

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2019**

THURSDAY, MAY 10, 2018

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:04 a.m. in room SD-124, Dirksen Senate Office Building, Hon. Roy Blunt (chairman) presiding.

Present: Senators Blunt, Alexander, Moran, Capito, Lankford, Kennedy, Rubio, Hyde-Smith, Murray, Durbin, Shaheen, Merkley, Schatz, Baldwin, Murphy, and Manchin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF THE HON. ALEX AZAR, SECRETARY

OPENING STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. The Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies will come to order.

I'm certainly pleased, Secretary Azar, to have you here this morning. I'm sure we're going to have a number of questions about your budget, and I'd preface that by saying that we understand that the final congressional action and Administration action on fiscal year 2018 occurred after you were asked to submit your budget. Still, there are things we need to talk about.

The actual budget you submitted was \$1.9 billion or 2.1 percent lower than the bill we just passed. And then in addition to that there's another \$5.6 billion that shifts from the mandatory side to the discretionary side in your budget. I think when you add all this up, the budget is actually more like 16 percent lower than the budget we just voted on, and I'm sure we're going to talk about that and look at that.

The budget request had to be submitted when it had to be submitted. But throughout the bill, looking at some of our priorities—medical research, early childhood education, the preparedness programs—are programs there will be questions on. I certainly agree that we ought to look everywhere we can for savings. We should look for programs that aren't working and make that decision that this is just an idea that wasn't necessarily a bad idea, but it didn't

work; look for programs that we can combine to where we eliminate both redundancy and administrative cost, but at the same time the committee will want to be heard on what we think should happen.

Senator Murray and I worked hard to craft a bill for your department this year that I think reflected the priorities of our members, of the Department itself, and the Administration. We provided a \$3 billion increase for the National Institutes of Health, and over the past 3 years we've increased NIH (National Institutes of Health) research, that budget, by 23 percent. We'll have Dr. Collins in, in a few days, to talk about that.

I also, Mr. Secretary, understand there are some questions from OMB about the way we believe that money should be spent, and we'll be insisting on the way we believe that money should be spent. The President agreed to this budget. Management from OMB is one thing. Trying to decide what the congressional priorities should be from OMB would be another thing.

We're committed and will remain committed, along with you, to addressing the opioid epidemic. Opioids have passed car accidents as the number-one cause of accidental death in the country. That budget was increased by \$2.55 billion, a 244 percent increase. At some point I think we want to look pretty carefully and be sure we're not increasing that budget faster than the money can reasonably be spent, but a lot of that increase, a little over half of that increase, \$1.5 billion, is flexible funding for the states, and I would also think that right now is a good time to let the states help us figure out what works and what doesn't work, and where it works and where it may not work. It's a great advantage of our system, and this is a crisis that needs to be dealt with quickly but needs to be dealt with in a way that allows states to try as many things as they think might work.

I know in Missouri we're doing the medication first approach, combined with counseling. Other states are doing that, and other states are looking at this in a different way. But that flexibility, I think, at least initially, is going to be very important, and it may turn out to be very important throughout this crisis because it's a big country with lots of different issues to be addressed.

I think it's important, and our committee has gone on record thinking it's important, to treat mental health just like we treat any other health problem. I think as those issues are coupled with opioid dependency, the mental health efforts are clearly an integral part of whether we are successful in the opioid issue, but they're also, I think, critically important as we look to overall health.

We have made a big increase in mental health funding in the omnibus. In fact, it was \$306 million; \$160 million of that increase went to the mental health block grant, and another \$100 million went to a new program targeted at certified community behavioral health clinics. I'm pleased that both the medical research and funding to combat the opioid epidemic were reflected in your budget, but I was disappointed that we didn't see as strong a commitment in your budget as we just made in our spending bill.

I'm also concerned about the proposed elimination of LIHEAP (Low Income Home Energy Assistance Program), which is the heating/air conditioning assistance program. The children's hospital

graduate medical education, I actually don't know where that money is supposed to come from if it doesn't come from discretionary. I'd like to figure out a way that graduate medical education for children's hospitals has a dedicated source, just like all other graduate medical education has. Zeroing it out would not be the way to solve that problem unless you've got a better replacement, and I'd like to see a permanent replacement.

Also, I have concerns that some of the health workforce programs are not as supported in this budget as I think they will be in a product that comes out of this committee.

But you have a big job. We appreciate the job you do. I personally appreciate the great expertise you bring to it, having been in the Department before, having worked in this area for so long, and I appreciate that. But our job is to work together to try to make what we do better, and I'm pleased to get to work with Senator Murray as we do that.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ROY BLUNT

Good morning. Thank you, Secretary Azar, for appearing before the Subcommittee today to discuss the Department of Health and Human Services' fiscal year 2019 budget request. This is your first time testifying before this Subcommittee and we look forward to hearing your testimony.

The fiscal year 2019 discretionary budget request for the Department is \$1.9 billion, or 2.1 percent, lower than the Omnibus passed in March. However, the request includes shifting nearly \$5.6 billion in funding from the mandatory side of the budget to the discretionary side, and provides \$10 billion in multi-year funding for opioids, of which \$7 billion is unallocated. Adjusting for these to make an apples-to-apples comparison, the request for the Department is \$14 billion, or 16 percent, lower than fiscal year 2018. These decisions artificially inflate the budget request and forced you to significantly cut or eliminate programs unnecessarily.

While this budget request is an improvement over the one we received last year, it still had you making difficult decisions and balancing competing priorities throughout the bill—from medical research, to early childhood care and education, to preparedness programs. In addition, you had to submit your request for fiscal year 2019 before Congress had finished its work on the fiscal year 2018 bill. That required many decisions before you knew which programs Congress would set as priorities.

I agree that there are many places in the Department's budget we should look to for savings. You bring a fresh perspective to the HHS budget and I hope we can work together to identify programs that are ineffective or no longer needed and put that funding to better use elsewhere.

The Omnibus that Senator Murray and I helped craft set the Department on a strong path forward for this year. We worked very hard to ensure that it reflected the priorities of our Members, the Department and this Administration, and the best needs of the country. Importantly, it provided significant investment to three of my priorities.

First, the Omnibus provided a \$3 billion increase for the National Institutes of Health. Over the last 3 years I have been Chairman, we have provided a 23 percent increase for medical research. This is particularly important because without Federal investment, we would not be able to continue to make progress on life-saving treatments and cures that affect millions of Americans.

Second, I remain committed to addressing the opioid epidemic. Many families across the country never thought they would need to worry about someone they love overdosing on opioids just 10 years ago. Now, opioid overdoses surpass motor vehicle accidents as the number one accidental death in the country. The Omnibus provided an increase of \$2.55 billion, or 244 percent, for health programs focused on opioid abuse. In particular, it provided \$1.5 billion in flexible funding for States, focused funding on States with the highest mortality rate related to opioid use disorders, improved surveillance efforts in all 50 States, and targeted funding towards rural communities that are hardest hit by this epidemic. I hope that with your leadership, the Department will allocate funding quickly so that States and communities can continue their efforts to address the crisis.

Finally, it is important to address mental health as we would any other physical condition. Nearly one in five American adults suffer from a diagnosable mental disorder and less than half of adults with any mental illness receive mental health treatment. This is particularly critical now that mental health issues are often coupled with an opioid use disorder, making these individuals more likely to use drugs than those not affected. As Chairman of this Subcommittee, we increased funding for mental health programs by \$306 million in the Omnibus, including \$160 million for the Mental Health Block Grant and \$100 million for a new program targeted at Certified Community Behavioral Health Clinics whose sole focus is to expand access to comprehensive mental health services.

I was pleased that both medical research and funding to combat the opioid epidemic were reflected in your budget request. I understand you had to make tough choices, but was disappointed there was not a stronger commitment to mental healthcare which I understand is a priority of yours as well. I am also concerned about the eliminations of LIHEAP (pronounced lie-heap), Children's Hospitals Graduate Medical Education, and the majority of the health workforce training programs. While I understand difficult choices had to be made, I believe it's unlikely this Subcommittee will support these eliminations.

However, I think you submitted a budget that is a good place to begin negotiations. My goal is for us to work together to identify priorities and find common ground while responsibly allocating taxpayers' resources.

Mr. Secretary, I look forward to hearing your testimony today and appreciate your dialogue with us about these important issues.

Thank you.

Senator BLUNT. Senator Murray, if you have some opening comments, we'll turn to those right now.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. All right. Well, thank you very much, Chairman Blunt.

Welcome, Secretary Azar. Glad to see you back and recovered and with us today.

I'm interested to hear your testimony about the Department's fiscal year 2019 budget request, though I have to tell you there are a lot of things in it that concern me. While I know you were not part of this administration when they started working on this budget request, you have made it clear that you do plan to continue some of the alarming ideological approaches this administration has taken since day one.

A budget isn't just a set of numbers. It's actually a statement of values and priorities, and this budget seems to have been written by an administration that believes the goal of the Department of Health and Human Services is to raise families' healthcare costs and undermine patients' access to care, and it is not. It's clear instead of fighting to make our healthcare system stronger, instead of prioritizing ways to make it more affordable or accessible or effective for our families and patients, this administration is continuing to prioritize healthcare sabotage.

It's clear instead of proposing solutions to make sure everyone can get the healthcare they need regardless of their background or a preexisting condition, this administration will continue to put in place policies that weaken patients' protections, take coverage away from people, and put their needed healthcare further out of their reach.

And this budget does take an alarming step backwards when it comes to women's healthcare, continuing a much larger trend we've seen from the Trump-Pence Administration. Time after time, the Trump-Pence approach has put ideology over women's health and

reproductive freedom, like the recent moves to undermine the Title X family planning program and the healthcare providers that offer very important services to women across the country who might not get the care they need otherwise.

And then I'm very concerned about the way you've handled the Teen Pregnancy Prevention Program, terminating grants in the middle of a 5-year cycle, a decision that was made with little rationale and apparently at the direction of political appointees against the advice of career staff, and significantly changing the focus of that program to promote a single ideological approach, a decision which is contrary to congressional intent, which is to support, and I quote, "programs that have been proven effective through rigorous evaluation."

Page after page of this budget request raises new red flags: proposals to cut CDC (Centers for Disease Control and Prevention) by over \$2 billion, which would devastate the agency's crucial work to promote immunizations, combatting emerging infections, preventing chronic disease, and keeping our communities healthy.

The budget eliminates safety net programs and critical assistance to millions of people, like the LIHEAP program the Chairman mentioned, and the Community Service Block Grant, which gives States resources to address the challenges of poverty.

It eliminates the Social Services Block Grant and reduces Temporary Assistance for Needy Families, programs that help families face adversity and keep their heads above water.

It cuts \$975 million from the Health Resources and Services Administration workforce programs, which support training for every type of healthcare provider.

It eliminates funding for Preschool Development Grants, which we recently authorized and funded on a bipartisan basis to provide high-quality preschool to tens of thousands of families.

So this is not the budget of an administration that values fighting to keep our communities healthy. It's not the budget of an administration that values evidence, science, and good policy-making practice. And it is actually not the direction this committee chose to take in our recent bipartisan spending bill.

As you know, that 2-year bipartisan budget agreement we reached in February provided major new investments to address the opioid crisis, childcare and early learning needs, and more. We now hear that the Administration is going to submit a second rescission package and undo many of these investments. I want to make it clear today that we will vigorously oppose any effort to undo the bipartisan deal the President signed into law. Both sides made a commitment to that deal. Our side didn't get everything we wanted, and neither did the Republicans, but a deal is a deal. Any attempt by the Administration to break its promise by rescinding or failing to spend the omnibus funding would be a major breach of faith.

So, in addition to asking about your budget request, I'm very interested in hearing how you plan to implement the funding increases we did include in the omnibus, especially in responding to the opioid crisis and childcare. I was glad to see your budget at least maintains the level of funding Congress directed the Administration to spend, \$10 billion in multi-year funding, for activities re-

lated to the opioid crisis. Of that amount, you're proposing to allocate \$2.8 billion in 2019 to agencies funded within the bill.

As you know, Chairman Blunt and I agreed to increase funding for the Childcare and Development Block Grant by over \$2.3 billion, almost double what we spend now, to help improve childcare options for struggling families, and agreed to increase Head Start by over \$600 million. I have heard from families in Washington State and around the country about their struggle to find and afford quality childcare, so I'm really glad we were able to take a step in the right direction, and I hope we can keep working to increase investments in childcare and early learning so every parent can afford childcare and every child is prepared to succeed in kindergarten and beyond.

It's not only the right thing to do, it is a smart investment for families, communities, and our economy. It is one of the many urgent issues facing our families that Democrats and Republicans should be able to come together to address, like the alarmingly high maternal mortality rate, or the epidemic of gun violence and the lack of research into this issue which you yourself, Mr. Secretary, has said is a priority.

And Democrats are going to keep making the case that we should take steps to actually help families address these problems instead of proposing cuts that do the opposite. And we will keep urging Republicans to work with us to make that happen.

So, Mr. Secretary, I look forward to hearing what you have to say on these issues and discussing my concerns further during the questions and answers.

Thank you very much, Mr. Chairman.

Senator BLUNT. Thank you, Senator Murray.

As I've said already today, Secretary Azar, we're pleased that you bring your skills and your dedication in this area to the job you're doing, and you've done a lot of things that other people would not have been able to accomplish even in the last few months. We're glad you're here and look forward to your testimony.

SUMMARY STATEMENT OF HON. ALEX AZAR

Secretary AZAR. Chairman Blunt and Ranking Member Murray, and members of the committee, thank you very much for inviting me to discuss the President's budget for the Department of Health and Human Services for fiscal year 2019, and also my personal thanks for being willing to reschedule in light of my recent illness. Thank you for that accommodation.

It's an honor to be here, and it's an honor to serve as the Secretary of HHS (Health and Human Services). Our mission is to enhance and protect the health and well-being of all Americans. It's a vital mission, and the President's budget clearly recognizes that.

The budget makes significant strategic investments in HHS' work. Among other targeted investments, the budget requests \$34.8 billion for the National Institutes of Health, \$5.8 billion for the Food and Drug Administration, and \$2.8 billion for priority bio-defense and emergency preparedness programs.

The President's budget especially supports four particular priorities that we've laid out for the Department, issues that the men and women of HHS are hard at work on already: first, fighting the

opioid crisis; second, increasing the affordability and accessibility of health insurance; third, tackling the high price of prescription drugs; and fourth, transforming our healthcare system into a value-based direction.

In addition, it strongly supports the ongoing work HHS does to keep Americans safe from natural disasters and infectious diseases.

First, the President's budget brings a new level of commitment to fighting the crisis of opioid addiction and overdose that is stealing more than 100 American lives from us every single day. Under President Trump, HHS has already disbursed unprecedented resources to support access to addiction treatment. This budget would invest \$3.5 billion in fiscal year 2019 to further address the opioid epidemic and serious mental illness. Within that allocation, for example, the budget dedicates \$1.2 billion to the State targeted response to the opioid crisis grants, and invests \$150 million specifically to confront the crisis in high-risk rural communities. Recognizing that we need new tools and private-sector innovation to defeat this epidemic, the budget proposes \$500 million to continue the NIH public/private partnership to develop new addiction treatments and non-addictive approaches to pain management.

The budget also supports programs that have a proven record of improving the lives of Americans who suffer from serious mental illness. We at HHS are pleased that Congress, including members of this committee, responded to the President's call for these investments, choosing to significantly boost HHS funding to confront the opioid crisis in the recent omnibus spending bill.

The second priority I will highlight is our commitment to breaking down the skyrocketing cost of health insurance, especially in the individual market. The budget proposes an historic transfer of resources and authority from the Federal Government back to the States, empowering those who are closest to the people and who can best determine their needs, while also bringing balance to the Medicaid program.

Third, prescription drug costs in our country are simply too high. List prices are too high. Seniors in government programs are overpaying due to lack of negotiating tools. Out-of-pocket costs are too high, and foreign governments are freeloading off of our investments in innovation.

To address these problems, the budget proposes a five-part reform plan to further improve the already successful Medicare Part D program by straightening out incentives that too often serve middlemen more than they do our seniors or the government program.

The budget also proposes Medicaid and Medicare Part B reforms to save patients money on drugs and provide strong support for FDA's (Food and Drug Administration) efforts to spur innovation and competition in the generic drug market.

We also want Medicare and Medicaid and our entire system to pay for health and outcomes rather than procedures and sickness. Our fourth departmental priority is to use the powers we have at HHS to drive value-based transformation throughout the entire healthcare system. This budget takes steps toward that shift, laying the groundwork for the value-based vision that I announced this spring. Our system may be working for entrenched incum-

bents, but it isn't working for patients or the taxpayer, and that has to change.

Finally, I want to highlight this budget's investments in HHS efforts to keep Americans safe from a range of threats, from natural disasters to international infectious threats like Ebola and pandemic flu. The budget funds a continuation of the successful public/private partnership such as the Biomedical Advanced Research and Development Authority, which has already launched 35 FDA-approved products since its establishment in 2006. The budget also provides U.S. support for the Global Health Security Agenda, an effort to build other countries' response capacity so we can prevent infectious threats from ever reaching our shores in the first place.

The President's budget will make the programs we run really work for the people they are meant to serve, including by making healthcare more affordable for all Americans. It will make sure our programs are on a sound fiscal footing that will allow them to serve future generations too, and it will make the investments we need to keep Americans safe. Delivering on these goals, as the President's budget does, is a sound vision for the Department of Health and Human Services, and I'm proud to support it.

Thank you, and I look forward to the committee's questions this morning.

[The statement follows:]

PREPARED STATEMENT OF HON. ALEX M. AZAR II

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

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

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

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

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

TACKLING THE OPIOID EPIDEMIC

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

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

The President's Budget recognizes the devastation caused by this crisis in communities across America, by providing a historic new investment of \$10 billion in HHS

funding to address the opioid crisis and serious mental illness, and building upon the work started under the 21st Century Cures Act.

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

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

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

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

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

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

EFFECTIVELY TREATING SERIOUS MENTAL ILLNESS

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

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

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

ADVANCING HEALTH REFORM THAT WORKS

A Washington-centric, one-size-fits-all approach to healthcare —especially in insurance markets most affected by Obamacare—is simply not working and must change. The President's Budget proposes a bold plan to redirect a significant

amount of healthcare funding back to the States and individuals, where healthcare decisions should be made, while also taking major steps to encourage innovation and better quality of care.

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

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

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

Bringing Down Drug Prices

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

Sustainable Medicaid and Medicare Reforms

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

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

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

BOOSTING UPWARD ECONOMIC MOBILITY

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

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

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

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

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

PROMOTING EFFICIENCY AND INNOVATION IN SCIENTIFIC WORK

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

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

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

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

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

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

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

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

Chemical, Biological, Radiological, and Nuclear Threat Preparedness

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

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

Natural Disaster Preparedness

Following the powerful hurricanes and historic wildfires of 2017, HHS remains ready to respond to any and all hazards when disaster strikes. The Budget ensures the Department is able to support essential emergency preparedness activities to refine our disaster responses. In particular, Hospital Preparedness Program resources will continue to be allocated to States and localities according to risk, ensuring communities with more risk have the necessary coordination and resources. The Budget also continues to provide \$50 million to support the National Disaster Medical System. Through this cost-effective and successful program, HHS trains and deploys

teams of American healthcare professionals from across the country to provide medical care to our fellow Americans in the event of an emergency.

Global Health Security

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

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

Cybersecurity

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

STRENGTHENING THE INDIAN HEALTH SERVICE

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

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

* * * * *

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

PHARMACY COSTS

Senator BLUNT. Well, thank you, Secretary.

We'll have time for a second round of questions. Other members will come later. So, as much as possible, let's try to stay within 5 minutes on our first round, and if you have more questions and want to stay, that would be great. And if you have more questions you want to submit for the record that would be acceptable as well.

Let's just start with pharmacy costs. You mentioned some key principles there. I know the Administration is going to have a major announcement tomorrow. Can you put a little more detail on the points that you've already made today, how those could be used, Medicare Part D and otherwise, the middleman issue? Anything you want to explain to us further there would be helpful.

Secretary AZAR. You bet. Thank you, Mr. Chairman. What we want to do is, of course, we want to balance the need to support innovation and the development, as this committee is very committed to, of the next generation of therapies for our people and the

people of the world, but we want to balance that with access for patients, and very importantly, we want to make sure those prescription drugs are affordable.

On that affordability front, we're trying to address four key problems. The first is list prices. Every incentive in the system is towards higher list prices. How might we help reverse the incentives on list prices?

The second is ensuring that our programs are up to date in ensuring that we get the best deal possible for these drugs, so negotiating the best deals possible and ensuring our programs have those tools.

The third is ensuring that there's adequate competition. At the end of the day, multiple products, multiple generics, multiple branded products, swift entry of generics, ending any kind of patent gaming that prevents generic entry is critical to long-term price reduction in our system.

And then the fourth area is our patients' out-of-pocket expenses. As we've seen changes and transformations in insurance design over the last decade, patients are being asked to assume more of the cost of drugs when they show up at the pharmacy or get the bill at the hospital or doctor's office for those drugs, and how do we address that out-of-pocket.

So those are the areas we're going to be focused on tomorrow when the President rolls out his game plan.

Senator BLUNT. I would say on the list price versus the net price issue, that whatever we do here needs to always also keep in mind people who aren't on any government program, people who, for whatever reason, haven't been able to afford or have chosen not to have an insurance plan that they thought didn't meet their needs. They're the ones who, more often than not, at least initially, are asked to pay the list price that virtually nobody else is paying, and we need to be sure we're aware of that at the same time.

DURABLE MEDICAL EQUIPMENT

On durable medical equipment, Mr. Secretary, you've been forward leaning in trying to help solve that problem. In our State, in Missouri, there are a lot of urban Missourians, suburban Missourians who live in communities that have lots of options. They can shop. There's competition. There are lots of Missourians that don't have that at all, and I think in June of 2013 we had 199 suppliers of durable medical equipment, many of them the only suppliers in rural communities. We're down now to 152.

I think the Office of Management and Budget just released a rule that you sent them last year. What will that do to encourage people to continue to provide the kind of medical equipment that allows people to stay at home rather than their other option, which is much more expensive for taxpayers in most cases or for the nursing home that leads to Medicaid and all kinds of Federal costs, where durable and medical equipment being available often can make the difference in whether that happens or not, available and supported by somebody who is able to really support the upkeep and servicing of the equipment?

Secretary AZAR. Well, Mr. Chairman, thanks to you and other members of the Senate and the House, we appreciate always being

aware of the concern on rural durable medical equipment and the impacts that the reimbursement program was having on them, and that inspired us to act with the rule that we put out yesterday that we hope will provide some relief to rural DME (Durable Medical Equipment) providers. Ensuring that access for reasons you said is absolutely vital. To not do so can be pennywise and pound foolish.

Senator BLUNT. I think you've established a rate for most of the rest of this year. What do you expect to happen after that?

Secretary AZAR. So what we're going to do is we want to take the learnings. We had been on track for 2019, but we've actually put a pause on that to make sure we take the learnings from this experience of what we've seen in terms of what's happened to rural durable medical equipment. Of course, in the rule that came out yesterday we've come up with a 50-50 blended rate that we think will provide a lot of relief to these rural DME providers.

We've also, in the budget, asked for two changes to how competitive bidding can work, and I hope we'll get support from Congress on this. The first is that we would pay winning suppliers, winning bidders, at their bid amounts rather than just at the lowest bid. There had been some bottom-feeding behavior going on that was actually making it unsustainable in rural communities to be a DME supplier even if you won the bid. And the second is to expand competitive bidding to all areas so that the bids are localized. So a rural provider isn't being judged and paid on, for instance, whatever an urban community bidding process would have resulted, which was the challenge under the current system.

So we are very open-minded. We want to make sure this program works. Rural DME is very important, so we would seek any input and want to work collaboratively with both sides of the aisle to just make sure 2019 works better than it has.

Senator BLUNT. Thank you, Mr. Secretary. I'll have some more questions later.

Senator Murray.

TITLE X

Senator MURRAY. Thank you very much.

Again, thank you for being here today.

I wanted to ask about Title X. It is the only Federal program dedicated to providing family planning and related preventive care, including birth control and life-saving cancer screenings to uninsured or under-insured and low-income people. Every year Title X providers serve more than 4 million women, men, and young people.

Now, while your budget does maintain the level funding for Title X at \$286 million, as Democrats and Republicans agreed to in the spending deal we just reached and sent to the President, your budget actually would undermine access to care by attempting to exclude Planned Parenthood from participation in this. They provide basic healthcare service to 2.4 million patients every year. They serve more of the program's targeted population than any other Title X-funded provider, including four out of ten patients who receive contraceptive care through the program.

So, Mr. Secretary, do you think the Federal Government should be in the business of telling women which doctors they can and can't see?

Secretary AZAR. So, Senator, we share your prioritization and concern for the Title X program, as you said, in our budget. We funded it at a level amount, and we want to ensure that that program works for the women and men who are able to make use of it. We want to make sure we've got a robust group of providers that are available that are able to reach people so they get the services. We want to ensure that it reaches a broad range of family planning services, which, of course, is the mandate in the Title X statute. So we want to have a diverse group of suppliers, of grantees, and we want to make sure that we have the full broad range of family planning services available per the statute.

Senator MURRAY. Okay. Can you commit to maintaining a network of safety-net providers that will deliver the full range of high-quality family planning services to 4 million people nationwide?

Secretary AZAR. So, we believe that whatever we would do with Title X will ensure appropriate access to Title X services, as well as broader services more generally. Our grant process is actually seeking out a broad reach of providers and grantees who would be available for individuals.

Senator MURRAY. Okay. Well, I hope that you will make the commitment to not remove a provider that actually provides 41 percent of the currently served, and we'll be watching that very carefully.

AFFORDABLE CARE ACT

Let me ask you about ACA (Affordable Care Act) while you're here. As you know, President Trump campaigned on the promise to guarantee affordable healthcare for everyone and protect people with preexisting conditions. It has been really disconcerting to see this Administration sabotage the healthcare system in many ways, driving up premiums. A recent study showed that millions more people are becoming uninsured.

So I'm concerned that now, in another attack on patients' healthcare, HHS is proposing to expand the sale of short-term junk plans that allow insurance companies to deny coverage to people with preexisting conditions and exclude essential healthcare benefits, like cancer treatment or maternity care. Many of these junk plans spend as little as 50 cents of every premium dollar they collect on actual medical care, spending the rest on executive compensation, marketing, and overhead.

Federal protections ensure that no one can be denied coverage or charged more based on their health status. So I want to be very clear, your proposed rule actually undermines those critical protections. Do you agree that the short-term plans your rule is promoting are allowed to actually deny coverage for individuals with preexisting conditions or charge them higher premiums or exclude these critical benefits?

Secretary AZAR. Senator, we share the goal. We want people to have access to competitive, affordable health insurance. Unfortunately, the Affordable Care Act is not delivering on that. We want to keep working with you on changes to make insurance affordable for individuals. But pending legislative changes, we want to make

available to individuals who have been the 28 million men and women who have been forgotten and forced out of that market some kind of option. It may not be the right option for everybody, and we want to be very transparent about that. For some individuals, it may be better than nothing.

So these same short-term plans are what the Obama Administration had for 8 years——

Senator MURRAY. Well, those were short term, and the short-term plans guarantee none of the critical consumer protections that are included in the individual insurance market, coverage for hospitalization, mental health and substance use disorder. Actually, a recent report found one that doesn't cover hospital stays on weekends. So your proposed rule would extend those very short-term plans which deny these coverages to a full year.

So I'm really concerned that part of what is driving up premiums today is this rule, and I'm very concerned that families who enroll in these plans will have no idea and will be stranded without coverage when they are sick. So again, this is something we'll be following very carefully.

Thank you, Mr. Secretary.

Senator BLUNT. Senator Alexander.

INSURANCE RATES

Senator ALEXANDER. Thank you, Mr. Chairman.

Welcome, Mr. Secretary. Senator Murray and I agree on many things. One thing we do not agree on is health insurance. For example, as you just said, the short-term plan she's talking about is the same short-term plans that existed throughout almost the entire Obama Administration, and I want to congratulate the Administration on the associated health plan proposal which has the prospect of letting employees of small businesses have a chance to have the same kind of insurance that an IBM employee might have at much less of a cost and with the same protections. You couldn't be charged more because of a preexisting condition. You couldn't have your coverage denied because of a preexisting condition. You'd have to give coverage to your kids up to age 26, and there couldn't be lifetime limits.

And in addition, rates didn't start going up with President Trump. They started going up with President Obama. In 2013, with the beginning of Obamacare, they went up 176 percent in Tennessee since 2013. We had a proposal which a month ago President Trump asked Speaker Ryan and Senator McConnell to put in the omnibus spending bill. They agreed. It was said it would reduce rates by 40 percent. It wouldn't have changed essential health benefits. It would have allowed coverage for preexisting conditions, no lifetime limits, so the Democrats blocked it. So that's a difference of opinion we have about who is responsible for the high rates which are coming because of Obamacare, and Democrats blocked our proposal a month ago.

