building a quality improvement capability and encouraging innovations that promote safe, effective, and efficient care delivery.

In 2017, IHS implemented a national provider credentialing and privileging system. This system standardizes and streamlines the credentialing process across the IHS. Privileging and performance evaluations of IHS practitioners is a key element tracked in the new system that helps address quality and patient safety. The IHS credentialing and privileging policy is being updated to support the new system.

b. The Inspector General has already looked into IHS and have issued numerous recommendations, the majority of which remain outstanding. Where are IHS and HHS on implementing OIG's recommendation?

Response: The OIG review described above was initiated on March 22, 2019. This OIG review is in progress, and no recommendations have been made at this time. It is titled "*Sufficiency and Implementation of IHS Patient Abuse Policies.*" OIG anticipates completing its investigation with recommendations for IHS by the end of calendar year 2019 or early 2020.

The OIG is continuously monitoring IHS in its audit, investigation, and evaluation work. IHS is actively working through the implementation of all open recommendations, and submitting timely progress reports to OIG. Current open recommendations on a variety of audit and evaluation reports include:

- OIG reports issued in 2018 – 9 open recommendations (purchase and travel cards, audit resolution).
- OIG reports issued in 2017 – 15 open recommendations (IT controls).
- OIG reports issued in 2016 – 5 open recommendations (quality of care).

3. The President's budget includes a $1.6 billion request for the VA's electronic health record modernization. The budget also begins a multiyear effort to modernize the Indian Health Service's electronic health record system. How does HHS plan on assisting IHS on modernizing their electronic health records (EHR)?

Response: The HHS Health Information Technology (HIT) Modernization Research

Project began in September 2018 and will conclude in September 2019. The results from this project will serve to inform IHS about the options best suited to modernize its HIT infrastructure. The project's timeline is as follows:

- Project Planning and Strategy – completed November 2018.
- Convene an Expert Advisory Panel on IHS HIT – completed January 2019.
- IHS, Tribal, and Urban Indian Organization Facility HIT Assessment – completed April 2019.
- HIT Community of Practice – completed April 2019.
- HIT Analysis and Recommendations – scheduled to be completed by June 2019.
- HIT Initiatives Roadmap and Strategy – scheduled to be in draft by July 2019 and completed by September 2019.

Once the project is completed, IHS will be better positioned to plan and develop a detailed timeline for the modernization of its electronic health record system. The FY 2020 Budget proposes $25 million for IHS to begin transition to a new and modernized Electronic Health Record system. This funding will lay the groundwork to improve the quality of care, reduce the cost of care, promote interoperability, simplify IT service management, increase the security of patient data, enhance cybersecurity, and update infrastructure across rural locations to enable a successful Electronic Health Record transformation.

The IHS manages advisory committees composed of members of tribes, tribal organizations, and representatives of the federal government to ensure participation in addressing issues such as the Resource and Patient Management System and the HIT modernization effort, including the Direct Service Tribal Advisory Committee and the Tribal Self-Governance Advisory Council. In addition, IHS established the Information System Advisory Council (ISAC) to guide the development of a co-owned and co-managed Indian health information infrastructure and information systems.

With help from IHS' tribal partners, the ISAC examines the larger impact of IHS' HIT platforms. The ISAC has a chartered responsibility to make technology recommendations and priorities to the IHS Director. IHS concurrently engages in tribal consultation and urban confer to gather input and assist our decision making process. This process has included several listening sessions combined with a broad array of stakeholder and community engagements. Feedback from the ISAC, listening sessions, and engagement with HHS and other federal programs will ultimately converge to provide the IHS with good information to help determine a best path forward.

The Honorable Richard Hudson

1. Mr. Secretary, I want to ask you about cybersecurity at the Department. As estimated in the Budget-in-Brief, the annual estimated cost of cyber attacks for the health industry is $6.2 billion. HHS has a critical role as the Sector Specific Agency for the health sector to help prepare the sector for attacks, and to respond when one occurs, like the 2017

WannaCry ransomware attack. This, of course, is a separate and distinct role from HHS' internal enterprise cybersecurity work to keep the networks and data secure. The Healthcare Sector Coordinating Council, which provides for collaboration between the health sector and the government has, in the last year, significantly increased its resources and support to the sector. As part of its Sector Specific agency responsibilities, how is HHS working to help and support the Sector Coordinating Council in this work?