OPIOID EPIDEMIC RESPONSE

Now, one area we agree on is the urgent need for response to the opioid epidemic. Senator Murray and I in our health committee unanimously, after several hearings, reported a bill a few weeks

ago, with contributions from 38 Senators with more than 40 proposals, to attempt to give States and communities and doctors and hospitals and judges more tools to deal with our largest public health epidemic.

Have you had a chance to review that bill, and does the Administration support it?

Secretary AZAR. Thank you, Senator, and thank you for your commitment around helping to make options more affordable for individuals under the Affordable Care Act. And also we thank the committee and the Congress for the bipartisan work on opioids.

I have reviewed some of the elements of the bill, been briefed on them. The Administration doesn't yet have a formal position, as you know, on the legislation, but there are so many very good things in there that I'm sure we'll continue to work together through the process of deciding on the Administration's position.

Senator ALEXANDER. May I ask you to give it your priority? Because the House of Representatives is working on opioids this month. They hope to produce a bill. I hope that our bill could go to the floor this summer, have contributions from other Senators. We invited many of them from other committees to meet the witnesses at ours, and we would hope to be able to deal with this problem this summer.

MEDICARE AREA WAGE INDEX

Let me move to something called the Medicare Area Wage Index. This is an index which has a big effect on how hospitals are reimbursed, the 5,500 hospitals in the country, and from our way of thinking there is a big unfairness. Because of the wage index, for example, if a hospital in Connecticut billed \$100 to Medicare next year, it would receive about \$126. But if a hospital in Tennessee billed Medicare for \$100, it would receive \$82.

As a result of that, a number of us in States, because of that discrimination, have introduced legislation to try to adjust the Hospital Area Wage Index because it's causing hospitals to close. CMS (Centers for Medicare and Medicaid Services) announced a rural hospital initiative, but it didn't include any relief from the Area Wage Index.

Have you thought of ways to adjust the Area Wage Index to make it fairer, and especially to focus on rural hospitals?

Secretary AZAR. Senator, thanks for raising that issue. The wage index is one of the more vexing issues in Medicare, and challenging, in part because of the budget neutrality and adjustment. For any one State on the wage index actually hurts other States and leads to this constant back and forth of winners and losers there. We have and the prior administration had suggested to Congress that we would like to work together to actually come up with statutory changes to adjust the wage index approach to ensure better equity. Every year we are dealing with challenges in many States, in particular some rural areas, but we have issues constantly in certain East Coast States. So we would welcome the chance to work with you and others on appropriate reforms.

NIH FUNDING

Senator ALEXANDER. My time is up, but I want to conclude by saying one other area we agree on in this committee. Senator Blunt and Senator Murray deserve great credit for their leadership as they focus on biomedical research and funding for the National Institutes of Health, and we hope to continue that.

Senator BLUNT. Thank you, Senator Alexander.
Senator Durbin.

MEDICAL RESEARCH FUNDING

Senator DURBIN. Following up on that, thank you, Mr. Secretary, and I want to thank the three Senators to my left for their leadership on medical research. I'm disappointed that the President's budget calls for a reduction of 6.2 percent in spending at the National Institutes of Health. I hope that we have the wisdom to ignore that suggestion and continue to move forward in critical medical research.

The 32.5 percent decrease suggested by the President's budget for the Centers for Disease Control is equally vexing when you consider what we face now across this country in terms of public health challenges. So I'm counting on the three colleagues to my left, who have shown real leadership in this area. I hope Congress can show a better approach to the Administration.

TOBACCO ADDICTION

Let me ask you to join with me in thinking for a moment about the issue of addiction today and how it has changed. I spent a major part of my congressional career fighting big tobacco for personal reasons, for family reasons, and for obvious public health reasons, and there are indicators that we started moving just slightly in the right direction, and the best indicator was the fact that we've seen a decrease in tobacco smoking among kids, from 28 percent in the year 2000 to 8 percent in the year 2016. That's dramatic, because we learned that if you don't hook kids early while they're making the wrong decisions and are immature, it's very difficult to convince them to become cigarette smokers later in life. Good news.

OPIOID ADDITION

Now let's talk about the sobering bad news that we face. We know from the opioid crisis that it strikes everywhere, not just in the inner city but in wealthy suburbs and small towns. I can prove it in my State. Everyone sitting here can prove it in their own State. It is an insidious epidemic, the worst drug epidemic we have faced in America, period. Now it is morphing into a new version of that epidemic that is even more frightening with the use of these synthetic narcotics like fentanyl, which can be produced, sadly, in a laboratory over a span of 48 hours in the United States. It's no longer a question of the poppy fields growing somewhere around the world. It's our backyard, and the opportunity people have to make fentanyl, to addict people, and to kill them with this synthetic drug.

E-CIGARETTE CONSUMPTION

But it's not the only addiction. There is another one that I want to call to your attention that on your watch is becoming alarming. Between 2011 and 2015 the use of e-cigarettes, vaping, among high school kids increased more than 10-fold, from 1.5 percent to 16 percent. In my State of Illinois, 27 percent of high school students are using vaping devices and e-cigarettes. I talked to Dr. Gottlieb about this. When we confront the industry they say, no, this is about getting people off of cigarettes, on to vaping, which is not as dangerous.

Well, that might make sense. Maybe that argument might have some merit until we look at the products that are for sale. Let me show you some of those products for the record.

These are vaping products available, supposedly for adults to get off of using tobacco products.

Jam Monster, a blueberry packaging flavor, which they say is the same as jam, butter, and toast.

Here's another good one here, soft-serve ice cream flavors.

Then when it comes to the flavoring, cupcakes, and raspberry yogurt cupcakes. Raspberry jelly if you don't like raspberry yogurt. Maybe you're lactose intolerant.

[Laughter.]

Senator DURBIN. But the difficulty we have is that these are becoming so pervasive, so insidious, and so fast that when the FDA says we'll get around to this in 4 or 5 years, we don't have the time, Mr. Secretary. We don't have the time. We need to commit ourselves now to stop this.

Did you read the Washington Post this morning? They're talking about the kids in the schools in the suburbs here can't bring flash drives to school anymore because it looks too much like a vaping product and they mistake one for the other. They're taking doors off the bathroom stalls in schools because kids are going into those stalls to vape during the course of a day.

This is a galloping addiction and one that is affecting children across our country. My obvious question to you is what's this Administration going to do about it?

Secretary AZAR. Well, thank you. We share your goals here, totally. In fact, just last week the FDA went after—I don't know if it's those precise products. If not, they will be. These products that are clearly being marketed towards and aimed towards children, we are going after them, we will go after them.

While the Commissioner has laid out an agenda that tries to balance having alternative nicotine delivery devices available as a means for exiting combustible addiction from cigarettes and other devices, we must ensure that these alternative nicotine delivery devices are not marketed for or become an entry point into tobacco, exactly the concern that you were expressing, and we will be very vigorous in going after any bad actors that are trying to market or aiming towards entry points for children or others into addiction.

So I think we're completely aligned. We need to just talk. We want to ensure that we get adequate regulation and that we develop this space of the exit path for combustible tobacco. We want to make sure that that develops but that it's done the right way,

uncompromising in terms of any kind of entry path for children or others into tobacco addiction. We would share that goal completely, Senator.

E-CIGARETTE CONSUMPTION

Senator DURBIN. I will tell you that while the jury is out on this conversion from combustible tobacco to vaping, as to whether that actually is a legitimate purpose for this product, while the jury is out, the vigor and commitment of the industry in hooking our kids is unmatched, and I don't think there's a sense of urgency or emergency in this Administration yet for something that could end up being, sadly, part of your legacy, to have stood by and watched as the percentage of kids in America became addicted, hopelessly addicted to nicotine through these products.

Senator BLUNT. Thank you, Senator Durbin.

Senator Lankford.

Senator LANKFORD. Thank you, Mr. Chairman.

I appreciate the comments, and I agree completely on the issue on the vaping and things that are targeted towards children, what's going on in the opioid epidemic, and I look forward to working with the Secretary and with all of Congress on that issue, as well as what I would raise as an issue.

MARIJUANA LEGALIZATION

Congress has been kind of double-minded on the issue of one point of promoting marijuana legalization, and the other point of trying to be able to go after vaping. So I would hope that we would speak with a consistent voice on these issues, that encouraging more people to use marijuana doesn't exactly help us either long term, and that we should be consistent on our message to not say opioids are bad but marijuana is good.

PHARMACY BENEFIT MANAGERS

Let me go back to one of your comments earlier you made in your opening statement. You talked about the middleman in prescriptions. I assume you're talking about the PBMs (pharmacy benefit managers). That has been a big issue and a major driver of cost. Obviously, when the EpiPen conversation came out for the first time, millions of Americans heard about PBMs for the first time and started asking questions about it. It's been a big issue for a while.

Where is that going right now in the ongoing conversation about how the dollars for any of those prescriptions are getting to the producer or dealing with the consumer or the person delivering it in the pharmacy but not to the PBM in the middle?

Secretary AZAR. Thank you for asking about that. That will be a focus of the President's announcement tomorrow, addressing every element of the pharmaceutical pricing channel, including those who negotiate for so many of us, the pharmacy benefit managers, and their role. They serve a very important purpose.

Senator LANKFORD. Sure they do.

Secretary AZAR. But I think it's very important that we address the incentives in the system, who are they working for, who are they being paid by, and where do the savings go to.

Senator LANKFORD. Well, it's been clear that insurance companies are purchasing pharmacies and such to get access to the PBMs in the middle. Seeing that that becomes the pathway to actually greater profits is actually being able to own that PBM. But it's also, as you mentioned in your opening statement, questions about competition. If competition is important, local pharmacies are important.

RURAL PHARMACIES

Let me ask for your perspective on this, as well. For the local pharmacist, especially a rural pharmacist, and the DIR fees that are coming back, trying to recapture some of these, how do we protect the local pharmacy in rural areas to make sure that we still have those local pharmacies, that not everything is mail order but patients have the opportunity to be able to ask face-to-face questions on it, but we're not trying to go back 6 months later and trying to recapture things from a DIR fee?

Secretary AZAR. Senator, I'm glad you raised this issue. It is something that's been on my radar and is a concern for me, and I'm going to actually ask our Inspector General to ensure that he's looking into this question. The issue you're raising, as I understand it, is often when you have these large pharmacy benefit managers that own their own mail-order specialty pharmacy but they also have to interact with local or non-owned specialty pharmacies, are these DIR fees essentially taxes imposed differentially and unpredictably on those independent pharmacies in a way that puts them at a competitive disadvantage from the owned ones.

I think this is an important issue worthy of study because, as you said, there should be a level playing field and there should be good competition. So I'm going to ask the IG (Inspector General) at HHS to look into this issue.

Senator LANKFORD. Thank you. I appreciate that very much because that is an issue, and it shouldn't be months later when they actually find out about the DIR fees. So a local pharmacy will charge a client \$10 for a pharmaceutical, and then a DIR fee comes back later that's a \$9 clawback on it 6 months later. That pharmacy is obviously long gone. They're now going to go back to their customer and say I undercharged you on this. It's become a big issue for them, and it's related to what Senator Alexander was talking about before with the wage index.

WAGE INDEX

If you've got a cardiologist in Oklahoma doing a procedure, the wage index becomes a big issue because the device they may put in, whether it be a pacemaker or any other valve, whatever it may be, the device is the same cost whether you're in Oklahoma or New York City. But in Oklahoma, the cardiologist makes a tiny amount because most of the cost of reimbursement is the device, while in New York City the device, which has the same cost, the cardiologist gets a very large amount. So what happens is if you're a cardiologist, your tendency is to move to the East Coast where you can get

paid more for the same procedure. If we want to have fair medical treatment for everyone across the country, we've got to also be able to balance out not just the cost of the device and reimbursement but also what the doctors themselves are being reimbursed on it.

RURAL HOSPITALS

Let me also mention to you as well about the rural hospitals. We've got multiple layers I'm going to try to chat with you about because some of them are issues that you all are dealing with, like the abortion surcharge that's ongoing. Obamacare, in the very earliest days, said that has to be a separate billing amount, but it obviously has proved not to be so and is one of those things I want us to be able to work on to be able to establish.

But for rural hospitals, in 2015, 15 hospitals were designated as vulnerable rural hospitals. By 2016, we had 42 hospitals that were designated as vulnerable. By 2017, we had 41 hospitals, but in the same time four of those hospitals are closed. We have major issues that are rolling out with the Affordable Care Act which disproportionately hit those rural hospitals.

I know you all are making some recommendations on this. I just want to be able to say this is of epic importance to rural hospitals, that we do resolve some of the issues that we have there in reimbursements, telehealth, all of those things that become so important. We're losing emergency rooms, and we're losing access in rural areas, and it will be exceptionally important to deal with that.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Lankford.

Senator Manchin.

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

Thank you, Secretary. It's good to be with you.

JESSIE'S LAW

First of all, we finally got a bill called Jessie's Law, and I think I sent you a letter on that. I want to follow up on that because it's such a commonsense piece of legislation. This little beautiful girl, Jessie Grubb, as you know, had an injury, and she was an addict, and she was trying to clean up, and she was doing very well in rehab. She had a running injury and went to the Michigan hospital and told the doctors. Her parents were with her. She was so proud of being a recovering addict and wanted to be very careful about the markings on all of her transcripts as far as her admission to the procedure she was going to need.

To me, I just thought it was commonsense, are you allergic to penicillin, something very critical. It wasn't. She got discharged, the doctor didn't see it, gave her a prescription of OxyContin, and she had overdosed by that evening and died.

So what we're saying is this piece of legislation, you all have it now to set some guidelines and rules, making sure about the procedure. So I think what I need, and I know you feel the same, committing your agency to begin work on these standards and disseminating it as quickly as possible. Medical professionals all over the country are going to have guidelines of how they mark if there was a patient coming in identifying themselves of this nature.

Have you all started, or have you received that in the office?

Secretary AZAR. I have not been briefed in our efforts in response yet, but I can assure you that will be a high priority for us as we share the goal. We want to make sure that gets all——

Senator MANCHIN. This was all preventable. Senator Capito was a co-sponsor with me on this. It should have never happened, and they just want to make sure this beautiful little girl didn't die in vain, and saving others. So for all your staff here, it's called Jessie's Law. It was in the omnibus bill. You have a letter on that. We'd be happy to work with you. I know that Senator Capito's staff would be the same, anything we can help you with.

DRUG PRICING

Let me go right into—because people say how come I can order drugs from Canada and get them so much cheaper? Why are the drugs so expensive? Why are pharmaceuticals charging so much? Why are drugs protected for such a long period of time before they're able to be sold as cheaper generic drugs?

The whole pricing structure, the PBMs, the purpose of PBMs, are you all looking at that? They're telling me that it's the pricing structure and how we sell drugs to the consumer is why the cost is so much different than anyplace else in the world.

Secretary AZAR. Tomorrow the President will be rolling out a comprehensive plan around drug pricing that addresses all aspects of the channel, including the role of the pharmacy benefit managers, drug companies, others in the system, highlighting exactly the types of issues you're raising, and also going after this question of foreign governments that free ride off of American investments.

Senator MANCHIN. Would you say, Secretary, that a lot of the pricing in America, being some of the highest cost in the world for life-saving drugs and drugs that are needed for quality of care for people, is it because of the pricing, the way we sell it, the way we get it to market that's causing that?

Secretary AZAR. I don't believe it's the selling and marketing is the reason. It's basically government structures and payer systems. What happens in the United States, some of our plans and some of our approaches actually drive as good or better deals as some of the socialist systems abroad, and then in other parts of programs and for other medicines foreign governments, socialist single-payer systems get a better deal.

Now, often that deal comes at the cost of rationing and access, and patients who are suffering from cancer or HIV/AIDS or MS or rheumatoid arthritis, they can't get access to the medicines that you can here in the United States because that's exactly what the socialist systems do. So it is a balance.

But what the President is going to be trying to do is trying to tackle the elements of our program, how do we make them better so that we pay less and of course, get foreign governments to pay more.

OPIOID EPIDEMIC

Senator MANCHIN. I have to hurry up real quick. I look forward to that report tomorrow, and if we can start down the path and get

cheaper drug prices and access to cheaper drugs on the market in America, it's going to be very helpful to West Virginia.

We have in West Virginia the largest per capita economic burden in the country as far as opiate deaths, as you know. The amount of money, how it was being disbursed out before, was not based on the amount of rate of per capita deaths that you had. It was based on population, and I think Senator Capito and I both have been working on this.

So what we need is you working with us, a commitment to work with us to make sure the money is getting to the front line. You have a war on drugs. We are the front line. We are on the battlefield every day, and States like us in different parts of the country. Have you all recognized that? Are you directing the money to come to the areas of need?

Secretary AZAR. Yes, and thank you for that concern. We appreciate the flexibility that this committee and Congress gave us in the omnibus to actually target money towards the highest-burden States on opioids, and we will faithfully—

Senator MANCHIN. We have a 15 percent set-aside, but that depends on how quickly and how capably you all are able to administer it to make sure it gets to that front line, because we're in need. We're very much in need.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Manchin.

Senator Kennedy.

Senator KENNEDY. Thank you, Mr. Chairman.

Mr. Secretary, how are you?

MEDICAID ENROLLMENT

How many people are on Medicaid?

Secretary AZAR. The actual numbers on Medicaid—you know, Senator, I want to make sure I've got that exactly—70 million. I'm sorry.

MEDICAID WORK REQUIREMENTS

Senator KENNEDY. Okay. Do you know anybody on Medicaid who is able to work, or on any social program who is able to work—and by “able to work,” I mean not elderly and not disabled—who doesn't want to work?

Secretary AZAR. I certainly hope all would. I hope all would. I view those as being able to work and working, when one is able, as such a fundamental aspect of one's own dignity, as well as, we think, healthcare—

Senator KENNEDY. We can agree with all that. I don't know anybody. I mean, I'm not saying there aren't folks out there, but I've never talked to a person on Medicaid who was able to work that didn't appreciate that he or she would be better off with a job and being able to buy their own health insurance.

I've seen numbers that show we have 28 million people on Medicaid who are not elderly and not disabled, who could work if they could find a job but don't work. I've seen numbers that show we spend about \$150 billion a year on that subset. I've seen numbers that say about 40 percent of those 28 million don't have children.

I think part of the problem is that many of these folks—I'm not saying all. I mean, I'm not naïve. But many of these folks would like to know the dignity of work, but they need a little help about getting that job.

Now, the economy is rocking. I think it's because of our tax bill. I know there are some who disagree with that. I don't understand why the Administration does not loudly and aggressively say, look, the free market—and by that I mean being able to get a job—has done more to lift people out of poverty than all the social programs put together, and if you don't believe me, I give you China. It's not the Communist Party that lifted so many of the people in China out of poverty. It was because they adopted a form, anyway, of capitalism.

And I don't understand why the Administration—and I wish you would take this back to the President, because I think he'll agree with me—doesn't say, look, we don't want to throw people out in the cold, but we want to help them understand the dignity of work. It's a win/win. It's better for our fellow Americans to know the dignity of work, and it's better for the American taxpayer. And let's put together an aggressive program that's not optional for the States. My governor doesn't want to do it. My governor—I believe in more freedom. My governor believes in more free stuff. That's just the way it is. I'm not criticizing him, I'm just describing him.

But put together a program not to throw people out in the cold but just to say, look, let us help you get a job. You can keep your benefits, but let us help you get a job. If your children were older, we'll help you get that job. We'll point you in the right direction. We'll help you find a way to get to work. You've got to do it for 20 hours a week. You can keep your benefits. You'll feel better about yourself, and let's do it.

I appreciate that CMS is willing to grant waivers, but why don't we take the next step? Why don't you take the lead on that?

Secretary AZAR. I believe the President has led boldly here with the welfare reform executive order, with what we're doing in Medicaid—

Senator KENNEDY. How about if we pass a bill?

Secretary AZAR. Well, we would work with Congress. SNAP (Supplemental Nutrition Assistance Program), the SNAP program, the President has wanted work requirements in there.

Senator KENNEDY. But they're optional.

Secretary AZAR. Yes, but then—

Senator KENNEDY. Sorry to interrupt, and I'm not trying to be rude, I'm really not, but I'm down to 11 seconds. We don't need to make it optional, and we need you to take the lead, and the President. I mean, the President is kind of busy right now. He's working on a lot of stuff. I'd like you to take the lead, and CMS to take the lead and say this is a win/win, and we're not going to kick people out in the cold. We're going to help them know the dignity of work. Taxpayers will be better off. They will be better off. And it's not going to be optional for governors.

Sorry, Mr. Chairman.

Senator BLUNT. Thank you, Senator Kennedy.

Senator Murphy.

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

CMS REIMBURSEMENT

I know that Senator Alexander isn't here, but I just want to make a note for the committee and for the Secretary on the reason why we have the wage differential. I say it because Senator Alexander referenced the difference in payments to Connecticut and to Tennessee.

We're a big country. We have different costs of living. We have different rates of pay from State to State, and that is the reason why Medicaid and Medicare reimburses slightly differently. It, of course, results in the average Connecticut taxpayer sending \$14,000 to the Federal Treasury and the average Tennessee taxpayer sending about \$8,000 to the Federal Treasury. If we are interested in equity and parity, then we'd be more than happy to adjust tax rates to send \$8,000 to the Federal Treasury instead of \$14,000. And if that was the deal, then maybe we'd be happy to accept less in Medicare reimbursement. But there's a reason why you pay a little bit more for Medicare in Connecticut. That's also the same reason why the Federal Treasury gets a lot more from Connecticut. I'd point that out for the record.

INSURANCE RATES

I want to continue along the line of questioning from Senator Murray, Mr. Secretary, on this campaign of sabotage that's been waged by the Administration, driving up rates all across the country. This is a quote from the head of the largest health insurance company in Maryland, talking about why they were going to be dramatically increasing rates, especially for plans that tend to be used by sicker patients.

He attributed these rate increases to the continuing actions on the part of the Administration to systemically undermine the market and make it almost impossible to carry out our mission. In making that statement, he talked specifically about PPO plans, which are favored by sicker patients, people with chronic illness. In fact, in one of those plans in the recent rate filing, premiums went up by 90 percent in Maryland.

INSURANCE PLANS

So it gets me to this question of the short-term plans, the junk plans, what we would call the short-term plans and the effect that it will have on the market. The worry, of course, as you know, and the reason why President Obama moved the time duration down to 3 months, is that because these plans are not subject to the requirements that you cover people with preexisting conditions the same, that you have a minimum standard of benefits, you'd have a migration of healthy people to these plans and you'd leave all the sick people, people with preexisting conditions, behind. I think you're already seeing that in the price increases on the exchanges. So that's the reason why the Obama Administration said, listen, we're going to make these short-term plans actually short term, 3 months.

So how do you gauge what insurance companies are already predicting, that there will be a massive migration of healthy people into these short-term plans that are now effectively a complemen-

tary option to the exchanges, driving rates up for people with pre-existing conditions, people who simply can't go on those plans if they don't cover everything that they need?

Secretary AZAR. Senator, first, good to see you again.

I would say first it's important to remember that what's been proposed—nothing is final, but what's been proposed on the short-term plans is to restore what President Obama had in place until the eve of his retirement from office. He kept 12 months in place the entirety of his presidency in the program.

It's next important to remember that of the about 10 million people in the individual market, over 82 percent of them, we're buying their insurance for them. They're subsidized. People are not going to be leaving subsidized insurance with the full slate of benefits for these short-term plans. The individuals that these plans are going to be available for and it's going to make sense for are the folks who have been left out in the cold by the Affordable Care Act now, those 28 million folks who are sitting out there who can't afford these skyrocketing price increases that happened under President Obama in his own plan. We're just trying to make options available. They're not going to be right for everybody. We're being very transparent about that, but we want those for options for those if it makes sense for them.

But what we really have to be working on together is fixing what is wrong, what's not working here, which is the Affordable Care Act. It's not delivering. The price increases were happening before President Trump. They're continuing. It's not functioning, and we want to work together to come up with a new system.

ACA ENROLLMENT

Senator MURPHY. With all due respect, it's just not true that it's not functioning. Even with this deliberate campaign of sabotage, even with the Administration cutting the open enrollment period, even with the Administration stopping the marketing of these plans, even with the Administration refusing to pay for the navigators, the same number of people signed up last year that signed up the year before. I don't think that will continue because at some point 90 percent price increases are going to force people off no matter how big the subsidies get.

So I'm very worried, Mr. Chairman, about the separation of the market into very healthy and very sick as these short-term plans now become true, viable options right next to the exchanges. I look forward to continuing the dialogue. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Murphy.

Senator Capito.

Senator CAPITO. Thank you, Mr. Chairman.

Thank you, Mr. Secretary, for being here.

21ST CENTURY CURES

I'd like to follow up on a question that my fellow Senator from West Virginia talked about, and you and I have talked about this, and that is trying to target the 21st Century Cures dollars to the tip of the spear where we have the highest age-adjusted mortality rate in the country.

I just want to ask for a clarification, because my understanding when we talked about this was that the last tranche of money that went out, it went out on the old formula basis, but the next tranche of money that's coming out in September or October will have this target adjusted.

Could you kind of confirm that for me and maybe explain a little bit?

Secretary AZAR. Yes, absolutely. Thank you, Senator. As I mentioned to Senator Manchin, we appreciate both. There's the targeted holdback from the omnibus of, I think, 15 percent, if I remember correctly.

Senator CAPITO. Right.

Secretary AZAR. That is deliberately targeted to the highest-burden States. But in addition, we appreciate the flexibility that Congress gave us now on the remainder of the money that we would put out in September to also, with regard to that money, try to focus it on the highest-burden areas of the country. So I think on both sides of the fence there would be our goal to target where most needed in the country.

Senator CAPITO. Well, I think that makes a lot of sense. To those of us in States who are not as highly affected as our States are at the very beginning, if we don't nip this in the bud where we are and find best practices, unfortunately I think it's going to cascade in the numbers that we see in our area.

Another area of concern that I have, we see a lot of money going into this, we see a lot of recovery and treatment and a spectrum of solutions, and I welcome all of that, from drug courts to naloxone to medication-assisted treatment to help with foster families, et cetera, et cetera.

OPIOID RECOVERY CENTERS

I do have in the back of my mind a concern, and we've seen some news reports where recovery centers have sort of sprouted up without the proper oversight as to what type of treatment is being offered, what kind of recovery programs. In some cases, I believe there was a case where in the treatment program, the person who was in charge of that, or the owner of it, was actually giving the users more drugs to keep them sort of at bay.

So I don't know where your quality control is on this. Is it more at the State? Is it at your level? And what you all are doing about that.

Secretary AZAR. So, I'm glad you raise that. It's a really important question, and that's something that even on the last round of funding that went out, the \$495 million that went out just a couple of weeks ago, SAMHSA (Substance Abuse and Mental Health Services Administration), with Dr. Ellie McCance-Katz, imposed conditions there, for instance, that the money could only go to treatment centers that used medication-assisted therapy, because we know that works and it ought to be available if the precious money that the Congress has allocated is being spent there.

We're going to keep looking as we move forward to September again on best practices, best approaches. We want to be collaborative, but we also want to make sure this money doesn't just get spent any which way but goes towards the real approaches that are

going to work to help solve this problem, so exactly the kind of situation you're talking about. The learning process for us is primarily State regulation. But we, of course, through the grant process as we release the money, can impose conditions on that, on how that should be spent. And as we learn, get input from you and others, what's working and not working and where there are risks of abuse, we want to take advantage of the opportunity.

Senator CAPITO. I welcome that. I would also say our local—in West Virginia, we also have Recovery Place, and we also have Rea of Hope that are abstinence treatment, and they have some success here, a lot of success. So we just need quality reassurance that we're not getting pop-ups to solve a very deep and devastating problem.

ALZHEIMER'S FUNDING AND RESEARCH

The other area of concern for me in health, and it's such a large area in general, is Alzheimer's and what we're doing in terms of treatment research, helping caregivers, palliative care, all the things. I'm personally touched by this in my own family, as many of us are.

So from the Department's perspective, I know you're doing research. I know Medicare is trying to help with some of these issues. What perspective can you bring to us today?

Secretary AZAR. Well, of course, we've got a comprehensive and deep commitment around Alzheimer's, just as you do. At NIH, with the money that this committee allocates to us, I think we're currently supporting over 140 clinical trials in that space. It's an area I happen to be quite familiar with also. We need to keep looking in the Medicare and Medicaid space to see ways that, again, my theme of not being pennywise and pound foolish, are there ways that we can support caregivers and others and non-traditional ways, I think, to ensure that we avoid perhaps early institutionalization of individuals.

Senator CAPITO. Right.

Secretary AZAR. So I'm open for any ideas and best approaches that we can take across the board. In addition to our research support, also on our payment side, how we can help the families who are dealing with this devastating disease.

Senator CAPITO. Thank you.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Capito.

Senator Schatz.

Senator SCHATZ. Thank you, Mr. Chairman.

CONNECT FOR HEALTH ACT

Secretary Azar, thank you for the conversation the other day. I want to follow up on it. I want to talk about something rare, something we all agree on, and that is telehealth. You said you're a big supporter of telehealth. I'm pleased to be able to work with you on the implementation.

We still have a bill called the Connect for Health Act, which is bipartisan and bicameral. About half of it was enacted in the last CR (Continuing Resolution). So we're going to make good progress in that space, lifting certain restrictions around Medicare. But the

last piece, and for me the Holy Grail, is to give the Secretary waiver authority, assuming his or her actuaries determine that waiving barriers to telehealth around Medicare would pay for itself.

So I'd like you to talk about how you would use that waiver authority and how we would expand access and reduce cost.

Secretary AZAR. Senator, again, thank you for the discussion we had on this. I do think this is a very bipartisan area where we can all get together, whether it's in rural health, remote frontier health, or just containing cost and being efficient. That's the world of telehealth. The biggest challenge, of course, is that our payment systems are sort of frozen in the 1960s so often in Medicare and Medicaid.

If I were to be given that authority, probably the single biggest countervailing pressure we have is, of course, integrity and ensuring program integrity there through telehealth, that we don't see abuse. I mean, I think so many of the rules that we have is some bad provider did something, and so you put a rule in place. Obviously, we have to do it with respect to the taxpayer, program integrity, but I would want to be very forward leaning here on implementing any authority; again, pennywise and pound foolish. Using telehealth, expand the network of providers, expand the reach to communities, really help in rural and frontier communities, and lower the cost of care. So I'm with you on this one.

Senator SCHATZ. Thank you. I think reaching veterans, reaching people in rural communities, helping with the opioid crisis, asthma, psychiatric/psychological treatment, all of it can be done through telehealth. And I think the transformation in our society is that if 10 years ago you were instructed to interact with your clinician through a device, you would be irritated, and now there is a category of clients or patients who, if they are not able to interact with their clinician through a device, they are irritated. So this is transformational, and I know the Chair and Ranking Member are very supportive.

STATE ACA FLEXIBILITY

I want to ask you another question. Clearly, your philosophy—I'm not sure if it's fair to call it Federalism, but you want to provide maximum flexibility to States in terms of interpreting ACA and other statutes and in terms of configuring the healthcare system that makes most sense either through the State insurance commissioner or through the legislature.

So I want to ask you maybe a ticklish question, a tough one, which is it is one thing to provide flexibility if it is in the interests of your view of where healthcare should go. What if a State comes to you and says we want to do a Medicaid public option? What if a State comes to you and says we want to do something left leaning, progressive leaning, more coverage, and more government involvement?

I am assuming, because of my brief interactions with you and your reputation, that you would provide the same flexibility as it relates to a progressive proposal that you would provide to anything that is designed to, in my view, evade or undermine ACA.

Secretary AZAR. I think you've seen that with our behaviors. For instance, our collaborative approach working with the State of

Maryland on their all-payer program that they've had, which some would have a lot of concern depending on ideology, but we've tried to work with them to see if it's a model of value-based payment that they're approaching, and we've tried to be very collaborative in working with them.

We also, in our budget proposal, have a proposal to Congress that we would offer up to five States the opportunity to negotiate directly drug pricing through their Medicaid programs to test and see if that can deliver better results than the rebate program.

So we try to be open-minded. We have certain restraints around Medicare and Medicaid waiver, of course, protecting the public fist. There are certain budget neutrality requirements that, depending on what one wanted to try to do at a State level, might also run contrary to that, and that might be an outer-limit barrier, certainly.

INDIVIDUAL MANDATE

Senator SCHATZ. And I'll just have one final question. Tom Price said that repealing the individual mandate will harm the pool and likely have individuals younger—you know this. You know the quote. It's adverse selection. It will drive costs up. Do you agree with Tom Price? Do you think he misspoke?

Secretary AZAR. I think he—my understanding is he backed away from that statement a little bit later.

Senator SCHATZ. I understand he backed away.

Secretary AZAR. But I will tell you my view on the individual mandate, which is I really do not believe that it will have a significant impact on our risk pool, the repeal of that. We already had 6.7 million Americans paying \$3.1 billion of taxes a year, 80 percent of them earning \$50,000 or less, because they can't afford this insurance, it doesn't work for them. I think the people who were getting in that pool, as I mentioned earlier to Senator Murphy, are people who we're basically subsidizing access to. It's not the mandate that's gotten them there. It's that we are basically giving them insurance. That's why they're in there. So I don't see the premium—

Senator SCHATZ. It just seems you're such a person who relies on data and expertise in so many instances, but you are disagreeing with the consensus among actuaries and healthcare experts of exactly what the individual mandate did.

But my time has expired. Thank you.

Senator BLUNT. It has. There will be time for a second round if anybody wants to ask more questions.

Senator Moran.

Senator MORAN. Senator Blunt, thank you.

Mr. Secretary, thank you for being here. I don't know you as well as I'd like, and I look forward to developing a strong relationship. There are so many things within your Department that are so important to the citizens I represent.

This may be me doing more talking than you, and I apologize for that, but I want to highlight some things in your budget request that are, in my view, worthy of my reaction.

NIH FUNDING

First of all, NIH. The budget that is before us is a \$6 million reduction in NIH funding. I would indicate to my colleagues, and certainly to the Ranking Member and Chairman of this committee, that we ought to continue our efforts in finding ways to fund NIH at increasing rates and certainly without reductions.

In a broader sense, I think we as a Congress for a long time have focused on who is going to pay for healthcare, as compared to how can we make healthcare less expensive. The focus is how we shift unaffordable healthcare to someone else who it is still unaffordable for. So it seems to me that the underlying cause of why healthcare is expensive is where we ought to focus, and you are doing that, and I appreciate that.

NIH, in my view, is one of those things. Not only does it improve people's quality of life and longevity, it's wonderful for families. But if we could find the delay to the onset of Alzheimer's, if we can eliminate cancer, reduce diabetes, all those things have a tremendous cost consequence, and we ought to be pursuing them.

GLOBAL HEALTH FUND

In regard to the CDC, I would advocate for continued funding of the Global Health Fund. One of the things that was said recently in the rescission discussion from OMB (Office of Management and Budget) was that Ebola, in a sense they were saying that Ebola has been taken care of, no reports of Ebola. There were two reports from Congo shortly thereafter. But I also would say that regardless of reports of Ebola, we need to continue to have the funding necessary for the infrastructure so that we don't start anew, we don't have the crisis that we had when Ebola arrived. And for us, this is not just a problem in Africa or elsewhere in the world. The consequences of Ebola and other highly contagious, deadly diseases has a huge consequence upon Americans, and we saw that with Ebola.

So I would highlight the importance of not eliminating the infrastructure that's in place to fight these highly dangerous and contagious diseases even though there may not be a report of that particular disease at the moment.

So those two things I wanted to mention.

PHARMACY BENEFIT MANAGERS

I walked in as Senator Lankford from Oklahoma was talking about drug pricing transparency, PBMs. Senator Capito and I have long been supporters of legislation that requires transparency in the PBM world. I can tell you our legislation has not advanced very rapidly, and I would look forward to hearing from you, knowing from you how we could be of assistance to you in your department's efforts.

But this issue of rebates that's now front and center, I think maybe our conversation is better had once the announcement from the Administration occurs as to what your plan, what your policies are going to be. But this, again, is an example of if we can find ways to reduce unnecessary costs in healthcare and the cost of healthcare, we can reduce the unnecessary cost of healthcare.

So I applaud the Department's efforts in regard to drug reform, and particularly as it relates to PBM transparency and the rebate issue. I'm encouraged.

340(B)

You and I visited on the phone, I guess it's now last week. I would highlight for you once again the importance of the 340(b) program. Our hospitals, from our largest in our most urban settings to our critical access hospitals, all of them are fragile. This is a funding source that helps the patient as well as the provider, and in your alterations, if there are any, of 340(b), I guess we're now waiting on the courts to tell us some direction, provide us some direction, but I would highlight the importance of this 340(b) program.

There are 127 hospitals in Kansas; 80-some of them are critical access hospitals. Almost without exception, they're hanging on by a thread, and any alteration in their reimbursement rate means that there is going to be less access to healthcare in rural places in particular, but in urban places as well, and particularly the core center of urban centers. We have both in Kansas. Johnson County is our suburbs of Kansas City. One of the smallest towns in our State is Johnson City. So from east to west, this is a huge issue.

It highlights for me—I didn't realize when sequestration was passed that we had across-the-board cuts as they affected critical access hospitals. I thought sequestration would not apply to critical access hospitals. I didn't vote for sequestration, but as a bad policy, it's the wrong way to approach the appropriations process. But I would have never thought that we would reduce across-the-board funding that affects critical access hospitals that are to be paid on a cost basis. This 2 percent across-the-board cut, my view, my colleagues and I need to make sure that this is not extended even further and look for opportunities for its demise.

TRIBAL MEMBERSHIP DESIGNATION

Perhaps the only last point I would make, Mr. Chairman, is tribal labor sovereignty, the words I use. CMS, the Center for Medicare and Medicaid Services, has taken upon themselves to declare Native Americans to be classified as a racial group rather than as citizens of a tribe. I think you're wrong. I think tribes should be treated and deserve the sovereignty that they are entitled to by our Constitution and our longstanding understanding that Tribes are governmental, not racial, and I hope that CMS will take a look at that issue once again on behalf of the Tribes.

Thank you for answering all my questions.

[Laughter.]

Senator MORAN. At least I can say thank you for listening to my comments.

Secretary AZAR. If I might, Mr. Chairman, we did just earlier this week revise that guidance on CMS, so we'll be happy to get that to you.

Senator MORAN. With regard to Tribes?

Secretary AZAR. With regard to the community engagement, and if you're talking about the community engagement participation in

States that have received those waivers and Tribal connectivity to that, we have actually issued modified guidance on that this week.

Senator MORAN. I'll take a look. Thank you very much.

Senator BLUNT. Thank you, Senator Moran.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

DRUG PRICING

Welcome, Secretary Azar. I want to start with the issue of the high price of prescription drugs.

Reports showed last year that the pharmaceutical industry spent over \$170 million in lobbying, deploying over 880 lobbyists to influence Washington policymakers. This investment paid off for their CEOs and shareholders. First-quarter earnings saw seven of the largest drug companies in aggregate receiving \$12.1 billion in profits. This is since the beginning of this year.

Meanwhile, large drug corporations received a tax cut from the Republican tax bill, and have spent a combined \$50 billion on new stock buybacks, and enriched shareholders and executives while still continuing to increase prices on existing drugs.

Now, I understand that the President will be outlining a plan to address drug prices. We've been anticipating it since his big announcement at the State of the Union address, and I'll be very interested in hearing what will be included.

At your confirmation hearing before the HELP committee, we had an exchange on this issue of the ever-increasing price of particular prescription drugs, and you blamed, and I quote, "the system" for the rising cost of prescription drugs, but you never singled out the role that drug corporations play in this system.

So I want to know whether the Administration's plan is going to include actions that hold drug companies specifically accountable for their role in setting the price of drugs and increasing the price of drugs. Yes or no?

Secretary AZAR. Oh, yes it will.

Senator BALDWIN. Okay.

Secretary AZAR. All players will be impacted. As I said, it's a systemic issue which requires a systemic, multi-factorial solution. That's what the President will be rolling out tomorrow, absolutely.

FAIR DRUG PRICING ACT

Senator BALDWIN. I sent a letter with Senator McCain to the President asking that he look at and support our Fair Drug Pricing Act. That requires basic transparency for drug companies when they plan to increase the price of their drugs. Will a component of the President's plan be a call for basic transparency for drug corporations particularly, but across that system generally?

Secretary AZAR. Senator, I'm sure you'll understand I'm not in a position to preempt the President of the United States tomorrow by saying what he will and won't announce. So I apologize, but I'm happy to get back to you after that and discuss the issue of transparency. But in terms of any particulars of the President's announcement, I'm afraid I do need to demure until tomorrow. My apologies, though.

Senator BALDWIN. Well, then we will follow up on that. I think for us as policymakers, that's one of the most key aspects, and certainly as we advocate on behalf of our constituents.

SHORT-TERM HEALTH PLANS

I want to turn to the issue of the short-term health plans. During the partisan repeal debate last year, thousands and thousands of Wisconsinites called on Washington to protect their care. The Administration, in my opinion, continues to undermine and sabotage the Affordable Care Act and create more instability in the marketplace.

That is what I view as a pretty radical proposal to expand the ability of companies to sell these skimpy short-term health plans that don't include basic consumer protections that are required, of course, in participation in the Affordable Care Act, particularly things like preexisting condition coverage, and they exclude basic health benefits like maternity care or substance abuse treatment.

PREEXISTING CONDITIONS

I think some of my colleagues know that when I was a child I was branded with the label "preexisting condition" after a childhood illness, and my family couldn't find a health plan that would cover me. Your plan would take us back to those days by allowing more junk plans and for longer periods of time. One of those plans sold in Wisconsin today excludes coverage for preexisting conditions and refuses to cover non-emergency hospital services on the weekend.

Do you believe that insurance companies should be allowed to deny coverage or charge more for those with preexisting conditions?

SHORT TERM INSURANCE PLANS

Secretary AZAR. So, these plans, which are only a compensation for the failure of the Affordable Care Act markets for those for whom it's not working, the 28 million people who do not have insurance because they've been shut out of that market, they can't afford what's there, we're trying to bring back something that President Obama had, which are these short-term plans. People need to go in with their eyes open. They are not right for everybody. They will help in transitional cases. They might be available for those who cannot afford care. We're trying to just make more options available there. The Labor Department—

Senator BALDWIN. But you make them from 3 months to—

Secretary AZAR. To 12, exactly what President Obama had up until the eve of the end of his presidency. Twelve months is what is the proposal, just to restore what President Obama had the entirety of his presidency.

Senator BALDWIN. So this is, right now, 3 months.

Secretary AZAR. Three months he changed in October of 2016, reverted it to put it back to 3 rather than 12. It's an option. It's not meant to be the be-all and end-all. It's just for—we're trying to help those forgotten men and women who are sitting there with any options we can make available to them.

Senator BALDWIN. Why don't you add a requirement that those cover preexisting conditions?

Secretary AZAR. Well, if we start making them the equivalent of the Affordable Care Act, we'll end up with the same pricing regimes. We'd be replicating that. We just want to make other options available for those for whom it makes sense. Again, we're being very transparent. These will not make sense, necessarily, for all people. It's for folks for whom it makes sense. We want to have options available and let them choose.

Senator BLUNT. Thank you, Mr. Secretary.

Thank you, Senator Baldwin.

Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman.

And thank you, Secretary Azar, for testifying today.

RURAL AMERICA

I'm from Brookhaven, a small town in southwest Mississippi, so I'm well aware of the challenges that a rural State presents in healthcare. But I was pleased to learn that the CMS recently released the agency's very first rural health strategy intended to improve the quality of life for Medicare beneficiaries who live in rural areas. So I thank you for working to ensure that the voices of rural patients and healthcare providers are heard, and when your department considers payment policies and regulations, also that consideration.

Secretary Azar, can you discuss further how your fiscal year 2019 budget request will support health in rural America?

Secretary AZAR. Thank you very much, Senator, and it was a pleasure to meet you over the phone. Thank you for that.

COMMUNITY HEALTH CENTERS

First, the budget has \$5.1 billion for community health centers. The community health centers serve 1 in 12 Americans around the country, but in particular 86 million patients, 1 in 6, living in rural areas. So our bipartisan support for the community health center program is, of course, vital to healthcare in the rural communities.

We also, with the opioid epidemic, we've added something very novel in here, which is a \$150 million program for opioid treatment focused in rural areas. And then, of course, we have the program that you mentioned that we've just laid out, the CMS rural health agenda. We have programs there, for instance, that would allow Medicare Advantage programs to deliver telehealth services and other services in a rural area more economically.

I also want to look if you or others can identify where we have barriers in our payment regimes or regulations that impede alternative or innovative methods of care delivery in a rural setting. We know the issue in Mississippi of rural hospitals suffering and closing. Maybe traditional hospital models aren't the best way to deliver care or economically feasible. Are we getting in the way of the creativity of new models for delivering the kind of care that's needed in those communities?

RURAL PHYSICIANS

Senator HYDE-SMITH. Thank you. Also, rural America has 20 percent of the population and 9 percent of physicians. When I was in the Mississippi legislature, we worked to establish the Mississippi Rural Physicians Scholarship Program to help address the shortage of physicians in the rural areas in the State, and it was a great benefit. We're still reaping those benefits today. But how does your budget request support physician workforce in rural places like Mississippi?

Secretary AZAR. So what we've tried to do is prioritize the programs that we believe work the best, especially in getting providers to go to underserved areas, and those are the scholarship and tuition reimbursement programs. As you look at, say, the HRSA (Health Resources and Services Administration) budget, our focus there is direct service care delivery, and then workforce training that is based on scholarship and tuition reimbursement. We just find that those programs deliver health professionals, and they also have service obligations connected to them that help us get people into remote areas, underserved areas, to be able to deliver, as opposed to the programs that we have that are, for instance, just more subsidy payments to institutions. The individual targeted ones, we think there are decades of evidence to show that those really do work in delivering. We want to focus in that space.

Senator HYDE-SMITH. Right. Thank you.

Senator BLUNT. Thank you, Senator Hyde-Smith.

Senator Merkley.

Senator MERKLEY. Thank you very much. I wanted to follow up on that question about physicians and the shortage, because it seems like we're all competing everywhere, our rural areas, our Veterans' Administration, as so many practitioners are Baby Boomers and retiring, and so many of us are Baby Boomers and we need more healthcare.

GRADUATE MEDICAL EDUCATION FUNDING

So in that context, I was somewhat surprised at the \$48 million cut to graduate medical education, and also on the nursing program a \$145 million cut for nursing workforce development. All I'm hearing from my medical community is we need to train more doctors and more nurses and more PAs, so why does it make sense to cut these programs?

Secretary AZAR. So, with regard to the second program that you mentioned, the nursing program, that would get to the comment I was just making around the types of programs. The ones that support scholarship tuition reimbursement that are individually focused we think really can deliver. The institutional subsidy ones, in a scarce environment, we think are less effective.

In terms of graduate medical education, what we've proposed is to combine the children's graduate medical education, Medicare and Medicaid graduate medical education into a single program funded by general fund revenue rather than focused on Medicare and Medicaid. Of course, we all benefit from the training of these physicians and nurses through the GME program, and then allowing us to—right now, we're frozen in 1996. This would give us flexi-

bility to actually target specialties, as well as areas that most need GME (Graduate Medical Education) training.

Senator MERKLEY. Because I have so little time, I'm going to cut you off there and just note that it appears that even when those are added together, there's less money for physician training, and there's a lot less money for nurse training. While providing grants to go to rural areas is something that benefits my rural areas, it doesn't increase the overall numbers, and that's the core problem. Otherwise, everyone is just competing for a pool that's way too small.

HEPATITIS B AND C

Let me turn to hepatitis B and C. This is Hepatitis Awareness Month. I'm just going to keep this very short. There's been a big increase in hepatitis B and C. Are you aware of it, and will you support helping to take on this issue as we're here in this month when our attention is supposed to be focused on it?

Secretary AZAR. Absolutely, and so much of it is connected to this opioid epidemic. So we look forward to working with you on that.

MEDICARE FOR ALL

Senator MERKLEY. It is very connected, absolutely.

When you talked about the junk plans you said, well, it's nice to provide as many options to people as possible, let them choose their options. Well, why not let people choose Medicare as an option? Senator Chris Murphy and I and several of my colleagues have introduced a bill that says let people choose a Medicare policy if they want, a public option. We created a public option in Oregon under Worker's Comp that cut the cost in half. Rhode Island copied Oregon's model with a public option, cut the cost of care in half.

So under your philosophy, why not allow a Choose Medicare option?

Secretary AZAR. The challenge with the Medicare for All type approach is that we already have sustainability issues for our senior citizens in Medicare, and we thought that—

Senator MERKLEY. Okay, I'm just going to cut you off there, because this is a program separate from the existing pool for Medicare. This would be Medicare Part E, and it spends the money people spend on an exchange but lets them choose a better organized option that competes with the regular insurance options. If you're really for competition, why not support a public option? I certainly think that citizens—and we see this in polling—would overwhelmingly like to see that they could have this choice on the exchange, or enable their employers to be able to choose this.

Secretary AZAR. You're not going to be able to afford Medicare without a subsidy, and that would undermine already the fiscal sustainability of Medicare. We heavily subsidize Medicare—

Senator MERKLEY. Just stop there, because you obviously haven't read the bill or you wouldn't say that, because this is a stand-alone competition on a level playing field parallel to the way we do it in Oregon for Workers Compensation. Take a look at it. Look for things that are market-based that actually work rather than undermining Medicare for all citizens across this country, as embedded in your current budget.

MEDICAID BLOCK GRANT

And speaking of that, the Medicaid block grant strategy that you've laid out based on Graham-Cassidy, this would cut about \$2,500 per recipient in Oregon. We have one of the lowest uninsured rates in the country, and you just referred to your concern about those who don't have insurance. We have a very low rate because we've really actively worked on Medicaid expansion, and it's helped everyone in rural Oregon, and urban, because the uncompensated care has dropped dramatically, meaning our clinics are thriving, or at least doing far better than in States that didn't expand Medicaid.

I was just in a State that had three rural hospitals shut down because they didn't expand Medicaid and they didn't have the finances to go forward. So why go to a program that will produce the closing of rural clinics and rural hospitals desperately needed across America?

Secretary AZAR. So, the Affordable Care Act Medicaid expansion as it is, is an open-ended entitlement that is not going to be sustainable for us as taxpayers or for our government in the future, and what we try to do is focus that on the individuals who for now there is a significant disincentive towards the children, disabled, and the aged in Medicaid towards able-bodied adults through the expansion. It's financial. It's basic math in terms of the incentive structure of how the Affordable Care Act was structured. So we're trying to put Medicaid on a more sustainable path forward for taxpayers and for the future of the program.

Senator MERKLEY. Sustainable means cutting healthcare for poor people and damaging rural America, and that's just unacceptable.

Senator BLUNT. Thank you, Senator Merkley. If you want to have a second round of questions, we'll have those.

Senator Rubio.

Senator RUBIO. Thank you.

Thank you, Mr. Secretary, for being here today. We got a chance to briefly talk about this, so I wanted to explore it further with you.

MADE IN CHINA 2025

So, there's a program that China is undertaking. It's called Made in China 2025. The plan is to dominate the 10 biggest technologies of the future. One of those 10 is the pharmaceutical industry, in particular biopharma. In fact, it was the second largest investment in China last year.

And the way they do it is twofold. One is they block off their own market to foreign competition, and they do this in other industries. They're doing it now with biopharma. But the other is, frankly, they just steal intellectual property, and they do that through a number of methods, the foreign-domestic partnerships they require in the pharmaceutical industry. If you go do business in China, you have to partner with one of their companies. They have a track record of stealing intellectual property. Obviously, if you're not paying for the research and are benefitting from it, it's not just unfair and illegal, it's an incredible advantage.

The other is they buy small companies, including here domestically, that have key research components of other industries. We should anticipate the same in pharmaceuticals.

And the third, frankly, is they just steal it. They break into computers through a cyber attack, they buy a business, or they go after the researchers, and that's the part that I'm most concerned about. You know, we spend a lot of money through NIH to fund biomedical research, and a lot of that is done through universities, and I'm concerned about that because universities are soft targets, and they're soft targets for two reasons. First, universities don't think this way. They operate in collaborative environments with other people, and they're not used to an adversarial set-up that this proposes.

But the other is I wonder whether they have the systems set up to protect themselves for intellectual property theft, and that could be ranging from cyber all the way to actually being able to identify individuals and partners they're working with who ultimately are really just transferring intellectual property back to a Chinese company or the Chinese government to give them a competitive advantage.

I would just say that if their growth in this field and advances were being driven by better innovation, more investment and all these sorts of things, then it would be on us to become more innovative and invest more. But when a significant part of their advances on technology in general, and biomedicine in particular, is driven by intellectual property theft, I also believe this has significant national security implications for our country. I challenge people to think for a moment what the world would look like if the latest, greatest cures for diseases, including potentially things like Alzheimer's that are going to have a very significant impact on our budgets for years to come, were controlled by China, the amount of leverage that that would provide them geopolitically and the like.

So I was curious whether anyone at these agencies is thinking about this, thinking about how to protect our research, knowing that this industry is the target of a nation with a long track record of stealing intellectual property.

Secretary AZAR. Senator, thank you very much for raising and highlighting what is a very important issue. It is one that is on our radar. It is one we are working, and I'd be happy to work with you offline also in appropriate settings to discuss this. But I think you have hit on a really quite important issue.

EMERGENCY PREPAREDNESS

Senator RUBIO. All right. The second question is more local, and it has to do with preparedness. During the 2017 hurricane season, my office at one point became, in many ways, a triage center, largely centered on getting Federal agencies to communicate with each other and States. This was particularly problematic in Puerto Rico, where there were delays in getting supplies and HHS medical teams to the island. I want to say there were multiple occasions in which FEMA (Federal Emergency Management Agency) or the Department of Defense caused delays in being able to get HHS supplies to Puerto Rico.

FEMA took days to approve flights for HHS medical teams and some medical supplies. They took a week, the DOD (Department of Defense) took a week to respond to the initial request for medical teams to Puerto Rico.

Have we learned any lessons from Puerto Rico, from the hurricanes in 2017? Because I think this has applicability not just because we're entering hurricane season now, but I think this has applicability for natural disasters in the future or, quite frankly, biological attacks or any other mass public health threat we might face.

Secretary AZAR. Again, thank you for raising what is an issue very much on my radar. We actually just had a session with DOD and other interagency partners on lessons learned from the last season preparing for this, with a focus in particular on transportation resources and our ability to deploy, because we are, of course, often dependent on others for transport. So there is a major focus on lessons learned from the unprecedented cycle of hurricanes that really taxed our system, and I'm hopeful that we have systems worked out better, and connectivity even better, to make sure we serve our people well.

Senator RUBIO. Thank you.

Senator BLUNT. Senator Shaheen.

Thank you, Senator Rubio.

Senator SHAHEEN. Thank you, Mr. Chairman.

Mr. Secretary, thank you for taking time to speak with me yesterday. I appreciated the call and the conversation.

OPIOID EPIDEMIC FUNDING

As I told you, one of the biggest challenges we are grappling with in New Hampshire is the opioid epidemic and how to respond to that. I have been very concerned about making sure that the small States like New Hampshire, like West Virginia—I understand Senators Capito and Manchin asked about this—are able to get help because of the overdose rate, not just based on our population but because of the high overdose death rate. New Hampshire ranks third in the country right now, first when it comes to fentanyl overdoses, and we have additional impacts that are not felt in some of the bigger States.

So I'm hoping that you will commit to working with me and with the committee to ensure that those States that are hardest hit by the epidemic, not just in terms of population but based on overdose death rate, will get some additional assistance to help us.

Secretary AZAR. Thank you for raising this important issue, and thank you for your leadership in the committee's work on this, because it has been a concern of ours, and we've heard that. In the coming grant cycle coming out of the omnibus, not only did the Congress give us a 15 percent set-aside for the hardest-hit States but in addition has given us the flexibility, which we intend to use, on the remainder of our grant programs to also target those based on the burden of this crisis.

Senator SHAHEEN. And do you have any sense of when the decision will be made about that \$142 million, which is the set-aside?

Secretary AZAR. I know generally the next round is expected in September, to get out in September. I don't know if, on the set-

aside amount, if that's on a different timeline. I'd be happy to get back to you on that.

Senator SHAHEEN. Thank you.

DRUG PRICING

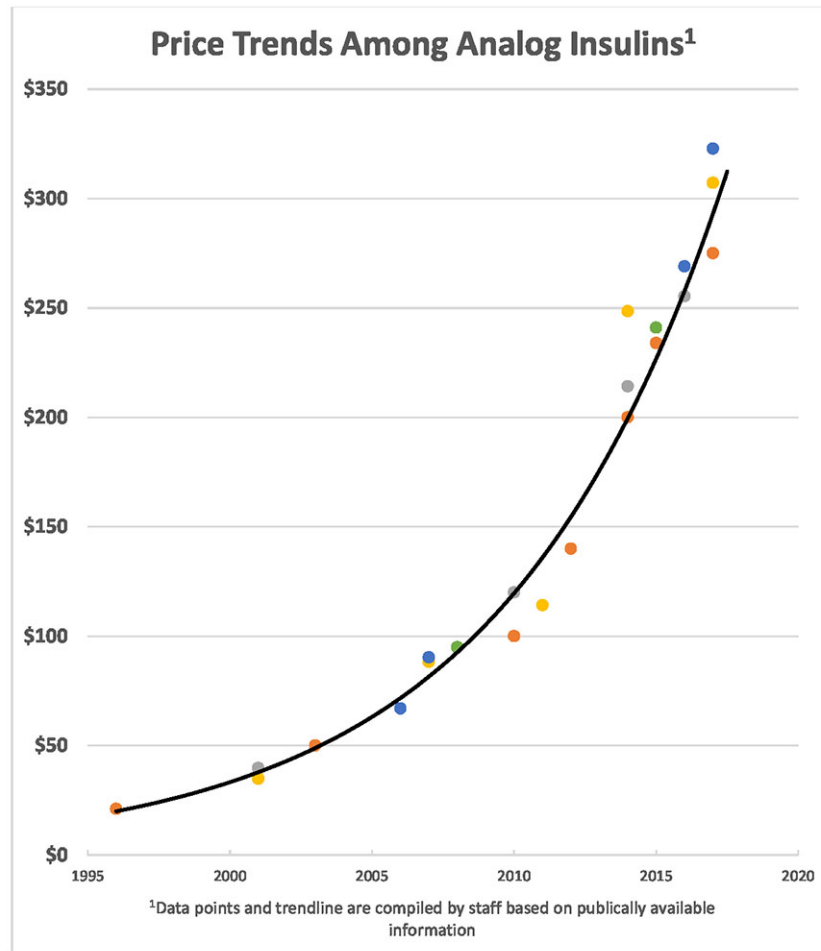
We also talked about drug pricing, which I think is a huge issue. It's not just an issue for families who can't afford drugs, particularly senior citizens, but also in terms of driving up the cost of healthcare.

One of the issues that I'm most concerned about, having attended the Aging Committee hearing on the cost of insulin, is what's happening with the price of insulin. I don't know if you can see this. You can probably just see the trajectory of pricing, but this is insulin prices, this line, and we should have had it blown up.

Mr. Chairman, can I ask that this be entered into the record?

Senator BLUNT. Without objection.

[The information follows:]



Senator SHAHEEN. But what it shows is that these insulin prices started going up dramatically in 2003, after we passed Medicare Part D. So clearly there is a correlation, or I believe there is a correlation between what's happening with the cost of insulin, and I'm sure other drug prices, and our failure to negotiate with pharmaceutical companies.

But can you talk about what you can do at HHS to help address the cost of insulin? Which is not an option for people who need it; it's life or death.

Secretary AZAR. I'd like to, if I could, speak generally about what we need to do around the drug issue. First, in the budget proposal that we have in this fiscal year 2019 budget, we actually have a five-part plan that we would propose to Congress around restructuring many elements of the successful Part D drug program, but taking learnings from the last 15 years, and I think you've high-

lighted one, which is the incentives in the system towards higher list price.

Given that we as taxpayers sit at what's called the catastrophic period, at the end there, if the drug with its list price can march on through there and get to the catastrophic period, we the taxpayers bear 80 percent of that cost, and the drug plan only bears 15 percent of that. We've proposed to Congress to flip that around to give those drug plans more of an incentive to cram down those list prices. So that's an important part of what we're driving towards.

Of course, tomorrow the President will lay out even more focused on these issues of list prices that you so rightly raised.

Senator SHAHEEN. Well, thank you. I appreciate that and look forward to hearing the announcement.

TITLE X FUNDING

HHS recently issued a funding opportunity announcement for Title X family planning grant dollars that really alters the focus from selection of grantees who have focused on contraceptive care towards abstinence-only approaches. Now, we have the lowest teen pregnancy rate ever in this country's history right now, and most of the data that I've seen indicate that that's because we have focused on contraceptive care, on access to reproductive healthcare for not just young people but for everyone.

So I don't understand why we are fooling around with something that's been working to address the issue of unplanned pregnancy, and particularly teen pregnancy, to focus on an approach that all of the data that I've seen shows doesn't work.

Secretary AZAR. Senator, in the funding announcement that we did there, the intention was to comply with the statutes, the mandate of a broad range of family planning services, so not just contraception but natural family planning, which is, in fact, called out expressly in the statute. So not meant to favor one over the other but ensure the broad range of availability, streamline our grant-making processes to make it more efficient. So the intention there is a broad range of providers, as well as serve the full range of services that Title X asks us to provide.

Senator SHAHEEN. Thank you. I have a follow-up, but I'll do that for the record.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Shaheen. If you want to ask your question in a second—well, go ahead and ask it right now.

Senator SHAHEEN. Well, again, do I misunderstand when I look at this funding opportunity announcement? As I said, my interpretation is that it focuses more on abstinence-only approaches. Do I misunderstand?

Secretary AZAR. It offers natural family planning as one part of comprehensive or a broad range of family planning but doesn't set aside, I don't believe, or preference one over the other but rather has the full range of availability and says that if a provider wishes to provide in the one category, they can. But there's nothing that says that one is disadvantaged by providing in the non-natural family planning, the contraceptive type arena. So I think it's meant to encourage the broad range, which is exactly the language of

Title X, the broad range of family planning services. So I believe it's meant to be ecumenical, agnostic.

Senator BLUNT. I think there will be follow-up questions, obviously, for the record. Let me mention a handful of them that I'm going to be asking to make sure that both you and our staff know I want to ask these questions, at least. There will be other questions to be asked.

I would suggest that I believe our communication has gotten better under your leadership. I think it can always be better, and hopefully we continue to do that.

UNACCOMPANIED CHILDREN

On the unaccompanied children issue, I'm not comfortable with what we know from the Department. So if you can help us with information so we can have a little more ability to think about that and plan that.

RECOVERY AUDITS

We'll be asking a question about the recovery audits. I know the U.S. District Court recently ruled that HHS needs to pay the backlog of claims by 2021, which is important because particularly small and rural hospitals generally can't afford to have a staff of auditors and lawyers fight these. The longer they stay in this line and don't get their issue decided, the more challenging it is for them. I know your budget requests an additional \$70 million for this purpose. One of the questions will be whether you think that actually meets the court deadline that by the end of 2020 everybody currently in this long list of recovery audits is going to have their situation dealt with.

MENTAL HEALTH

Also, on the mental health side, I would hope that you continue to look at excellence in mental health, this eight-State pilot, and determine how that can become, if the pilot produces what I believe it will, how that can become a part of our future policy and our future funding for treating mental health like all other health.

BEHAVIORAL HEALTH CLINICS

We have a certified community new investment of \$100 million for behavioral health clinics to provide treatment for Americans that suffer on a clinic and community basis where they can ask for part of that \$100 million. That's a new program, but we'll be asking to see if that program is working.

HHS TRANSFERS

On another topic of transferring responsibilities to NIH, I would just say that one of us is not understanding the discussion here. We have the same request as last year to transfer a bunch of things like National Institute of Occupational Safety and Health, the National Institute of Independent Living and Rehabilitation Research to NIH. It's been the view of the committee that NIH has enough to do, and that's a priority, and those other things bog them down. We probably need to be sure we understand your argu-

ment on the transfer. It's the second time you've made it. Let's see that we give you a chance to make that case.

So from me and the committee you'll get those and other questions.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman. Let me just make comments on two things, and I do have one more question for you.

TEEN PREGNANCY PREVENTION

On the teen pregnancy prevention program Senator Shaheen referenced, actually I was in Washington State a couple of weeks ago and I spoke to the Director of the King County Public Health Department. They operate a program called FLASH. It's the Family Life and Sexual Health program. It was one of the previous TPP grantees whose funding was terminated by your office in the middle of their 5-year grant. My understanding is that widespread use of the FLASH curriculum has had really great results. The teen birthrate in King County fell by 63 percent since 2008, and despite that, your office terminated it.

I just want you to know that you're effectively throwing away really valuable data that these grantees have collected over the past 3 years that could really help us inform pregnancy prevention. Actually, I want you to know, too, that the bipartisan Commission on Evidence-Based Policymaking, which was established by myself and Speaker Paul Ryan, highlighted the TPP program, Teen Pregnancy Prevention, as an example of a Federal program developing increasingly rigorous portfolios of evidence.

So I know this is a subject of litigation right now in terms of our grantee and you can't comment, but I will continue to follow this, and I'm really concerned that we're throwing away valuable research with the changes you proposed.

MATERNAL MORTALITY

The other issue I just want to highlight for you is maternal mortality. I am really troubled that greater proportions of women in this country are now dying of pregnancy-related complications, more than any other developed country in the world, and the U.S. is the only country where the rate of these deaths has been rising. That is really troubling to me, and it is just so critical that we improve systems of maternity care, including both clinical and public health systems. We've got to work on eliminating this really preventable maternal mortality and severe morbidity rate that we're seeing across the country, so I will be talking with you about that.

GUN VIOLENCE RESEARCH

And then I do have one final question, and that is on gun violence research. The last time you and I spoke and met, we talked about the Centers for Disease Control and Prevention reengaging in gun violence research. I've spoken with Dr. Redfield, the new CDC Director, about that, and since then Kaiser Permanente actually announced it will invest \$2 million to start working on this issue, along with a group of seven bipartisan governors who

launched a consortium to study it. That just reinforced for me that it's time for CDC to return to do the same.

Dr. Redfield actually had the best quote. He said, "The CDC is the best science-based, data-driven agency in the world. We should be using them."

So I wanted to ask you, do you intend to—actually, can you reprogram or transfer funds today from HHS to CDC to begin this work?

Secretary AZAR. I don't know about that, but I've spoken to Dr. Redfield, as I had previously with Dr. Shulkin, to make clear our understanding of the Dickey Amendment, which is that we're not prevented from using appropriated funds if we appropriated funds for research on violence, including gun violence research. We do that at NIH today. We've got ongoing programs and past programs on violence and gun violence research at NIH, as you know, because you appropriated the money. NIH's pools of money are much more fluid and open for peer-reviewed funding of programs. But CDC is not that way. We are very directed in where the money goes there.

Senator MURRAY. But can't you reprogram? If this is a priority for you, I believe that you can reprogram or transfer funds directly for this reason.

Secretary AZAR. I'm not aware. I'd have to look into that.

Senator MURRAY. Okay. If you could do that and get back to me?

Secretary AZAR. Will do.

Senator MURRAY. Or I'll ask you, are you intending to include gun violence research funding in your next budget submission?

Secretary AZAR. That would be a matter between the Department and OMB on the budget submissions. I couldn't comment on where we will be as an administration on the funding.

Senator MURRAY. Well, as Secretary, would you be willing to ask for that in the next budget?

Secretary AZAR. Again, I cannot reveal my deliberative work with the White House on that.

Senator MURRAY. Okay. Let me say, would you please look at that as a priority?

Secretary AZAR. I absolutely appreciate your concern there. Thank you.

Senator MURRAY. Thank you.

Senator BLUNT. Thank you, Senator Murray.

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

ADDITIONAL COMMITTEE QUESTIONS

The record will stay open for one week for additional questions.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

NATIONAL INSTITUTE OF HEALTH

Question. Last year, the budget proposed moving the Agency for Healthcare Research and Quality to the NIH. That proposal was rejected. This year, the budget once again proposes this move, as well as also moving the National Institute of Occupational Safety and Health and the National Institute of Independent Living and

Rehabilitation Research to NIH. I am concerned that the addition of these new Institutes takes NIH out of its defined role as a biomedical research agency. The budget proposal appears to have taken any “research” related organization and moved it to the NIH. I do not think that is in the best interest of NIH.

What is the goal of these moves?

Answer. The goal of consolidating targeted research programs from across HHS—AHRQ/NIRSQ, NIOSH (from CDC), NIDILRR (from ACL)—into NIH is to focus resources on the highest priority research so these programs benefit from the NIH research infrastructure, which we anticipate will improve coordination and outcomes. NIH will continue to implement strategies to increase operational efficiencies and administrative reforms.

Question. What are the benefits to NIH in adding these new centers?

Answer. The fiscal year 2019 Budget proposes consolidating HHS research programs into three new institutes within the NIH. The Budget provides \$256 million for the activities of the Agency for Healthcare Research and Quality (AHRQ), consolidated into the National Institute for Research on Safety and Quality. The National Institute for Occupational Safety and Health (NIOSH), including the Energy Employees Occupational Illness Program (EEOCIPA), currently administered by the Centers for Disease Control and Prevention, and the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR), currently administered by the Administration for Community Living, are also proposed for consolidation into the NIH.

Consolidating targeted research programs from across HHS—AHRQ/NIRSQ, NIOSH, NIDILRR—into NIH allows high priority research programs to benefit from focused resources and NIH research infrastructure, which we anticipate will improve coordination and outcomes. NIH will continue to implement strategies to increase operational efficiencies and administrative reforms.

UNACCOMPANIED ALIEN CHILDREN PROGRAM

Question. The Department of Justice recently announced it would criminally prosecute all undocumented individuals apprehended attempting to enter the country illegally between points of entry. How many children does the Administration expect will be referred to HHS as a result of this policy change?

Answer. HHS is closely working with our DHS partners to anticipate and plan for the potential number of unaccompanied alien children (UAC) referrals and their length of stay in our care. Historically, the timing and number of UAC referred to HHS each year for care and custody has been difficult to predict with any certainty and we assess need for capacity growth or decline on an ongoing basis.

Question. What if any preparations has HHS made to properly care for additional children referred to them as a result of this policy change?

Answer. When there are concerns about having adequate capacity to receive referrals of unaccompanied alien children, HHS seeks out additional bed space to meet increased demand. HHS first expands the number of beds available with existing state licensed grantee care provider facilities. If necessary, HHS seeks bed space with a state licensed facility that is not currently housing UAC. In the event of an influx, defined as a period where the number of UACs exceeds the standard capabilities of Federal agencies to process, transport, or shelter with existing resources, HHS may open a temporary emergency shelter, which we call an Influx Care Facility. During recent months, HHS has taken all of these steps, adding over 2,300 beds since early May by increasing bed capacity at permanent grantee shelters, expanding the temporary shelter in Homestead, FL, and seeking additional capacity at a temporary influx site.

Question. HHS and DHS recently signed a Memorandum of Agreement (MOA) modifying existing data collection and sharing procedures related to reviewing the suitability of potential sponsors. DHS also recently issued a proposed regulation on the same issue. How does HHS expect this MOA to impact HHS’ administration of the UAC program?

Answer. Some changes will be made related to information gathering and sharing to implement the MOA between HHS and DHS. HHS has created new policies and procedures as a result. We will receive from DHS more detailed information about UAC that will enable HHS to better respond to gang affiliation. We also believe that the partnership with DHS will enable HHS to conduct improved background checks of potential sponsors to support our efforts to ensure the well-being of UAC when they are released from our care.

Question. Does HHS expect this will increase the length of time children are in HHS’ custody?

Answer. The implementation of the MOA is still in the early stages, so its impact on the length of time children are in HHS' custody is unclear at this time. If the length-of-stay did increase, one factor would be the result of HHS receiving more comprehensive information related to ensuring sponsor suitability and the safety of UACs.

Question. Regarding both policy changes described above, does HHS have any revised estimates of funding needs for the UAC program in fiscal year 2018 or fiscal year 2019, relative to fiscal year 2018 enacted appropriations and the fiscal year 2019 budget request?

Answer. HHS is closely monitoring its shelter capacity needs in coordination with our interagency partners, evaluating its resource needs and, if necessary, will seek to maximize currently available resources and authorities. As always, we will continue to work with Congress as we learn more.

COLDWATER CREEK

Question. The community in St. Louis, particularly those near the Coldwater Creek area, have been waiting for a report to be released by the Agency for Toxic Substances and Disease Registry. This report will assess whether hazardous materials such as radioactive waste and other chemicals have migrated from storage sites into the Coldwater Creek area. ATSDR originally expected to file a final assessment in 2016, but have yet to receive a report. I am concerned this report is 2 years delayed and want to ensure it is provided quickly.

Will HHS commit to issuing this report this summer?

Answer. HHS is committed to releasing the report on Coldwater Creek as soon as we can practically do so. The report currently in the final stages of scientific review with CDC/ATSDR's standard process. ATSDR has been working closely with the community in St. Louis to inform them of its work to assess exposures to radiation contamination at Coldwater Creek. We recognize the importance of the assessment to the community members and we want to make sure it is as accurate and thorough as possible. The report will be posted on the ATSDR website for comment once it has completed the scientific clearance process.

MEDICARE APPEALS

Question. HHS has been working for years to reduce the backlog of Medicare appeals, but continues to project a backlog of over 500,000 appeals. What will be the impact of the additional \$75 million provided in the fiscal year 2018 Omnibus?

Answer. The additional \$75 million provided in the fiscal year 2018 Omnibus will help OMHA expand its adjudication capacity by acquiring additional ALJ teams to hear currently pending and newly filed appeals. When fully staffed in fiscal year 2019, OMHA will have approximately 170 ALJ teams with the ability to adjudicate approximately 170,000 appeals annually. In fiscal year 2019, HHS projects receipts at OMHA to exceed 100,000 appeals and continuing to rise in subsequent years. The fiscal year 2018 Omnibus funding level will finally allow OMHA to steadily adjudicate pending cases. At this level, OMHA projects to eliminate the backlog in approximately 7 years.

Question. How has HHS created a more consistent process at the Office of Medicare Hearings and Appeals to discourage continued appeals?

Answer. OMHA has implemented a number of measures to improve and expedite the appeals process. OMHA has established a National Substantive Legal Training Program for new ALJs and attorneys, with yearly judicial education to increase consistency in decisionmaking and address program integrity issues. Regulations effective March 20, 2017 have expanded OMHA's ability to process Level 3 appeals by providing for review of certain appeals by attorney adjudicators rather than ALJs, implemented processing efficiencies at OMHA, and resolved many areas of confusion among stakeholders. In addition, beneficiary appeals have been prioritized to optimize timely adjudication. The OMHA Case Processing Manual (OCPM) initiative is establishing OMHA-wide common business practices for the adjudicative process, and OMHA is using strategic case assignments to assign appellants with a large number of filings to a single ALJ, facilitating potential consolidated proceedings and more efficient adjudication. These "big box" assignments are then rotated among ALJs in accordance with the Administrative Procedure Act. OMHA has a Statistical Sampling Pilot to resolve large groups of appeals, and its Settlement Conference Facilitation initiative is providing a less costly alternative to ALJ hearings. Thanks to these efforts, and CMS's efforts implemented at appeal levels 1 and 2, the Department has seen a drop in OMHA's annual receipt levels since the peak in fiscal year 2014 which saw OMHA receive over 470,000 appeals in 1 year.

Question. Your budget requests an additional \$70 million over fiscal year 2018 to work through the backlog of appeals. If this request is appropriated, how quickly will the backlog be reduced?

Answer. HHS projects that, with current administrative actions in place, the fiscal year 2018 funding, and additional resources and authorities requested in fiscal year 2019, once OMHA is fully staffed, the backlog could be eliminated in approximately 4 years.

In addition, the fiscal year 2019 President's Budget and the Audit & Appeals Fairness, Integrity, and Reforms in Medicare Act of 2015 (AFIRM), introduced by the Senate Finance Committee, propose additional authorities that would be useful in reducing the pending backlog of Medicare Appeals more efficiently, and allow for future receipts to be addressed at lower levels. These authorities include changing the Medicare Appeal Council's standard of review; remanding appeals to the redetermination level with the introduction of new evidence; increasing the minimum amount in controversy for Administrative Law Judge (ALJ) adjudication of claims to equal the amount required for judicial review; establishing magistrate adjudication for claims with amounts in controversy below the new ALJ amount in controversy threshold; expediting procedures for claims with no material fact in dispute; limiting appeals when no documentation is submitted; requiring a good-faith attestation on all appeals; and establishing a post-adjudication user fee for unfavorable appeals at the third and fourth levels of appeal. With fiscal year 2018 Omnibus funding, the Department's current administrative actions, and these authorities in place, the Medicare Appeals process will be better structured to encourage resolution of cases earlier in the process and resolving a greater volume of appeals.

MENTAL HEALTH

Question. The fiscal year 2018 Omnibus included a new investment of \$100 million for Behavioral Health Clinics to provide treatment to Americans that suffer from mental illness, particularly in areas impacted by the opioid crisis.

The fiscal year 2018 Omnibus included a new investment of \$100 million for Behavioral Health Clinics to provide treatment to Americans that suffer from mental illness, particularly in areas impacted by the opioid crisis. How will these funds help those with mental illness receive treatment and when does HHS expect grants awards to be announced?

Answer. The purpose of this program is to increase access to and improve the quality of community behavioral health services through the expansion of Certified Community Behavioral Health Clinics. The CCBHC Expansion grant program will provide access to services for individuals with serious mental illness (SMI) or substance use disorders (SUD), including opioid disorders; children and adolescents with serious emotional disturbance (SED); and individuals with co-occurring disorders (COD). SAMHSA expects that this program will improve the behavioral health of individuals across the nation by providing comprehensive community-based mental and substance use disorder services; treatment of co-occurring disorders; advance the integration of behavioral health with physical healthcare; assimilate and utilize evidence-based practices on a more consistent basis, and promote improved access to high quality care. CCBHCs provide a comprehensive collection of services that create access, stabilize people in crisis, and provide the needed treatment and recovery support services for those with the most serious and complex mental and substance use disorders. CCBHCs integrate additional services to ensure an approach to healthcare that emphasizes recovery, wellness, trauma-informed care, and physical-behavioral health integration. CCBHCs provide services to any individual, regardless of their ability to pay or their place of residence. Data is currently being collected on the program to gauge effectiveness and identify lessons learned. Grants will be awarded by September 30, 2018.

Question. When does HHS expect to report preliminary and final results of the current Excellence in Mental Health pilot program?

Answer. SAMHSA is responsible for producing an annual report to Congress in December of each year, until 2021. The reports will be based on an ongoing evaluation overseen by ASPE, drawing on multiple data sources including state reported quality measures, clinic cost reports, site visits, clinic progress reports and telephone interviews. In order to measure the impact of the program on utilization patterns and costs of a full range of mental health services compared to Medicaid beneficiaries with similar demographic and diagnostic conditions who do not receive CCBHC services during the demonstration, Medicaid claims data from four states will be used. This quantitative portion of the evaluation will examine changes in inpatient, outpatient, and emergency care for both physical and behavioral health conditions for four states with the strongest data and comparison groups. Because

of the lag in the availability of the claims data we do not anticipate that all of the necessary data will all be available for analysis until at least 2 years after the second year of the pilot ends. As a result, the report on these impacts will be available in the final report in December, 2021. The remainder of the reports to Congress will utilize primarily qualitative data, and report on cost and quality measures as soon as they are available. A summary of the planned report content is highlighted below:

- The first Report to Congress should be out shortly, and focuses on the characteristics of state delivery systems and CCBHCs at the beginning of the demonstration, planned partnerships, and plans for service provision, including whether CCBHCs had to change services or provide new services. The report will also discuss state plans for monitoring the quality of CCBHC services, as well as which PPS model the state selected.
- The second Report to Congress, due in December, 2018, focuses on how well CCBHCs established relationships with other providers, including formal relationships. It discusses how well they were able to bill and generate claims and encounter data, what types of services and evidence-based practices are being implemented, and whether they are using telehealth or other providing services in other locations. It will also discuss care coordination practices, staffing patterns, and staff training.
- The third Report to Congress, due in December, 2019, will focus on whether the CCBHCs sustained their partnerships and delivery of required services, including whether they maintained staffing levels and training. It will discuss information sharing practices across providers to coordinate care, as well as the use of evidence-based practices. Because the first year of the demonstration quality measures and cost reports will be available in time for this report, the report will also discuss CCBHC performance on quality measures and whether CCBHCs used the quality measures to improve care. The cost reports will allow the report to address what the costs of care were, and whether they deviated from expectations. It will also report on whether states changed the payment rates based on the first year of the demonstration's costs.
- The four Report to Congress, due in December, 2020, will focus on changes in the quality measures over the course of the demonstration, as well as changes in costs, utilizing both years of cost and quality data. It will investigate whether the costs and performance data vary by state, depending on the prospective payment used. It will also investigate whether quality bonus payments were made to clinics.
- The final Report to Congress, due in December, 2021, will include information on service utilization patterns and costs of Medicaid beneficiaries in the CCBHCs compared to a comparison group. It will also summarize the findings of the previous reports, and provide recommendations concerning whether the demonstration program should be continued, expanded, modified or terminated.

STRATEGIC NATIONAL STOCKPILE

Question. I appreciate the Department's continued communication as HHS works to shift the Strategic National Stockpile (SNS) from CDC to ASPR.

How will HHS continue to rely on CDC expertise when deciding the necessary products to purchase for the stockpile?

Answer. CDC participates in and provides subject matter expertise to the ASPR-led Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which HHS created to provide a venue for sharing information across agencies with a role in medical countermeasures. CDC will remain an active participant in PHEMCE workgroups and committees as a forum to ensure important clinical, regulatory, laboratory, and scientific input is accounted for in decisions related to the life cycle of SNS products. ASPR has committed to continue to fund in fiscal year 2019 most of the subject matter expertise at CDC that has been providing support to SNS activities.

Further, to continue to increase collaboration across the Department, ASPR requested, and CDC has assigned, a senior CDC staff member to work as a liaison within the ASPR Immediate Office. Additionally, ASPR is identifying an ASPR employee to serve as a liaison at CDC in Atlanta.

Continued inclusion of CDC in PHEMCE ensures that CDC's scientific, epidemiological, clinical, and public health expertise helps inform decisionmaking related to Medical Countermeasures (MCMs), such as requirement setting and acquisition of MCMs for the Strategic National Stockpile, which can be most effectively used to significantly reduce morbidity and mortality from public health emergency threats. CDC expertise is also important to help inform the practical requirements of dis-

persing MCMs by public health departments, monitoring use of MCMs, and assessing MCM use. CDC also maintains strong partnerships and trust with State, Local, Tribal, and Territorial (SLTT) public health entities and clinicians, who serve as some of the frontline providers for MCMs. While the SNS transitions to ASPR management, CDC will continue to provide this expertise through the PHEMCE and the SNS annual review process.

Question. Does HHS plan to keep any SNS related funding within CDC to cover CDC's ongoing SNS costs?

Answer. In order to ensure a smooth transition with no degradation of operational capability, ASPR and CDC have set up several joint SNS transition workgroups to evaluate all aspects of this program transition. Ensuring CDC's continued ability to provide, in a collaborative and transparent fashion, scientific, clinical, regulatory, laboratory, and SLTT coordination expertise will be a critical component to ensuring the ongoing successful operations of the SNS. While some details are still under review, ASPR has committed to fund transition activities to meet costs CDC may incur related to the SNS itself. Once finalized, HHS would be pleased to provide a full briefing for Committee staff on the SNS transition details before the end of the fiscal year.

QUESTION SUBMITTED BY SENATOR MARCO RUBIO

Question. CMS recently proposed a rule for 2019 Medicare hospital payments. This proposal mentioned revising the Medicare payments for the cutting edge immunotherapies, known as CAR-T therapy. Oncology drugs are often administered on an outpatient basis, but these new CAR-T therapies must be given on an inpatient setting. Yet, the costs of these drugs are only really covered by CMS if administered on an outpatient basis.

CMS' recent IPPS proposal would not go into effect until 2019, yet Moffitt Cancer Center is one of two NCI-designated cancer centers that is capable of administering both of these breakthrough CAR-T treatments. Because of Moffitt's commitment to patients, they are absorbing the difference between the price of the drug, which is either \$373,000 or \$475,000, and the \$20,000 that Medicare reimburses. But Moffitt cannot do this forever.

Would you be willing to work with cancer centers like Moffitt to address the reimbursement shortfalls that are taking place through 2018, before CMS' proposed payment reforms go into effect?

Answer. HHS/CMS is considering the potential challenges in Medicare payment structures for new treatments like CAR-T therapies. Two CAR T-cell therapy drugs received FDA approval in 2017—Novartis's Kymriah and Kite Pharma's Yescarta. For Medicare, CAR-T therapy is paid for use in the hospital outpatient setting under the Outpatient Prospective Payment System (OPPS), and in the hospital inpatient setting under the Inpatient Prospective Payment System (IPPS).

In the hospital outpatient setting, effective April 1, 2018, both Kymriah and Yescarta have been approved for transitional pass-through payment status under the OPPS. Drugs under pass-through status are generally paid at average sales price plus 6 percent.

Under the IPPS, payment for CAR-T is currently bundled into the Medicare payment for the inpatient stay and thus there is no separate CAR-T payment rate. In the fiscal year 2019 Medicare IPPS proposed rule, CMS proposed the assignment of CAR-T related procedure codes to the bone marrow transplant diagnosis related group. CMS also invited comments on alternative approaches to establishing payments for fiscal year 2019.

CMS has received applications for IPPS new technology add-on payments for Kymriah and Yescarta for fiscal year 2019. It is also seeking public comment on these applications in the fiscal year 2019 IPPS proposed rule. Under the new technology add-on payment policy, one of the criteria for an additional payment is that the technology represents an advance in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. The deadline for submitting comments on the fiscal year 2019 IPPS proposed rule is June 25.

However, because Moffitt Cancer Hospital is a PPS-Exempt Cancer Hospital it is generally paid based on reported cost and not under the Inpatient Prospective Payment System.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

MATERNAL MORTALITY

Question. It is deeply troubling that greater proportions of women in this country are dying of pregnancy-related complications than in any other developed country in the world, and the U.S. is the only country where the rate of these deaths has been rising. It is essential that we improve systems of maternity care, including both clinical and public health systems, to eliminate preventable maternal mortality and severe morbidity across the United States.

What can HHS do to reverse the rising rates of maternal death, and what will it take for the Department to take greater leadership to address this issue?

Answer. Since 2016, CDC has collaborated with CDC Foundation and the Association of Maternal Child Health Programs on a project to help state-based maternal mortality review committees (MMRCs) produce stronger data on maternal mortality. These data can be used to better understand and prevent maternal mortality. The project also works to foster information sharing between MMRCs.

To support this effort, CDC developed the Maternal Mortality Review Information Application (MMRIA). MMRIA facilitates case abstraction to help MMRC members to (1) understand the story of a woman's life and the events leading to her death and (2) support routine analyses to inform prevention, and (3) share a common language that helps MMRCs to collaborate with each other in case review and reporting.

Through this work, a Report from Nine Maternal Mortality Review Committees was released in February 2018. The report found that about 60 percent of pregnancy-related deaths are preventable and highlighted key opportunities for prevention. Additional key findings include:

- Nearly half of all pregnancy-related deaths were caused by hemorrhage, cardiovascular and coronary conditions, cardiomyopathy or infection.
- Mental health conditions are a leading cause of death, and also an important contributor.
- Deaths from hemorrhage, cardiovascular conditions and preeclampsia/eclampsia are highly preventable.
- The leading causes of maternal deaths vary by race. For example, 12 percent of maternal deaths among black women are due to preeclampsia or related conditions, compared to only 5 percent of white maternal deaths.

CDC has invested in Perinatal Quality Collaboratives (PQCs) to improve outcomes for mothers and infants. PQCs are state networks of teams working on quality improvement. PQC members identify healthcare processes that need to be improved and use the best available methods to make changes as quickly as possible. PQCs have contributed to important improvements in healthcare and outcomes for mothers and babies, including reducing deliveries before 39 weeks of pregnancy without a medical reason and reducing severe pregnancy complications. As MMRCs have increased capacity, PQCs can work with them to address the prevention recommendations that emerge from the Review Committee process. CDC currently supports PQCs in 13 States (Colorado, Delaware, Florida, Georgia, Illinois, Louisiana, Massachusetts, Minnesota, Mississippi, New Jersey, New York, Oregon and Wisconsin), to improve population outcomes in maternal and child health.

Question. Does HHS support increased investment in successful evidence-based programs to prevent maternal deaths, such as the Safe Motherhood Initiative, or the Alliance for Innovation in Maternal Health and Healthy Start?

Answer. HRSA is committed to supporting continued investments in evidence-based strategies to prevent maternal deaths and leverages existing resources and programs to address this important issue. For example, earlier this year HRSA released a notice of funding opportunity for the Alliance for Innovation on Maternal Health Initiative. The goals of this award will be to facilitate widespread implementation of the current maternal safety bundles and/or resources by maintaining the existing 10 AIM state-based teams, and accepting 25 new state-based teams; develop new maternal safety bundles and/or resources that address new topics in the quality and safety of maternity care practices; develop and implement a national campaign focused on the current state of maternal mortality and severe maternal morbidity that highlights the impact of AIM, and how the maternal safety bundles improve maternity care practices; and prevent 1,000 maternal deaths and 100,000 cases of severe maternal morbidity in the United States by 2023. An award announcement will be made before the end of fiscal year 2018.

HRSA also continues to support the Healthy Start program, which currently funds 100 competitive grants in 37 States and DC to reduce disparities in infant mortality and improve perinatal outcomes for women and children in high-risk com-

munities throughout the nation. Healthy Start aims to reduce these disparities by empowering high-risk women and their families to identify and access needed services to improve the health of mothers and children before, during, and after pregnancy. The Healthy Start program will be recompeted in fiscal year 2019 and will serve women and families across the nation through approximately 100 new grants. Prevention of maternal deaths remains a priority. HRSA plans to incorporate recommendations from the Maternal Mortality Summit in future HSRA activities on maternal mortality and will continue to explore opportunities to utilize existing resources to support evidence-based programs to address this important public health issue.

In addition, HHS supports continued resources for the Safe Motherhood Initiative to support Maternal Mortality Review Committees to increase access to robust, accurate data gathered through a standardized approach that can inform strategic, data-driven actions to prevent maternal mortality.

Question. Is the Department taking action to address the disparities that women of color face when it comes to maternal mortality? What steps are being taken?

Answer. Considerable racial disparities exist with respect to maternal mortality, with black women almost 4 times more likely to die from pregnancy-related complications than white women. CDC is working to better understand the disparities through better data. Data from the Building U.S. Capacity Project Report from Nine Maternal Mortality Review Committees was released in February 2018 including important data to begin to better understand the disparities in maternal mortality. This report found that the leading underlying causes of death varied between non-Hispanic white and non-Hispanic black pregnancy-related deaths.

Among non-Hispanic white pregnancy-related deaths, the leading underlying causes of death were:

1. Cardiovascular and coronary conditions (at 15.5 percent),
2. Hemorrhage (at 14.4 percent),
3. Infection (at 13.4 percent),
4. Mental health conditions (at 11.3 percent), and
5. Cardiomyopathy (at 10.3 percent).

These top five causes represent 64.9 percent of non-Hispanic white pregnancy-related deaths.

Among non-Hispanic black pregnancy-related deaths, the following were the five leading underlying causes:

1. Cardiomyopathy (at 14.0 percent),
2. Cardiovascular and coronary conditions (at 12.8 percent),
3. Preeclampsia and eclampsia (at 11.6 percent),
4. Hemorrhage (at 10.5 percent), and
5. Embolism (at 9.3 percent).

These causes represent just 58.1 percent of non-Hispanic black pregnancy-related deaths, suggesting a broader diversity of pregnancy-related causes of death among non-Hispanic black women than among non-Hispanic white women.

CDC is providing assistance to states to gather, analyze and use data to better understand how pregnancy-related mortality can be prevented in their states. Including data addressing both the clinical and non-clinical contributors to maternal deaths will allow states to fully address racial, geographic, and economic disparities in maternal mortality.

HEALTHCARE MARKETPLACES

Question. Last October the Trump Administration halted cost-sharing reduction (CSR) payments to qualified health plans, creating chaos in the individual insurance market at the exact time that most insurers were finalizing their premiums. The move resulted in increased premiums and reduced issuer participation for the 2018 plan year. This was one of many decisions the Administration made to sabotage our healthcare system and was in line with President Trump's statement that the best political course of action would be to let the marketplaces "explode."

Ending CSR payments was one of numerous other policies that contributed to an unstable market and rising premiums, including expanding the use of "junk," short-term plans, slashing advertising and in-person assistance, and weakening the essential health benefits. That said, state regulators are stepping in to mitigate the damage.

Most states across the country adopted a strategy called "silver loading" in which they allowed or required insurers to load the entire cost of CSR non-payment onto silver-level coverage. "Silver-loading" had the unintended effect of increasing the value of advance premium tax credits that enrollees receive while mitigating premium increases on bronze- and gold-level coverage. As a result, the Kaiser Family

Foundation estimated that a 40-year-old with an annual income of \$25,000 had access to at least one free bronze plan in 1,679 counties. That same study found that the lowest-cost gold plan was cheaper than the lowest-cost silver plan in 478 counties.

Officials from the Department of Health and Human Services are consistently declining to Response questions regarding whether the Department will permit silver-loading for the 2019 plan year.

Will HHS let states permit or require insurers to load the cost of CSR non-payment onto silver-tier plans for the 2019 plan year?

Answer. CMS continues to look at a number of factors in the health insurance market impacting patient cost.

Question. When will you advise issuers of this decision?

Answer. CMS continues to look at a number of factors in the health insurance market impacting patient cost.

LYMPHEDEMA

Question. Many of my colleagues and I have been committed to helping patients suffering from chronic lymphatic system failure (lymphedema). This is not just one disease but a condition that can occur primary or secondary when the lymph vessels and/or nodes are compromised—a condition that does not have a cure. We hear about it now far more frequently due to increased cancer survivorship, but it can present in almost 40 different rare diseases or be acquired from over a dozen other traumatic causes. Given the expansive medical literature, which cites effectiveness of compression garment therapy and the cost savings associated with reductions in complications, hospitalizations, and physician and therapy visits, up to 3 million Medicare beneficiaries stand to benefit by better managing this chronic condition. The need for this was acknowledged and outlined originally by the Center for Medicare and Medicaid Services 2001 Decision Memo (CAG-00016N).

Will HHS prioritize a rule providing coverage for these items and supplies this year?

Answer. Medicare's coverage criteria and benefit categories has remained largely unchanged since the program was first established more than 50 years ago. It is important to make sure that we are not being short sighted and failing to cover a treatment or item that will improve health and save money simply because it does not fit into a benefit category in Medicare. I would be happy to work with you and with CMS to explore whether separate coverage of and payment for compression garments is possible under the Medicare Part B benefit categories established in the statute.

Question. We are facing a child care crisis in this country, with parents struggling to find and pay for high-quality, early childhood education. I was proud to fight for a commitment in the fiscal year 2018 Bipartisan Budget Act to double funding for child care for fiscal year 2018 and fiscal year 2019, and I look forward to working with my colleagues to ensure that we are able to sustain and build on these increases long term. The fiscal year 2018 Omnibus joint explanatory statement outlines the Committee's expectations that the Department should support states as they work to effectively use the \$2.37 billion increase to the Child Care and Development Block Grant provided in fiscal year 2018. What are the Department's plans for meeting that expectation, especially when it comes to helping states accomplish the goals outlined in the explanatory statement and sustain those goals in the long-term?

Answer. The additional \$2.37 billion doubled the discretionary funding for the Child Care and Development Fund (CCDF), leading to an overall increase in CCDF funding of about 41 percent. With this increase, the Department will make about \$8.1 billion available to states, territories, and tribes. Under the CCDF final rule published in September 2016, states must meet all statutory and regulatory requirements by October 1, 2018, with the exception of background check requirements, for which states may receive time-limited extensions. States and territories will be submitting their CCDF Plans for fiscal year 2019–fiscal year 2021 this summer. These plans will provide HHS with updated information about the status of implementation across the country.

To help CCDF grantees accomplish the goals outlined in the explanatory statement and sustain those goals in the long-term, the Department will be issuing guidance outlining current requirements and priorities that align with the Joint Explanatory Statement, providing training and technical assistance through the early childhood and school-age training and technical assistance system in collaboration with the Office of Child Care and, sharing relevant research to inform state and local policymakers as they continue to implement CCDBG reauthorization and the

increased funding through research reports and briefs posted online and sent to grantees and through webinars and presentations at conferences such as the CCDF State and Territory Administrators Meeting (STAM). The Department will also use increased oversight to ensure compliance with CCDBG Act requirements. Oversight will be done through the review and approval of the fiscal year 2019–2021 CCDF State and Territory Plans and the fiscal year 2020–2022 CCDF Tribal Plans and through onsite monitoring.

Question. How does the Department plan on engaging with stakeholders as they spend the increased funds to ensure technical guidance and assistance is meeting their needs?

Answer. The Office of Child Care (OCC) Regional Staff are the first point of contact for engaging with states, territories, and tribes as they plan for, and spend, the increased funds. They work closely with CCDF grantees to provide guidance, answer questions, track progress on implementation of reauthorization through the state plan amendment process, and direct issues to the Office of Child Care Central Office. The different centers in the early childhood and school-age training and technical assistance system engage with CCDF Lead Agencies through the OCC Regional Staff to assess their training and technical assistance needs and provide resources and supports that are responsive to individual grantee requests. Additional information about the technical assistance available to CCDF Lead Agencies is available at <https://childcareta.acf.hhs.gov/about-acf-tta-system>. OCC is hosting calls with CCDF Lead Agencies to provide updates and respond to questions from administrators. In person meetings with administrators will also provide the opportunity to discuss CCDF Lead Agency progress and challenges. These meetings include regional meetings, the national State and Territory Administrators Meeting (STAM) in August, and three Tribal conferences across the country this fall.

Question. On April 10th, President Trump issued an executive order entitled “Reducing Poverty in America by Promoting Opportunity and Economic Mobility.” The executive order outlined “Principles of Economic Mobility”, which included improving employment outcomes by strengthening work requirements. The executive order directed the Department of Health and Human Services to review all regulations, guidance documents, and work requirements in its public assistance programs to determine if they align with those principles of economic mobility. Most research, including reports done by the Center on Budget and Policy Priorities and the Urban Institute, shows that work requirements have not proven to be effective in helping families secure stable, well-paying jobs that get them off assistance for good. What data and evidence is HHS using to evaluate its regulations, guidance documents and public assistance programs as it pertains to the effectiveness of work requirements?

Answer. The President’s Executive Order states that “bipartisan welfare reform enacted in 1996 was a step toward eliminating the economic stagnation and social harm that can result from long-term Government dependence.” This success can be seen in the data. After welfare reform, the employment rate of single mothers rose from an average of 58.6 percent in the 5 years preceding welfare reform (1991–1995) to an average of 70.2 percent in the 5 years after reform (1997–2001).¹ As a result, the official poverty rate among single mother-led families fell from 44.0 percent in 1994 to 33.0 percent in 2000 and was still well below pre-welfare reform levels in 2016 (35.6 percent).² While the strength of the TANF program in promoting employment has faded over time, as part of this review, we intend to reinvigorate the focus on employment and personal responsibility throughout HHS programs in order to generate further increases in employment and reductions in poverty for all Americans.

Question. What metrics will HHS be using as it evaluates programs in order to comply with the directives outlined in the executive order?

Answer. While review of our programs, regulations, and guidance documents continues as directed by EO 13828, HHS intends to pursue policies that will help grow the capacity of low-income individuals to reduce their need for and dependency on safety net benefits—this is how we will evaluate the success of programs and policies. Our goal will never be solely to reduce caseloads in assistance programs, but to help recipients move beyond their need for that assistance.

Question. The fiscal year 2018 Omnibus joint explanatory statement directs the Department to provide the necessary technical assistance, monitoring and oversight to assist and evaluate states’ activities to improve infant plans of safe care for pre-

¹ ASPE tabulations from the Current Population Survey, Annual Social and Economic Supplement.

² US Census Bureau, Historical Poverty Tables, Table 4, <https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-people.html>.

nately-exposed infants, as defined in the Child Abuse Prevention and Treatment Act. What are the Department's plans for fulfilling that directive?

Answer. ACF has reserved a at least \$25,000 of the \$60 million increase in CAPTA State Grants to support monitoring of states' implementation of Plan of Safe Care (POSC). Due to the shortened timeframe for carrying out and developing a monitoring protocol in fiscal year 2018, the Children's Bureau plans to carry out a limited number of site visits to several states across the regions during the remainder of fiscal year 2018. The purpose of the CAPTA POSC Site Visit is to gain a greater understanding of the state's policies and practices related to the Comprehensive Addiction and Recovery Act of 2016 (CARA) amendments to CAPTA POSC. The site visit will assist us in identifying promising practices, as well as the challenges and barriers to the implementation of POSC, and provides an opportunity to discuss potential technical assistance needs. Following the site visit, the Children's Bureau will provide summary information on the site visit, including identifying strengths of the state's implementation of POSC, existing challenges and barriers, as well as resources and technical assistance opportunities.

Question. What technical assistance and guidance does the Department plan on providing to states regarding plans of safe care?

Answer. The National Center on Substance Abuse and Child Welfare (NCSACW), which is an HHS initiative jointly funded by SAMHSA and ACF continues to provide technical assistance to states in a variety of ways to support their efforts in protecting infants born substance-exposed and support the implementation of the CARA amendments to CAPTA. These efforts include:

- Substance Exposed Infant In-Depth Technical Assistance (SEI IDTA): The SEI IDTA is designed to advance the capacity of tribes, states, and community agencies to improve the safety, health, permanency, and well-being of substance-exposed infants (SEIs) and the recovery of pregnant and parenting women and their families. The program works with states and local communities to strengthen collaboration among child welfare, substance use disorder treatment, and the courts, as well as medical communities, early care and education systems, home visiting, and other key partners, including the implementation of plans of safe care.
- Regional Convenings—The NCSACW has worked to plan and facilitate a regional convening of states working to implement comprehensive and collaborative approaches to Plans of Safe Care for infants with prenatal substance exposure and their families/caregivers.

The NCSACW responds to a large number of technical assistance requests related to opioid-related issues, including medication-assisted treatment, neonatal abstinence syndrome, prenatal substance exposure and plans of safe care. Requests for technical assistance are tailored to the specific needs of the state, as well as addressing the needs of multiple states when appropriate. Technical assistance may include: responding to requests for information; disseminating written materials and resources, and conducting webinars/conference calls.

In addition, in September 2017, the Children's Bureau funded the National Quality Improvement Center for Collaborative Community Court Teams (QIC-CCCT) to support demonstration sites that establish or enhance collaborative community court teams to design, implement, and test approaches to address the rise of substance use disorder nationally and the increase in the number of infants and young children entering foster care and caregivers. In an effort to support data-driven, multi-system collaborative team approaches across the country, the QIC-CCCT will support demonstration sites to improve or develop their capacities to collaboratively serve families; design, implement, and test approaches to support the needs of substance exposed infants, including addressing the provisions of CARA; and generate knowledge for the field. In April 2018, 15 sites in 9 States (Oklahoma, California, Alabama, Ohio, Georgia, Florida, Arizona, Alaska, and Texas) and tribal communities were selected to participate in the work of the QIC.

Question. How will the Department continue to monitor States' progress in meeting the needs of this population and their families?

Answer. To the extent funds are available for this purpose, we will continue to carry out the process described above. However, regardless of funding, we will continue to address CAPTA compliance.

Responding to changes made by the CAPTA Reauthorization Act of 2010, ACF issued guidance requiring all states to submit new CAPTA state plans, including state plan assurances signed by the governor. Once states provide the assurances, the state is in compliance with CAPTA.

If ACF learns there may be a discrepancy between what a state submitted in its CAPTA state plan and the actual practices within the state, ACF will explore

whether a problem actually exists. If the state fails to correct the deficiency within a specified timeframe, the state risks losing its CAPTA grant funds.

Question. The fiscal year 2018 Omnibus provided an additional \$260 million for grantees to increase their program hours, in alignment with the requirement in the Head Start Program Performance Standards (HSPPS) that all programs offer extended duration services by 2021. What percentage of programs currently meet the HSPPS duration requirements with 100 percent, 50 to 100 percent, 1 to 50 percent, and zero percent, respectively?

Answer:

Head Start (HS) Center-Based (CB)

Approximately 37 percent of HS CB programs operate 100 percent slots at 1,020 hours.

Approximately 11 percent of HS CB programs operate between 50 percent and 100 percent slots at 1,020 hours.

Approximately 34 percent of HS CB programs operate between 1 percent and 50 percent slots at 1,020 hours.

Approximately 18 percent of HS center based programs operate no slots at 1,020 hours.

Head Start (HS) Family Child Care (FCC)

Approximately 88 percent of HS FCC programs operate 100 percent slots at 1,380 hours.

Approximately 3 percent of HS FCC programs operate between 50 percent and 100 percent slots at 1,380 hours.

Approximately 9 percent of HS FCC programs operate no slots at 1,380 hours.

Early Head Start (EHS) Center-Based (CB)

Approximately 80 percent of EHS CB programs operate 100 percent slots at 1,380 hours.

Approximately 3 percent of EHS CB programs operate between 50 percent and 100 percent slots at 1,380 hours.

Approximately 2 percent of EHS CB programs operate between 1 percent and 50 percent slots at 1,380 hours.

Approximately 15 percent of EHS CB programs operate no slots at 1,380 hours.

Early Head Start (EHS) Family Child Care (FCC)

Approximately 99 percent of EHS FCC programs operate 100 percent slots at 1,380 hours.

Approximately 1 percent of EHS FCC programs operate no slots at 1,380 hours.

Question. What is the estimated cost of meeting 100 percent Head Start center-based duration requirement by 2021?

Answer. We estimate the cost of meeting the Head Start 100 percent center-based duration requirement by 2021 will be an additional \$800 million beyond the funding that has already been appropriated. This estimate assumes fiscal year 2019 funding, but costs can be expected to increase over time due to rising costs of living each year.

Question. Research shows that continuous access to full-day, full-year early childhood services improves the likelihood of successful outcomes for young children from low-income backgrounds. However, HHS recently waived the requirement that 50 percent of Head Start center-based programs extend their services to the equivalent of full-day, full-year by August 2019. The notice of the waiver stated that this action was necessary due to insufficient funding. Given this, what is the rationale for the fiscal year 2019 President's Budget proposing a Head Start funding level that is \$589 million below the fiscal year 2018 enacted level (and only \$22 million above the fiscal year 2017 enacted level)?

Answer. At the time, HHS made the determination to waive the requirement for 50 percent of Head Start center-based programs to extend their hours of program operation, only \$294 million had been appropriated to support this service duration increase, which was significantly less than the estimated cost for all programs to meet the 50 percent requirement. Rather than causing a large reduction in children served in Head Start programs as the result of a Federal requirement, HHS waived the requirement in order to allow programs flexibility to design program schedules that best meet their community needs. Head Start programs can still offer full-day, full-year services if that schedule meets their community needs and is approved through their grant application. The fiscal year 2019 request makes decisions about funding levels within responsible fiscal constraints; additional investments targeted to duration increases are not proposed.

Question. What is the rationale for the budget request's proposal to merge funds for the Early Head Start-Child Care Partnerships into the Head Start base grants?

Answer. The current appropriations language requires grantees to track and allocate regular Head Start and Early Head Start funding separately from Early Head Start Expansion and Early Head Start—Child Care (EHS-CC) Partnership funding across up to six accounts. This separate tracking and allocation is administratively burdensome and does not result in any benefit to grantees or the government. Merging the funding would allow these programs to continue to operate in the same way while eliminating unnecessary administrative work for grantees and the government.

Given the increases Congress provided in fiscal year 2018 above the requested level for this program, some technical changes to the appropriations language are necessary to ensure the Department is able to meet the intended goals of the unrequested increases and retaining the extended period of availability for the new third round of grants.

Question. Other than simplifying reporting requirements for grantees, will the requested bill language have effect on Early Head Start-Child Partnerships, Early Head Start expansion, or Early Head Start conversion?

Answer. While a very small number of 3-year-olds served in EHS-CC Partnership family child care programs would need to be transitioned to Head Start or other settings if the funding were to be merged in appropriations language, the existing EHS-CC Partnerships, EHS conversion, and EHS expansion grants would all be able to continue in exactly the same way they are currently operating because these models and activities are all allowed under the Head Start Act and the Head Start Program Performance Standards.

The current appropriations language states that funds appropriated specifically for EHS-CC Partnerships, EHS Expansion, and EHS conversion funds "are available to serve children under age 4" whereas funds used to operate Early Head Start under the base appropriation may serve "families with children under age 3" (Section 645A(c)(2) of the Head Start Act). Currently, the flexibility to serve children up to age 4 has been exercised only by a small number of family child care programs in EHS-CC Partnership grants, not by center-based EHS-CC Partnerships or EHS expansion programs. Based on 2017 Program Information Report (PIR) data, only 4 percent of children in EHS-CC Partnership and EHS Expansion programs are at least age 3 at enrollment. If the EHS-CC Partnerships funding were to be included in the base appropriation, any of those children who had not already aged out of the program once the consolidation occurs would need to transition into Head Start slots, which could be Head Start slots in centers or in family child care settings. Because EHS-CC Partnership grants receive their annual awards late in the fiscal year, grantees would operate most of the fiscal year 2019 program year on their prior year funding, which would give them additional time to transition 3-year-old children into other settings before receiving fiscal year 2019 funding. OHS would work with grantees to ensure smooth transitions for these children in the event that language is included to merge funding for Early Head Start-Child Care Partnerships into the Head Start base appropriation.

Question. Head Start programs are playing a unique and important role in addressing the effects of substance use disorders, including as a result of the opioid epidemic, on low-income young children and their parents. Infants born with prenatal exposure are at higher risk for short term and long-term effects, including related to growth, behavior, cognition, language, and achievement. (<http://pediatrics.aappublications.org/content/pediatrics/131/3/e1009.full.pdf>) Head Start programs need more resources, including teacher and mental health consultants, to continue to respond to these effects, as well as the trauma young children are experiencing as a result of the epidemic. How is HHS leveraging Head Start and its existing local relationships to address the issue of prenatal drug exposure, including neonatal abstinence syndrome, as well as increased trauma?

Answer. All Head Start programs are required to collaborate with numerous community partners to facilitate access to responsive services for their families to help meet family needs and goals. These partners include Healthcare providers, including child and adult mental health professionals, Medicaid managed care networks, dentists, other health professionals, nutritional service providers, providers of prenatal and postnatal support, and substance abuse treatment providers.

Additionally, the ACF Office of Head Start (OHS) partners with the American Academy of Pediatrics to manage its National Center on Early Childhood Health and Wellness (NCECHW) and provide education, training and resources to its grantees. Grantees and their Health Services Advisory Committees partner with agencies in the community to provide resources to children and families at risk of impacts from substance misuse, including trauma. To date, the NCECHW has developed a

substance misuse landing page where programs can obtain information and resources related to what staff should know, how programs can help, basics on opioids and substance misuse, reducing risks for neonatal exposure, caring for children exposed to substances, and preparing for sensitive conversations. For many years, Early Head Start programs have educated pregnant women on the dangers of substance misuse and all Head Start programs provide families with resources to educate them about the dangers of substance misuse and its impact. Family service workers and mental health consultants assist programs in responding to the needs of families and in leveraging resources including health and mental health resources in the community to provide additional support to families.

In addition, OHS has a Memorandum of Understanding (MOU) to coordinate resources and align policies at the national level with the Health Resources and Services Administration, Bureau of Primary Health Care (HRSA/BPHC), as well as to foster a partnership at state and local levels, that will lead to an increase in access to quality, culturally and linguistically appropriate comprehensive primary healthcare services in states where programs exist. Under this agreement, HRSA and OHS will work collaboratively to support the development and strengthening of linkages between their programs at the local or state level and establishment of measures for evaluation of improved health, dental, and behavioral health outcomes and health center access and utilization.

Question. How is the Department supporting the 1,600 Head Start grantees to address the increased workload and challenges as a result of the opioid epidemic?

Answer. The Office of Head Start (OHS) is providing information and training and technical assistance related to substance misuse and specifically the opioid crisis. Through its website, Early Childhood Learning and Knowledge Center (ECLKC) resources are being disseminated to all grantees (<https://eclkc.ohs.acf.hhs.gov/mental-health/article/substance-misuse>.) These materials include educational materials about opioids and substance misuse and impact on children and families.

Head Start, home visitors, and child care staff often have a window into the real-life circumstances and needs of families. These programs may be the front-line in identifying issues that signal substance misuse. It can be hard to navigate these complex situations, but Head Start programs have unique opportunities to engage families and even prevent harm to children. Head Start programs can be a valuable resource to families by helping them to know what services are available in the community. A Head Start program's Health Services Advisory Committee (HSAC) can develop policies, guidelines, and community partnerships by knowing the eligibility requirements of programs that serve families impacted by opioid misuse. This information is necessary when discussing service and treatment options with families.

In addition, this summer, OHS is holding an Expert Work Group on Substance Use Disorder with a focus on the opioid epidemic and its impact on young children and their families. The work group will be comprised of experts on substance use disorders, with a focus on the opioid crisis and its impact on young children and how to support local Head Start programs in responding to the opioid epidemic. Experts are expected to share their current research and knowledge with a focus on the types of strategies that would be most helpful to those serving children and families.

- We anticipate the following outputs from this Work Group: Summarized notes, proceedings, and key messages from the expert work group will be shared;
- Standardized PowerPoint presentations developed as an outgrowth of the meeting that can be shared with grantees;
- Increased knowledge of current and future work by each national Training/Technical Assistance (T/TA) center that can be used or modified across all T/TA centers to help to support grantees;
- Repository of core documents that can be modified and supplemented with information germane to a variety of recipients;
- Stronger consensus in the field regarding the most effective strategies for supporting young children, families, programs and communities impacted by opioid use disorders; and
- Increased knowledge of successful community-level pilots and projects that may help other communities develop similar programs and strategies.

Question. Head Start programs have been tackling the issues resulting from the opioid epidemic for years, providing behavioral, mental health, and community supports to children affected by this crisis, as well as other drug crises. As HHS makes decisions about how to implement increased funds and address the opioid epidemic, how will HHS engage the Office of Head Start to share best practices with Head Start agencies and other early childhood education programs across the country?

Answer. OHS has a long history of providing support and assistance to families impacted by substance misuse and other trauma. OHS utilizes existing systems and

partners in order to bolster its response to the current crisis. For example, OHS is partnering with colleagues in HHS that include other ACF agencies such as the Children's Bureau, and other operating divisions such as SAMSHA, CDC, and NIH, and sharing information and resources that can be disseminated to Head Start grantees, child care providers, and early childhood programs across the country. OHS's website (ECLKC) is a resource for all early childhood programs; training materials and resources are available to everyone at no cost.

In addition OHS, is a co-lead with HRSA and SAMHSA on the Interagency Workgroup on the Impact of Opioids on Young Children and Families, which includes a wide variety of participants across agencies. The purpose of the group is:

- To share information and materials related to the impacts of opioid misuse on pregnant women, infants, and their families, to ensure that we all have access to the most up-to-date resources and information;
- To share resources and guidance that each agency or program is developing for its grantees (or other audiences), to ensure clarity and consistency across programs and agencies, to the extent possible, and to reduce duplication;
- To share what each agency/program is learning from its grantees and the field (both in terms of challenges and strategies for addressing the issue) that can be captured and shared more widely in order to promote best practice and innovation; and
- To share what each agencies is doing to address the issue so that all involved agencies are more aware of the range of Federal resources and activities being devoted to this crisis.

Information from the workgroup helps to drive information that OHS can make available to grantees via the ECLKC substance misuse landing page.

Question. Does the Department believe that HHS should fund adoption agencies that refuse to house children in loving homes because the adoption agency objects to children being raised by same-sex couples?

Answer. Title IV-E of the Social Security Act provides Title IV-E agencies with significant latitude to determine how and under what conditions an agency will license or approve prospective foster or adoptive parents. The Act requires each state or tribe operating a Title IV-E program to designate or establish a licensing authority that establishes and maintains standards for foster homes and child care institutions that are reasonably in accord with nationally recommended standards. The Act does not apply the foster family home licensing standards to adoptive family homes, rather, an agency must place a child for adoption in accordance with applicable state, tribal, and local law.

HHS does not impede the placement of children in eligible same-sex households and also does not impede the full participation of religious organizations in foster care and adoption. As a general matter, HHS supports the prompt placement of children in loving homes according to the best interests of the child and supports giving states flexibility in meeting that standard consistent with Federal law.

Question. If HHS's position is that such type of discrimination should not be funded by taxpayer dollars, what course would the agency take if the adoption refuses to place children in same-sex households due to their religious beliefs?

Answer. As a general matter, HHS supports the prompt placement of children in loving homes according to the best interests of the child and supports giving states flexibility in meeting that standard consistent with Federal law.

Everyone deserves to be treated with respect and given every protection afforded by the Constitution and laws passed by Congress. We will examine any particular situation that arises on these issues with sensitivity and will apply the law to the facts of each particular case fairly, impartially, and appropriately. This means we cannot prejudge cases or hypothetical scenarios but must wait until a concrete complaint is brought before us.

Question. Valid and reliable data on children involved in our child welfare system is critical for understanding and improving our nation's support for our most vulnerable children and families. Unfortunately, the Adoption and Foster Care Analysis Reporting Systems (AFCARS) data points have not been updated since they were first finalized in 1993. In December 2016, HHS finalized a critical rule to update these data points to align with congressional mandated provisions of laws such as the Fostering Connections to Success and Increasing Adoptions Act of 2008 and the Preventing Sex Trafficking and Strengthening Families Act of 2014. I was particularly glad to see new information collected on educational stability for children and youth in foster care, which is critical for implementing the Every Student Succeeds Act with fidelity. On March 15th, HHS proposed to amend and delay these important updates for 2 years with reporting not expected until October of 2021. Please explain why HHS believes it is acceptable to delay the collection of congressionally-

mandated data elements until 2021, especially in light of the fact that states have been planning for these upgrades since 2016.’

Answer. In response to EO 13777, the Department of Health and Human Services’ (HHS) Regulatory Reform Task Force identified the AFCARS regulation as one where there may be areas for reducing reporting burden and where costs may exceed benefits. HHS published on March 15, 2018 an Advance Notice of Proposed Rulemaking (ANPRM) seeking public suggestions for streamlining the AFCARS data elements and removing any undue burden related to reporting AFCARS, per the directive of the E.O. The delay allows HHS time to consider the comments to the ANPRM and, if necessary, use them to draft a NPRM proposing revisions to the AFCARS that are in line with the directive of the E.O. It will also allow title IV–E agencies ample time to consider the full impact the data reporting from the December 2016 AFCARS final rule and provide HHS with specific comments on the burden associated with the December 2016 final rule.

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

Question. In February, Congress passed and the President signed into law the most significant reforms to our Nation’s child welfare system in decades. The Family First Prevention Services Act (FFPSA) reorients our child welfare system toward prevention by allowing states to draw down Federal funds for evidence-based prevention services in two areas: (1) in-home parent skills-based programs; and (2) substance abuse and mental health treatment services, for children at “imminent risk” of entering foster care. Understanding the scope of programs that will meet the “evidence-based” standard and disseminating this information to states and child welfare agencies will take significant collaboration between the various agencies with jurisdiction over prevention services, including but not limited to the Administration for Children and Families, Substance Abuse and Mental Health Services Administration, and the Health Resources and Services Administration. How will you promote collaboration between the relevant agencies tasked with ensuring effective implementation of FFPSA, particularly before the October 1st deadline for HHS to release guidance on the practice criteria required for the prevention services as well as a pre-approved list of services and programs that meet the law’s evidence standards?

Answer. Over the next few months, the Administration for Children and Families intends to consult broadly across HHS and the field in the development of the criteria by which interventions will be assessed in determining which interventions are approved for funding under the title IV–E prevention services program. HHS has held an External Stakeholder meeting, including the National Governor’s Association, National Association of Counties, and National Conference of State Legislators, and has met with county child welfare directors in Colorado and Minnesota. The Children’s Bureau has also issued a Federal Register Notice seeking comment on proposed criteria for identifying evidence-based practices for implementation of FFPSA. Further meetings and listening sessions are planned for the coming months.

Question. As Director of the Office of Refugee Resettlement, Scott Lloyd had denied young women, even those who are pregnant as a result of rape, of their constitutional right to access abortion. ORR has reportedly posted instructions for young women to seek counseling from crisis pregnancy centers that discourage abortions, and to provide brochures with misleading information including inaccuracies on the medical risks of abortion. At the House Appropriations hearing this past March, Secretary Azar stated that he will “absolutely comply with the law and constitution as determined by the courts.” A Federal judge has ordered the Department to stop blocking children in its care from obtaining abortions, and to post a notice in shelters to inform them of their right to decide whether to have an abortion. What is the Department doing to ensure that ORR complies with the court’s order to stop blocking access to abortion care?

Answer. ORR has already sent notice to all of its shelters informing them of the requirement to post the notice ordered by the district court, has followed up on its instruction, and has informed the minority of shelters with conscientious objections that corrective action is necessary. The Department expects full compliance with the district court’s order. In addition, the Department has appealed the district court’s order to the Court of Appeals for the D.C. Circuit, but will continue to comply with the district court’s order as long as it stands.

Question. How are you enforcing the requirement that all ORR-funded shelters post a notice informing minors of their rights?

Answer. ORR monitors all care providers for compliance with ORR policies and, when applicable, court orders. Monitors have been informed of notice requirements and will ensure compliance with the court order from U.S. District Court Judge Tanya Chutkan. Programs subject to the court order have also been notified of the order. If ORR receives information that a program is not in compliance with the court order, ORR will investigate and act accordingly. Project Officers have been instructed to contact each of the facilities they oversee to ask about the facility's compliance with the court order. Federal Field Specialists that routinely visit facilities have also been instructed to ensure compliance with the court order. Facilities not in compliance are subject to corrective actions.

Question. As the Office of Refugee Resettlement consolidates funding for refugee support services, how is it implementing the expectation in the fiscal year 2018 Omnibus that activities funded in the Social Services, Targeted Assistance, and Prevention Health be continued at the same funding levels as in fiscal year 2017?

Answer. Under the proposal presented in the fiscal year 2018 Budget and adopted in the fiscal year 2018 Omnibus, ORR will ensure funding levels for Social Services, Targeted Assistance, and Refugee Health Promotion (formerly Prevention Health) will be funded as close as possible to fiscal year 2017 levels within the current budget.

Question. In a United Nations panel on April 10th, Office of Refugee Resettlement Director Scott Lloyd said the Administration is trying to "improve the legal framework whereby this [Unaccompanied Children] program can be more focused on those who have legitimate claims for asylum or Special Immigrant Juvenile Status." What options is ORR considering to achieve this stated goal of improving processing of unaccompanied children through the immigration system, including changes through Federal rulemaking as well as internal policies and procedures?

Answer. ORR is currently working with DOJ and DHS to determine how the three agencies can improve the processing of UACs in the immigration system.

Question. How do those changes align with the Trafficking Victims Protection Act, the Homeland Security Act, and the Flores settlement?

Answer. Any changes will align with the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, the Homeland Security Act of 2002, and the Flores settlement agreement.

QUESTIONS SUBMITTED BY SENATOR RICHARD J. DURBIN

CHILD TRAUMA

Question. Experiencing traumatic events—such as witnessing violence or a parent's opioid addiction—can create toxic stress on a young child's developing brain and body. Exposure to these sorts of traumas (also known as adverse childhood experiences) at a young age increases the likelihood that children enter the foster care system, misuse substances, face mental health challenges, or develop chronic diseases—all health consequences that the Department seeks to address through various grant programs. Effective interventions and tools exist to mitigate the impact of trauma and to prevent long-term negative health outcomes, such as by strengthening protective factors, building nurturing environments, encouraging trauma-informed practices, and building strong two-generational interventions. It is imperative that these child-serving systems that may come into contact with children and families that have experienced trauma have the training and resources to identify and support such children with appropriate interventions and referral systems.

Along with Senator Capito and leadership of this Subcommittee, I included report language in the fiscal year 2018 Senate Labor-HHS-ED appropriations bill, which was effectuated with enactment of the Omnibus appropriations bill addressing activities under the Department related to children exposed to trauma (bill-wide directive found on page 14 of Senate Report 115–150). The report language encourages the Department to "examine practices already supported by Federal agencies and solicit public feedback in order to identify, recommend, and disseminate best practices for the identification, referral, and implementation of trauma-informed interventions in child and youth-serving settings" and "promote programs that incorporate trauma-informed best practices." Indeed, helping children and families cope with traumatic experiences can help uplift our communities and improve health outcomes, and is a cost-effective way to fulfill the mission of the Department.

How is your Department implementing this report language to better support children who have faced traumatic experiences?

Answer. The Department continues to enhance coordination, identify trauma-informed best practices, and promote programs to identify, appropriately refer, and

implement supportive interventions for, children and their families who have experienced trauma.

The HHS Strategic Plan, fiscal year 2018–2022 addresses trauma as part of our strategic goal to strengthen the economic and social well-being of Americans across the lifespan. The Strategic Plan recognizes how trauma has lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being. HHS supports multiple trauma-informed care initiatives³ to integrate a trauma-informed approach into health, behavioral health, and related systems, to reduce the harmful effects of trauma and violence on individuals, families, and communities. HHS also works across the Federal Government, and with States, territories, Tribes, and faith-based and community organizations, to address trauma associated with injuries and violence.

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has initiated an informal interagency working group on child trauma that includes partners within HHS, such as Administration on Children and Families, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the Substance Abuse and Mental Health Administration (SAMHSA), along with Federal partners in agencies outside HHS, including the Departments of Justice, Education, and Labor. ASPE hosts a monthly call of this working group for the purpose of coordination of Federal efforts on child trauma, and is working to understand both the scope of work across agencies and any coordination efforts on the ground in local communities receiving Federal funding for trauma-informed interventions for children, youth, and their families.

HHS funds 23 State health departments through the Core State Violence and Injury Prevention Program,⁴ which helps States implement, evaluate, and disseminate strategies that address the most pressing injury and violence issues, including child abuse and neglect, traumatic brain injury, domestic violence, and sexual violence. HHS also works across the Federal Government, and with States, territories, Tribes, and faith-based and community organizations, to address trauma associated with injuries and violence.

For example, we will expand bullying prevention and youth dating violence prevention partnerships to support safety and well-being. We will assess, and increase, the capacity of medical and behavioral health practitioners, nonprofits, faith-based and community organizations, licensed social workers, child welfare professionals, housing authorities, and public health agencies to provide comprehensive and survivor-informed services for victims of human trafficking. HHS will enhance the cultural competence of the workforce in the delivery of social services to children, youth, and families through research, technical assistance, and training, including information on addressing and mitigating the impact of trauma. We will also support the integration of trauma-informed, family-focused behavioral health services with pediatric primary care.

Most recently, the HHS Substance Abuse and Mental Health Services Administration and the Administration of Children and Families co-hosted a human trafficking and child trauma expert panel meeting on May 2–3, 2018, to inform recommendations on how to strengthen prevention, clinical care and coordination, and the availability of resources and technical assistance to address both the impact of exploitation and to mitigate trauma that puts individuals at greater risk for human trafficking.

HRSA supports several programs for healthcare, clinician training, and research to improve access for vulnerable and underserved populations, many of whom have experienced or witnessed trauma. HRSA supports programs that train pediatric primary care providers to recognize exposures to adverse childhood experiences, as well as programs that promote trauma informed care in school-based settings. The Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents provides evidence-driven recommendations for healthcare professionals to address during well-child visits, including social determinants of health such as poverty, parental mental illness or substance use, and parental incarceration. HRSA also leads a Federal interagency effort to improve emergency care for children experiencing mental health crisis in rural areas, which encourages identification, referral, and treatment of trauma. Additionally, HRSA has developed and adopted an agency-wide Strategy to Address Intimate Partner Violence, committing to making a systems-level impact on intimate partner violence and trauma awareness, screening, and treatment across the healthcare and public health sectors.

ASPE is also funding research in the upcoming fiscal year that will formally scan Federal agencies to identify supported approaches and promote programs that incor-

³ <https://www.cdc.gov/injury/stateprograms/index.html>.

⁴ <https://www.cdc.gov/injury/stateprograms/index.html>.

porate trauma-informed best practices aimed at building resilience in children, youth and their families. Previously, as part of the Behavioral Health Coordinating Committee, ASPE participated in efforts to compile the HHS Guide to Trauma-informed Human Services,⁵ an online compendium of Federal and federally supported resources that provides an introduction to the topic of trauma and a roadmap to information relevant to human services agencies.

The Children's Health Act of 2000 authorized the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop a national grant program to focus on child and adolescent trauma, the National Child Traumatic Stress Initiative (NCTSI). The purpose of the NCTSI is to improve the quality of trauma treatment and services in communities for children, adolescents, and their families who experience or witness traumatic events, and to increase access to effective trauma-focused treatment and services for children and adolescents throughout the nation.

The initiative addresses child trauma issues by creating a national network of grantees—the National Child Traumatic Stress Network (NCTSN) or Network—that works collaboratively to develop and promote effective trauma treatment and services for children, adolescents, and their families. The NCTSN is a unique network of frontline providers, family members, researchers, and national partners committed to changing the course of children's lives by improving their care and moving scientific gains quickly into practice across the United States.

The NCTSN is comprised of three types of centers:

- The National Center for Child Traumatic Stress (NCCTS)—(Category I) develops and maintains the collaborative network structure, supports resource development and dissemination, and coordinates the Network's national child trauma education and training efforts.
- The Treatment and Service Adaptation Centers (TSA)—(Category II) are intended to have broad geographic coverage and expertise in a range of trauma areas, service systems, settings, and populations. TSA centers provide training and consultation to support the specialized adaptation and implementation of effective evidence-based treatment and service approaches for communities across the Nation.
- The Community Treatment and Services Centers—(Category III) provide and increase access to effective trauma-focused treatment and services in community settings and youth-serving systems.

The NCTSN Learning Center for Child and Adolescent Trauma, <https://nctsn.org>, offers over 300 web-based training resources that has supported approximately 200,000 users across the country. In addition, the Learning Center hosts live training events. The dissemination of standardized, effective, trauma-informed clinical interventions is a central means by which the NCTSN seeks to advance the standard of care for traumatized children and to increase the nation's capacity to meet the needs of these children. In recognition of the diverse needs of the child and adolescent populations served by NCTSN sites across the country, over 30 interventions and treatments developed or adapted by the NCTSN have spanned a continuum of evidence-based and evidence-supported interventions ranging from rigorously evaluated interventions to promising and newly-emerging practices.

MATERNAL AND INFANT MORTALITY.

Question. The U.S. is one of only 13 countries in the world where new moms are dying at rates higher today than they were 25 years ago. Women of color are three to four times more likely to die from pregnancy-related complications than white women. Our babies are not faring better—in 1960, the U.S. ranked 12th among developed countries in infant mortality. Today, we rank 32nd out of 35. Black infants in America are twice as likely to die as white infants. We know that increasing women's access to healthcare would help—which is why we should not allow “junk plans” that exclude maternity benefits and why the 18 States who have refused to expand Medicaid should do so immediately.

But, what else should HHS be doing to address this problem?

Answer. HRSA is committed to improving the health of women, infants and children including addressing disparities in maternal and infant mortality and morbidity. The response to Q2A below includes additional descriptions of HRSA's ongoing investments to address maternal and infant mortality and morbidity. HRSA programs focus on continuous quality improvement and ways to improve our impact, as well as enhance the capacity of states and stakeholders to address these public health issues. For example, HRSA supports the Alliance for Innovation on Maternal Health and Safety Initiative, or AIM, a national data-driven maternal safety and

⁵ <https://www.acf.hhs.gov/trauma-toolkit>.

quality improvement initiative that implements maternal safety bundles—small, straightforward sets of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes—within birthing facilities to address leading causes of maternal death, such as hemorrhage and hypertension. Through AIM, HRSA works directly with women’s health practitioners in birthing facilities reaching 1,780,000 annual births or 45 percent of all annual births in the U.S. In fiscal year 2018, HRSA is doubling the investment in AIM to \$2 million to support the existing state teams and add 25 new state-based teams. Further expansion of evidence-based safety bundles in all states would increase the chances of improving outcomes such as those we’ve seen with AIM investment to date.

As another example, HRSA is building on early successes from its Collaborative Improvement and Innovation Network (CoIIN) on Infant Mortality which seeks to reduce infant mortality in areas with high annual rates, as well as disparities in infant mortality and related perinatal outcomes, through support of collaborative improvement, collaborative innovation, and the spread and scale of best practices to reduce infant mortality. The CoIIN launched in 2012 at the request of southern state health officials, and was the first multi-state public health quality improvement initiative to address infant mortality. A recent study led by HRSA researchers evaluated data from 2011–2014, comparing outcomes before and after the CoIIN’s original 18–24 month project period in the Department of Health and Human Services Regions IV/VI.⁶ Early elective delivery decreased by 22 percent in the South, versus 14 percent in other regions. Alabama and Louisiana showed the largest reductions in the nation at more than 40 percent. Results in the South also showed that the rates of stopping smoking during pregnancy increased by 7 percent, infant back sleep position increased by 5 percent, and preterm birth fell by 4 percent; other regions only showed improvements of 2 percent for each of the outcomes measured. Preliminary data indicating CoIIN’s success in the South and in the subsequent national expansion to all states (2014–2017) led to current HRSA support of four IM CoIIN teams aiming to improve preconception health, increase use of early prenatal care, increase safe sleep practices, and address social determinants of health. Twenty-one States are participating in the current phase of IM CoIIN.

Question. What HHS programs are most important for improving maternal and infant health outcomes and addressing these stark racial disparities?

Answer. HRSA supports several programs and activities to improve the health of America’s mothers, infants, and children in order to ensure that all children and families are healthy and thriving, and have a fair shot at reaching their fullest potential. The HRSA-supported Title V Maternal and Child Health Services Block Grant program, a Federal-state partnership, helps reduce health disparities, improves access to healthcare, and improve the quality of healthcare for mothers and children in 59 States and territories. Title V Federal funds, combined with state investments, support service systems that address maternal and child health needs identified by each state such as reducing infant mortality; assuring access to care for all mothers and children; providing comprehensive care for all women before, during, and after pregnancy and childbirth; providing preventive and primary care services for all infants, children, and adolescents; and providing comprehensive care for children and adolescents with special healthcare needs.

HRSA also supports community-based strategies to reduce disparities in infant mortality and improve perinatal outcomes for women and children in high-risk communities through the Healthy Start program. Healthy Start empowers high-risk women and their families to identify and access comprehensive health and social services to improve the health of mothers and children before, during, and after pregnancy. Healthy Start targets communities with infant mortality rates that are at least 1½ times the U.S. national average and/or with high indicators of poor perinatal outcomes, particularly among non-Hispanic Black and other disproportionately affected populations. Healthy Start funds 100 competitive grants that reach 127 counties in 37 States and the District of Columbia.

Another key program in improving maternal health outcomes is HRSA’s Alliance for Innovation in Maternal Health Initiative (AIM). AIM seeks to prevent maternal deaths and cases of severe maternal morbidity by working with states and hospitals to implement maternal safety bundles—small, straightforward sets of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes. AIM is working with 13 States and more than 667 hospitals and targets complications including obstetric hemorrhage, severe hypertension, and venous thromboembolism, and also seeks to avoid low-risk primary cesarean births and reduce racial disparities associated with prenatal care. Addition-

⁶ <https://www.hhs.gov/about/agencies/iea/regional-offices/index.html>.

ally, HRSA is working to improve women's health prior to pregnancy by focusing on women's preventive services. Through a coalition of experts, HRSA maintains the Women's Preventive Services Guidelines which identifies certain preventive health screenings and services to be provided without cost-sharing. These guidelines help ensure women have access to standard level of care.

Lastly, HRSA supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry through the Maternal, Infant and Early Childhood Home Visiting (MIECHV) Program. Among the ways the program seeks to improve the lives of children and families, the MIECHV program focuses on improving maternal and child health outcomes. In these voluntary programs, trained professionals meet regularly with expectant parents or families with young children in their homes, building strong, positive relationships with families who want and need support. MIECHV state and territory grantees provided nearly 4.2 million visits from fiscal year 2012 through fiscal year 2017. In fiscal year 2017 states reported serving more than 156,000 parents and children in 893 counties across all 50 States, the District of Columbia, and five territories. In addition, a recent report on maternal mortality review committee data showed mental health conditions (including substance use disorders) to be one of the leading causes of pregnancy-related death. The MIECHV Program supports mothers who experience depression by providing support, resources and referrals, as needed. In fiscal year 2016, 44 States reported comparable data on maternal depression. The overall screening rate among these 44 States was 82 percent, with 15 States reporting screening rates of 95 percent or more.

Question. Do you believe that the Medicaid program should cover postpartum care for longer than the currently required 2 months?

Answer. We are committed to making sure the right patient gets the right treatment at the right time. While the Federal Government establishes general guidelines for Medicaid, states design, implement and administer their own programs. HHS believes that States understand best the unique needs of their residents and has committed to restoring balance to the Federal and State partnership. Through our Maternal and Infant Health Initiative, which is designed to improve the rate and content of postpartum visits and increase the use of effective methods of contraception among women in Medicaid and CHIP, CMS works to provide States with the information they need to inform their policies. Through this initiative, CMS has offered states several reports, webinars, and opportunities to share best practices. In addition, to support HHS's maternal and perinatal health-focused efforts, CMS recently identified a core set of measures for voluntary reporting by state Medicaid and CHIP agencies that will be used by CMS to measure and evaluate progress toward improvement of maternal and perinatal health in Medicaid and CHIP.

OPIOIDS/CDC GUIDELINES FOR DOCTORS

Question. Pharmaceutical companies bear the lion's share of blame for today's opioid epidemic—for misleading doctors and the public about the risks of opioids and for over-producing prescription painkillers (14 billion). But from there, opioids get to Americans from a prescription pad—for every 100 patients who receive a one-week opioid prescription, 9 of them will still be taking opioids 1 year later.

Four out of five recent heroin initiates report prior nonmedical pain reliever use. The CDC recognizes that the medical community must be part of the solution and employ more responsible opioid prescribing. The CDC released the "Opioid Prescribing Guidelines for Chronic Pain," a guideline that was sent to every practitioner nationwide. These guidelines are clear—they state: "in general, do not prescribe opioids as the first line treatment," and recommend "less than 3 day supply for acute pain."

Should opioid prescribers have to go undergo mandatory training on the latest knowledge about the risks and benefits of opioids?

Answer. The Department is engaging on multiple fronts with respect to education of healthcare providers, and in particular, prescribers, on the risks and benefits of opioids.

CDC supports the education of prescribers on the risks and benefits of opioids as well as safe and effective pain management, including the recommendations included within the CDC Guideline. While enacting and executing decisions around mandatory education of providers falls outside of CDC's purview as an agency, CDC would encourage the widespread dissemination and education of safer opioid prescribing practices given that such guidance is informed by the best available scientific data. The ways in which CDC encourages the uptake and use of the recommendations within the Guideline include the sharing of the Guideline document itself, as well as other resources developed through various channels. CDC has cre-

ated an interactive training series and a webinar series for healthcare providers that offer the ability to earn continuing education credits. The interactive, web-based training features self-paced learning, case-based content, knowledge checks, and integrated resources to help healthcare providers gain a deeper understanding of the Guideline. Another way in which CDC is working to operationalize Guideline recommendations within clinical practice is through the development and piloting of Guideline-informed quality improvement (QI) measures. CDC has developed voluntary QI measures, aligned with the recommendations contained in the Guideline, which are intended to support practice improvement for primary care practices by tracking opioid prescribing and providing feedback to clinicians through a data dashboard.

CDC-funded state health departments also are involved with a wide breadth of work related to provider outreach and education. One particular strategy to align opioid prescribing practices with Guideline recommendations is to implement academic detailing, a practice where unbiased and evidence-based information is presented to medical providers to affect behavior change. The in-person and one-on-one academic detailing session is based on principles of social marketing and the health behavior model. Across CDC's program portfolio, each funded state has different programmatic goals and resources for planning and implementing provider outreach and education. Currently, about a third of the states funded through CDC's Prevention for States program are engaging in work that use the principles of academic detailing as a model to drive behavior change among providers.

Specific to medical education, CDC sees a benefit in facilitating the use and uptake of the Guideline within curricula across the continuum of medical education, including medical education programs, residency training and transition into the clinical workforce, and continuing medical education. Shortly following the release of its Guideline, CDC engaged with 60 medical schools that previously had pledged to incorporate some aspect of the Guideline within their respective educational curricula for the forthcoming academic year. While the discussions were beneficial, CDC learned that each academic institution operates very differently and that there is inherent value for organizations to share and learn promising strategies from their peers, as opposed to from CDC as a Federal entity.

To that end, CDC has newly initiated work toward the planning and implementation of a convening of leaders across the continuum of medical education, in order to highlight best practices and strategies in aligning curricula, training, and continuing education with safer opioid prescribing practices, including those enumerated within the Guideline. CDC aims to engage leaders and program directors who represent entities across undergraduate and graduate medical education, residency training programs, and faculty continuing medical education programs. Such individuals may include, but may not be limited to, those at the highest level of leadership (i.e., Deans of Medical Schools, Heads of Residency Programs), those who direct curricula development and implementation, and any others who make decisions on behalf of entities whom we would want to engage through this work. As a result of this convening, CDC would aim to have in place an implementation guide highlighting strategies across the continuum of medical education and clinical training that would be of value to the broader field. Additional outcomes would also include increasing CDC knowledge and insight on how current Guideline translational tools and resources are used and how CDC can address remaining gaps with future materials, as well as determining the needs of educators on the front lines of medical education on how best to integrate safer opioid prescribing practices within curricula.

In addition to external entities mentioned above, CDC also regularly collaborates with Federal partners to implement the Guideline and to ensure alignment across the Federal landscape. For example, the Department of Veterans Affairs, Department of Defense, and the Indian Health Service released an updated clinical practice guideline for opioid therapy for chronic pain based in part on the CDC Guideline. The Centers for Medicare & Medicaid Services (CMS) has also changed program quality measures and Medicare's Merit-based Incentive Payment System quality measures to be consistent with the Guideline (e.g., on high-dose opioid prescribing, review of PDMP data). CDC shares updated Guideline resources and educational materials with fellow agencies that can help inform their efforts. These collaborations extend to its partners in public safety as well. Earlier this year, DEA sent an email notification to 1.7 million registrants to encourage Guideline-concordant care among providers.

FDA's Opioid Policy Steering Committee is currently considering the issue of whether opioid prescribers should have to undergo mandatory training, taking into account comments it has received from two recent FDA public hearings on the opioid crisis. FDA recently announced its plans to expand the risk management

plans (known as Risk Evaluation and Mitigation Strategies, or REMS)—with which it requires the manufacturers of certain opioids to comply—to incorporate, for the first time, all opioid analgesics that are intended for use in the outpatient setting, including the immediate-release formulations. FDA has revised the associated Blueprint for how providers should be educated about prescribing opioids, and it is requiring this training be made available to all providers likely to come into contact with patients who are prescribed these medicines, including nurses and pharmacists.

In addition to changing their quality measures, CMS has undertaken a number of other steps to help decrease opioid prescribing and to educate providers about the risks to beneficiaries. In the 2019 Medicare Parts C and D Final Call Letter, CMS finalized a new policy that requires Part D sponsors to implement a hard safety edit to limit initial opioid prescription fills for the treatment of acute pain to no more than a 7 days' supply for opioid naïve beneficiaries. For chronic opioid users, CMS finalized the expectation that all sponsors implement real-time safety alerts at the time of dispensing as a proactive step to engage both patients and prescribers about overdose risk and prevention, including use of a new opioid care coordination edit at 90 morphine milligram equivalent (MME) per day and additional soft safety edits to alert the pharmacist about duplicative opioid therapy and concurrent use of opioids and benzodiazepines. The care coordination edit and other opioid-related strategies implemented for Part D beneficiaries finalized in the Call Letter support adoption of the CDC Guideline for Prescribing Opioids for Chronic Pain. Through parallel rule-making, CMS also implemented the provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA) that provide for a drug management program under which Part D sponsors will be able to limit at-risk beneficiaries' coverage for frequently abused drugs to certain prescribers and pharmacies ("lock-in"). In addition, CMS has sent 24,000 letters to Medicare physicians that were prescribing at higher rates than their peers. CMS is also working to promote effective, alternative pain treatments that are not as addictive as opioids, including by disseminating best practices guidance to state Medicaid agencies. These actions and many more will be taken as part of CMS's three part response to the opioid epidemic, focusing in prevention, treatment, and data.

With the increases received in fiscal year 2018 for opioids, HRSA will support current Behavioral Health Workforce Education and Training grantees who partner with health centers to develop integrated, interprofessional care teams to improve access to opioid use disorder and other substance use disorder treatment.

QUESTIONS SUBMITTED BY SENATOR JACK REED

Question. Preserving funding for the Low Income Home Energy Assistance Program (LIHEAP) has been a bipartisan priority that I have been proud to work on each year with my colleague from Maine, Senator Susan Collins. While this Administration has proposed eliminating this vital program, I was pleased that the recent Omnibus appropriations law provided an additional \$250 million, and that HHS promptly distributed those funds to states.

Do you intend to continue HHS' longstanding commitment to ensuring that vulnerable households have access to home energy assistance? Will you also commit to distributing these funds to states as quickly and at as high a level as possible, based on Congressional appropriations?

Answer. The HHS Budget proposed the elimination of this program to prioritize funding for other human services activities. LIHEAP is not the only program helping low-income households pay their heating and cooling bills. State and local governments provide significant funding assistance, and the majority of states prohibit utilities from discontinuing a household's energy in periods of severe weather.

Once LIHEAP funds are appropriated, HHS is committed to distributing them as quickly as possible. The fiscal year 2018 Omnibus, included \$3.6 billion for LIHEAP, an increase of \$250 million above the fiscal year 2017 appropriation. All remaining fiscal year 2018 LIHEAP funding was released to states on April 23, 2018.

Question. The child welfare community in Rhode Island is enthusiastic about the opportunity to transform the approach to foster care through the Families First Prevention Services Act. When does the Department plan to issue regulations or guidance to implement the new law?

Answer. We intend to provide maximum flexibility to states in our implementation of Families First. As such, we will use subregulatory guidance in order to transmit instructions to states and tribes on how to comply with the changes whenever possible. We expect to issue such guidance in the form of Program Instructions (PI) as soon as July on the title IV-B and Chafee programs, the changes to the title IV-

E Foster Care Maintenance Payments (FCMP) Program, the title IV–E Adoption Assistance phase-in delay, and the optional effective date delays. HHS will implement the title IV–E Prevention Services Program through PIs that we expect to publish in the first quarter of Federal fiscal year 2019, most likely near the end of this calendar year.

Question. What are the plans for technical assistance to help states build the capacity and infrastructure to implement it?

Answer. ACF's implementation plan includes the provision of training and technical assistance to states as we roll out guidance over the summer. For example, SAMHSA and ACYF jointly fund the National Center on Substance Abuse and Child Welfare, which is available to assist states with developing collaborative practices to expand access to family-centered treatment services on a system-wide basis.

Question. There have been recent reports that the Department of Health and Human Services is making arrangements to house migrant children on military bases in anticipation of an increase of unaccompanied immigrant minors due to the Administration's new policy to separate children of asylum seekers from their parents. Please provide details of the Department's discussions with the Department of Defense and the Department of Homeland Security on these plans, including the legal authority to separate families, detain children, and hold them in custody in this manner.

Answer. HHS's authority extends only to children that meet the legal definition of an unaccompanied alien child found at 6 U.S.C. 279(2) as determined by DHS. HHS defers to DHS concerning the separation of families. HHS's authority for, and obligation with respect to, the care and custody of UAC is found in the Homeland Security Act of 2002 and the Trafficking Victims Protection Reauthorization Act of 2008. Under these statutes, and in accordance with the Flores v. Reno Settlement Agreement, HHS may place children in temporary emergency shelters, which may include temporary shelters located on a military installation, when there is a situation where HHS's normal bed capacity is overwhelmed. The policies governing an influx can be found in Section 1.7 of the ORR Guide: Children Entering the United States Unaccompanied. ORR will examine other available non-DoD installation options before attempting to open an influx care facility on DoD property.

Question. Has the Department estimated how many children will be placed in its custody?

Answer. We are closely working with our DHS partners to plan for expansion of program capacity, similar to activities in past years when large numbers of unaccompanied alien children (UAC) were referred to ORR for care. The UAC program will consider potential impacts, including number of UAC referrals, length of stay in our care, capacity needs, and cost estimates. As always, this program is very unpredictable and we will continue to work with Congress as we learn more.

Question. What accommodations are being considered for young children and minors with special needs?

Answer. HHS has policies in place to ensure that all children in its care have their needs met. HHS does not place children under the age of 13 or a child with special needs in an emergency influx care facility.

Question. What are the potential impacts on the children's health and well-being from being forcibly separated from their parents and detained on a military base? Does the Department have a plan to mitigate these impacts?

Answer. HHS works to ensure that each UAC's needs are met while they are in the care of the agency. All care facilities have clinicians and case managers to provide support and counseling to UACs.

Question. Does the department track and make available any data on negative health effects experienced by children who are separated from their parents and detained in this manner?

Answer. ORR does not systematically track or make publicly available data on the health needs of UACs.

Question. Do I have your commitment to spend these funds to expand the number of funded states and allow currently funded states to expand their lead poisoning prevention programs?

Answer. The fiscal year 2018 Omnibus provided \$35 million in funding for CDC's Childhood Lead Poisoning Prevention Program, representing an \$18 million increase over fiscal year 2017. In fiscal year 2017, CDC funded a total of 48 funded programs from 38 States, 5 large cities, 4 counties, and the District of Columbia. In fiscal year 2018, CDC anticipates funding additional state, local, territorial, or tribal agencies, as well as providing supplemental funding to enhance activities for the 48 existing funded programs for the following four lead poisoning prevention strategic activities related to:

1. Strengthening blood lead testing

2. Strengthening surveillance
3. Strengthening linkages to ensure children exposed to lead receive appropriate follow-up services
4. Strengthening population-based interventions

Question. My bipartisan legislation with Senators Capito and others, the Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act, recently passed the Senate. Should this legislation be passed by the House and signed into law, as is expected, how do you plan to implement the STAR Act's provisions to do expand biorepositories, improve surveillance of childhood cancer, develop best practices for the treatment of late effects of childhood cancers, improve collaboration among providers so that doctors are better able to care for this population as they age, and create innovative models of care for childhood cancer survivors establish. Will you join us in supporting funding for the initiatives authorized in the legislation?

Answer. Thank you and your colleagues for your leadership and support for childhood cancer research. HHS appreciates that the STAR Act aims to build upon and complement childhood cancer research and programs already underway with HHS support, including at the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the Centers for Disease Control and Prevention (CDC). If the STAR Act is signed into law, HHS will certainly work to implement its provisions to the best of our ability with the funds made available to us by Congress.

HHS remains committed to advancing progress for childhood, adolescent, and young adult cancer patients and survivors and their families. NIH and NCI will continue to support critical investments in childhood cancer survivorship research, including the Childhood Cancer Survivor Study; and pediatric biospecimen collection and related resources, including the Children's Oncology Group Biorepository and the Pediatric Cooperative Human Tissue Network. CDC will continue to support and improve surveillance on childhood, adolescent, and young adult cancers through its National Cancer Registries Program. Research supported by NCI and other NIH Institutes and Centers will continue to inform best practices in long-term pediatric cancer survivorship care, including the treatment and management of the late effects of cancer therapy. HHS will leverage pediatric oncology expertise across our operating divisions to review HHS activities related to workforce development for healthcare providers who treat pediatric cancer patients and survivors.

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

Question. I continue to be concerned by the Department's proposal to increase the availability of so-called "short-term, limited-duration insurance plans" that are not required to meet consumer protection and comprehensive coverage requirements under the Affordable Care Act. These insurance policies are not required to cover preexisting conditions, are not required to cover essential health benefits and can charge sick patients more in premiums.

Given the likelihood for consumer confusion resulting from the availability of these skimpy insurance products, will the Department consider restoring the advertising and consumer outreach funding for Health Insurance Marketplace coverage that was reduced by 90 percent last year?

Answer. The federally-Facilitated Exchange will conduct its sixth Open Enrollment later this year. The Exchange is now an established marketplace for individuals seeking insurance. Last year we had our most cost effective and successful open enrollment to date. The Exchange has grown in visibility and become more familiar to Americans seeking health insurance. CMS spent more than \$100 million on promotional activities during Open Enrollment 2017 (nearly double what was spent in 2015) but saw enrollments decline by 10 percent since the previous year.

The Health Insurance Marketplace advertising budget is now consistent with its advertising spending for Medicare Part D and Medicare Advantage. As a comparison, 11.8 million consumers selected or were re-enrolled in an Exchange plan during Open Enrollment 2018, while 41.3 million Americans are enrolled in Medicare Part D and another 19.1 million are enrolled in Medicare Advantage. CMS's combined advertising budget for Medicare Parts C and D is \$9.7 million.

CMS will continue to leverage the capabilities of the private sector as well to ensure our partners, such as agents and brokers, are equipped with the necessary resources to educate consumers on their coverage options.

Question. I worked with Senator Collins on the bipartisan National Clinical Care Commission Act, which President Trump signed into law last year. I appreciate the Department's recent efforts to approve the charter for the National Clinical Care Commission and to seek nominees for the Commission. Can you provide any addi-

tional information on the Department's timeline for finalizing Commission membership and providing additional regulatory guidance on the Commission's activities?

Answer. The Office of Disease Prevention and Health Promotion is coordinating the efforts of the National Clinical Care Commission. The final nominations are expected by the end of June.

Question. The fiscal year 2019 budget request would eliminate funding for the Prevention Research Center program within the Centers for Disease Control and Prevention (CDC). I am concerned about the loss of this funding and the potential impact on the important work conducted by academic and medical research centers in New Hampshire, especially in relation to seniors with health needs and individuals with mental health issues and substance use disorders. How does the Department of Health and Human Services (HHS) plan to fill this void if the funding is cut?

Answer. The fiscal year 2019 Budget eliminates funding for the Prevention Research Centers (PRCs), which work with academic institutions to conduct research and disseminate prevention interventions across the United States. In fiscal year 2018, CDC will fund PRCs at 26 universities in 24 States to study how individuals and communities can avoid or counter the risks for chronic illnesses. The PRC program has developed and evaluated many effective, practical public health strategies and programs, which can continue to be disseminated throughout the country. CDC's chronic disease prevention portfolio will continue to focus on implementation of the most effective existing interventions, working with community organizations and state and local public health agencies.

Question. The role of HHS in administering global health funding, including HIV/AIDS funding, means that the Department is responsible for implementing components of the expanded "global gag rule," also known as the "Mexico City Policy." HHS participated in the State Department's initial review of the policy earlier this year, but the majority of HHS grants and cooperative agreements had not received new funding at the time of review. How are agencies within HHS monitoring the effect of this policy on women's access to healthcare, including a full range of family planning methods and counseling, rates of unsafe abortion and maternal mortality?

Answer. To assess the impact of the policy on HIV/AIDS services, the President's Emergency Plan for AIDS Relief (PEPFAR) will continue its routine capture, monitoring, and use of age and sex disaggregated data, by partner and by site, to track precisely whether and to what extent the Protecting Life in Global Health Assistance (PLGHA) policy may affected life-saving activities related to HIV/AIDS. The Department of State has worked closely with USAID, HHS, and DoD to implement the policy consistently, examine progress in carrying it out, and monitor its effects.

Question. I am very troubled that as of April 1st, halfway through the fiscal year, only 10,548 refugees have been resettled, just 23 percent of this admissions determination and 73 percent fewer than the same time period last year. What measures are the Office of Refugee Resettlement (ORR) taking to maintain the capacity of refugee-serving organizations across the country to provide robust assistance for refugees and to ensure the long-term sustainability of the U.S. refugee resettlement network?

Answer. ORR continues to use its current budget to support the resettlement agencies.

Question. The fiscal year 2018 Consolidated Appropriations Act accepted the Administration's proposal to consolidate funding for Targeted Assistance, Refugee Health Promotion, and Refugee Social Services under one funding line. However, Congress explicitly stated that it expects activities previously funded under the three lines to continue in fiscal year 2018 at the same level as fiscal year 2017. How is ORR administering this funding to ensure that, in compliance with this Act, these programmatic activities continue at the same level as fiscal year 2017?

Answer. ORR will ensure funding levels for Social Services, Targeted Assistance, and Refugee Health Promotion will be funded as close to possible to fiscal year 2017 levels within the current budget.

Question. The fiscal year 2018 Consolidated Appropriations Act also includes language in Senate Report 115-150 strongly encouraging HHS to increase the percentage of eligible arrivals served by the matching grant program and to give matching grant organizations flexibility in administering their programs. How is ORR implementing this guidance from Congress?

Answer. As a result of a lower number of refugee arrivals, grantees are able to offer enrollment to all eligible individuals at the locations where the program is available. Additionally, and for the first time since 2007, the per-capita funding amount has increased to \$2,500 from \$2,200. The required grantee match also increased to \$1,250. Finally, ORR continuously assesses and makes adjustments to program guidelines to ensure enrolled individuals receive high quality services lead-

ing to economic self-sufficiency while affording the grantees the flexibility to innovate in service delivery.

Question. Due to this Administration's newly-announced policy to separate all children from their parents when apprehended by Customs and Border Protection (CBP). How many additional children does ORR anticipate serving in fiscal year 2018 who have been separated at the border from their parents?

Answer. We are closely working with our DHS partners to understand the potential impacts of their new policy on the UAC program including number of referrals, length of stay in our care, capacity needs and cost estimates. As always, this program is very unpredictable and we will continue to work with Congress as we learn more.

Question. How does this number compare with ORR's existing capacity to serve unaccompanied children?

Answer. ORR will expand its capacity to provide shelter and care to UACs as needed.

Question. What is the estimated cost to the taxpayer of holding these additional children under ORR custody?

Answer. We are closely working with our DHS partners to understand the potential impacts of their new policy on the UAC program including number of referrals, length of stay in our care, capacity needs and cost estimates. As always, this program is very unpredictable and we will continue to work with Congress as we learn more.

Question. How does ORR plan to coordinate with DHS and DOJ to ensure continued communication and eventual reunification between parents and the children separated from them at the border and placed under ORR custody?

Answer. ORR is collaborating with DHS and DOJ to make sure that children who can be reunified with their parents are reunified in a timely and safe manner. ORR and DHS have developed and issued a notice to clearly inform parents about how to contact their children in ORR's custody. ORR is also working with care providers to help link children to parents in detention.

QUESTIONS SUBMITTED BY SENATOR JEFF MERKLEY

Question. In April, press reports indicated that the Center for Medicare and Medicaid Services had refused to grant requests from tribal governments to exempt tribal members from Medicaid work rules. A "Dear Tribal Leader" letter and subsequent related statements made by HHS personnel on the issue of American Indian and Alaska Native (AI/AN) exemption from Medicaid work requirements revealed a startlingly poor understanding of the unique legal status of Indian tribes and their members under Federal law, the U.S. Constitution, treaties, and the Federal trust relationship.

While I was encouraged to see that CMS dropped its erroneous claim that exempting tribes from work requirements raised civil rights issues, I remain concerned that CMS' deference to state agencies on this issue represents a further erosion of the principle of tribal sovereignty and an abdication of the Federal Government's trust responsibilities.

I request that you provide the Committee with the following information:

How much in Medicaid reimbursements did tribal and IHS providers receive in the last year for which data is available?

Answer. IHS can only provide information about Federal Medicaid reimbursements. Tribal entities who have exercised self-determination directly receive their Medicaid reimbursements and are not required to report them to the IHS. For the most recent complete year, fiscal year 2017, IHS' Federal Medicaid collections were: \$259,886,004.

Question. As you know, the U.S. Government has a trust responsibility to provide healthcare to Native Americans. If a state were to impose a work requirement and knock a significant population of Native Americans off of Medicaid, how would HHS address the resulting revenue gap for tribal and IHS providers and ensure that they can continue treating their patient populations?

Answer. The Department is working with states that want to implement Medicaid community engagement requirements to ensure that the requirements are reasonable, achievable, and tailored to the goal of promoting positive health outcomes for beneficiaries. For instance, the Department has worked with states to include program features such as: permitting Medicaid beneficiaries to engage in a broad range of activities to satisfy the requirements (such as community service on or off tribal lands, participation in workforce participation programs including tribal workforce participation programs, caring for children or for family members with disabilities

and medical conditions, or participating in substance abuse treatment); exempting from the requirements various individuals (such as those in substance use disorder treatment or rehabilitation, or those caring for family members); and requiring states to provide a range of reasonable accommodations to participants with disabilities so they can meet requirements or be exempted from them if they are unable to do so.

Question. Given that providing healthcare to Indian people is a Federal responsibility, which is codified through numerous Federal laws and treaties, why is it appropriate that States determine how Indian people are treated?

Answer. The Indian Health Service, a Federal program, is the healthcare system for many American Indians and Alaska Natives. Members and descendants of a federally recognized tribe are eligible to receive care at IHS facilities.

Medicaid is also an important source of health coverage for American Indians and Alaska Natives, but that program is administered by states, subject to Federal approval. The Social Security Act allows states to propose Medicaid demonstration projects to test innovative ways of designing and administering their state Medicaid programs. Given that Medicaid is a state-administered program, the Department requires states to consult with tribes and seek their advice on how state demonstration projects, including any community engagement requirements, would be implemented with respect to tribal members who are Medicaid beneficiaries. This long-standing policy recognizes the sovereign nature of the tribes by requiring government-to-government consultation.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

EXPANDING ACCESS TO TELEHEALTH FOR MEDICARE BENEFICIARIES

Question. I was pleased to hear that you would be “very forward leaning” if you were to receive the authority from the CONNECT for Health Act to waive barriers to Medicare fee-for-service reimbursement for telehealth.

Please provide an update on how HHS plans to support and use telehealth to expand provider networks, improve access, and lower the cost of care.

Answer. Telehealth can provide innovative means of making healthcare more flexible and patient-centric. Innovation within the telehealth space could help to expand access to care for Medicare beneficiaries, particularly within rural and underserved areas. We are working to implement the provisions of the Bipartisan Budget Act of 2018 that support greater access to telehealth services for Medicare beneficiaries in the areas of home-based dialysis care, stroke care, and care from certain Accountable Care Organizations.

The Centers for Medicare & Medicaid Services (CMS) has previously sought information regarding ways that it might further expand access to telehealth services within its current statutory authority, and pay appropriately for services that take full advantage of communication technologies. CMS has been reviewing comments and considering commenters’ suggestions for future rulemaking and any appropriate sub-regulatory changes. Furthermore, in their Calendar Year 2018 Medicare Physician Fee Schedule Final Rule⁷ released last November, CMS expanded access to Medicare telehealth services by paying for more services through new additions to the list of Medicare telehealth services and making it easier for physicians and practitioners to bill for these services.

In addition, in May 2018, CMS released the agency’s first Rural Health Strategy, intended to provide a proactive approach on healthcare issues to ensure that the nearly one in five individuals who live in rural America have access to high quality, affordable healthcare; one of the five objectives of this strategy is to advance telehealth and telemedicine. In continued collaboration with CMS, agencies across HHS, including the Health Resources and Services Administration (HRSA), will work to implement this strategy. Improving access to telehealth services reflects CMS’s work to modernize Medicare payments to promote patient-centered innovations. HHS looks forward to continuing its work with Congress and other stakeholders to identify additional ways in which it can further expand access to telehealth services within Medicare and reduce the administrative burden for healthcare providers to bill for these services.

TELEHEALTH AND MEDICARE ADVANTAGE

Question. With the passage of CONNECT for Health Act provisions in the Bipartisan Budget Agreement of 2018, Medicare Advantage organizations can account for

⁷ <https://www.gpo.gov/fdsys/pkg/FR-2017-11-15/pdf/2017-23953.pdf>.

telehealth services in their 2020 bids. Currently, in the Medicare Managed Care Manual, the Centers for Medicare and Medicaid Services (CMS) lists “Telemonitoring,” “Remote Access Technologies,” and “Enhanced Disease Management” as examples of possible supplemental benefits.

Are you planning to revise the Medicare Managed Care Manual to clarify that the use of remote monitoring and telehealth to deliver chronic care management services is a basic benefit rather than a supplementary benefit?

Answer. As part of the Balanced Budget Act of 2018, Congress passed, and the President signed into law, changes that will allow Medicare Advantage (MA) plans to offer additional telehealth benefits beyond those currently paid for in Medicare Part B (Fee-for-Service), starting in 2020. CMS knows that it is important that plans and beneficiaries have accurate and timely information about these changes in time for the 2020 plan year. As it does regularly when there are changes in Medicare Advantage, CMS will update the Medicare managed care manual to reflect those changes, as well as announcing the policy changes in the annual MA Call Letter.

Question. Please provide an update on how CMS plans to address this imbalance. Is CMS willing to make a case-by-case adjustment as it did with Puerto Rico?

Since Medicare Advantage penetration continues to grow, will CMS correct the fee-for-service spending calculation for all Medicare Advantage organizations to be more accurately representative of the expected spending for Medicare Advantage beneficiaries?

Answer. HHS is aware that areas of the country in which there are a higher proportion of beneficiaries who do not have Part B compared to the rest of the nation, such as Hawaii, face different challenges than those areas of the country that do not have a similar population. This Administration is committed to promoting healthcare choice and competition across the United States, and Medicare Advantage plays an important role in our efforts. HHS is open to having a conversation with stakeholders in Hawaii in order to better understand the unique challenges they face. CMS will continue to analyze this issue and consider whether any adjustments to the methodology on this point may be warranted in future years.

QUESTIONS SUBMITTED BY SENATOR TAMMY BALDWIN

Question. President Trump recently signed my bipartisan RAISE Family Caregivers Act (Public Law 115–119) into law, which I authored with my colleague Senator Collins. This new law would formally recognize and support the over 40 million family caregivers who are overlooked in our healthcare system. It helps ensure that older adults and loved ones with disabilities receive the highest quality care in their own homes. Every day, family caregivers do right by their loved ones, and I’m proud to say that we’re now doing right by them. But, in order to fulfill this promise, it is essential that you begin swift implementation of the law by immediately establishing the Family Caregiving Advisory Council that is charged with providing you timely advice to inform the national Caregivers Strategy.

Will you agree to work with me and Senator Collins to support family caregivers by swiftly and faithfully implementing this measure?

Answer. The RAISE Family Caregivers Act requires the Department to promote improvement of the Federal, State and community systems that support family caregivers. The two primary functions of the RAISE Act are to: (1) establish a national Family Caregiving Strategy with recommendations for ensuring person- and family-centered care, assessment and service planning, information on accessing hospice and palliative care, respite options, financial security and workplace issues, and delivering service in an effective and efficient manner; and (2) establish a Family Caregiving Advisory Council of Federal and non-Federal representatives to provide recommendations and identify best practices to recognize and support family caregivers.

The Act did not authorize the creation of new programs or services, and specified that work should be accomplished within existing resources. The Department has been exploring all options for implementing the Act with existing HHS authorities and appropriations.

Question. Will you commit to establishing the Advisory Council immediately in fiscal year 2018?

Answer. The RAISE Act did not authorize an appropriation for the creation of new programs or services, and specified that work should be accomplished within existing resources. HHS has sought but not yet identified existing authorities and appropriations that would allow the Department to proceed with implementation of the Act.

Question. Last year in China, 192 people contracted the H7N9 strain of avian influenza and 79 died. While that virus is not jumping from birds to humans with a great rate of frequency, reports indicate that the CDC remains concerned. Recent studies show that the virus is only several mutations away from being able to easily spread from human to human, which could ignite a deadly global pandemic. It is essential—and one of my top priorities to help ensure—that our country is prepared to take on this serious health threat before it arrives. The Assistant Secretary for Preparedness and Response recently released the Public Health Emergency Medical Countermeasure Enterprise budget, which called for \$632 million for fiscal year 2019 for pandemic influenza. However, your HHS fiscal year 2019 Budget only requests \$250 million. Can you explain this gap in requested funding, and what HHS is doing to ensure our Nation is prepared for this known health threat that may be only a plane ride away?

Answer. The Public Health Service (PHS) Act, as amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), requires the Office of the Assistant Secretary for Preparedness and Response (ASPR) to lead the development of a coordinated 5-year budget plan for medical countermeasure (MCM) development and to update the plan annually. The 2016–2020 PHEMCE Multiyear Budget was transmitted to Congress and made publically available in December 2017.

The report includes spending estimates for the HHS PHEMCE agencies (ASPR, CDC, FDA, and NIH) that are equal to actual appropriations in fiscal year 2016 and fiscal year 2017, the fiscal year 2018 President's Budget, and use a professional judgment budget to estimate potential investments for two future years (fiscal years 2019–2020). The spending estimates for fiscal year 2019 are considered a professional judgment budget, which were developed without regard to the competing priorities that are considered in the budget development process. These priorities must be considered as future President's Budgets are developed. The spending estimates included in the Multiyear Budget are subject to change in the future.

The fiscal year 2019 President's Budget was transmitted to Congress this past March. The request included \$250 million for pandemic influenza activities funded from the Public Health and Social Services Emergency Fund. This funding level represents an increase of nearly \$200 million over the fiscal year 2017 appropriated level. The Department greatly appreciates the \$250 million appropriated to the PHSSEF for pandemic influenza in the fiscal year 2018 Omnibus.

ASPR continues to monitor the H7N9 strain of avian influenza. Through BARDA, ASPR has:

- Responded to the 2017 H7N9 crisis, awarding three contracts for production of approximately 20 million regimens of vaccine antigen for H7N9 influenza vaccine from the 2016–2017 Yangtze River virus lineage candidate vaccine virus provided by CDC to achieve National Pre-Pandemic Influenza Vaccine Stockpile preparedness goals; and
- Supported a clinical study to assess the safety and antigen-sparing capacity of adjuvants that are maintained in the National Pre-Pandemic Influenza Vaccine Stockpile, when combined with recombinant-based vaccine for the 5th Wave/ Yangtze River lineage H7N9 influenza virus circulating China.

Question. How are you ensuring we are utilizing new cell-based pandemic influenza technologies?

Answer. HHS is committed to development of new vaccine technologies, in order to improve the Nation's ability to respond to an influenza pandemic, as well as to address seasonal influenza. Since 2010, BARDA has supported the licensure of both cell-based and recombinant influenza vaccine technologies. The new technologies have the potential to increase the U.S.'s manufacturing capacity and shorten the manufacturing timelines for seasonal and pre-pandemic vaccines. BARDA both utilizes these investments from a readiness and procurement stance, as well as continues to make targeted investments to further improve the Nation's preparedness posture. As part of BARDA/ASPR's pandemic influenza preparedness strategy, contracts are in place with all US licensed influenza vaccine manufacturers, including the manufacturers of recombinant and cell-based influenza vaccines, to allow production and delivery of vaccine to the United States Government in the event of a pandemic. BARDA has also purchased cell-based pre-pandemic influenza vaccine for the pre-pandemic influenza vaccine stockpile (2013 H7N9 vaccine), and is currently supporting production, stability testing, and clinical trial evaluation of recombinant and cell based pre-pandemic influenza vaccines to inform future purchases. Finally, BARDA continues to fund advanced development of these technologies, particularly cell-based pandemic influenza technologies. This funding has supported development of a more efficient manufacturing process, which if approved by FDA, will translate into greater seasonal vaccine output and faster pandemic response.

Question. The opioid epidemic has far-reaching and deadly public health impacts including the spread of infectious diseases. We have seen reports across the country of spikes in HIV cases linked to injected drug use, and the CDC estimates a 133 percent increase in acute HCV infection due to opioid use. While I am encouraged by the budget provisions that speak to the opioid crisis, I am concerned that this plan does not prioritize evidence-based public health resources, including access to primary care and preventive services, which will be needed to address outbreaks of infectious diseases. Can you describe how the Administration will emphasize the public health interventions, research, and workforce support necessary to prevent, track, and treat opioid-related infectious diseases?

Answer. The rising rates of infectious diseases associated with injection drug use are of great concern.

CDC is working to address bloodborne infectious diseases linked to intravenous drug use by sharing the best available science and approaches to prevent the spread of these diseases, getting people treated, and reducing the injection drug use that puts people at greater risk of getting infected. CDC is building state and community capacity for comprehensive approaches for preventing, tracking, and combating infectious diseases stemming from the opioid crisis by:

- Collaborating to help states and communities track disease patterns, determine if they are at risk for disease outbreaks, and implement proven prevention strategies.
- Providing technical assistance to state and local health departments and community-based organizations on the most effective strategies to engage people who inject drug, and connect them to treatment and prevention services for drug use and infectious diseases.
- Using molecular surveillance to identify clusters of viral hepatitis and HIV infections. This information can direct prevention activities to stop disease transmission

With additional resources provided to CDC in fiscal year 2018 for opioids, HHS will continue to expand and enhance its comprehensive public health response to the opioids crisis by working with state, territorial, and tribal health departments to address the full range of public health consequences of opioids, including infectious diseases.

Similarly, with the increases provided in fiscal year 2018, HRSA will expand and improve access to opioid and substance use disorder treatment through the Community Health Centers and National Health Service Corps programs.

In April 2018, the NIH launched the Helping to End Addiction Long-term (HEAL) Initiative,⁸ to speed scientific solutions to stem the national opioid public health crisis. This Initiative will build on extensive, well-established NIH research, including basic science of the complex neurological pathways involved in pain and addiction, implementation science to develop and test treatment models, and research to integrate behavioral interventions with medication-assisted treatment for Opioid Use Disorder (OUD).

In fiscal year 2019, the President's Budget includes a request for \$40 million within CDC to eliminate new infections, and where relevant, decrease the prevalence of HIV, hepatitis B virus, hepatitis C virus, STIs such as syphilis, and tuberculosis in select states and jurisdictions at high risk for these diseases, including those with high rates of opioid-related transmission.

Question. On February 23, 2018, HHS issued a delayed Funding Opportunity Announcement (FOA) for the Title X Family Planning Program. I am concerned that the language in this announcement indicates a shift from evidence-based, comprehensive family planning services toward abstinence-only-until-marriage education. Why was this FOA delayed, and what organizations does HHS plan to prioritize in awarding Title X grants, given these shifting priorities?

Answer. HHS recognizes the FOA was delayed, but the current funding announcement streamlines the application process. This improvement makes it easier and more efficient for a wide variety of organizations to submit quality applications, enabling more women and men to receive excellent care through the Title X program. This funding announcement is now closed. Applicants have submitted their proposals and each will be subject to the same, objective assessment process. In addition, this FOA is currently the subject of litigation. As a result of both the ongoing litigation and the ongoing grant review process, HHS cannot comment at this time on future plans regarding the grant process or future awards.

Question. Last year before the HELP Committee, the National Academy of Sciences said that pharmaceutical companies could easily absorb revenue losses from lower prices by reducing buyback programs and executive compensation, in-

⁸ <https://www.nih.gov/research-training/medical-research-initiatives/heal-initiative>.

stead of reducing R&D, which is often threatened. If drug prices fell, do you think it would be right for drug companies to cut more from R&D than from buybacks and executive compensation? What do you think the majority of executives would choose?

Answer. HHS recognizes that the current drug ecosystem requires dramatic change. The Administration understands that the drug pricing problem is complex and has multiple parts: high list prices, overpaying in government programs, high out-of-pocket costs, foreign governments' underpaying for drugs. They are connected in a way that attempting to squeeze one end of the balloon won't lead to lasting change and requires a broad-based, systematic approach to the problem.

Recognizing these challenges, in May, the Administration released the "American Patients First" Blueprint, which will bring immediate relief to American patients while also delivering long-term reforms. There are four strategies for reform set out in the administration's drug-pricing blueprint: improved competition, lowering out-of-pocket costs, enhanced negotiation, and incentives for lower list prices.

Question. Pharmaceutical executives receive an inordinate amount of their compensation in the form of stock-based pay. Over the last 10 years, the top pharmaceutical companies spent an average of ninety-nine percent of their profits buying back their own stock and issuing dividends. Pharma's financialized business model draws heavily on taxpayer-funded investment in research. Yet drug company profits overwhelming benefit executives and wealthy shareholders. How will you ensure that American drug companies serve the taxpayers who have subsidized them and the public interest instead of just their shareholders?

Answer. HHS is committed to getting more value for the prescription drugs that patients and taxpayers purchase. The Trump Administration has already taken a number of significant administrative steps. It proposed in the President's fiscal year 2019 Budget, to improve competition and end the gaming of regulatory processes, support better negotiation of drug discounts through government insurance programs, create incentives for pharmaceutical companies to lower list prices, and reduce consumer out-of-pocket spending at the pharmacy and other care settings. For example, FDA approved or tentatively approved over 1,000 generic drugs in 2017, which is the greatest number of FDA generic approvals in a calendar year by over 200 drugs. These generic approvals saved American consumers and taxpayers nearly \$9 billion in 2017.

In May, the Administration released the "American Patients First" Blueprint, which will bring immediate relief to American patients, while also delivering long-term reforms. The Blueprint proposes new strategies and takes bold actions to improve competition and end the gaming of regulatory processes, supports better negotiation of drug discounts through government insurance programs, creates incentives for pharmaceutical companies to lower list prices, and reduces consumer out-of-pocket spending at the pharmacy and other care settings.

Question. In February 2018, the Administration released "Reforming Biopharmaceutical Pricing at Home and Abroad." That report makes the baffling claim that American drugs prices are too high because drug companies' global financial returns are "unfairly low" [because foreign governments set lower drug prices]. In response, the report recommends that the U.S. force foreign governments to raise their drug prices, to make financial returns to U.S. pharmaceuticals 'fair.' It is very clear to me what U.S. drug companies would do with additional profits—they would give them to their shareholders. The 18 pharmaceutical companies in the S&P500 spent an average of ninety-nine percent of their profits on buybacks and dividends over the last 10 years. Why does the Administration think that if drug companies got additional cash they would do anything other than reward their shareholders?

Answer. HHS is committed to getting more value for the prescription drugs patients and taxpayers purchase. In May, the Administration released the "American Patients First" Blueprint, which will bring immediate relief to American patients, while also delivering long-term reforms. The many interacting drivers in the current pharmaceutical market, including growth in international price controls, have created an environment of high list prices and increased consumer out-of-pocket spending. The blueprint identifies four key strategies to realign the system: improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs. Short and long term actions the Administration is taking on all of these fronts will bring relief to American consumers and taxpayers.

Question. WHO is currently pushing countries to implement its 2016 guidance related to the promotion of foods for infants and young children. The guidance would restrict communication about and promotion of milk products for children up to age three. This contradicts international and US dietary guidelines that recognize dairy products as an excellent source of nutrition for toddlers. How is the United States

working at the WHO to promote good nutrition of and role of dairy in nutritious diets, in keeping with U.S. nutrition guidelines?

Answer. The Administration agrees that more balanced approaches are needed to address nutrition issues, including improving nutrition among infants and children. At the 71st World Health Assembly (WHA) this May, the U.S. delegation successfully advanced this view in negotiating a resolution on infant and young child feeding. The U.S. delegation emphasized developing, implementing and evaluating evidence-based recommendations; WHO technical support to Member States upon request; and the importance of taking into account national context in determining which voluntary approaches, policies, or mandatory approaches to apply. In addition, the U.S. delegation successfully negotiated out of the resolution any direct references to the 2016 WHO guidance.

In 2016, the 69th World Health Assembly (WHA) adopted a resolution welcoming the World Health Organization (WHO) Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children. In the U.S. statement on the resolution—and in subsequent interactions with WHO, with other Member States, and with other stakeholders—the United States government emphasized improving nutrition among mothers, infants and young children as an important public health priority; that children over 6 months of age need nutrient-rich complementary foods from a variety of sources; and the importance of this time period for child health and development.

The WHO guidance does not seek to prohibit the marketing of all milk products consumed by young children, limit product availability, or discourage the general inclusion of age-appropriate dairy products such as milk, cheese and yogurt in the diets of young children. WHO intends the guidance to complement, not replace, domestic and global recommendations for feeding infants and young children, including current recommendations on feeding breastfed and non-breastfed infants and young children. The document does recommend that countries prohibit the promotion of breast-milk substitutes marketed for feeding children up to 3 years of age. The voluntary guidance is a technical document and is not binding on Member States or on other actors. U.S. departments and agencies regularly interact with WHO, other Member States, and stakeholders to urge the development of evidence-based guidelines, tools and recommendations, applied according to national or local context, in order to improve nutrition. HHS continues to lead processes, in coordination and collaboration with the U.S. interagency, to solicit and provide evidence-based feedback to WHO on its nutrition work, and to convey the importance of providing countries with clear, evidence-based recommendations.

Question. Vaccines are among the most cost-effective clinical preventive services, however, outbreaks of diseases that were once nearly insurmountable in the U.S. are again threatening children's health due to inadequate vaccination rates. One measles outbreak in Minnesota last year exceeded the total number of cases in the entire U.S. for 2016. The CDC's Immunizations Program is critical to help improve our ability to prevent and respond to outbreaks of vaccine preventable diseases. The president's fiscal year 2019 budget proposes to cut funding for CDC's Immunizations Program by approximately \$98 million. How will the Administration ensure that adults and children are receiving the necessary vaccinations to protect them from outbreaks of measles and other vaccine-preventable diseases?

Answer. At this funding level, CDC will continue to provide assistance to the 64 immunization awardees for state infrastructure awards and vaccine direct assistance. CDC will continue providing technical assistance and laboratory support to states and local communities responding to vaccine-preventable disease investigations, including outbreaks.

QUESTIONS SUBMITTED BY SENATOR CHRISTOPHER MURPHY

Question. I know that you have made delivery system reform a priority since coming back to HHS. You have laid out several times four broad shifts in policy that you think will accelerate the move toward a system that rewards value.

Among those, you have said that the Federal Government needs to use Medicare to drive innovation faster as we move from volume to value-based reimbursements. A natural way to do this would be to use the Center for Medicare and Medicaid Innovation (CMMI), which is tasked with the development and testing of innovative healthcare payment and service delivery models. Just last week, President Trump announced a rescission package that included an \$800 million cut to the Innovation Center. This is despite the fact that the Congressional Budget Office has said that on average, the Innovation Center produces an almost four to one return in reduced Federal Medicare costs over a 10-year period.

Do you support this proposed cut to CMMI?

Answer. Given the long-term fiscal constraints facing our Nation, the President is committed to using all available tools to put our fiscal house back in order. As the first of several proposed rescissions packages, this Administration is fully committed to protecting taxpayers, and urges Congress to do the same.

For CMMI, the rescission of \$800 million is in excess of the funds needed by the Innovation Center in fiscal years 2018 and 2019. In fiscal year 2020, CMMI will receive a new mandatory appropriation of \$10 billion.

Question. Will this proposal hinder your ability to drive delivery system reform? Is there a statutory reason why this funding cannot be rolled over into the future?

Answer. No, it will not. Under the Affordable Care Act, Congress appropriated \$10 billion for fiscal years 2011 through 2019 for activities initiated under the Innovation Center's statutory authority, including for the Innovation Center to test new payment and service delivery models. The law appropriates an additional \$10 billion for each subsequent decade.

The Innovation Center was created to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and CHIP while preserving or enhancing quality of care.

The initial years were focused on establishing and operationalizing the Innovation Center. With a few exceptions, most of the models the Innovation Center has tested or is currently testing launched after 2015.

For CMMI, the rescission of \$800 million is in excess of the funds needed by the Innovation Center in fiscal years 2018 and 2019.

Question. As you may know, around two-thirds of veteran suicides involve a firearm. The Veteran's Administration (VA) has funded research studies to determine the factors associated with Veteran suicide, including access to lethal means. VA researchers have looked at interventions to delay or reduce access to guns for individuals at risk of suicide. This research has led the VA to design and implement programs that effectively mitigate suicide risk in this population that include lethal means reduction. In the general population, more than half of suicides involve a firearm. Does the current funding landscape allow for research on lethal means reduction in high-risk groups and/or the general population?

Answer. CDC works to prevent injuries and violence through a host of programs spanning surveillance, development and evaluation of recommendations, and implementation of effective strategies. CDC currently conducts and funds research on a variety of related topics, including youth violence, child maltreatment, domestic violence and sexual violence. These are the topical line items that are supported through CDC's annual appropriation for both research and non-research activities.

CDC has, and continues, to support data collection (public health surveillance) activities to document the public health burden of suicide and firearm injuries and death in the U.S. Understanding the patterns, characteristics, and impact of firearm violence is an important step toward preventing firearm injuries and deaths in the United States.

In addition, NIH is committed to understanding effective public health interventions to prevent suicide. Studies of lethal means restriction (i.e., limiting access to lethal methods used for suicide), including but not limited to access to firearms, are an important part of these efforts. More generally, NIH-supported research on the causes and prevention of firearm violence addresses a range of topics, such as understanding environmental and sociocultural risks for firearm violence; means restriction for people who are at-risk for suicide; and pediatrician counseling for parents on safety practices, including safe firearm storage.

Suicide is the 10th leading cause of death in the United States, and in 2016, firearms accounted for more than half of all suicide deaths.⁹ To address this public health concern, the National Institute of Mental Health (NIMH) supports a diverse portfolio of suicide prevention research, including efforts to investigate means restriction for individuals who are at high risk for suicide. For example, one study examined emergency department means restriction counseling discharge practices for at-risk patients.^{10,11} This study incorporated input from hospital decision makers, leaders of law enforcement organizations, gun retailers, and shooting ranges.^{12,13,14} This project identified practical and temporary safe storage options for families with a member who is at high risk for suicide, laying the groundwork for the develop-

⁹ <https://webappa.cdc.gov/sasweb/ncipc/leadcause.html>.

¹⁰ https://projectreporter.nih.gov/project_info_description.cfm?aid=8976244&icde=22718749.

¹¹ <https://www.ncbi.nlm.nih.gov/pubmed/29248278>.

¹² <https://www.ncbi.nlm.nih.gov/pubmed/29704978>.

¹³ <https://www.ncbi.nlm.nih.gov/pubmed/29436398>.

¹⁴ <https://www.ncbi.nlm.nih.gov/pubmed/28933926>.

ment of community-based firearm safety efforts.¹⁵ Currently, NIMH funds research that aims to develop and test a patient-centered, web-based firearm lethal means decision aid to augment clinician-delivered counseling by enabling at-risk individuals and their families to determine how best to reduce home firearm access (e.g., through locking devices or temporary out-of-home storage). This approach offers the potential to significantly enhance current care, reduce access to lethal means of suicide, and ultimately reduce suicides by firearm.¹⁶ Another NIMH-funded study is focused on preventing suicide in children and adolescents by enhancing the implementation of Safety Check, an evidence-based firearm means restriction intervention, in pediatric primary care across 13 healthcare systems. Successful implementation strategies from this study may inform large-scale interventions to prevent suicides by firearm.¹⁷ In addition, NIMH supports a data linkage study to identify precursors of firearms injury and suicide among veterans, with the aim of reducing fatal and nonfatal traumatic injuries among veterans.¹⁸ Suicide prevention research is a high priority for NIMH, and near-term investments in suicide reduction strategies have great potential for long-term impact.

QUESTION SUBMITTED BY SENATOR JOE MANCHIN, III

JESSIE'S LAW

Question. In 2016, we lost a young woman with great potential named Jessica Grubb. Jessie was a great student, a loving daughter and sister, and an avid runner. She was also recovering from an opioid addiction.

When she had surgery for an infection related to a running injury, both Jessie and her parents told her doctors and hospital personnel that she was a recovering addict and not to be prescribed opioids. Unfortunately, Jessie's discharging physician did not know that she was a recovering addict and sent her home with a prescription for 50 oxycodone pills. That night, she overdosed and passed away in her sleep.

That is why I introduced Jessie's Law to require HHS to establish standards for hospitals and medical professionals for prominently displaying substance use disorder history—just like any deadly allergy—in a person's medical record when that information is provided by the patient.

This language was included in the fiscal year 2018 Omnibus.

Secretary Azar, will you commit to me that your agency will immediately begin working on these standards and disseminate them as quickly as possible to medical professionals all over the country? This is just a commonsense step that will ensure that hospitals and medical professionals have access to the information that they need to provide medically appropriate care and keep us from losing more people like we lost Jessie Grubb.

Answer. Yes, efforts are actively underway to ensure that substance use disorder data are more readily available to healthcare providers and practitioners. The Department is examining ways in which to better align 42 CFR Part 2 with HIPAA, in order to ensure that the sharing of information on SUDs is more comparable to other chronic diseases.

QUESTIONS SUBMITTED BY SENATOR PATRICK J. LEAHY

PATENT SYSTEM AND DRUG PRICES

Question. Brand drugs now account for more than three out of every four dollars spent on prescription drugs. The administration's blueprint to lower prescription drug costs notes that greater competition lowers prices, which in turn benefits patients. Unfortunately, abuse of the patent system is delaying patient access to new, more affordable, FDA-approved medicines. Examples of this practice include Humira, Restasis, and Revlimid and patent abuse are becoming an increasingly common practice.

The fiscal year 2019 Budget and the American Patients First blueprint does not address, in any form, the increasing use of our patent system to extend monopolies and keep drug prices high for patients.

¹⁵ <https://www.ncbi.nlm.nih.gov/pubmed/27842186>.

¹⁶ https://projectreporter.nih.gov/project_info_description.cfm?aid=9513052&icde=37016442.

¹⁷ https://projectreporter.nih.gov/project_info_description.cfm?aid=9276816&icde=39675968.

¹⁸ https://projectreporter.nih.gov/project_info_description.cfm?aid=9321294&icde=38281695.

How does the administration intend to identify and tackle clear abuses of the patent system to make sure that generics and biosimilars are able to enter the market according to the timeline Congress intended?

Answer. In 2017, FDA Commissioner Gottlieb established the Drug Competition Action Plan. Through this plan, FDA is working to help ensure consumers can get the medicines they need at affordable prices, including by helping ensure access to safe and effective generic drugs. One of the three major components of the plan is reducing the so-called “gaming” that frustrates and delays generic drug approvals and extends brand monopolies beyond what Congress intended with the Hatch-Waxman Amendments of 1984.

FDA has made significant progress in advancing the goals of the plan. For example, in July 2017, the Agency held a public meeting on “Administering the Hatch-Waxman Amendments” to gain input on how FDA can ensure an optimal balance between encouraging innovation in drug development and accelerating the availability to the public of lower-cost alternatives to brand name drugs. One of the specific issues FDA solicited input on was how the balance struck in the Hatch-Waxman Amendments has been affected by practices and trends related to patents. This was a well-attended and successful meeting, and over 90 substantive comments were submitted to the public docket. The Agency is currently assessing these comments as it continues to actively identify new initiatives that can enhance efforts to provide more safe, effective, and high-quality generic medicines to the public, and address “gaming,” including abuses of the patent system, that exploits rules and loopholes in our system to delay generic approval and thereby extend a drug’s monopoly beyond what Congress intended.

The fiscal year 2019 Budget proposal also includes an important legislative fix to address gaming related to the Hatch-Waxman Amendments. As background, in the Hatch-Waxman Amendments, Congress provided a period of 180-day exclusivity for certain first generic applications as an incentive for generic manufacturers to challenge patents on innovator drugs that might otherwise prevent approval or delay generic entry into the market. This exclusivity, which is generally designed to reward certain generic drug sponsors with a finite period of marketing exclusivity, was intended to encourage generic drug development that might not have been undertaken otherwise. In some cases, however, the legal framework surrounding this exclusivity has delayed generic competition to an extent that was not intended by the Hatch-Waxman Amendments, and in ways that do not serve the public health. The fiscal year 2019 President’s FDA Budget proposal would address some of these issues by enhancing generic competition in areas where 180-day exclusivity is blocking such competition for extensive periods of time in certain circumstances, including situations where first generic applicants may be deliberately parking their 180-day exclusivity to delay approval of subsequent generic applicants who have also challenged the patents on the innovator product.

FDA also prioritizes its work to facilitate greater availability of biosimilar and interchangeable products. Increased access to these products should lead to greater price competition in the biological product marketplace and help bring down the costs of these important products. Although FDA has approved 10 marketing applications for biosimilars as of May 25, 2018, we are aware that many of these approved biosimilars have not yet been marketed. Although the challenges faced by the manufacturers in marketing of these products may be outside the Agency’s control, FDA remains focused on creating and maintaining a rigorous, modern, and efficient review program for biosimilar and interchangeable products.

Building on the success of the Drug Competition Action Plan, described above, FDA will soon be launching a comprehensive Biosimilars Action Plan that will outline a number of policies and actions the Agency intends to put forward to enhance the efficiency of FDA’s review of marketing applications for biosimilar and interchangeable products; to increase regulatory certainty for biosimilar manufacturers and other stakeholders; to educate stakeholders about biosimilar and interchangeable products; and to reduce gaming of FDA regulations or other attempts to unfairly delay market competition.

LOWER DRUG COSTS ABROAD

Question. It is well-documented that brand-name prescription drug prices in the United States exceed the costs for the same brand drug in other countries. For the top-selling brand drugs in the United States, the costs are two-to-three times the price of the same drug overseas. In the administration’s blueprint on drug prices, HHS proposes to work in conjunction with the Department of Commerce and USTR to “address the unfair disparity between drug prices in America and other developed

countries” through “appropriate regulatory changes and seeking legislative solutions.”

Is there any evidence of a pharmaceutical company lowering the price of a brand drug in the U.S. because of a price increase in another country?

Answer. U.S. consumers and taxpayers generally pay more for brand drugs than do consumers and taxpayers in other OECD countries. In effect, other countries are not paying an appropriate share of the necessary research and development to bring innovative drugs to the market and are instead freeriding off of U.S. consumers and taxpayers. As part of President Trump’s blueprint on drug prices, “American Patients First,” HHS is actively reviewing what can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equally between the U.S. and other developed countries.

Question. What policies, if any, are the administration considering that would compel pharmaceutical companies to lower drug prices in the United States as a result of our trade agreements?

Answer. As part of President Trump’s blueprint on drug prices, “American Patients First,” HHS is actively reviewing what can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equally between the U.S. and other developed countries.

FAMILY SEPARATION

Question. The Department of Homeland Security (DHS) recently announced that it will implement a “zero tolerance” policy and refer 100 percent of adults illegally crossing the border for criminal prosecution—even if they arrive with children. This will establish a de facto family separation policy, forcibly breaking up families and sending children into the custody of your agency. DHS has thus far refused to make public its memo outlining this new “zero tolerance” policy.

Given your agency’s formal role in housing and caring for children separated from their families at the border, has your agency issued any memoranda or guidance to accompany DHS’ “zero tolerance” policy memo? If so, can you please provide all such documents to this Committee?

Answer. ORR continues to implement the Unaccompanied Alien Children (UAC) Program in compliance with Federal law and the Flores settlement agreement, and to provide care to all UAC in its custody. ORR has not issued any guidance because additional guidance is not necessary.

Question. Have you estimated how many additional children will end up in the care of the Office of Refugee Resettlement (ORR) as a result of the Trump administration’s new “zero tolerance” policy?

Answer. HHS is working closely with our DHS partners to anticipate and plan for the potential number of unaccompanied alien children (UAC) referrals and their length of stay in our care. Historically, the timing and number of UAC referred to HHS each year for care and custody has been difficult to predict with any certainty and the Department assesses need for capacity growth or decline on an ongoing basis.

Question. Have you estimated the increased cost associated with this influx of children?

Answer. We are working closely with our DHS partners to understand the potential impacts on the UAC program, including number of referrals, length of stay in our care, capacity needs, and cost estimates. As always, this program is very unpredictable and we will continue to work with Congress as we learn more.

Question. Will you submit an updated budget request for ORR to reflect these costs?

Answer. HHS is closely monitoring its shelter capacity needs in coordination with our interagency partners, evaluating its resource needs and, if necessary, will seek to maximize currently available resources and authorities. As always, we will continue to work with Congress as we learn more.

Question. Please provide the average duration in ORR for unaccompanied children on a monthly basis for fiscal year 2014 through fiscal year 2018 (to date).

Answer: [The information follows:]

Fiscal Year 2014	Average Length of Stay
Oct	40
Nov	37
Dec	33
Jan	40
Feb	35
March	26
April	24
May	21
June	16
July	19
Aug	25
Sept	29
Fiscal Year 2015	Average Length of Stay
Oct	31
Nov	30
Dec	30
Jan	32
Feb	34
March	32
April	29
May	31
June	31
July	32
Aug	35
Sept	35
Fiscal Year 2016	Average Length of Stay
Oct	33
Nov	34
Dec	32
Jan	32
Feb	35
March	35
April	33
May	32
June	35
July	38
Aug	39
Sept	38
Fiscal Year 2017	Average Length of Stay
Oct	34
Nov	34
Dec	34
Jan	38
Feb	43
March	57
April	77
May	74
June	61
July	42
Aug	35
Sept	40

Fiscal Year 2018	Average Length of Stay
Oct	42
Nov	44
Dec	44
Jan	50
Feb	56
March	56
April	52

Question. Reports confirm that your agency is inspecting four military installations for their suitability to shelter unaccompanied minors and children separated from their families at the border. The Obama administration resorted to temporarily sheltering children in military installations after an unexpected surge in border crossings by unaccompanied minors. However, your agency is proactively searching for more space to house children. These inspections comes just weeks after the Trump administration announced a new “zero tolerance” prosecution policy that will separate potentially thousands of additional children from their families and send them into your agency’s care. How many additional children is your agency expecting to shelter in these military installations as a result of the Trump administration’s new “zero tolerance” prosecution policy?

Answer. HHS is closely working with our DHS partners to anticipate and plan for the potential number of unaccompanied alien children (UAC) referrals and their length of stay in our care. ORR uses influx care facilities only until space in a state-licensed care facility is available. Prudent planning requires HHS to proactively search for more space to house UAC during an influx situation. Similar to recent years, HHS is considering whether military facilities are a viable option for use as influx care facilities. No final decisions have been made at this time and HHS continues to evaluate the situation on an ongoing basis. As always, this program is very unpredictable and we will continue to work with Congress as we learn more.

Question. Will these military installations be subject to the same regulations and standards applying to HHS facilities currently sheltering unaccompanied minors and children separated from their families at the border?

Answer. HHS has policies in place for all influx care facilities that are in compliance with the Flores agreement. These policies are found in Section 1.7 of the ORR Guide: Children Entering the United States Unaccompanied. In the event a military base is used to house UACs, the policies in Section 1.7 would apply.

Question. Will uniformed and armed military personnel be assigned duties that require them to interact with children sheltered at these military installations?

Answer. No. HHS remains responsible for the care, supervision, and services for all UAC in HHS custody. Consistent with past practice, HHS only occupies unused portions of DoD installations.

REFUGEE RESETTLEMENT

Question. For fiscal year 2018, the Trump administration established a refugee admissions level of 45,000—a historic low particularly when considering the scale of the global humanitarian crisis we face. But even more troubling, as of May—more than midway through the current fiscal year—only 12,000 or so refugees have been resettled. At this pace, the administration will not even resettle half of the 45,000 refugees it has committed to admitting this fiscal year.

What are the Office of Refugee Resettlement’s projections for the number of refugees it expects to serve and resettle for the remainder of fiscal year 2018?

Answer. ORR does not have a role in the admission of refugees and is therefore not in the best position to estimate the number of refugees that will arrive. ORR will continue to provide services to all refugees who apply and meet eligibility requirements.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. In January of this year, 44 Senators and I wrote to the President in support of including funding for the Low Income Home Energy Assistance Program (LIHEAP) in the President’s fiscal year 2019 Budget. Unfortunately, the Administration chose to again eliminate this lifesaving program. In a response to our letter, Office of Management and Budget (OMB) Director Mulvaney cited a GAO report from 2010, which observed patterns of fraud and abuse in the program as one of the justifications for eliminating funding. OMB Director Mulvaney’s letter contends

that taxpayer dollars need to be spent efficiently and in an accountable manner and that LIHEAP is susceptible to fraud and abuse. GAO's 2010 report makes six recommendations which, according to GAO, were all implemented even before the report was released.

If HHS has indeed implemented all of GAO's recommendations, as GAO has noted, what new examples can you provide regarding whether the program still susceptible to fraud and abuse, and how so?

Answer. The program's susceptibility to fraud and abuse is only one of the reasons for not funding LIHEAP. LIHEAP is not the only program helping low-income households pay their heating and cooling bills. State and local governments provide significant funding assistance, and the majority of states prohibit utilities from discontinuing a household's energy in periods of severe weather.

Question. Families in Vermont often have to make impossible choices between putting food on the table, medical care or home heating. Do you believe assisting low income families with heating costs is a worthy objective?

Answer. LIHEAP is not the only program helping low-income households pay their heating and cooling bills. State and local governments provide significant funding assistance, and the majority of states prohibit utilities from discontinuing a household's energy in periods of severe weather.

Question. Do you support elimination of the LIHEAP Program? If so, why?

Answer. The HHS Budget reflects a commitment to exercising fiscal stewardship by streamlining government services and making the best possible use of taxpayer dollars. We are proposing the elimination of this program to prioritize funding for other human services activities. LIHEAP is not the only program helping low-income households pay their heating and cooling bills.

SUBCOMMITTEE RECESS

Senator BLUNT. The subcommittee will stand in recess.

[Whereupon, at 12:04 p.m., Thursday, May 10, the subcommittee was recessed, to reconvene subject to the call of the Chair.]