Response: The Department of Health and Human Services (HHS) is the Sector Specific Agency (SSA) for the Healthcare and Public Health Sector and co-SSA, with the Department of Agriculture, for the Food and Agriculture Sector. HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) leads healthcare and public health cybersecurity efforts within the sector. ASPR also serves as a co-lead on the Healthcare and Public Health (HPH) Joint Councils Cybersecurity Working Group (JCWG), to address issues and develop solutions to improve cybersecurity among a wide variety of HPH Sector stakeholders. In 2018, HPH JCWG membership increased from 58 individual members to 330 and there is currently seven federal departments on board.

HHS established the Health Sector Cybersecurity and Coordination Center (HC3) to support the defense of the Healthcare and Public Health Sector's information technology infrastructure by strengthening coordination and information sharing within the sector and by cultivating cybersecurity resilience, regardless of organizations' technical capacity.

HHS is strengthening the Health Sector Government Coordination Council (GCC) for the Healthcare and Public Health Sector, that includes Federal, State, Local, Tribal, and Territorial (FSLTT) agencies, to reinforce and expand the FSLTT engagement with the Sector.

Recent HHS accomplishments include:

- Maintaining 12 active Task Groups within the HPH JCWG examining critical cyber security issues faced by the Sector.
- Published "Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP)." The four-volume publication seeks to raise awareness for executives, health care practitioners, providers, and health delivery organizations, such as hospitals on cybersecurity issues and practices. Specifically, it explores the five most relevant and current threats to the industry and recommends 10 cybersecurity practices to help mitigate these threats.
- Hosted a weekly webinar series based on the HICP to focus on the five cybersecurity threats and corresponding mitigation practices.
- In coordination with FDA, published the "Medical Technology and Health IT Joint Security Plan." This plan provides guidance on better cybersecurity practices for health information technology professionals in developing a security plan.
- Supported four Joint Cybersecurity exercises simulating complex attacks against the Critical Health Sector infrastructure.

The Honorable Earl L. "Buddy" Carter

1. As a pharmacist, I am keenly aware of how important it is for a patient to have access to the medicine they need. While I understand the desire to lower drug prices, I have some concerns about the administration's proposal regarding the six protected classes within Medicare. For example, I am worried about epilepsy patients not having the same access to innovative anticonvulsants for the treatment of epilepsy. Even though there are more than 20 antiepileptic drugs (AED's) available, patients with this kind of chronic disease can still have a difficult time maintaining control of the symptoms without the full range of medicinal options available. Studies show that as many as 40% of patients with epilepsy are still unable to completely control their seizures. What's more, patients with epilepsy forced to step through several therapies prior to the one prescribed by their physician may have reduced effectiveness of that final drug than if they had simply started with the doctor-prescribed treatment in the first place. The risk of a patient not having access to the drug that works for them, particularly for a disease like this, can literally be a matter of life and death. How have you balanced the implications of interrupting an otherwise stable patient in considering the protected classes proposal?

   Response: Under the current protected class policy, Part D sponsors are permitted to utilize step therapy (ST) and prior authorization (PA) on new starts (that is, enrollees initiating the therapy), with respect to five out of the six protected classes (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, and immunosuppressants for the treatment of transplant rejection, but not antiretrovirals). Further, CMS conducts reviews of ST and PA criteria as part of the annual formulary review and approval process, and will only approve PA and ST criteria that are clinically supported. As such, under the current policy, a Part D sponsor is not permitted to interrupt a patient's course of treatment to require the patient to meet step therapy requirements.

   In CMS' *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses Proposed Rule*, issued in November 2018, CMS proposed broadening the use of prior authorization and step therapy. Our goal is to provide additional flexibility so that Part D sponsors could better manage the benefit from a clinical as well as a cost savings perspective. We believe that the existing beneficiary protections, including our extensive clinical formulary review and approval process, would adequately protect enrollees from the inappropriate application of PA and ST requirements. Moreover, we would have effectively limited most ST criteria to new starts as best practice, except when a change in therapy is clinically supported by the recognized compendia or widely accepted treatment guidelines. When step therapy is applied, we would have expected to approve PA or ST requirements with initial treatment that is comparably supported by recognized compendia or widely accepted treatment guidelines.

   In the Final Rule issued on May 16, 2019, CMS concluded, based on comments received during the rulemaking process, that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to PA or ST requirements outweighed the

potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility. Therefore, in the Final Rule, CMS finalized a codification of existing policy that allows Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except for antiretroviral medications, only for new starts, to determine if a drug's intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications.